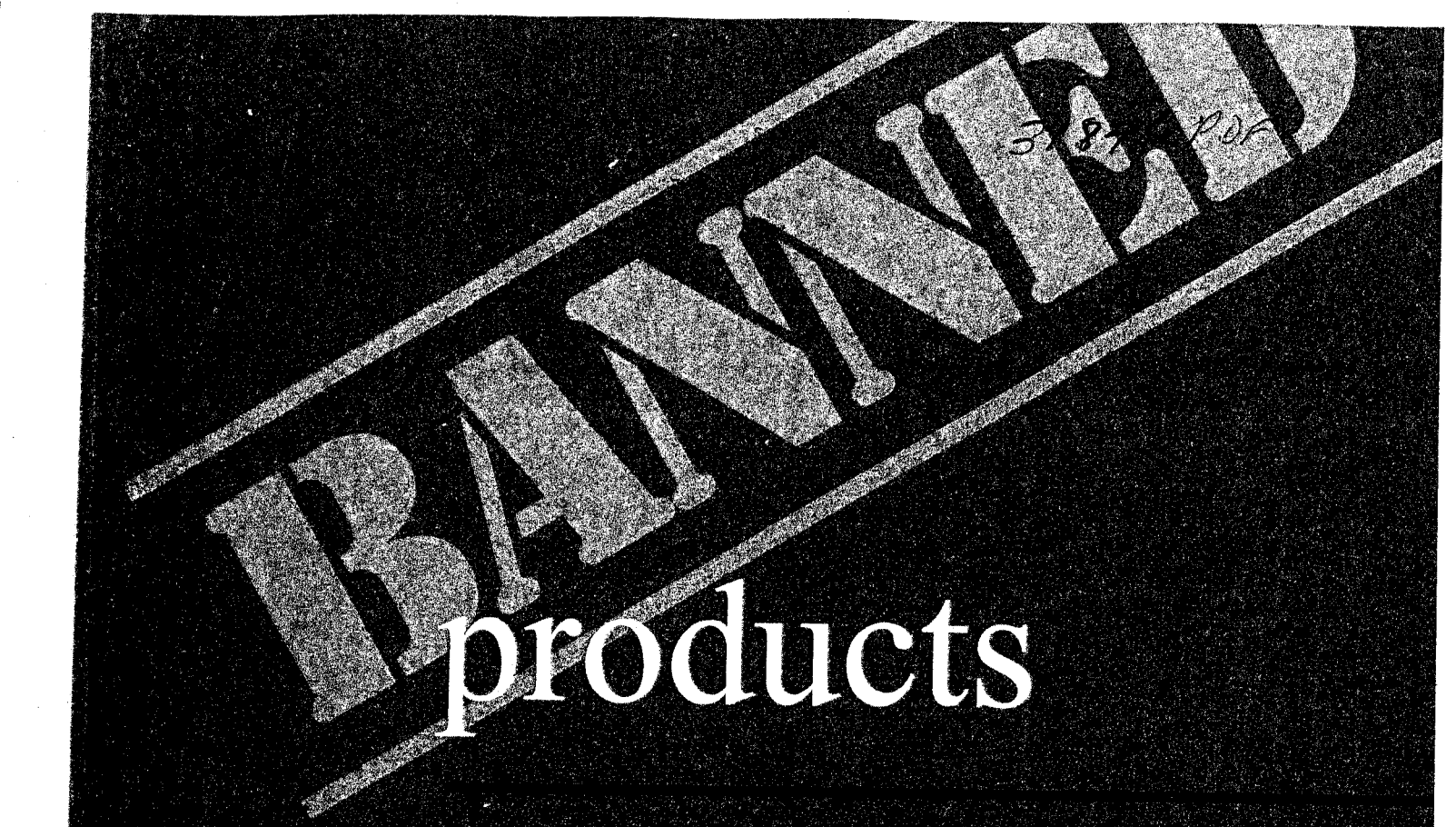

products

Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or not Approved by Governments

Sixth issue

Pharmaceuticals

UNITED NATIONS

ST/ESA/253

Department for Policy Coordination and Sustainable Development

Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or not Approved by Governments

Sixth Issue

Pharmaceuticals

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NOTE

Symbols of United Nations documents are composed of the capital letters combined with figures. Mention of such a symbol indicates a reference to a United Nations document.

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INTRODUCTION

1. The Consolidated List of Products whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or not Approved by Governments is part of a continuing effort in the United Nations system aimed at disseminating information widely on products harmful to health and the environment. It constitutes a tool which helps Governments to keep current with regulatory decisions taken by other Governments and assists them in considering the scope for their own eventual regulatory action. It enables government agencies which review applications for product registration to ascertain easily restrictive regulatory decisions made in other countries. It complements and consolidates other information on the subject produced within the United Nations system, including the World Health Organization (WHO)'s quarterly bulletin WHO Drug Information and its Pharmaceuticals Newsletter.

2. The 1992 United Nations Conference on Environment and Development (UNCED) provided impetus to the ongoing work of the United Nations system in the area of chemical safety. In Chapter 19 of Agenda 21, entitled "Environmentally Sound Management of Toxic Chemicals", six programme areas were approved for action. One of them, "Information exchange on toxic chemicals and chemical risks", corresponds directly to the purposes for which the List was established. In this regard, decisions of intergovernmental bodies such as the Special Session of the General Assembly to review the implementation of Agenda 21 and the International Conference on Chemical Safety are likely to affect the composition and future direction of the List. These developments will be carefully reviewed in order to make appropriate changes in the future issues of the List.

Background

3. In 1982, the General Assembly, "aware of the damage to health and the environment that the continued production and export of products that have been banned and/or permanently withdrawn on grounds of human health and safety - is causing in the importing countries", and "considering that many developing countries lack the necessary information and expertise to keep up with developments in this field", requested the Secretary-General to prepare a consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or not approved by Governments (resolution 37/137 (see annex I)). The General Assembly specified that the list should be easy to read and should contain both generic/chemical and brand names, as well as the names of all manufacturers and a short reference to the decisions taken by Governments that had led to the banning, withdrawal or severe restriction of the products.

4. Subsequently, the General Assembly requested that an updated consolidated list should be issued annually and that its format should be kept under continuing review, with a view to its improvement. It also decided that the legislative and commercial sections of the list should continue to be published in one document (resolution 39/229 and decision 41/450 (see annex I)).

5. Since its inception, interagency consultations are held periodically to discuss issues of concern to participating organizations. In 1985, the United Nations Secretariat, in close cooperation with WHO and UNEP, carried out an in depth review of the List which covered arrangements for the preparation of future issues; such as the need for criteria for the inclusion of products; the question of introducing into the List certain types of information such as the legal and public health context of regulatory actions, which had not been included in the first issue of the List; and the treatment of commercial data.

6. As a result of the review the coverage of the List was expanded and new arrangements were made for its production. A memorandum of collaboration was agreed upon between the United Nations, WHO and UNEP/IRPTC, which outlined the division of responsibilities among these three organizations taking into account their respective areas of competence and the concerns expressed by Member States. Accordingly, WHO collects, screens and processes the information relating to regulatory measures taken by Governments on pharmaceutical products, and on the health-related and environmental reasons for these measures, and UNEP/IRPTC performs a similar function with regard to chemical products. The United Nations Secretariat co-ordinates these inputs, ensures that relevant information available in other organizations is utilized for the purposes of the List, and collects and reviews the commercial data. It also edits, translates and publishes the List.

Scope and presentation

7. At the last review in 1995, in which the United Nations Secretariat, UNEP, WHO and ILO participated, it was decided, as a cost saving measure to print the List every two years. Given the limitations of a single bulky volume it was also considered prudent to divide the List into two volumes - to be printed separately in alternate years with one volume containing only information related to pharmaceuticals and the other containing information on all the chemicals - each with a distinct issue number. The current (6th) issue is the first to be published under this arrangement, it has over 400 pages and covers pharmaceutical products which are regulated on account of their chemical composition. It is divided into two parts containing regulatory and commercial information respectively.

Part One

8. Part one, prepared jointly by the United Nations and WHO, presents in a unified manner information on restrictive regulatory decisions taken by Governments on pharmaceutical products. While the information cannot be regarded as exhaustive, either in terms of products or regulatory measures, it covers regulatory actions taken by a total of 77 Governments on 368 pharmaceutical products. In this context it should be noted that decisions taken by a limited number of Governments on a specific product may not be representative of the position of other Governments, particularly in view of differing risk-benefit considerations. It is also important to realize that all pharmaceutical and chemical products are potentially harmful if not correctly used. In addition, the fact that a given product is not listed as regulated by a country does not necessarily mean that it is permitted in that country. Rather it could mean that the relevant regulatory decision has not yet been communicated to the United Nations or to WHO, or that the product has not been submitted for registration. It is also important to note that the issue of the efficacy of products is not addressed in the regulatory text, but is an aspect that may be crucial when a Government is considering a product for regulatory action of its own.

9. To ensure that the List focuses on products harmful to health and the environment, criteria for the inclusion of products were developed in 1985 and transmitted to Governments for their comments. The criteria, revised in the light of the comments received, is contained in annex II. The application of the criteria has significantly facilitated the screening of information for the List. However, the interpretation by the Governments of the criterion "severely restricted", in particular, continues to vary widely, leading to considerable inconsistency in reporting on national restrictive regulatory measures. When necessary, additional information and/or clarifications is requested from Governments, and products which clearly do not meet the criteria have been omitted after consultation with Governments. Information received from non-governmental organizations is also verified with Governments. When there is evidence that a listed product is no longer available, or the safety issue has been resolved, the need for retaining the entry in subsequent issues of the List is routinely reviewed.

10. Psychotropic and narcotic substances scheduled under one of the international conventions are included only where a Government is controlling a substance more rigorously than required under the relevant international convention.

11. The regulatory information also includes references to the relevant legal and statutory documents in order to enable the user to ascertain the legal context and scope of the regulations. Such references cannot be given for some pharmaceuticals, since product licences are often made or amended by an administrative decision which is not published. Brief explanatory comments also appear, where necessary, to clarify certain regulatory actions and place them into the current context. There are also bibliographical references to scientific and technical studies by international organizations relating to some products.

12. Products are listed alphabetically within sections; International Non-Proprietary Names (INN) have been used whenever possible to identify pharmaceutical products. Each product entry includes, where available, the Chemical Abstracts Service Registry Number (CAS number); other scientific names, common names and synonyms; the effective date on which the regulation came into force; a summary of regulatory measures taken by Governments; brief explanatory comments where necessary; and legal and bibliographical references. Entries are listed in chronological order by effective date of government action. A listing of the references cited in Part One and, if available, the addresses, where copies of the documents can be obtained, are given in annex III.

Part Two

13. Part Two, compiled by the United Nations Secretariat, presents commercial information, including data on trade names, relating to a large proportion of the products covered in Part One. It provides an easy method to cross-reference commercial names with recognized common scientific names, under which the regulatory data is presented. Trade name data is included for most of the monocomponent pharmaceutical products. There is no trade name data for combination pharmaceutical products. It should be noted that manufacturers and distributors may maintain a trade name while changing the ingredients or the formulation. Therefore it is important to check the contents of a specific product using an identified trade name in order to ensure the accuracy of the reference to a given product.

14. The first step in compiling the commercial data is to review various on-line data bases and commercial directories for alternative nomenclature for the regulated products. Commercial names were then separated from alternate scientific names. Trade names were collected irrespective of the manufacturer's form of ownership and include transnational and national enterprises from all regions.

15. The commercial information is organized under the same headings as the regulatory data in order to facilitate easy reference. Each product entry includes the product name and CAS number and a listing of known trade names.

Consolidated List Users' Guide

If you are interested in finding out what restrictive legislative action has been taken on a product or what commercial information is available in this issue of the Consolidated List - say for example, on Chloroform - you would look up the page reference in the alphabetical listing of products (pages vii-xiii). But if you only know one of the trade names under which it is available in the market, such as 'Endal', you would consult index C (pages 299-354). On the other hand if you are looking for it by one of its scientific names, for example, 'TRICHLOROMETHANE', you would consult index B (pages 287-298). Also if only a CAS number of a product is known, you would look into index A (pages 281-285) for product name and the page reference. In addition to indices described above, a classified listing of products (pages xv-xxi) is also included, grouping the products according to their usage. Furthermore, a list of three letter country codes used throughout the publication to denote countries and territories is given on page (xxiii).

LISTING OF PRODUCTS BY PRODUCT NAME

I) PHARMACEUTICALS (MONOCOMPONENT PRODUCTS)

I) PHARMACEUTICALS (MONOCOMPONENT PRODUCTS) ...(Continued)

6. ANTIINFECTIVE DRUGS

I) PHARMACEUTICALS (MONOCOMPONENT PRODUCTS) ...(Continued)

I) PHARMACEUTICALS (MONOCOMPONENT PRODUCTS) ...(Continued)

I) PHARMACEUTICALS (MONOCOMPONENT PRODUCTS) ...(Continued)

17. NERVOUS SYSTEM, DRUGS ACTING ON THE

DRUGS NOT SCHEDULED INTERNATIONALLY

NARCOTICS SCHEDULED UNDER SINGLE CONVENTION ON NARCOTIC DRUGS

PSYCHOTROPICS SCHEDULED UNDER CONVENTION ON PSYCHOTROPIC SUBSTANCES

I) PHARMACEUTICALS (MONOCOMPONENT PRODUCTS) ...(Continued)

I) PHARMACEUTICALS (MONOCOMPONENT PRODUCTS) ...(Continued)

24. VITAMINS, MINERALS, ENZYMES

II) PHARMACEUTICALS (COMBINATION PRODUCTS)

LIST OF CODES USED FOR COUNTRIES, TERRITORIES AND AREAS

@EC	European Community	**ITA**	Italy
@WD	World	**JOR**	Jordan
ARE	United Arab Emirates	**JPN**	Japan
AUS	Australia	**KOR**	Korea Republic of
AUT	Austria	**KWT**	Kuwait
BEL	Belgium	**LBN**	Lebanon
BGD	Bangladesh	**LIY**	Libyan Arab Jamahiriya
BGR	Bulgaria	**LKA**	Sri Lanka
BHR	Bahrain	**MAR**	Morocco
BRA	Brazil	**MEX**	Mexico
BRB	Barbados	**MUS**	Mauritius
CAN	Canada	**MYS**	Malaysia
CHE	Switzerland	**NGA**	Nigeria
CHL	Chile	**NLD**	Netherlands
COE	Council of Europe	**NOR**	Norway
COG	Congo	**NPL**	Nepal
CRI	Costa Rica	**NZL**	New Zealand
CUB	Cuba	**OMN**	Oman
CYP	Cyprus	**PAK**	Pakistan
DDR	German Democratic Republic [1]	**PAN**	Panama
DEU	Germany, Federal Republic of [1]	**PER**	Peru
DNK	Denmark	**PHL**	Philippines
DOM	Dominican Republic	**PRT**	Portugal
EGY	Egypt	**ROM**	Romania
ESP	Spain	**RWA**	Rwanda
ETH	Ethiopia	**SAU**	Saudi Arabia
FIN	Finland	**SDN**	Sudan
FRA	France	**SGP**	Singapore
GBR	United Kingdom	**SUN**	Union of Soviet Socialist Republics [2]
GHA	Ghana	**SUR**	Suriname
GRC	Greece	**SWE**	Sweden
HKG	Hong Kong	**TCD**	Chad
HND	Honduras	**THA**	Thailand
HUN	Hungary	**TUN**	Tunisia
IDN	Indonesia	**TUR**	Turkey
IND	India	**USA**	United States
IRL	Ireland	**VEN**	Venezuela
IRN	Iran	**YEM**	Yemen
IRQ	Iraq	**ZAF**	South Africa
ISL	Iceland	**ZMB**	Zambia
ISR	Israel	**ZWE**	Zimbabwe

The designations employed and the presentations of the material in this publication do not imply the expression of any opinion whatsoever on the part of the Secretariat of the United Nations concerning the legal status of any country, territory city or area or its authorities, or concerning the delimitation of its frontiers or boundaries.

[1] Through accession of the German Democratic Republic to the Federal Republic of Germany with effect from 3 October 1990, the two German States have united to form one sovereign State. As from the date of unification, the Federal Republic of Germany acts in the United Nations under the designation of "Germany".

[2] Country names employed are the same under which regulatory information was received originally.

CONSOLIDATED LIST OF PRODUCTS WHOSE CONSUMPTION AND/OR SALE HAVE BEEN BANNED, WITHDRAWN, SEVERELY RESTRICTED OR NOT APPROVED BY GOVERNMENTS

Sixth Issue

Pharmaceuticals

PART I

REGULATORY INFORMATION

PHARMACEUTICALS

MONOCOMPONENT PRODUCTS

Product name **Acetanilide**

C.A.S. number **103-84-4**

Scientific and common names, and synonyms

ANTIFEBRIN
N-PHENYLACETAMIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
JPN	July 1971	This analgesic and antipyretic has been banned for use in over-the-counter preparations due to the risk of aplastic anaemia. It was subsequently voluntarily withdrawn from prescription products. **WHO comment:** Acetanilide, a para-aminophenol derivative with analgesic, antipyretic and weak antiinflammatory activity, was introduced into medicine in 1886. It subsequently proved to be excessively myelosuppressive and has been superseded by safer alternatives.

Product name **Acetarsol**

C.A.S. number **97-44-9**

Scientific and common names, and synonyms

ACETARSONE
N-ACETYL-4-HYDROXY-M-ARSANILIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
MUS	9 Mar. 1982	Under the Pharmacy and Poisons (Prohibitions of Harmful Drugs) Regulations, this drug is deemed "harmful" by the Ministry of Health and is prohibited for import, manufacture, storage, distribution, sale, possession, use, export or other transaction. (Reference: (MPPHD) Pharmacy & Poisons (Prohibitions of Harmful Drugs) Regulations,,, Mar. 1982) **WHO comment:** Acetarsol, which has antiprotozoal and antitrichomonal activity, has largely been discarded for systemic use because of its potential to cause systemic poisoning. However, topical preparations for vaginal trichomoniasis are still available and it is included in low concentrations (equal to or less than 0.45%) in some medicated toothpastes.

Product name **Acetylfuratrizine**

C.A.S. number **1789-26-0**

Scientific and common names, and synonyms

N-(6-(2-(5-NITRO-2-FURYL)VINYL)-1,2,4-TRIAZIN-3-YL) ACETAMIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
JPN	July 1977	Withdrawn from all marketed preparations on the grounds that it has been superseded by safer and more effective preparations.
SAU		The withdrawal of nitrofuran compounds is under consideration since they have been superseded by safer and more effective preparations.
VEN		Not approved for use and/or sale.

...(Continued)

Legislative or regulative action

Product name **Acetylfuratrizine** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Acetylfuratrizine, a nitrofuran derivative, was formerly used as an antiinfective agent. It has, however, been superseded by safer compounds and WHO has no information to suggest that it remains commercially available.

Product name **Acetylsalicylic acid (paediatric)**

C.A.S. number **50-78-2**

Scientific and common names, and synonyms

ASPIRIN
BENZOIC ACID, 2-(ACETYLOXY)-
SALICYLIC ACID ACETATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
CHE	1986	The Intercantonal Office for Drug Control has decided that products containing salicylates should bear on the package a warning against use by children under twelve years of age, except on medical advice. The package leaflets directed to both physicians and patients should additionally include warnings concerning Reye's syndrome in both the sections "Limitations of use" and "Undesirable effects". (Reference: (CHBCM) Bulletin Mensuel, 8,, 1986)
IRQ	1986	The National Board for the Selection of Drugs has decided to prohibit the sale of products containing acetylsalicylic acid without a medical prescription. The product information should contain a warning that acetylsalicylic acid should be avoided in children suffering from influenza or chickenpox and that children under 12 years of age should receive acetylsalicylic acid only on medical advice.
ISR	Feb. 1986	The Ministry of Health has ordered that preparations of acetylsalicylic acid intended specifically for children be subjected to prescription control and that all preparations should contain a warning referring to the reported risk of Reye's syndrome in children and young adults with fever due to viral infections.
ITA	June 1986	The Italian Health Council has decided that all products containing acetylsalicylic acid should bear the following warning: "Consult your physician before administering this product to children and teenagers with viral diseases such as influenza or chicken pox. Discontinue use immediately if persistent vomiting or undue sleepiness occurs.".
IRL	9 June 1986	The National Drugs Advisory Board, in agreement with manufacturers, requires that all paediatric dosage forms be available on prescription only. All preparations should carry the warning "This product should not be given to children, particularly those under 12 years of age, without medical advice.".
GBR	10 June 1986	The Committee on Safety of Medicines has advised that acetylsalicylic acid should not be administered to children under 12 years of age except on medical advice. Leading manufacturers have declared their intention to stop supplying paediatric preparations.
AUS	11 June 1986	The Adverse Drug Reactions Advisory Committee has warned that acetylsalicylic acid should not be given to children and teenagers with fever. The warning does not relate to use for disorders in children and teenagers who do not have fever.
ESP	7 Aug. 1986	The Director General for Pharmacy and Health Products of the Ministry of Health has issued guidelines for package inserts for preparations containing acetylsalicylic acid. A warning should be included stating that the preparation should be administered to children and adolescents with febrile conditions such as influenza or varicella only on medical advice.

...(Continued)

Product name **Acetylsalicylic acid (paediatric)** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
HKG	1 Sep. 1986	The Medical and Health Department requires that the product information for all preparations containing acetylsalicylic acid must warn against its use in children under 12 years of age, except on medical advice. Manufacturers are urged to withdraw all paediatric preparations.
DEU	Oct. 1986	The Federal Health Office requires pharmaceutical preparations containing acetylsalicylic acid to bear a warning against use for feverish conditions in children and young people unless on medical advice and only if other measures have failed.
OMN	Dec. 1986	The Central Drug Committee has informed doctors and pharmacists that no products containing acetylsalicylic acid (aspirin) should be given to children under 12 years of age who have chicken pox, influenza or any other febrile illness. Paediatric aspirin preparations will be available only from pharmacies. Products for export containing acetylsalicylic acid should bear the following statutory warning on new packs:"This product should not be given to children, particularly those under 12 years of age, without medical advice."
EGY	1987	The Technical Committee for Drug Control has decided that the product information of all paediatric pharmaceutical products containing acetylsalicylic acid should bear the following warning: "Consult a physician before giving aspirin to children aged less than 12 years, especially in cases of influenza and chickenpox, to avoid risk of Reye's Syndrome." (Reference: (EGYDC) Decision of the Egyptian Technical Committee for Drug control, vol.5(2), 1, 1987)
CHL	2 Feb. 1987	The Institute of Public Health of Chile has decided that all pharmaceutical products containing acetylsalicylic acid should carry a warning on the label that the drug should not be given to children under 12 years of age with febrile viral diseases without consulting a doctor. (Reference: (CHLRS) Resolution of the Minister of Health, No.01042,, Feb. 1987)
DNK	1 July 1987	The National Board of Health has decided that pharmaceutical preparations containing acetylsalicylic acid in paediatric dosages (less than 200mg/tablet) should bear the following warning: "Not to be given to feverish children without consulting a doctor.".
NGA	Jan. 1987	Because of the suspected link between the use of acetylsalicylic acid in children below the age of 12 years and Reye's syndrome, importation, manufacture, sale and distribution of paediatric products containing acetylsalicylic acid or other salicylates have been prohibited. The labels of non-paediatric products must bear the warning: "Not for use in children below 12 years of age". (Reference: (NGAPN) Pharmanews, 10(11), 15, 1988)
SGP	1 Dec. 1987	The Ministry of Health has made it mandatory for all aspirin products to bear the cautionary label: "Caution: not to be given to persons below the age of 16 years except under the direction of a doctor" before the products can be sold in the market. The public is advised not to give their children any medicine containing aspirin unless otherwise advised by the doctor. (Reference: (SGPMA) Medicines Act (Chapter 176), No.S 230/87, 1078, Aug. 1987)
SWE	1988	The National Board of Health and Welfare has revised the product information for preparations containing acetylsalicylic acid to recommend that they should not be taken by febrile children under 18 years of age and to indicate that paracetamol is the drug of choice in these circumstances. (Reference: (SSLMS) Information från Socialstyrelsens Läekemedelsavdelning, Vol.12(6), 145, 1987)
BEL	1 Jan. 1988	The Ministry of Public Health and the Environment requires pharmaceutical products containing acetylsalicylic acid to bear the following warning: "This medicine contains acetylsalicylic acid. Do not use in feverish children without medical advice.". (Reference: (BELMD) Ministerial Decree,,, June 1987)
USA	June 1988	The United States Food and Drug Administration has revised the labelling of products containing acetylsalicylic acid to read: "Children and teenagers should not use this medicine for chickenpox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness, reported to be associated with aspirin." (Reference: (FEREAC) Federal Register, 53(111), 21633, 1988)

...(Continued)

Product name **Acetylsalicylic acid (paediatric)** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NLD		The Board for the Evaluation of Medicines requires information for patients on products containing acetylsalicylic acid to contain the statement: "To be used in children with chickenpox or influenza only on the advice of a doctor.". **WHO comment:** Acetylsalicylic acid, a nonsteroidal antiinflammatory, analgesic and antipyretic agent, was introduced into medicine in 1899 and has since been widely available in over-the-counter preparations. Recent studies carried out in the USA have shown an association between acetylsalicylic acid consumption in children and the development of Reye's syndrome (a rare condition characterized by a combination of encephalopathy and liver disorder and usually preceded by an acute viral illness, such as influenza, diarrhoea, or chicken pox). Although these studies were initially criticized for their design, there is now a broad consensus that a link between acetylsalicylic acid and Reye's syndrome has been established, particularly since the reported incidence of Reye's syndrome in the United States has fallen appreciably since the association was first postulated in 1980. In the interim, many drug regulatory authorities have acted to caution against the use of the drug in children and young adults with febrile conditions. Even within this group the risk of exposure is remote and has been estimated to be of the order of 1.5 per million. Acetylsalicylic acid retains a valuable place in medicine and remains in the WHO Model List of Essential Drugs. (Reference: (WHODI) WHO Drug Information, 1, 5, 1985)

Product name **Acitretin**

C.A.S. number **55079-83-9**

Scientific and common names, and synonyms

2,4,6,8-NONATRAENOIC ACID, 9-(4-METHOXY-2,3,6-TRIMETHYLPHENYL)-3,7-DIMETHYL-2,4,6,8-NONATETRAENOIC ACID, (ALL-E)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
@EC	14 Dec. 1990	The Committee for Proprietary Medicinal Products recommended that the product information for preparations containing acitretin should state that contraception should be maintained for 2 years after cessation of treatment and that patients should not donate blood for 1 year after the end of therapy. (Reference: (CPMPPO) Pharmacovigilance Opinion, 9,, 14 Dec. 1990)
FRA	June 1991	The marketing authorization for products containing acitretin was suspended, on the grounds that the analysis of blood samples from patients receiving the drug had indicated etretinate to be a possible metabolite. Acitretin was reintroduced in April 1991 with an amended product information stating that contraceptive measures must be taken for a minimum of one year after discontinuation of treatment and preferably for two years and that patients should not donate blood either during treatment or for one year thereafter. (References: (FRAMHS) Ministry of Health and Social Affairs,,, 27 Oct. 1990; (FRAMS) Ministry of Social Affairs and Integration,,, June 1991) **WHO comment:** Acitretin, a retinol derivative, was introduced in 1989 for the treatment of severe psoriasis. By the end of 1990, acitretin was confirmed to be metabolized in part to etretinate. Marketing authorization was suspended temporarily in France while the product information was modified to conform to the recommendations issued by the Committee for Proprietary Medicinal Products of the European Communities. Acitretin remains registered in several countries. See also WHO comment for etretinate.

Product name **Acridine derivatives**

C.A.S. number **260-94-6**

Scientific and common names, and synonyms

ACRIFLAVINE
AMINACRINE
ETHACRIDINE
EUFLAVINE
PROFLAVINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ITA	1973	These products are only available as topical disinfectants in concentrations not higher than 1%.
DNK	Sep. 1979	Proflavine was withdrawn from all dental-care products in May 1978, following demonstration of mutagenic activity in vitro. Euflavine was similarly withdrawn as of September 1979. No direct evidence exists of any risk to man and the extent to which these substances penetrate mammalian cells is uncertain. Nevertheless, the Registration Board has recommended that the restriction should apply to all acridine disinfectants "that many regard as obsolete and whose safety is questionable".
VEN		Not approved for use and/or sale. **WHO comment:** Acridine derivatives with antiseptic and disinfectant activity, including acriflavine, proflavine and euflavine, were formerly used in the treatment of infected wounds and burns. Such use has largely been discontinued on the grounds that safer and more effective alternatives are now available. Following demonstration of the mutagenic activity of proflavine in 1978 it was withdrawn from dental products in Denmark. Subsequently, euflavine was similarly withdrawn.

Product name **Alclofenac**

C.A.S. number **22131-79-9**

Scientific and common names, and synonyms

BENZENEACETIC ACID, 3-CHLRO-4-(2-PROPENYLOXY)-
(4-ALLYLOXY-3-CHLOROPHENYL) ACETIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
IRL	1977	Products containing alclofenac were rejected following evidence of metabolite mutagenicity.
CYP	1979	Withdrawn following reports that an epoxide urinary metabolite has mutagenic activity.
DEU	1979	Registration has been suspended following the voluntary withdrawal of alclofenac in the United Kingdom.
GBR	1979	Alclofenac was voluntarily withdrawn by the manufacturer following reports of skin rashes associated with its use.
ITA	1979	Withdrawn following reports that an epoxide urinary metabolite has mutagenic activity.
NZL	1979	Voluntarily withdrawn from the market.
EGY	Mar. 1984	Pharmaceutical preparations containing this antiinflammatory agent no longer qualify for registration to avoid the potential risk associated with a urinary metabolite having mutagenic activity.
GRC	1985	Withdrawn from the market.

...(Continued)

Product name **Alclofenac** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DNK		Voluntarily withdrawn by the manufacturer.
IDN		Registration has been refused following reports that an epoxide urinary metabolite has mutagenic activity.
IND		Not approved for marketing following reports that an epoxide urinary metabolite has mutagenic activity.
JOR		Registration has been refused following reports that an epoxide urinary metabolite has mutagenic activity.
MAR		Registration has been refused following reports that an epoxide urinary metabolite has mutagenic activity.
		WHO comment: Alclofenac, a phenylacetic acid derivative with analgesic, antipyretic and antiinflammatory activity, was introduced in 1972 for the treatment of rheumatic disorders. In the late 1970s its use was associated with a high incidence of adverse effects, mainly skin rashes, and a urinary metabolite was reported to have mutagenic activity (positive Ames test). This resulted in the withdrawal of the drug, in some cases voluntarily, from several countries. In others registration has been refused. The reported mutagenic potential has been questioned by some investigators and the drug remains on the market in at least three countries with highly evolved regulatory authorities.

Product name **Allergen extracts**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	1 Apr. 1986	The National Board of Health and Welfare required producers of all marketed allergen extracts to file registration applications before 1 April 1986. Extracts currently available were allowed to remain on the market pending a final decision. However, having regard to recently reported adverse reactions, existing preparations derived from mites, moulds and certain domestic animals were withdrawn with immediate effect. Provision was, however, made for further clinical trial of such formulations.

Product name **Almitrine**

C.A.S. number **27469-53-0**

Scientific and common names, and synonyms

2,4-BIS(ALLYLAMINO)-6-(4-(BIS-(P-FLUOROPHENYL)METHYL)-1-PIPERAZINYL)-S- TRIAZINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU		The indications for use of almitrine have been restricted to chronic obstructive pulmonary disease with respiratory insufficiency.
		WHO comment: Peripheral neuropathy has been reported in a few patients receiving almitrine for long periods. The indications for treatment have consequently been restricted in the Federal Republic of Germany. Some other countries have advised doctors to maintain patients under close supervision throughout treatment and to restrict dosage to two out of every three months.

Product name **Aloxiprin**

C.A.S. number **9014-67-9**

Scientific and common names, and synonyms

POLYMERIC CONDENSATION PRODUCT OF ALUMINIUM OXIDE AND 0- ACETYLSALICYLIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GBR	Dec. 1986	The Committee on Safety of Medicines has advised that preparations containing the acetylsalicylic acid pro-drug aloxiprin should not be administered to children under 12 years of age except on medical advice. (Reference: (GBMIL) Medicines Act Information Letter, No.48,, Oct. 1986) **WHO comment:** Aloxiprin is a pro-drug of acetylsalicylic acid. See WHO comment for acetylsalicylic acid.

Product name **Alprostadil**

C.A.S. number **745-65-3**

Scientific and common names, and synonyms

PGE1, PROSTAGLANDIN E1
PROST-13-EN-1-OIC ACID, 11,15,-DIGYDROXY-9-OXO, (11alpha, 13E, 15S)-
(1R,2R,3R)-3-HYDROXY-2-((E)-(3S)-HYDROXY-1-OCTENYL)-5-OXOCYCLOPENTANEHEPTANOIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1991	Products for intravenous administration containing alprostadil were contraindicated in patients with cardiac disease, including inadequately treated coronary atherosclerosis, cardiac insufficiency and arrhythmia, cardiac infarction within the last six months, clinical or radiological suspicion of pulmonary oedema or infiltration, severe chronic airway obstruction, acute liver damage with elevation of transaminases or gamma-GT and an increased bleeding tendency. (Reference: (BGHBL) Bundesgesundheitsblatt, 3/91, 139, 1991) **WHO comment:** Alprostadil, a prostaglandin with vasodilating and platelet anti-aggregatory activity, was introduced in 1984 for the treatment of chronic arterial obstruction. Intravenous administration of the drug has been associated with adverse effects that have sometimes been severe. These include allergic reactions, pulmonary oedema and cardiac insufficiency. Interactions with antihypertensive agents, vasodilators, anticoagulants and inhibitors of platelet aggregation have also occurred. This has led the German agency to modify the approved product information of alprostadil preparations to warn against these adverse effects.

Product name **Amaranth**

C.A.S. number **915-67-3**

Scientific and common names, and synonyms

BORDEAUX-S
CI ACID RED 27
CI FOOD RED 9
COLOUR INDEX NO.16185
E123
FD&C RED NO.2

...(Continued)

Legislative or regulative action

Product name **Amaranth** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	1976	The provisional approval for use of amaranth as a colour additive has been withdrawn since no study is available to resolve the uncertainty over its safety.
EGY	1981	Having regard to the potential carcinogenicity of amaranth, no new preparations containing this substance will henceforth be considered for registration and manufacturers are to replace amaranth with alternative substances within a period of three years. (Reference: (EGYDC) Decision of the Egyptian Technical Committee for Drug control,,, 1981)
KWT	Apr. 1984	Amaranth is no longer approved for use in pharmaceutical preparations and food products. (Reference: (KTMD) Ministerial Decree, 156/84,, 1984)
OMN	1 Apr. 1986	Import of pharmaceutical products containing the colouring agent amaranth is prohibited.
		WHO comment: Approval of amaranth as a colouring agent in foods and pharmaceutical products was withdrawn by the United States FDA in 1976, on the basis of positive findings in carcinogenicity tests which were later disputed on technical grounds and which have not been confirmed in subsequent tests. It has since been withdrawn by some other national regulatory authorities because of uncertainty regarding its safety, but elsewhere it remains widely used.

Product name **Amfepramone**

C.A.S. number **90-84-6**

Scientific and common names, and synonyms

DIETHYLPROPION
1-PROPANONE, 2-(DIETHYLAMINO)-1-PHENYL-,
2-(DIETHYLAMINO)PROPIOPHENONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
TUR	1975	Amfepramone is prohibited for import, export, production, sale and distribution for reasons of harmful health effects; the lack of evidence of value in the long-term management of obesity; and the risk of dependency.
SWE	Jan. 1981	Amfepramone containing appetite suppressants have been withdrawn from the market. There is a lack of evidence of their value in long-term management of obesity, they have the potential for abuse and despite warnings they are frequently used over unacceptably prolonged periods.
OMN	11 Jan. 1987	Import and marketing of products containing amfepramone were prohibited. (Reference: (OMNCR) Circular, 2/87,, Jan. 1987)
ARE		Pharmaceutical preparations containing amfepramone are banned.
NOR		As a centrally acting appetite-reducing preparation, amfepramone is considered harmful and is not approved in Norway.
VEN		Amfepramone is not approved for use and/or sale.
		WHO comment: Amfepramone, a phenethylamine derivative introduced in 1957, is controlled under Schedule IV of the 1971 Convention on Psychotropic Substances. It remains available in many other countries with highly evolved drug regulatory authorities as an aid to weight reduction. (Reference: (UNCPS4) United Nations Convention on Psychotropic Substances (IV),,, 1971)

Product name **Amfetamine**

C.A.S. number **300-62-9**

Scientific and common names, and synonyms

(+/-)-alpha-METHYLPHENETHYLAMINE
AMPHETAMINE
BENZENEETHANAMINE, alpha-METHYL-, (+/-)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	1973	Anorectic drugs containing amfetamine were withdrawn from the market by the Food and Drug Administration due to evidence of abuse and a high risk of dependence.
ARE	9 June 1981	Pharmaceutical preparations containing amfetamine are banned. (Reference: (UAEMD) Ministry of Health Decree, No.694,, 1981)
TUR	6 Sep. 1982	Banned for production, import, export, sale and use.
OMN	10 May 1982	Import and marketing of products containing amfetamine were prohibited. (Reference: (OMNCR) Circular, 11/82,, May 1982)
MYS	July 1987	All products containing amfetamine or derivatives indicated as appetite suppressants have been withdrawn. (Reference: (MYSDC) Malaysian Drug Control Authority, No.10,, Apr. 1987)
NGA	1988	All products containing amfetamine have been banned. (Reference: (NGAPN) Pharmanews, 10(11), 15, 1988)
SAU		Centrally-acting appetite suppressants are severely restricted since they have been found to be ineffective in the management of obesity and they are subject to misuse. **WHO comment:** Amfetamine and its derivatives are potent central stimulants. Use of amfetamines has widely been discouraged due to abuse of their euphoric effect and their limited field of usefulness. Amfetamines have a place in the treatment of narcolepsy and in hyperkinetic syndrome in children. However, they are no longer recommended for use in obesity or depressive illness. Amfetamine is controlled under Schedule II of the 1971 Convention on Psychotropic Substances. (Reference: (UNCPS2) United Nations Convention on Psychotropic Substances (II),,, 1971)

Product name **Aminoglutethimide**

C.A.S. number **125-84-8**

Scientific and common names, and synonyms

2-(4-AMINOPHENYL)-2-ETHYLGLUTARIMIDE
2,6-PIPERIDINEDIONE, 3-(4-AMINOPHENYL)-3-ETHYL-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	1966	Withdrawn from the market following demonstration of serious toxic effects to thyroids, ovaries, adrenals and uteri of female rats, as well as atrophy and mottling of the adrenals of some male rats. Clinical experience showed that in some children it caused sexual precocity, masculinization of young females and other untoward effects including goitre with thyroid hypofunction.
SAU		Withdrawn from the market due to reported serious side effects.

...(Continued)

Product name **Aminoglutethimide** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Aminoglutethimide, a weak anticonvulsant, was introduced in 1960 for use in the treatment of epilepsy. However, its adrenocortical suppressant activity gave rise to serious adverse effects. The FDA decision in 1966 was taken in respect of a preparation indicated in epilepsy. In 1980 preparations containing aminoglutethimide were reintroduced in the USA exclusively for the treatment of Cushing's disease. In 1986 they were also registered in Saudi Arabia for use in Cushing's syndrome and for the treatment of breast cancer. In some other countries these preparations are additionally approved for carcinoma of the prostate.

Product name **Aminophenazone**

C.A.S. number **58-15-1**

Scientific and common names, and synonyms

AMIDAZOFEN
AMIDOPYRINE
AMIDOPYRINE-PYRAMIDON
AMINOPYRINE
ANTIPYRINE
DIMETHYLAMINOANTIPYRINE
DIMETHYLAMINOPHENAZONE
4-DIMETHYLAMINO-2,3-DIMETHYL-1-PHENYL-3-PYRAZOLIN-5-ONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
AUS	1965	Importation has been prohibited because of the potential hazard of bone marrow depression and fatal agranulocytosis. (Reference: (AUDEC) Report of the Australian Drug Evaluation Committee, No. 90)
FIN	1976	This ingredient was removed from non-prescription drugs owing to the potential hazard of bone marrow depression and agranulocytosis.
CHE	1977	Because of the potential to produce carcinogenic nitrosamines, this substance has been withdrawn from all analgesic/antipyretic preparations. Two major international manufacturers of such preparations voluntarily decided to remove this substance from their products.
DEU	1977	Because of the potential to produce carcinogenic nitrosamines, this substance has been withdrawn from all analgesic/antipyretic preparations. Two major international manufacturers of such preparations voluntarily decided to remove this substance from their products.
USA	Nov. 1977	The regulation providing for marketing of aminophenazone was revoked. However this drug is not known to have been marketed in the United States. (Reference: (FEREAC) Federal Register, 42, 53954, Oct. 1977)
JPN	Dec. 1977	Because of the potential to produce carcinogenic nitrosamines, this substance has been withdrawn from all oral preparations and subsequently from all other preparations.
ITA	1978	Products for oral use were withdrawn from the market due to the risk of formation of carcinogenic nitrosocompounds. Injectable products require warnings about the risk of hypersensitivity reactions.
KOR	1978	In view of its propensity to form a potentially carcinogenic n-nitroso compound, this product has been withdrawn from use.
AUT	Mar. 1978	In view of its propensity to form a potentially carcinogenic n-nitroso compound, pharmaceutical products containing aminophenazone and intended for oral use have been withdrawn.
THA	Nov. 1978	Registration permit has been revoked for pharmaceutical preparations containing this ingredient.

...(Continued)

Legislative or regulative action

Product name **Aminophenazone** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
IRL	1979	Products containing aminophenazone have been withdrawn.
DNK	Apr. 1979	At the recommendation of the Registration Board in Denmark, preparations containing aminophenazone and noramidopyrine for systemic use were withdrawn. This decision was based on the potential danger of bone-marrow depression and fatal agranulocytosis, suspected carcinogenic hazards and the availability of alternative products. (Reference: (UGLAAD) Ugeskrift for Laeger, 141, 873, Mar. 1979)
KWT	Dec. 1979	Banned for use and/or sale because of its dangerous side effects, mainly agranulocytosis. (Reference: (KTMD) Ministerial Decree, 556,, 1978)
YEM	Jan. 1980	The Supreme Board of Drugs has called for the withdrawal of all preparations containing aminophenazone.
GRC	Oct. 1980	The Ministry of Health and Welfare has withdrawn this product from domestic use. (Reference: (GRAGA) Ministry of Health Decision, 12946,, Dec. 1980)
ARE	9 June 1981	Pharmaceutical preparations containing aminophenazone are banned. (Reference: (UAEMD) Ministry of Health Decree, No.694,, 1981)
ROM	1982	The Minister of Health has recommended the gradual reduction in the use of this product until it has been phased out of use completely.
SDN	1982	The Ministry of Health no longer allows registration of preparations containing aminophenazone.
FRA	25 Jan. 1982	The Committee for Registration of Medicines has recommended that all preparations containing aminophenazone be withdrawn from the market by 1 January 1982.
TUR	Feb. 1982	After review of published information about this product, the Ministry of Health has decided on its withdrawal and recommends changing the composition of all products containing aminophenazone for systemic use, due to the potential danger of bone marrow depression and fatal agranulocytosis and the availability of alternative products. Export of this product is prohibited.
MUS	9 Mar. 1982	Under the Pharmacy and Poisons (Prohibitions of Harmful Drugs) Regulations, this drug is deemed "harmful" by the Ministry of Health and is prohibited for import, manufacture, storage, distribution, sale, possession, use, export or other transaction. (Reference: (MPPHD) Pharmacy & Poisons (Prohibitions of Harmful Drugs) Regulations,,, Mar. 1982)
IND	1983	Prohibited for manufacture, sale and import due to questionable therapeutic value; evidence of adverse effects on bone marrow as well as suspected carcinogenic hazards; and the availability of safer analgesic drugs. (Reference: (GAZIE) The Gazette of India: Extraordinary, II-3i,, 23 July 1986)
NPL	1983	All preparations containing aminophenazone have been banned from use.
PHL	Oct. 1983	Preparations containing aminophenazone are no longer allowed for use/sale due to serious side effects such as bone marrow depression and agranulocytosis.
RWA	1 Oct. 1983	Preparations containing aminophenazone have been banned following established evidence of the adverse effects of these preparations.
CHL	1984	Products containing aminophenazone have been withdrawn from the market in view of its carcinogenic potential.
DDR	1984	Aminophenazone has been replaced in pharmaceutical preparations due to its potential to form carcinogenic dimethylnitrosamine.
ETH	1984	Withdrawn due to the potential to produce carcinogenic nitrosamines.
HKG	1 Jan. 1984	The Pharmacy and Poisons Committee no longer allows the registration, sale or distribution of products containing aminophenazone.

...(Continued)

Product name **Aminophenazone** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BRA	23 May 1986	Registration of pharmaceutical products containing aminophenazone has been withdrawn and further production prohibited. (Reference: (BRAPT) Portaria do Servico Publico Federal, 9,, May 1986)
MYS	Nov. 1986	All products containing aminophenazone have been withdrawn. (Reference: (MYSDC) Malaysian Drug Control Authority, No.4,, Nov. 1986)
OMN	Mar. 1987	Import and marketing of products containing aminophenasone were prohibited. (Reference: (OMNCR) Circular, 11/87,, Mar. 1987)
BEL	1 Jan. 1988	Preparations containing aminophenazone have been placed in List IV of the Arrêté du Régent of 2 June 1946 and as such can be administered only on prescription. They must be kept in a poisons cabinet and carry the skull and cross-bones label. (Reference: (BELAR) Arrêté Royal,,, June 1987)
GHA	1 Sep. 1989	Products containing aminophenazone or its derivatives have been banned. (Reference: (GHAPDR) Pharmacy and Drugs (Banned Drugs) Regulations, Legislative Instruments, 1484,, 1989)
BHR		Preparations containing aminophenazone have been withdrawn.
GBR		Products containing aminophenazone have been withdrawn from the market due to the risk of agranulocytosis.
SGP		Aminophenazone and related salts have been banned for importation.
SWE		Products containing aminophenazone have been withdrawn from the market due to the risk of agranulocytosis.
VEN		Withdrawn from the market due to its carcinogenic potential.
		WHO comment: Aminophenazone, a pyrazolone derivative, has been used as an antiinflammatory and analgesic agent for over a century. Its use has been associated with cases of bone marrow depression and agranulocytosis and more recently it has been claimed to have a carcinogenic potential. Products containing aminophenazone have been formally withdrawn in many countries and marketing has been voluntarily suspended in others. Elsewhere, however, proprietary preparations containing this ingredient may remain available. (Reference: (WHODI) WHO Drug Information, 3, 9, 1977)

Product name **Aminophylline**

C.A.S. number **317-34-0**

Scientific and common names, and synonyms

AMINOPHYLLINUM
ETHYLENEDIAMINE
EUPHYLLINUM
METAPHYLLIN
THEOPHYLLAMINUM
THEOPHYLLINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NLD	May 1992	The Medicines Evaluation Board in The Netherlands has decided that tablet and suppository formulations ofpharmaceutical products containing aminophylline should no longer be marketed. Absorption rate from these formulations is slow and unpredictable, bioavailability of the suppository varies widely and the therapeutic range is narrow. (Reference: (GENMB) Geneesmiddelenbulletin, 25(5), 27, May 1992)

...(Continued)

Product name **Aminophylline** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Aminophylline, the ethylenediamine salt of theophylline, was introduced many years ago as a treatment for asthma and is listed in the 8th WHO Model List of Essential Drugs. It has been recognized for some 10 years that aminophylline preparations are not interchangeable because bioavailability can vary considerably. The resulting variability in drug absorption can lead to adverse effects including irritation of the mucosa. Allergic reation can also be an adverse effect of aminophylline. Theophylline functions similarly but is considered less of an irritant.

Product name **Aminorex**

C.A.S. number **2207-50-3**

Scientific and common names, and synonyms

AMINOXAPHEN
2-AMINO-5-PHENYL-2-OXAZOLINE
2-OXAZOLAMINE, 4,5-DIHYDRO-5-PHENYL-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1967	The Ministry of Health withdrew preparations containing aminorex, cloforex and chlorphentermine as a precautionary measure pending scientific evidence of a relationship between their use and the development of pulmonary hypertension.
VEN		Banned for use and/or sale.
		WHO comment: Aminorex, an anorexic agent, was introduced over twenty years ago for the treatment of obesity. Between 1967 and 1971 its use was associated with cases of pulmonary hypertension which led to its withdrawal in the Federal Republic of Germany. WHO has no information to suggest that this drug remains commercially available.

Product name **Amitriptyline**

C.A.S. number **50-48-6**

Scientific and common names, and synonyms

3-(10,11-DIHYDRO-5H-DIBENZO(A,D)CYCLOHEPTEN-5-YLIDENE)PROPYLDIMETHYLAMINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NOR	1992	The Medicines Control Authority has decided that the 50 mg tablet formulation of amitriptyline may be prescribed only in hospitals and specialized clinics because of the toxic potential of these products and the risk of overdosage and suicide with the high dose formula. (Reference: (NNSLM) Nytt fra Statens Legemiddelkontroll, 1, 9, 1992)
		WHO comment: Amitriptyline, a tricyclic antidepressant was introduced in 1961 for the management of endogenous depression and is listed in the 8th WHO Model List of Essential Drugs. Much of the adverse effects are caused by its antimuscarinic actions. These include dry mouth, cardiac arrhythmias, central nervous system disturbances, blood disorders and risk of suicide. The risk of suicide and dangers related to overdosage led the Norwegian Medicines Control Authority to put the higher strength formulation under prescribing restriction in 1992. The risk of death following overdosage is apparently higher for products containing tricyclic compounds as compared with nontricyclic products.

Legislative or regulative action

Product name **Amobarbital**

C.A.S. number **57-43-2**

Scientific and common names, and synonyms

AMYLBARBITONE
2,4,6(1H,3H,5H)-PYRIMIDINETRIONE, 5-ETHYL-5-(3-METHYL-BUTYL)-
5-ETHYL-5-ISOPENTYLBARBITURIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	July 1985	Withdrawn following discussions between the manufacturer and the National Board of Health and Welfare. Fatal intoxications and abuse are associated with use of preparations containing amobarbital.
NZL	1990	In agreement with the Department of Health, products containing amobarbital and amobarbital sodium have been withdrawn by the manufacturer. (Reference: (NZCSL) Clinical Services Letter, Department of Health, 258,, 16 July 1990)
		WHO comment: Amobarbital is an intermediate-acting barbiturate which is controlled under Schedule III of the 1971 Convention on Psychotropic Substances. See WHO comment for barbiturates. (Reference: (UNCPS3) United Nations Convention on Psychotropic Substances (III),,, 1971)

Product name **Amodiaquine**

C.A.S. number **86-42-0**

Scientific and common names, and synonyms

PHENOL, 4-((7-CHLORO-4-QUINOLINYL)AMINO)-2-((DIETHYLAMINO)METHYL)-
4-((7-CHLORO-4-QUINOLYL)AMINO)-alpha-(DIETHYLAMINO)-O-CRESOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
@WD	July 1986	Having regard to cases of agranulocytosis associated with prophylactic use of amodiaquine, the major manufacturer has removed malaria prophylaxis from the data sheet worldwide.
		WHO comment: Amodiaquine, an antimalarial agent related to chloroquine, was introduced over 40 years ago for the treatment and prophylaxis of malaria. The drug was voluntarily withdrawn in the United Kingdom in 1975 for commercial reasons but was subsequently reintroduced in 1985 to meet the medical demand for an antimalarial drug to deal with the rapid spread of chloroquine-resistant falciparum malaria in Asia and Africa. By 1986 a significant number of cases of agranulocytosis associated with prophylactic use, some of which were fatal, had been reported there and it has been estimated that the frequency of this risk is of the order of 1:2,000. Although most cases occurred when amodiaquine had been used in combination with other antimalarials, the major manufacturer decided to withdraw the prophylactic indication worldwide following discussions with experts. Preparations remain available for the treatment of acute attacks of malaria which involves only a short period of exposure to the drug. (Reference: (WHODI) WHO Drug Information, 1, 5, 1987)

Product name **Anabolic steroids**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
THA	Oct. 1989	Products containing anabolic steroids indicated for increasing appetite in children have been withdrawn, due to the risks of undesirable androgenic effects. All products containing anabolic steroids have been subjected to prescription control. (Reference: (THAMH) Ministry of Public Health,,, 15 Apr. 1991)
CAN	26 June 1992	Products containing androgenic-anabolic steroids are claffified in Schedule G of the Food and Drugs Act and the Schedule to the Food and Drugs Regulations with regard to the high prevalence of their abuse by athletes and high school children. They are now subject to import/export permits, licensing and prescription control. (Reference: (CANHW) Canada Health and Welfare,,, 13 Oct. 1992)
		WHO comment: Anabolic steroids were formerly used to increase weight in patients suffering from emaciation or debilitating diseases but have not proved totally successful. They are also used in the treatment of certain aplastic anaemias, breast cancer and in the prevention of osteoporosis. They have been subject to much abuse in athletes and malnourished children to increase body weight. Misuse in prepubertal children has been associated with undesirable effects, including precocious sexual development in males and virilization in females, which have led the Thai agency to withdraw products containing anabolic steroids indicated for increasing appetite in children.

Product name **Anagestone acetate**

C.A.S. number **3137-73-3**

Scientific and common names, and synonyms

PREGN-4-EN-20-ONE, 17-(ACETYLOXY)-6-METHYL-, (6alpha)
17-HYDROXY-6alpha-METHYL-PREGN-4EN-20-ONE-ACETATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1969	Following reports of breast tumours in dogs receiving anagestone acetate in combination with mestranol, the manufacturer withdrew preparations containing these drugs.
AUT	23 May 1969	Following reports of breast tumours in dogs receiving anagestone acetate in combination with mestranol, the manufacturer withdrew preparations containing these drugs.
KWT	1 Apr. 1970	Importation and marketing of preparations containing anagestone acetate is prohibited.
		WHO comment: Anagestone acetate, a synthetic progestogen, was introduced in 1968 as a component in oral contraceptive preparations. In 1969, it was shown to be associated with an increased risk of mammary tumours in dogs which led the United States Food and Drug Administration to order the termination of its use in all clinical trials. Subsequently the manufacturer withdrew preparations containing anagestone acetate, ultimately on a worldwide basis.

Product name **Androgens**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	Sep. 1989	Products containing androgens may no longer be indicated for suppression of lactation and prevention of breast engorgement in mothers who elect not to breastfeed. (Reference: (FDATP) Food and Drug Administration Talk Paper, T89-56,, 27 Sep. 1989) **WHO comment:** Androgens have been used for the prevention of postpartum breast pain and engorgement. However, because of the risk of rebound effect and since only 10% of women benefit therapeutically from such intervention, the United States Food and Drug Administration has requested manufacturers to stop labeling preparations containing androgens for this indication. The World Health Organization is not aware of similar action having been taken elsewhere.

Product name **Antihistamine (topical)**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
MYS	Nov. 1986	Antihistamines intended for local use were not approved. (Reference: (MYSDC) Malaysian Drug Control Authority, 1985-1987)
LKA	1 Jan. 1992	The Ministry of Health withdrew from sale cream formulations of antihistamines. It considers that antihistamine cream is of no value in hypersensitive skin rashes and that the preparations can themselves induce such rashes. (Reference: (LKADIB) Drug Information Bulletin, University of Peradeniya and Ministry of Health, 4(1),, 1992) **WHO comment:** Antihistamines have been used for many years as a treatment for hypersensitive reactions. The topical application of antihistamines is, however, associated with an unacceptable incidence of skin irritation and hypersensitivity reactions.

Product name **Aphrodisiac drugs**

Scientific and common names, and synonyms

CANTHARIDES
ESTROGENS
METHYLTESTOSTERONE
NUX VOMICA
STRYCHNINE
TESTOSTERONE
YOHIMBINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	8 Jan. 1990	All nonprescription products claiming to have aphrodisiac effects have been banned, on the grounds that they are unsafe and of doubtful effectiveness. Among the ingredients contained in these products are: cantharides, estrogens, methyltestosterone, nux vomica, strychnine, testosterone and yohimbine. (References: (FEREAC) Federal Register, 54(129), 28780, 1989; (FDATP) Food and Drug Administration Talk Paper, T89-42,, 7 July 1989)

Product name **Aprobarbital**

C.A.S. number **77-02-1**

Scientific and common names, and synonyms

APROBARBITONE
5-ALLYL-5-ISOPROPYLBARBITURIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	July 1985	Withdrawn following discussions between the manufacturer and the National Board of Health and Welfare. Fatal intoxications and abuse are associated with use of preparations containing aprobarbital. **WHO comment:** Aprobarbital is an intermediate-acting barbiturate. See WHO comment for barbiturates.

Product name **Aristolochic acid**

C.A.S. number **313-67-7**

Scientific and common names, and synonyms

ARISTOLOCHINE
8-METHOXY-6-NITROPHENANTHRO(3,4-D)-1,3-DIOXOLE-5-CARBOXYLIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1981	The Federal Health Office withdrew all preparations containing aristolochic acid from the national market following demonstration of a carcinogenic potential in a three-month toxicity study in rats. The Federal Health Office considers that aristolochic acid is a particularly potent carcinogen having regard to the unusually short period of exposure required for induction; the variety of tissues involved; the marked dose-effect relationship and the rapid progression of malignant changes after suspension of dosage. The regulatory decision relates not only to branded drugs containing aristolochic acid but to the sale of herbal preparations or extracts prepared from plants of the aristolochiaceae family. Only homeopathic preparations prepared to a dilution of at least 1:100,000,000,000 were exempted.
AUT	Aug. 1981	The Federal Ministry of Health and Environmental Protection has instructed pharmacists that, having regard to their apparent risks, preparations containing aristolochic acid have no justifiable use.
EGY	1982	Products containing aristolochic acid were withdrawn following demonstration of carcinogenicity in rats.
VEN		Not approved for use and/or sale. **WHO comment:** Extracts of aristolochiaceae have traditionally been used as a bitter for which a broad range of therapeutic effects has been claimed. Aristolochic acid is claimed to promote phagocytosis and to have immunostimulant activity. However, in 1981, a three-month toxicity study in rats revealed the carcinogenic potential of aristolochic acid and preparations containing this substance have since been withdrawn in several countries.

Product name **Arsenic-based compounds**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
AUT	Oct. 1969	All tonics, parenteral preparations, oral asthma remedies and vaginal tablets containing arsenic have been withdrawn in the light of the carcinogenic potential of arsenic-containing compounds.
PHL	Mar. 1976	Banned in any form for use in pharmaceuticals.
ESP	1 Oct. 1983	Preparations containing inorganic arsenicals have been withdrawn. (Reference: (ESPMC) Programa Selectivo de Revisión de Medicamentos, (1),, Sep. 1983)
ITA		These substances in tonics and reconstituents have been removed from the market owing to an unfavourable risk/benefit ratio. **WHO comment:** Arsenic-based compounds, which were used over 2000 years ago as both therapeutic agents and poisons, became the mainstay of chemotherapy earlier this century. Although such compounds have been largely superseded by safer and more effective alternatives, they remain important in the treatment of certain tropical diseases.

Product name **Astemizole**

C.A.S. number **68844-77-9**

Scientific and common names, and synonyms

1H-BENZIMIDAZOL-2-AMINE, 1((4-FLUOROPHENYL)METHYL)-N-(1-(2-(4-METHOXYPHENYL)ETHYL)-4-PIPERIDINYL)-1-(p-FLUOROBENZYL)-2-((1-(p-METHOXYPHENETHYL)-4-PIPERIDYL)AMINO)BENZIMIDAZOLE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NOR	1987	The medicines control authority has refused registration of astemizole because its prolonged half-life renders appropriate dosage difficult and the possibility of hepatic toxicity and adverse immunologically-mediated effects have not been adequately excluded. (Reference: (NNSLM) Nytt fra Statens Legemiddelkontroll, 4, 4, 1987) **WHO comment:** Astemizole, an H1-antihistamine, was introduced in 1983 and remains registered in many countries. The World Health Organization is not aware that registration has been refused in any other country.

Product name **Azapropazone**

C.A.S. number **13539-59-8**

Scientific and common names, and synonyms

APAZONE
1H-PYRAZOLO(1,2-a)(1,2,4)BENZOTRIAZINE-1,3(2H)-DIONE, 5-(DIMETHYLAMINO) -9-METHYL-2-PROPYL-
5-DIMETHYLAMINO-9-METHYL-2-PROPYL-1H-PYRAZOLO(1,2-a)(1,2,4)BENZOTRIAZINE-1, 3(2H)-DIONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1985	Indications are restricted to exacerbations of inflammatory degenerative rheumatism, soft tissue rheumatism and pain, post-traumatic swelling or inflammation. Preparations are contraindicated in children under six years of age.
OMN	Sep. 1986	The Ministry of Health has prohibited the import of preparations containing azapropazone except those intended for topical use.

...(Continued)

Legislative or regulative action

Product name **Azapropazone** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BEL	1 Jan. 1988	Preparations containing azapropazone have been placed in List IV of the 'Arrêté du Régent' of 2 June 1946 and as such can be administered only on prescription. They must be kept in a poisons cabinet and carry the skull and cross-bones label. (Reference: (BELAR) Arrêté Royal,,, June 1987)
AUT		Indications restricted to exacerbations of gout and other arthritic conditions. Treatment should not exceed seven days and doctors are advised not to prescribe this drug to children under 14 years of age or elderly patients. (Reference: (WIMAM) Wichtige Mitteilung ueber Arzneimittel, (1),, 1984)
		WHO comment: Azapropazone, which has anti-inflammatory, analgesic and antipyretic activity, was introduced in 1970 for the treatment of rheumatic disorders. Although sometimes classified as a pyrazolone derivative, the relationship with this group of compounds has been disputed and classification as a benzotriazine derivative might be preferable. Although, to date, it has not been associated with blood dyscrasias, some regulatory authorities have applied the same rigorous restrictions to its indications as they have applied to pyrazolone derivatives. The World Health Organization was informed that as of December 1987 azapropazone was available in some 27 countries.

Product name **Azaribine**

C.A.S. number **2169-64-6**

Scientific and common names, and synonyms

AS-TRIAZINE-3,5-(2H,4H)-DIONE, 2-(2',3',5'-TRIACETYL-beta-D- RIBOFURANOSYL)-
TRIACETYL AZAURIDINE
1,2,4-TRIAZINE-3,5(2H,4H)-DIONE, 2-(2,3,5-TRI-O-ACETYL-beta- RIBOFURANOSYL)-
2-beta-D-RIBOFURANOSYL-AS-TRIAZINE-3. -5(2H,4H)-DIONE 2',3',5'.- TRIACETATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	Aug. 1976	This antineoplastic agent, which was indicated only for severe, recalcitrant, disabling arthritis, was withdrawn from the market following reports of several serious thromboembolic and thrombotic reactions. Several of these lesions occurred in relatively unusual arterial sites (including the radial, ulnar, femoral and popliteal arteries) and one death resulted from pulmonary embolism.
THA	Feb. 1977	Products containing this ingredient have been banned.
MUS	9 Mar. 1982	Under the Pharmacy and Poisons (Prohibitions) of Harmful Drugs Regulations, this drug is deemed "harmful" by the Ministry of Health and is prohibited for import, manufacture, storage, distribution, sale, possession, use, export or other transaction. (Reference: (MPPHD) Pharmacy & Poisons (Prohibitions of Harmful Drugs) Regulations,,, Mar. 1982)
SAU		Withdrawn from the market following reports of adverse effects.
VEN		Not approved for use and/or sale.
		WHO comment: Azaribine, an antineoplastic agent, was introduced in 1975 for the treatment of severe, recalcitrant, disabling arthritis. Following reports of thromboembolic and thrombotic reactions, the drug was withdrawn in the USA in 1976. The causal relationship between azaribine and these events has been questioned and the drug remains available in the USA for investigational purposes.

Product name **ACE-Inhibitors**

Scientific and common names, and synonyms
ANGIOTENSIN-CONVERTING ENZYME INHIBITORS

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	Sep. 1988	The Federal Health Office re-emphasized that products containing ACE-inhibitors are contraindicated during pregnancy. Exposure to enalapril or captopril in utero has resulted in a state of potentially reversible anuria in newly born infants. (Reference: (BGHBL) Bundesgesundheitsblatt, 31/9, 369, 1988)
GBR	Dec. 1989	The product information of ACE-inhibitors including captopril, enalapril, lisinopril and quinapril was amended to emphasize that these products are contraindicated in pregnancy, following thier association with shortage of amniotic fluid in mothers and abnormal skull ossification, hypotension, renal failure and anuria in exposed infants. (Reference: (GBRCSM) Committee on Safety of Medicines, Current problems, 27,, Dec. 1989)
ITA	July 1990	Use of products containing ACE-inhibitors was contraindicated during pregnancy, following their association with shortage of amniotic fluid in mothers and imcomplete cranial ossification in neonates. (Reference: (BIFTI) Bolletino d'Informazione sui Farmaci, XIV(7):4,, 1990)
MYS	1992	Manufacturers and importers of products containing ACE-inhibitors were notified by the Drug Control Authority to include a warning that ACE-inhibitors have been shown to be fetotoxic in animal studies and their use in women in the later stages of pregnancy has been associated with an increased incidence of serious fetal/neonatal conditions. (Reference: (MYSDN) Berita Ubat-Ubatan (Drug Newsletter), 6(2):2,, 1992)
NZL	1992	Having regard to reports of foetal damage, including kidney failure and face or skull deformities attributed to angiotensin-converting enzyme inhibitors, women in New Zealand who become pregnant while receiving such a product have been advised to consult their doctor in order that an alternative treatment may be prescribed. (Reference: (NZCSL) Clinical Services Letter, Department of Health, 266,, 28 Aug. 1992)
PRT	1992	The Ministry of Health revised the product information for angiotensin-converting enzyme (ACE) inhibitorsto contraindicate their use during pregnancy. (Reference: (PRTIT) Informacao terapeutica, 1(1),, May 1992)
SWE	1992	The Medical Product Agency recommended that treatment with ACE-inhibitors be discontinued immediately should the patient become pregnant. (Reference: (SWEILS) Information från Läkemedelsverket, 2(3):89,, 1992)
USA	Mar. 1992	Product containing ACE-inhibitors, including captopril, fosinopril, benazepril, ramipril, lisinopril, enalapril, enalaprilat and quinapril were required to carry a boxed warning regarding risks of exposure during the later stages of pregnancy, following reports of kidney failure, and abnormalities in the face and cranium of the foetus. (Reference: (HHSNS) HHS News: US Department of Health and Human Services, P92-8,, 13 Mar. 1992)
ESP	21 Apr. 1992	The Directorate General of Pharmacy and Health Products of the Ministry of Health and Consumer Affairs decided that ACE-inhibitors treatment during pregnancy should be contraindicated. (Reference: (ESPOR) Ministerio de Sanidad y Consumo,,, 2 July 1992) **WHO comment:** Captopril, the first angiotensin-converting enzyme inhibitor, was introduced on the market in 1978. By 1981, its use during pregnancy had become associated with foetal abnormalities. Other ACE-inhibitors used during the late stages of pregnancy have subsequently been associated with sometimes severe adverse effects in the foetus, including kidney failure, anuria, hypotension and skull deformities. This has led several regulatory authorities to require that warnings against use in pregnancy be strengthened in the approved product information of these compounds.

Product name **Barbital**

C.A.S. number **57-44-3**

Scientific and common names, and synonyms

BARBITONE
DIEMALUM
DIETHYLMALONYLUREA
MALONAL
5,5-DIETHYLBARBITURIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ITA		This substance for use as a sedative has been removed from the market owing to an unfavourable risk-benefit ratio and the lack of substantial evidence of efficacy. **WHO comment:** Barbital is a long-acting barbiturate which is controlled under Schedule IV of the 1971 Convention on Psychotropic Substances. See WHO comment for barbiturates. (Reference: (UNCPS4) United Nations Convention on Psychotropic Substances (IV),,, 1971)

Product name **Beclobrate**

C.A.S. number **55937-99-0**

Scientific and common names, and synonyms

ETHYL(+)-2-[(alpha-(p-CHLOROPHENYL)-p-TOLYL)OXY)-2-METHYLBUTYRATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
CHE	1990	Having regard to two reports of fatal hepatitis, the marketing authorization of products containing beclobrate has been withdrawn. (Reference: (CHBCM) Bulletin Mensuel, 8,, 24 Sep. 1990) **WHO comment:** Beclobrate, an antihyperlipidaemic agent, was introduced into medicine in 1985. Although a causal relationship between the use of the drug and hepatic toxicity has not been established, the Intercantonal Office for the Control of Medicines has withdrawn marketing authorization since safer therapeutic alternatives are available. Beclobrate is not registered elsewhere.

Product name **Bencyclane**

C.A.S. number **2179-37-5**

Scientific and common names, and synonyms

3-((1/BENZYLCYCLOHEPTYL)OXY)-N,N-DIMETHYLPROPYLAMINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	Feb. 1991	In collaboration with the Federal Health Office, the manufacturer amended the approved product information of preparations containing bencyclane to contraindicate their use in epileptic patients; in patients who had sustained head injury within the previous 12 months; and in patients receiving treatment with pentoxifylline, naftidrofuryl, flunarizine or buflomedil. (Reference: (DEUFHO) Communication from Federal Health Office,,, 29 June 1992)

...(Continued)

Product name **Bencyclane** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Bencyclane, a vasodilator, was introduced in 1970 for the treatment of peripheral and cerebral vascular disorders. In 1991, its use was contraindicated by the German authorities in patients at risk of epilepsy following reports of convulsions in patients under treatment. Bencyclane is widely registered and the World Health Organization is not aware of restrictive action having been taken elsewhere.

Product name **Benorilate**

C.A.S. number **5003-48-5**

Scientific and common names, and synonyms

BENORYLATE
4-ACETAMIDOPHENYL SALICYLATE ACETATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GBR	Dec. 1986	The Committee on Safety of Medicines has advised that preparations containing benorilate should not be administered to children under 12 years of age except on medical advice. (Reference: (GBMIL) Medicines Act Information Letter, No.48,, Oct. 1986) **WHO comment:** Benorilate is the acetylsalicylic ester of paracetamol. See WHO comment for acetylsalicylic acid.

Product name **Benoxaprofen**

C.A.S. number **51234-28-7**

Scientific and common names, and synonyms

(+/-)-2-(P-CHLOROPHENYL)-alpha-METHYL-5-BENZOXAZOLEACETIC ACID
5-BENZOXAZOLEACETIC ACID, 2-(4-CHLOROPHENYL)-alpha-METHYL, (+/-)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
@WD	Aug. 1982	Following action in Denmark and reports from other countries, in particular of hepatic reactions in elderly patients from the United Kingdom, the drug was withdrawn worldwide by the manufacturer. Benoxaprofen had previously been withdrawn in several countries because of serious toxic effects on various organ systems, particularly the gastro-intestinal tract, the liver and bone marrow, in addition to previously known effects on the skin, eyes and nails. Subsequent to this decision, limited clinical trials were abandoned following demonstration of positive findings in carcinogenicity studies in mice. **WHO comment:** Benoxaprofen, a nonsteroidal antiinflammatory agent, was introduced in 1980 for the treatment of rheumatic disorders. Following reports of serious adverse effects, some of which were fatal, it was withdrawn in several countries prior to worldwide withdrawal by the manufacturer in 1982.

Product name **Benzarone**

C.A.S. number **1477-19-6**

Scientific and common names, and synonyms

2-ETHYLBENZOFURAN-3-YL 4-HYDROXYPHENYL KETONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	19 Oct. 1992	The Federal Health Office suspended the marketing authorization for pharmaceutical products containing benzarone. (References: (DEUFHO) Communication from Federal Health Office,,, 19 Oct. 1992; (DEUPD) BGA Pressedienst,,, 20 Oct. 1992) **WHO comment:** Benzarone is given by mouth and applied topically for treatment of various vascular peripheral disorders.The decision to suspend the marketing authorization results from several reports of toxic hepatitis, including one fatal case from within Germany. The product remains registered in Italy and France.

Product name **Benzyl alcohol**

C.A.S. number **100-51-6**

Scientific and common names, and synonyms

alpha-HYDROXYTOLUENE
alpha-TOLUENOL
BENZENECARBINOL
BENZENEMETHANOL
(HYDROXYMETHYL)BENZENE
PHENYLCARBINOL
PHENYLMETHANOL
PHENYLMETHYL ALCOHOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ISR	1982	The Ministry of Health has ordered that this preservative be excluded from solutions intended for parenteral infusions (in large volumes). In other parenteral preparations containing this preservative, the following warning should be added to the label: "Caution - not to be used in newly-born or premature infants".
USA	1982	The Food and Drug Administration has advised that benzyl alcohol should not be used as a preservative in drugs or fluids intended for parenteral administration in neonates, following reports of 16 deaths in neonates attributed to the use of 0.9% benzyl alcohol in water and saline used to clear intravascular catheters and to reconstitute drugs. Death followed signs of metabolic acidosis and convulsions. Both blood and urine contained high concentrations of benzoic and hippuric acid.
OMN	July 1982	Prohibited for import or sale as a preservative in water and normal saline intended for injection.
ITA	1983	The label for products containing this compound advises "Owing to benzyl alcohol presence, do not administer to children less than two years old".
GRC	1984	All preparations containing benzyl alcohol must carry the warning "Its use should be avoided in children under two years of age. Not to be used at all in neonates.".
DEU		The contraindications have been extended to include "Not to be used in neonates, particularly in the premature".
THA		The use of pharmaceutical preparations containing benzyl alcohol is severely restricted.
VEN		Subject to restricted use and/or sale.

...(Continued)

Product name **Benzyl alcohol** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Benzyl alcohol has been used as an antimicrobial agent in pharmaceutical preparations for many years. Parenteral administration of preparations containing 0.9% benzyl alcohol resulted in the death of 16 neonates in the USA in the early 1980s. Many countries subsequently warned against using such preparations in neonates. This decision is not applicable to the use of benzyl alcohol as a preservative in other circumstances or to its use in topical preparations and no country has placed a total ban on the compound.

Product name **Benzylpenicillin sodium (topical preparations)**

C.A.S. number **69-57-8**

Scientific and common names, and synonyms

BENZYLPENICILLIN
CRYSTALLINE PENICILLIN G SODIUM
MONOSODIUM (2S,5R,6R)-3,3-DIMETHYL-7-OXO-6-(2-PHENYLACETAMIDO)-4-THIA- 1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOXYLATE
PENICILLIN
PENICILLIN G

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	Feb. 1972	Topical preparations have been withdrawn from the market and are prohibited for export by the Food and Drug Administration due to the lack of effectiveness of these products and an unfavourable benefit-to-risk ratio. (Reference: (FEREAC) Federal Register, 37, 438, Feb. 1972)
ITA	1976	Preparations for rectal and topical use, including those intended for use in the mouth, have been withdrawn from the market owing to the risk of sensitization.
PHL	1976	Penicillin ointment and other penicillin-containing products for topical application have been banned for use/sale due to the risk of sensitization. (Reference: (PHADO) Administrative Order, 238,, 1976)
ETH	1978	Preparations for topical use have been withdrawn following reports of hypersensitivity.
BGD	June 1982	Use of all topical preparations was discontinued due to lack of effectiveness and risk of hypersensitivity reactions.
IND	1983	Skin and eye ointments have been prohibited for manufacture and sale for reasons of health risks associated with use and/or questionable therapeutic value. (Reference: (GAZIE) The Gazette of India: Extraordinary, II-3I,, 23 July 1986)
CHL		Pharmaceutical preparations intended for topical use containing penicillin and its derivatives were prohibited. (Reference: (CHLRS) Resolution of the Minister of Health, No. 10154,, Oct. 1986)
CYP		All products containing penicillin intended for topical use were withdrawn following a review of published information on hypersensitivity in treated patients.
ESP		Combination products containing penicillin for topical or rectal use will no longer be considered for registration since topically applied penicillin may evoke serious dermatitis and rectal absorption is insecure, irregular and inadequate.
THA		Ointment containing benzylpenicillin is not approved for use.
VEN		Not approved for use and/or sale.

...(Continued)

Product name **Benzylpenicillin sodium (topical preparations)** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Benzylpenicillin sodium, one of the first penicillin derivatives to be used in medicine, was introduced in the early 1940s. Topical preparations intended for use on the skin have been associated with allergic rashes and are in general no longer acceptable. However, topical preparations for specialized use, in particular in the eye and on open wounds, are available in many countries. Injectable preparations of benzylpenicillin are included in the WHO Model List of Essential Drugs. (Reference: (WHTAC1) Model List of Essential Drugs, 2nd Report of the WHO Expert Committee,,, 1985)

Bibliographical references

WHO FOOD ADD., 27, 105, 1991

Product name **Berberine**

C.A.S. number **2086-83-1**

Scientific and common names, and synonyms

BERBERICINE
BERBERIN
UMBELLATIN
5,6-DIHYDRO-9,10-DIMETHOXY-BENZO(G)-1,3-BENZODIOXOLO(5,6-A) QUINOLIZINIUM
7,8,13,13a-TETRAHYDRO-9,10-DIMETHOXY-2,3-METHYLENEDIOXY-BERBINIUM

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SGP	Oct. 1978	The Ministry of Health announced a prohibition on the importation and sale of preparations containing berberine following reports of jaundice, haemolytic anemia and kernicterus with brain damage in infants with glucose 6-phosphate dehydrogenase deficiency who were exposed either in utero or post-natally.
VEN		Not approved for use and/or sale. **WHO comment:** Berberine, an alkaloid contained in many plants including Berberis species, remains available in many tropical countries. Both traditional herbal remedies and tablet formulations containing this substance have been used in the treatment of gastrointestinal disease, and injectable preparations have been claimed to be of value in the treatment of cutaneous leishmaniasis. The action taken in Singapore relates to reports of jaundice, haemolytic anaemia and kernicterus with brain damage in infants with G6PD deficiency who were exposed either in utero or post-natally. Preparations for topical application are also available in some countries. These have not been associated with reports of systemic toxicity.

Product name **Beta ethoxylacetanilide**

C.A.S. number **539-08-2**

Scientific and common names, and synonyms

LACTIC ACID-p-PHENETIDINE
LACTYLPHENETIDINE
N-(para-ETHOXYPHENYL) LACTAMIDE
N-(4-ETHOXYPHENYL)-2-HYDROXYPROPANAMIDE
p-LACTOPHENETIDINE

...(Continued)

Legislative or regulative action

Product name **Beta ethoxylacetanilide** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	Mar. 1986	Preparations containing beta-ethoxylacetanilide have been withdrawn and will no longer be considered for registration. **WHO comment:** Beta-ethoxylacetanilide is an analogue of phenacetin. See WHO comment for phenacetin.

Product name **Bismuth salts**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
EGY	1975	Products containing bismuth subgallate were withdrawn due to a possible association with encephalopathy.
JPN	June 1975	Bismuth was banned in over-the-counter drugs due to psychoneurotic disorders found with use. In 1981 the indication for bismuth in preparations available only on prescription was restricted to diarrhoea.
GRC	1976	Bismuth subgallate was withdrawn in 1976 and bismuth subnitrate was withdrawn in 1980.
FRA	Sep. 1978	All oral proprietary medicinal products containing insoluble bismuth salts were removed provisionally from the market for a period of one year and have subsequently remained suspended on grounds of apparent neuropsychiatric toxicity. Relevant entries have not, however, been deleted from the French Pharmacopoeia and pharmacists remain entitled to compound prescriptions on the order of a doctor.
AUT	31 Dec. 1980	Pharmaceutical preparations containing salts or esters of bismuth were withdrawn following reports of encephalopathy associated with their use. Some eye ointments were exempted from this decision.
BGD	1982	Under the provisions of the Drugs (Control) Ordinance, products with bismuth have been banned. This substance is cited as a cause of encephalopathy. (Reference: (BGDCO) The Drugs (Control) Ordinance,,, 1982)
TUR	1982	After review of published information about this product, the Ministry of Health required manufacturers to remove insoluble bismuth salts from pharmaceutical products intended for oral use, with the exception of colloidal bismuth potassium citrate complex. Export of these products is prohibited.
MUS	9 Mar. 1982	Under the Pharmacy and Poisons (Prohibitions of Harmful Drugs) Regulations, this drug is deemed "harmful" by the Ministry of Health and is prohibited for import, manufacture, storage, distribution, sale, possession, use, export or other transaction. (Reference: (MPPHD) Pharmacy & Poisons (Prohibitions of Harmful Drugs) Regulations,,, Mar. 1982)
SWE	Sep. 1983	Preparations containing bismuth salts are now available on prescription only.
OMN	Apr. 1989	Import and marketing of antidiarrhoeal preparations intended for paediatric use containing bismuth salts were prohibited. (Reference: (OMNCR) Circular, 9/89,, Apr. 1989)
CUB		The use of bismuth subnitrate in paediatric preparations is prohibited on the recommendation of the National Paediatricians Group.
IND		Prohibited for manufacture and sale for reasons of health risks associated with use and/or questionable therapeutic value. (Reference: (GAZIE) The Gazette of India: Extraordinary, II-3i,, 23 July 1986)
ITA		Insoluble bismuth salts for oral administration carry a label with a warning concerning the advisability of avoiding prolonged use and high dosages. Products with other chemotherapeutic activity (other than anti-luetics) have been withdrawn from the market.
SAU		Bismuth subgallate remains available only for use in suppositories.

...(Continued)

Product name **Bismuth salts** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Bismuth salts were first introduced into medicine over two centuries ago and have since been used in over-the-counter preparations for the treatment of dyspepsia. In 1972 prolonged intake of high doses of bismuth subgallate was associated with cases of encephalopathy in Australia. Subsequently a similar association involving the subnitrate salt became evident in France. Preparations containing bismuth salts have since either been withdrawn or subjected to restrictive regulatory action in many countries. However, in some countries preparations containing bismuth subsalicylate, which retains a place in the management of dyspepsia, have been exempted from this restriction. Additionally, colloidal bismuth subcitrate is widely used in the treatment of gastritis and peptic ulcer disease. (Reference: (WHODI) WHO Drug Information, 2, 8, 1977)

Product name **Bithionol**

C.A.S. number **97-18-7**

Scientific and common names, and synonyms

BIS(2-HYDROXY-3,5-DICHLOROPHENYL)SULFIDE
2,2'-THIOBIS(4,6-DICHLOROPHENOL)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	Oct. 1967	Withdrawn from the market and prohibited for export by the Food and Drug Administration due to photosensitivity and cross-photosensitivity with other chemicals.
JPN	July 1971	Banned as an ingredient in cosmetics due to photosensitivity reactions.
		WHO comment: Bithionol, which has bactericidal and anthelminthic activity, was formerly available in soaps. By the late 1960s use of such preparations had been associated with a risk of photosensitivity reactions and cross-sensitivity with other halogenated disinfectants. This resulted in their withdrawal in the USA. Oral preparations of bithionol remain available for the treatment of paragonimiasis and fascioliasis.

Product name **Boric acid and borates**

C.A.S. number **10043-35-3**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
KWT	30 Mar. 1970	Any drug preparation intended for external use and containing boric acid should be labelled with the following warnings: "Only for external use." and "Do not apply to extensive areas of abraded or damaged skin.".
ISR	1973	Use of boric acid is prohibited except as a preservative in eyedrops and in dermal preparations in concentrations not higher than 1%.
KOR	1973	The Ministry of Health and Social Affairs has prohibited the manufacture of any baby powder which contains boric acid and sodium borate.
PHL	1973	By Administrative Order No. 195, all products for oral use and products for use in infants and children under three years of age have been prohibited. Products for external use must carry a special warning. These products have been reported to cause certain toxic reactions (disturbances in circulation, profound shock, convulsion) and fatalities with systemic absorption. (Reference: (PHADO) Administrative Order, 195,, 1973)

...(Continued)

Product name **Boric acid and borates** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
THA	Oct. 1973	Boric acid and borax are prohibited for use in baby powders.
IRL	1981	The Drugs Advisory Board has withdrawn all oral preparations. Some preparations for topical administration remain available but must bear a warning that they should not be administered to infants. (Reference: (IRDAB) National Drugs Advisory Board Annual Report, 12,, 1981)
DNK	1983	Subject to maximum concentration limits of 0.5% for peroral use, 1% for vaginal use and 3% for use in ear, eye or nose.
DEU	July 1983	The Federal Health Office has withdrawn the registration of the last remaining preparations containing either boric acid or its salts and esters. Exceptions to this order are made for ophthalmic preparations, mineral waters in which the boron content does not surpass that of ordinary drinking water, and some previously registered products containing phenylmercury dihydrogen borate.
DDR	1985	Boric acid has been eliminated from pharmaceutical and cosmetic preparations and is restricted to ophthalmic preparations for use as a buffer substance only. (Reference: (DDRMH) Regulation of Ministry of Health,,, June 1985)
JPN	July 1985	The Ministry of Health and Welfare banned boric acid and its salts except for eye application because of the toxicity of boric acid.
MYS	31 Dec. 1990	Products containing boric acid or borax for use in the oral cavity, rectum, vagina or on the skin and wounds have been withdrawn, having regard to reports of fatalities among infants and young children following accidental ingestion of these products or as a result of absorption from abraided skin. (Reference: (MYSPR) Ministry of Health Press Release, 15,, 28 Feb. 1990)
CRI		The Ministry of Public Health has prohibited the production, importation and sale of all products containing sodium borate (borax, sodium tetraborate) and boric acid in their composition, as well as their use as separate ingredients.
GBR		Following evidence that boric acid absorbed from topical preparations was responsible for the death of many healthy infants, the use of boric acid in topical preparations intended for use in infants has been prohibited.
IND		Preparations for children under three years of age prohibited for manufacture and sale for reasons of health risks associated with use and/or questionable therapeutic value.
ITA		Products for topical use are marketed with the following concentration limitations: not higher than 0.5% for stomatological use and not higher than 3% for any other use.
PER		Prohibited from use in cosmetic powders, due to their serious effects on the liver and kidney; and on the cardiovascular, digestive and nervous systems. Some fatalities have been connected to the use of these substances.
SAU		Use is restricted to ophthalmic preparations only.
USA		Following evidence that boric acid absorbed from topical preparations was responsible for the death of many healthy infants, the use of boric acid in topical preparations intended for use in infants has been prohibited. (Reference: (CFRUS) Code of Federal Regulations, 21-369.20, 204, 1985)
VEN		Subject to restricted use and/or sale.
		WHO comment: Boric acid and some borates were formerly extensively used as disinfectants and antiinflammatory agents. By the late 1960s an association between the death of many infants and application of high concentrations of boric acid contained in topical preparations used in the treatment of napkin rash had been established. This led to the restriction of the use of boric acid in pharmaceutical preparations by many regulatory authorities. In some countries it is now permitted only as an ingredient in ophthalmological preparations.

Product name **Bovine tissue derived medicines**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
IRL	1989	The National Drugs Advisory Board has decided that products containing bovine-derived components will notbe approved for marketing unless adequate evidence is provided that there is no potential for infectivity. (Reference: (IRDAB) National Drugs Advisory Board Annual Report, 1989, 28, Dec. 1990)
CHE	26 Mar. 1991	The Intercantonal Office for the Control of Medicines has prohibited as a part of the precautionary measures, the use of tissue from the high risk organs from cattle for the manufacture of medicines unless the tissues are derived from animals that are younger that six months, come from a country were no cases of bovine spongiform encephalopathy (BSE) have been reported and have not been fed animal material such meat, bone flour or fat. In addition, the manufacturing process should be capable of removing or reducing any potential for infection with BSE. Products containing only lactose of those that have the bovine material largely removed during manufacture procedure and those that cannot be withdrawn at short notice due to therapeutic importance are excluded from these measures, the latter only for a limited time. (Reference: (CHBCM) Bulletin Mensuel,,, 26 Mar. 1991)
FRA	23 July 1992	The Directorate of Pharmacy and Medicines of the Ministry of Health and Humanitarian Action has suspendedthe marketing authorization for medicinal products derived from bovine tissues. (Reference: (FRAMHH) Ministry of Health and Humanitarian Action,,, 23 July 1992) **WHO comment:** Bovine tissues are used to make important medicinal products such as heparin, glucagon, insulin and bloodfactors. In, 1986, bovine spongiform encephalopathy (transmitted from scrapie) was diagnosed in the United Kingdom. Restrictions on use of bovine material took into consideration the fact that the prion (sub-viral agent) causing the spongiform encephalopathy appears to be transmissible orally between species. As yet, there is no evidence of any direct causal relationship between scrapie and creutzfeld-jacob disease or any other spongiform encephalopathy of man. Nonetheless, a substantial array of research projects have been funded and in the interim precautionary measures were taken by the regulatory agencies.

Product name **Bromisoval**

C.A.S. number **496-67-3**

Scientific and common names, and synonyms

BROMISOVALERYLUREA
BROMVALERYLUREA
BROMVALETONE
BROMYLUM
2-BROMO-3-METHYLBUTYRYLUREA

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NLD	Jan. 1987	On request of the Board for the Evaluation of Medicines the manufacturers have withdrawn all products containing bromisoval having regard to their dependence potential and the risk of subsequent chronic intoxication. **WHO comment:** Bromisoval is a monureide sedative of long standing. It remains available in several countries. However, it releases the bromide ion and prolonged usage can result in chronic bromide accumulation and intoxication.

Product name **Bromocriptine**

C.A.S. number **25614-03-3**

Scientific and common names, and synonyms

ERGOTAMAN-3',6',18-TRIONE,2-BROMO-12'-HYDROXY-2'-(1-METHYLETHYL)-5-(2-METHYLPROPYL)-,(5'alpha)-
2-BROMO-alpha-ERGOCRYPTINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	Sep. 1989	Products containing bromocriptine may no longer be indicated for suppression of breast engorgement in mothers who elect not to breastfeed. (Reference: (FDATP) Food and Drug Administration Talk Paper, T89-56,, 27 Sep. 1989) **WHO comment:** Bromocriptine, a semisynthetic ergot alkaloid derivative and prolactin inhibitor was introduced into medicine in 1976. It is used in the prevention of lactation, but because of the risk of rebound effect and since only 10% of women benefit therapeutically from such intervention, the United States Food and Drug Administration has requested manufacturers to no longer indicate preparations containing bromocriptine for this purpose. The World Health Organization is not aware of similar action having been taken elsewhere.

Product name **Broxyquinoline (see also halogenated hydroxyquinoline derivatives)**

C.A.S. number **521-74-4**

Scientific and common names, and synonyms

5,7-DIBROMO-8-QUINOLINOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
JPN	Sep. 1970	The Ministry of Health and Welfare has prohibited the sale of clioquinol and broxyquinoline, and preparations containing them. These decisions were taken following reports that clioquinol might be one of the causes of subacute myelo-optic neuropathy (SMON).
ARE	9 June 1981	Pharmaceutical preparations containing broxyquinoline are banned. (Reference: (UAEMD) Ministry of Health Decree, No.694,, 1981)
SAU		Import of this product is prohibited.
VEN		Subject to restricted use and/or sale.
		WHO comment: Broxyquinoline is a halogenated hydroxyquinoline. See entry for halogenated hydroxyquinoline derivatives and WHO comment for clioquinol.

Product name **Bucetin**

C.A.S. number **1083-57-4**

Scientific and common names, and synonyms

3-HYDROXY-p-BUTYROPHENETIDIDE

...(Continued)

Product name **Bucetin** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1986	Preparations containing bucetin have been withdrawn from the market and will no longer be considered for registration. **WHO comment:** Bucetin is an analogue of phenacetin. See WHO comment for phenacetin.

Product name **Bufexamac**

C.A.S. number **2438-72-4**

Scientific and common names, and synonyms

2-(p-BUTOXYPHEYL)ACETOHYDROXAMIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
FRA	Dec. 1990	Because of reports of eczematous reactions, the indications for preparations containing bufexamac intended for topical application were restricted to the relief of pruritus in inflammatory dermatological conditions. These preparations could no longer be used for the treatment of eczema. (Reference: (FRARP) La Revue Prescrire, 11(106), 182, 1991)
DEU	Aug. 1991	The approved product information for preparations containing bufexamac was amended to warn against hypersensitivity reactions, including allergic contact dermatitis, generalized skin sensitization, urticaria, and contact eczema. (Reference: (DAZ) Deutsche Apotheker Zeitung, 131(31), VI, 1991) **WHO comment:** Bufexamac, an analgesic and anti-inflammatory agent, was introduced in 1974 for the topical treatment of a wide range of dermatoses. The drug is widely marketed and the World Health Organization is not aware of restrictive action having been taken elsewhere.

Product name **Buformin**

C.A.S. number **692-13-7**

Scientific and common names, and synonyms

BUFORMINE
BUTFORMIN
BUTYLBIGUANIDE
BUTYLDIGUANIDE
BUTYLFORMIN
GLYBIGIDUM
N-BUTYLDIGUANIDE
N-BUTYL-IMIDODICARBONIMIDIC DIAMIDE
1-BUTYLBIGUANIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DDR	1977	Following reports of lactic acidosis from several countries the use of buformin has been restricted. (Reference: (DDRZT) Zentrale Therapie Empfehlung Diabetes, add. 19, 8-11, 1978)
ITA	1978	Warnings and contraindications have been added to currently marketed products with this ingredient. It has been recommended that dosages lower than 100 mg/day be followed due to the risk of lactic acidosis.
DEU	Mar. 1978	Withdrawn from the market because of occurrence of lactic acidosis.

...(Continued)

Legislative or regulative action

Product name **Buformin** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
AUT	Sep. 1978	In conformity with decisions taken in several other countries, and following reports of occasional fatal cases of lactic acidosis, all products containing phenformin and buformin will be withdrawn. Metformin will remain available for use for limited indications.
BEL	1979	Voluntarily withdrawn from the market by the manufacturer.
IRL	1979	The biguanide hypoglycaemics, phenformin and buformin, were withdrawn from the market in Ireland in 1979 as a result of concern regarding lactic acidosis. Metformin will remain available but doctors are urged to ensure that patients receiving it are kept under regular surveillance. (Reference: (IRDAB) National Drugs Advisory Board Annual Report, 14,, 1979)
VEN		Subject to restricted use and/or sale. **WHO comment:** Buformin is an analogue of phenformin. See WHO comment for phenformin. (Reference: (WHODI) WHO Drug Information, 2, 4, 1977)

Product name **Bumadizone**

C.A.S. number **3583-64-0**

Scientific and common names, and synonyms

BUTYLMALONIC ACID MONO(1,2-DIPHENYLHYDRAZIDE)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1985	Indications restricted to severe exacerbations of rheumatism and acute gout. Duration of oral treatment should not exceed one week. Parenteral preparations are indicated exclusively for initiating therapy. A single injection only is recommended because local tissue damage may occur. Preparations are contraindicated in children under 14 years of age.
OMN	Sep. 1986	The Ministry of Health has prohibited the import of preparations containing bumadizone except those intended for topical use.
AUT		Indications restricted to exacerbations of gout and other arthritic conditions. Treatment should not exceed seven days and doctors are advised not to prescribe this drug to children under 14 years of age or elderly patients. (Reference: (WIMAM) Wichtige Mitteilung ueber Arzneimittel, (1),, 1984) **WHO comment:** Bumadizone, a pyrazolone derivative with antiinflammatory, analgesic and antipyretic activity, was introduced in 1972 for the treatment of rheumatic disorders. As it is structurally related to phenylbutazone it is subjected to rigorously restricted indications by some national regulatory authorities. See WHO comment for phenylbutazone.

Product name **Bunamiodyl**

C.A.S. number **1233-53-0**

Scientific and common names, and synonyms

CINNAMIC ACID, 3-BUTYRAMIDO-alpha-ETHYL-2,4,6-TRIIODO-,
2-(3-BUTYRAMIDO-3,4,6-TRIIODOPHENYL-METHYLENE)-BUTYRIC ACID

...(Continued)

Legislative or regulative action

Product name **Bunamiodyl** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	1964	The National Board of Health refused the approval of bunamiodyl on the grounds that its use is associated with adverse reactions.
USA	1964	The Food and Drug Administration withdrew bunamiodyl for oral cholecystography since repeat doses may be associated with oliguria, renal tubular necrosis, and death; the use of other cholecystographic agents within one week after bunamiodyl ingestion may be dangerous. It is contraindicated in patients with a history of renal disease. Evaluation of renal function should be performed before use of the drug. (Reference: (FEREAC) Federal Register, 36, 14493, Aug. 1971)
VEN		Not approved for use and/or sale. **WHO comment:** Bunamiodyl, an orally administered radio-opaque medium, was introduced in 1958 for use in the examination of the biliary tract. By 1964 its use had been associated with cases of renal failure, in some cases fatal, which resulted in its withdrawal by the United States Food and Drug Administration. Buniamiodyl was withdrawn worldwide by the manufacturer in 1984.

Product name **Buprenorphine**

C.A.S. number **52485-79-7**

Scientific and common names, and synonyms

21-CYCLOPROPYL-7alpha-((S)-1-HYDROXY-1,2,2-TRIMETHYLPROPYL))-6,14-ENDO-ETHANO-6,7,8,14-TETRAHYDRO-ORIPAVINE
6,14-ETHENOMORPHINAN-7-METHANOL, 17-(CYCLOPROPYLMETHYL)-alpha-(1,1- DIMETHYLETHYL)-4,5-EPOXY-18,19-DIHYDRO-3-HYDROXY-6-METHOXY-alpha-METHYL-,(5alpha, 7alpha, (S))-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NZL	22 Sep. 1983	Buprenorphine was included in Part IV of the Third Schedule of the Misuse of Drugs Act 1975. This implies that this substance is now subjected to the same controls as amobarbital, butobarbital and cyclobarbital. These include a requirement that prescriptions be written in triplicate on forms provided by the Department of Health.
AUT	1 June 1984	Subjected to control at national level analogous to that provided by Schedule I of the 1961 Single Convention on Narcotic Drugs.
DEU	1 Sep. 1984	Subjected to control at national level analogous to that applied to substances included in the 1961 Single Convention on Narcotic Drugs.
EGY	26 Nov. 1986	Withdrawn from the market. **WHO comment:** Buprenorphine, an opioid analgesic with both morphine agonist and antagonist activity, was introduced in 1978. It was originally considered to possess low dependence potential. However, it has latterly been identified as causing a socially significant abuse problem in several countries which have consequently subjected it to control in 1989 under Schedule III of the 1971 Convention of Psychotropic Substances. (Reference: (UNCPS3) United Nations Convention on Psychotropic Substances (III),,, 1971)

Product name **Cadralazine**

C.A.S. number **64241-34-5**

Scientific and common names, and synonyms

ETHYL 6-((2-HYDROXYPROPYL)AMINO)-3-PYRIDAZINYL)HYDRAZINECARBOXYLIC ACID ETHYL ESTER

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NOR	1992	The Medicines Control Authority refused an application for registration of the peripheral vasodilator, cadralazine on the grounds that the pharmacological and clinical documentation was inadequate. (Reference: (NNSLM) Nytt fra Statens Legemiddelkontroll, 1, 25, 1992) **WHO comment:** Cadralazine, a peripheral vasodilator, was introduced in 1989 for the treatment of arterial hypertension.In 1992, its association with serious side effects led to the refusal of registration in Norway. Animal experiments have demonstrated drug-related impairment of thyroid function as well as potential carcinogenicity and genotoxicity. It remains available for treatment of hypertension in Italy.

Product name **Calamus**

C.A.S. number **8015-79-0**

Scientific and common names, and synonyms

OIL OF CALAMUS

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	Nov. 1968	Withdrawn from the market and prohibited for export by the Food and Drug Administration on the basis of findings of animal carcinogenicity. (Reference: (FEREAC) Federal Register, 33, 17204, Nov. 1968) **WHO comment:** Calamus, the dried rhizome of acorus calamus, has been used as a bitter and carminative. The World Health Organization has no information further to the above regarding preparations containing calamus or to indicate that they are still commercially manufactured.

Product name **Camphor**

C.A.S. number **76-22-2**

Scientific and common names, and synonyms

ROOT BARK OIL
1,7,7-TRIMETHYLBICYCLO(2,2,1)HEPTANE-2-ONE
2-BORNANONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
FRA	17 Nov. 1983	The National Commission of Pharmacovigilance has recommended that preparations containing camphor be contraindicated in infants under 30 months and that they be used with caution in older children. This action results from reports of convulsions associated with topical application or inhalation.

...(Continued)

Product name **Camphor** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
EGY		The Technical Committee for Drug Control has published a warning that products containing camphor be contraindicated in infants under 30 months and that they be used with caution in older children. This action results from reports of convulsions associated with topical application or inhalation.
ITA		All pharmaceutical products containing camphor must bear the following warning: "This product is contraindicated in children under two years of age with a history of laryngospasm or convulsions. Caution must be exercised when older children are treated.". (Reference: (BIFTI) Bolletino d'Informazione sui Farmaci, (12),, 1984) **WHO comment:** Camphor, an aromatic crystalline substance with mild local anaesthetic activity, is available in preparations for both external application and inhalation. The use of such preparations has precipitated convulsions in susceptible infants. This has led several regulatory authorities to require the inclusion of appropriate warnings on labelling.

Product name **Canrenone**

C.A.S. number **976-71-6**

Scientific and common names, and synonyms

ALDADIENE
PREGNA-4,6-DIENE-21-CARBOXYLIC ACID, 17-HYDROXY-3-OXO-, gamma-LACTONE (17alpha)-
17alpha-(2-CARBOXYETHYL)-17beta-HYDROXYANDROSTA-4,6-DIEN-3-ONE LACTONE
17-HYDROXY-3-OXO-17alpha-PREGNA-4,6-DIENE-21-CARBOXYLIC ACID gamma- LACTONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1986	Preparations containing canrenone have been withdrawn having regard to the possible carcinogenic risk associated with long-term use. **WHO comment:** Canrenone, which has aldosterone antagonist activity, is a major metabolite of spironolactone and the major metabolite of potassium canrenoate. See WHO comments for potassium canrenoate and spironolactone.

Product name **Canthaxanthin**

C.A.S. number **514-78-3**

Scientific and common names, and synonyms

beta,beta-CAROTENE-4,4'-DIONE
CI FOOD ORANGE 8
COLOUR INDEX NO.40850
E.161.G

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	May 1985	The Federal Health Office has prohibited the use of canthaxanthin which is used in the treatment of certain photodermatoses and is contained in orally administered bronzing agents following reports of crystalline deposits in the retina.
DDR	Dec. 1985	Registration approval has been withdrawn due to proven accumulation of crystalline deposits in the retina. (Reference: (DDCI) Regulation of the Drug Control Institute,,, Dec. 1985)

...(Continued)

Legislative or regulative action

Product name **Canthaxanthin** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
AUT	31 Dec. 1985	The Federal Ministry of Health and Environmental Protection has agreed with the manufacturer to withdraw pharmaceutical preparations containing canthaxanthin following reports of crystalline deposits in the retina.
IRL	1986	Having regard to reported ocular toxicity associated with long-term use of the tanning agent canthaxanthin, the National Drugs Advisory Board has informed manufacturers that it will no longer be permitted as a constituent of medicinal products. In 1989 the Board was additionally advised that the compound be excluded from tanning preparations. (References: (IRDAB) National Drugs Advisory Board Annual Report,,, 1986; (IRDAB) National Drugs Advisory Board Annual Report,,, 1989)
EGY	1987	The Technical Committee for Drug Control has decided that canthaxanthin will no longer be accepted as a bronzing agent to avoid ophthalmic problems. (Reference: (EGYDI) Drug Information, 5(2), 1, 1987)
OMN	Sep. 1987	Import and marketing of products containing canthaxanthin were prohibited. (Reference: (OMNDI) Drug Information, 5(2):1,, 1987)
		WHO comment: Canthaxanthin, a naturally-occurring carotenoid with a deep red-orange colour, is widely used as a food colouring agent. Since the mid-1970s it has been included in oral 'artificial suntan' preparations. It is also available in preparations used in the treatment of certain photodermatoses. By the mid-1980s its use in such preparations had been associated with the accumulation of crystalline deposits in the retina. Reported functional changes relating to dark adaptation have been of marginal clinical significance and largely reversible. Nevertheless, this has led to the withdrawal of artificial suntan preparations containing canthaxanthin by several regulatory authorities. Preparations for treatment of photodermatoses remain available in some but not all of these countries.

Product name **Cartilage extract**

Scientific and common names, and synonyms
AQUEOUS CALF CARTILAGE & BONE MARROW EXTRACT

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	June 1992	The marketing authorization of injectable preparations containing calf cartilage and bone marrow extract was suspended, in the first instance, until 31 December 1992. The decision resulted from an apparent association with serious adverse effects including local intolerance and anaphylactoid reactions, renal insufficiency, pulmonary fibrosis and autoimmune diseases of the skin and muscles. (Reference: (DEUPD) BGA Pressedienst, 24,, 1992)
		WHO comment: A preparation containing calf cartilage and bone marrow extract was introduced in 1960 for the treatment of degenerative joint disease, and it is currently registered in several countries. In 1987, a risk-benefit assessment of the product was commissioned in Germany. This resulted initially in its use being contraindicated in patients with altered immune responses. Subsequently, the marketing authorization was suspended in Germany in 1992 when the product was associated with serious adverse effects.

Product name **Cathine**

C.A.S. number **492-39-7**

Scientific and common names, and synonyms

(+)-NORPSEUDOEPHEDRINE
(+)-THREO-2-AMINO-1-HYDROXY-1-PHENYLPROPYLPROPANE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	July 1981	Administration of centrally active appetite inhibiting preparations containing cathine has been restricted to four weeks. A warning concerning the risk of dependence has been included in the package leaflet.
PHL	Oct. 1983	Disapproved for use in appetite control due to the risk of drug dependency and other adverse effects such as apathy, depression, chronic gastroduodenitis, dyspeptic disorders and dreamy euphoria with loquacity.
GRC	1985	Not accepted as an appetite suppressant having regard to its low benefit-to-risk ratio (systemic side-effects). **WHO comment:** Cathine, a sympathomimetic amine, was formerly widely available in proprietary anorexic preparations. As dependence can occur and abuse has been reported, cathine has recently (1986) been subjected to control under Schedule III of the 1971 Convention on Psychotropic Substances. (Reference: (UNCPS3) United Nations Convention on Psychotropic Substances (III),,, 1971)

Product name **Cefaloridine**

C.A.S. number **50-59-9**

Scientific and common names, and synonyms

CEPHALORIDINE
PYRIDIUM,1-[(2-CARBOXY-8-OXO-7-[(2-THIENYLACETYL)AMINO)-5-THIA-1-AZABICYCLO(4.2.0)-OCT-2-EN-3-YL)METHYL)-,HYDROXIDE, inner salt, (6R-TRANS)-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ESP	1989	The marketing authorization of products containing cefaloridine has been withdrawn, having regard to their nephrotoxicity. (Reference: (ESPINS) Información Terapéutica de la Seguridad Social, 13(1), 7, 1989) **WHO comment:** Cefaloridine, a semi-synthetic cephalosporin antibiotic, was introduced into medicine in 1964 for the treatment of bacterial infections. It is considered to be the most toxic of the cephalosporins, and for this reason is now seldom used. Nevertheless, it still remains available in certain countries and the World Health Organization is not aware of restrictive actions taken elsewhere.

Product name **Cefalosporins (topical preparations)**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
CHL		Pharmaceutical preparations for topical use containing cefalosporin and its derivatives are prohibited. (Reference: (CHLRS) Resolution of the Minister of Health, No.10154,, Oct. 1986)

Product name **Cell preparations**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
AUT	Aug. 1987	Deep-frozen cell preparations used in the practice of cell therapy have been banned, on the grounds that fatalities associated with these products have been reported in the Federal Republic of Germany and that marketing authorization has been suspended in this country. (Reference: (DAZ) Deutsche Apotheker Zeitung, 127(34), 1720, 1987)
DEU	30 June 1988	The marketing authorization for injectable preparations used in the practice of cell therapy has been withdrawn, having regard to the serious and sometimes fatal reactions associated with these products, which have not been demonstrated to possess any therapeutic effect. (Reference: (DEUPD) BGA Pressedienst, 22,, 1988)
CHE	July 1988	All products prepared from fresh animal cells have been banned, on the grounds that fatalities associated with their use had been reported in the Federal Republic of Germany and that efficacy had not been demonstrated. (Reference: (CHBCM) Bulletin Mensuel,,, 31 Aug. 1988) **WHO comment:** Injectable preparations used in the practice of cell therapy were introduced into medicine many years ago.They contain cells from organs or tissues of fetal or juvenile animals of species such as sheep, cattle, swine and rabbits. A variety of indications were claimed by the manufacturers of these products, including adjuvant tumour therapy, Down's syndrome, ageing, immune defects, endocrine disturbances, diseases of the motor system, the central nervous system, the heart and vascular system and chronic liver disease. Whilst proof of efficacy in these indications has never been established, the use of cell preparations has been associated with severe, sometimes fatal adverse immunological reactions, particularly with anaphylactic shock and serum sickness. This has led to their withdrawal by regulatory authorities in the countries listed above.

Product name **Chenodeoxycholic acid**

C.A.S. number **474-25-9**

Scientific and common names, and synonyms

CHENODIOL
CHOLAN-24-OIC ACID, 3,7-DIHYDROXY-, (3ALPHA,5BETA,7ALPHA)-
3ALPHA,7ALPHA-DIHYDROXY-5BETA-CHOLAN-24-OIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NOR	1987	Chenodeoxycholic acid is not approved for registration on grounds of animal studies indicating a carcinogenic effect and because the risk of a cancer-promoting effect in man is considered significant. **WHO comment:** Chenodeoxycholic acid was introduced in 1975 for the treatment of cholelithiasis. It is available in several countries and the World Health Organization is not aware that registration has been refused in any other country.

Product name **Chloramphenicol**

C.A.S. number **56-75-7**

Scientific and common names, and synonyms

ACETAMIDE, 2,2-DICHLORO-N-(2-HYDROXY-1-(HYDROXYMETHYL)-2-(4- NITROPHENYL)ETHYL)-, (R-(R*,R*))
D-threo-(-)-2,2-DICHLORO-N-(beta-HYDROXY-alpha-(HYDROXYMETHYL)-p-NITROPHENETHYL)ACETAMIDE
LAEVOMYCETINUM

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1975	Use should be limited to treatment of acute attacks of typhoid and paratyphoid fever, purulent meningitis and life-threatening infections caused by sensitive organisms in which less dangerous antibiotics are ineffective or contraindicated.
JPN	Oct. 1975	Indications have been restricted.
DNK	1978	Doctors have been advised that systemic chloramphenicol should be used only in patients requiring admission to hospital. It is contraindicated in uncomplicated urinary tract infections. (Reference: (UGLAAD) Ugeskrift for Laeger, 140, 1165, 1978)
FRA	22 Sep. 1978	Products for topical application containing chloramphenicol have been withdrawn from the market, with the exception of eyedrops and ophthalmic ointments. Indications for products intended for internal use are restricted to serious infections caused by organisms sensitive to chloramphenicol when other potentially less dangerous products are ineffective.
PHL	July 1982	Severely restricted in use due to the risk of developing agranulocytosis. Limited to indications of typhoid fever, meningitis and brain abcess.
EGY	July 1983	All pharmaceutical preparations containing chloramphenicol should bear the following warning: "Not to be used for long periods or repeatedly, even in small doses, to avoid the risk of toxic effects such as bone marrow aplasia and acute leukaemia. Use should be restricted to cases not responding to other antibiotics".
NLD	1984	Doctors have been reminded that, even when applied topically in the eye, chloramphenicol may induce blood dyscrasias. When chloramphenicol appears to be the drug of choice, the susceptibility of the pathogenic organism should always be confirmed bacteriologically.
CAN	1985	Prohibited for administration to animals that may be consumed as food due to persistent residues in food products.
ESP	1 Mar. 1985	Registration of combination products containing chloramphenicol will no longer be considered because of the propensity of this drug to cause aplastic anaemia.
HUN	1987	Chloramphenicol has been banned for therapeutic purposes in milk- and egg-producing animals, having regard to its potential to induce aplastic anaemia in man, and the prolonged period during which residues remain demonstrable after withdrawal. (Reference: (HUNIH) National Institute of Occupational Health Notification,,, 25 May 1988)
IRL	Oct. 1989	The administration of chloramphenicol to all food-bearing animals (including horses) has been prohibited, on the grounds that the drug enters the food chain and may therefore cause adverse effects and transferable drug resistance in man. (References: (IRDAB) National Drugs Advisory Board Annual Report,, 312, 1987; (IRDAP) Animal Pharm, 187, 4, 6 Sep. 1989) **WHO comment:** Chloramphenicol, an antibiotic isolated from Streptomyces venezuelae in 1947, first became available for general clinical use in 1948. By 1950 it was evident that its use could cause serious, sometimes fatal, blood dyscrasias. However, it remains one of the most effective antibiotics for treating invasive typhoid fever and salmonellosis, some rickettsioses and serious infections caused by Haemophilus influenzae or anaerobic organisms. This is considered to justify its retention in the WHO Model List of Essential Drugs. (Reference: (WHTAC1) Model List of Essential Drugs, 2nd Report of the WHO Expert Committee, 722,, 1985)

Product name **Chlormadinone acetate**

C.A.S. number **302-22-7**

Scientific and common names, and synonyms

PREGNA-4,6-DIENE-3,20-DIONE, 17-(ACETYLOXY)-6-CHLORO
6-CHLORO-17-HYDROXYPREGNA-4,6-DIENE-3,20-DIONE ACETATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	Mar. 1972	Application for approval of oral contraceptives containing chlormadinone acetate withdrawn by the manufacturer on recommendation by the Food and Drug Administration after findings in beagle bitches showing an increased incidence of mammary tumours resulting from this component. (Reference: (FEREAC) Federal Register, 37(52), 5516, 1972)
GBR	1977	The product licence for an oral contraceptive containing this substance has been cancelled due to the risk of carcinogenicity.
ITA	1979	Withdrawn from the market because of an increased incidence of breast tumours in beagle dogs during the course of long-term toxicity tests.
EGY	1980	Chlormadinone was not approved having regard to its potential to cause breast tumours in dogs.
VEN		Not approved for use and/or sale.
		WHO comment: Chlormadinone acetate, a synthetic progestogen, was introduced in 1965 as a component in oral contraceptive preparations. In 1967, as a result of new regulations required by the United States Food and Drug Administration, chlormadinone acetate was submitted to long-term toxicity studies and by the early 1970s it was shown to be associated with an increased incidence of mammary tumours in beagle bitches which led to its withdrawal by several regulatory authorities. Subsequently the validity of the beagle bitch model as a predictor of carcinogenicity of steroid contraceptives has been contested by many national regulatory authorities and chlormadinone remains available in some countries for contraceptive purposes. In some instances it is indicated for treatment of progesterone deficiency and endometriosis, and of irregular uterine bleeding due to fibroids. (Reference: (WHODI) WHO Drug Information, 84.1, 5, 1984)

Product name **Chlornaphazine**

C.A.S. number **494-03-1**

Scientific and common names, and synonyms

beta-NAPHTHYLBIS(beta-CHLOROETHYL)AMINE
NAPHTHYLAMINE MUSTARD
N,N-BIS(2-CHLOROETHYL)- 2-NAPHTHYLAMINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DNK	1964	The National Health Service withdrew chlornaphazine, a drug used against lymphogranulomatosis, polycythaemia and chronic leukaemia, as it appeared to be carcinogenic especially in the bladder.
VEN		Not approved for use and/or sale.
		WHO comment: The World Health Organization has no information further to the above regarding preparations containing chlornaphazine or to indicate that they are still commercially manufactured.

Product name **Chloroform**

C.A.S. number **67-66-3**

Scientific and common names, and synonyms

METHANE, TRICHLORO-
TRICHLOROFORM
TRICHLOROMETHANE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GRC	1976	Not accepted in pharmaceuticals or cosmetics.
TUR	1976	Removed from all cough syrups after a decision by the Ministry of Health based on a review of published information regarding carcinogenicity in rats. Export of this product is prohibited.
JPN	May 1976	Banned by the Pharmaceutical Affairs Bureau in Drugs and Cosmetics for reasons of carcinogenicity.
USA	July 1976	Withdrawn from the market and prohibited for export in drugs and cosmetics by the Food and Drug Administration on the basis of findings of liver cancer in experimental mice and rats by the National Cancer Institute. (Reference: (FEREAC) Federal Register, 41, 26842, July 1976)
PAN	30 Nov. 1976	The Ministry of Health has banned the sale of pharmaceuticals containing chloroform. (Reference: (PANMR) Ministry of Health Resolution, 1843,, Aug. 1976)
SAU	1977	Sale or supply of any medicinal product containing chloroform has been prohibited by the Drug Committee.
BRA	25 May 1977	Products containing chloroform are prohibited. (Reference: (BRAPT) Portaria do Servico Publico Federal, No.15,, May 1977)
ITA	1978	Withdrawn from the market owing to suspected carcinogenicity.
CAN	Jan. 1978	National legislation has provided that no manufacturer or importer shall sell a drug for human use that contains chloroform as an ingredient. The Health Protection Branch has reviewed evidence from the National Cancer Institute in the US which suggests that chloroform may be carcinogenic in rats and mice when administered in high doses over prolonged periods. Export of this product is allowed with no requirement of foreign notification regarding domestic restrictions on its use. (Reference: (CANGZ) Canada Gazette,,, Nov. 1977)
NOR	Apr. 1978	Prohibited for use in pure form or as an additive to pharmaceutical preparations.
PHL	Apr. 1978	Prohibited for use as an ingredient in human drugs and cosmetics on the grounds of results of a study by the National Cancer Institute in the United States, suggesting that the substance may be carcinogenic in rats and mice when administered over prolonged periods. (Reference: (PHADO) Administrative Order, 341S,, 1978)
DDR	Dec. 1978	Registration approval for preparations containing chloroform has been withdrawn due to a carcinogenic potential. (Reference: (DDCI) Regulation of the Drug Control Institute,,, Dec. 1978)
GBR	1979	The Chloroform Prohibition Order has prohibited the sale or supply of any medicinal product containing chloroform. Certain exemptions apply. (Reference: (GBCHL) Chloroform Prohibition Order,,, 1979)
NZL	1980	Toothpaste formulations containing chloroform have been voluntarily withdrawn from the market.
DNK	1981	Registered for veterinary use only. (Reference: (DENBH) Danish National Board of Health, Circular Letter,,, Sep. 1981)
ETH	1981	Prohibited because of its carcinogenic effects.
ZWE	May 1981	Medicinal products containing more than 0.5% chloroform are prohibited because of the toxicity of the drug. Certain exemptions apply. (Reference: (ZWDCC) Drugs Control Council, News Bulletin, 1,, 1983)
DEU	1982	Prohibited for use and/or sale.

...(Continued)

Product name **Chloroform** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BGD	June 1982	Use of chloroform as an excipient in pharmaceutical preparations has been banned due to reported adverse effects.
DOM	1983	Domestic manufacturers and importers have been requested to eliminate this ingredient from their marketed products since pharmacological studies have shown it to be toxic to the liver and the heart, and to be carcinogenic.
BEL	12 Feb. 1983	Prohibited for sale. (Reference: (BELAR) Arrêté Royal,,, Feb. 1983)
NGA	1 Feb. 1985	Chloroform is not allowed in cosmetic and drug products since 1 Feb. 1985. From that date, import, export and sale of products containing chloroform became illegal. The decision was based on reports from literature of the carcinogenic effects of chloroform on animals and possible hepatotoxic and nephrotoxic effects after prolonged use by humans. (Reference: (AARNO) Administrative Action, MH.1856/S.3T, 112, 15 Sep. 1983)
IRL	1989	Having regard to their toxicity, approval for marketing of all preparations containing chloroform was withdrawn. (Reference: (IRDAB) National Drugs Advisory Board Annual Report,, 29, 1989)
OMN	27 July 1992	Sale and marketing of products containing chloroform were prohibited, having regard to reported adverse effects and toxicity. (Reference: (OMNCR) Circular, 27/92,, July 1992)
CUB		Following the action taken by the US Food and Drug Administration, the National Formulary Commission requested removal of chloroform from pharmaceutical preparations.
THA		The use of pharmaceutical preparations containing chloroform is severely restricted.
VEN		Subject to restricted use and/or sale.
		WHO comment: Chloroform was formerly widely used in pharmaceutical preparations as a solvent and preservative as well as for its anaesthetic and flavouring properties. By the late 1970s reservations concerning its safety, including positive results in a carcinogenicity screening programme sponsored by the National Cancer Institute in the USA, had led to considerable restrictions in its use in pharmaceutical preparations. While many pharmaceutical products containing chloroform have been withdrawn or reformulated to exclude this substance, it may still be incorporated in toothpastes and other specified products in some countries, subject to statutorily-imposed concentration limits. (Reference: (IARCCD) Chloroform: IARC Monograph, 20(20), 401-427, 1979)

Product name **Chloroquine**

C.A.S. number **54-05-7**

Scientific and common names, and synonyms

1,4-PENTANEDIAMINE, N4-(7-CHLORO-4-QUINOLINYL)-N1,N1-DIETHYL-
7-CHLORO-4-((4-(DIETHYLAMINO)-1-METHYLBUTYL)AMINO)-QUINOLINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
JPN	1975	Chloroquine was voluntarily withdrawn from production and sale by the manufacturer due to the risk of retinopathy associated with its use at high doses in the treatment of rheumatoid arthritis and related diseases.

...(Continued)

Product name **Chloroquine** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Chloroquine, a 4-aminoquinoline derivative, was introduced in the 1940s for the treatment and prophylaxis of malaria. It was subsequently found to be effective in higher and prolonged dosage in the treatment of lupus erythematosus, rheumatoid arthritis and nephritis. In the early 1970s its use in these latter conditions was largely discontinued when it was found that prolonged daily administration at high dosage was associated with cases of retinopathy resulting from local deposition of the compound. Chloroquine however remains a valuable drug. It can be used continuously at the dosages required for malaria prophylaxis for as long as five years without risk of undue accumulation and it is included in the WHO Model List of Essential Drugs for both its antimalarial and antiamoebic activity. (Reference: (WHTAC1) Model List of Essential Drugs, 2nd Report of the WHO Expert Committee, 722,, 1985)

Product name **Chlorphentermine**

C.A.S. number **461-78-9**

Scientific and common names, and synonyms

p-CHLORO-alpha,alpha-DIMETHYLPHENETHYLAMINE
1-(p-CHLOROPHENYL)-2-METHYL-2-AMINOPROPANE
4-CHLORO-alpha,alpha-DIMETHYL-BENZENEETHANAMINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1969	The Ministry of Health withdrew preparations containing aminorex, cloforex and chlorphentermine as a precautionary measure pending scientific evidence of a relationship between their use and the development of pulmonary hypertension.
BEL	1 Jan. 1988	Preparations containing chlorphentermine have been placed in List IV of the 'Arrêté du Régent' of 2 June 1946 and as such can be administered only on prescription. They must be kept in a poisons cabinet and carry the skull and cross-bones label. (Reference: (BELAR) Arrêté Royal,,, June 1987)
VEN		Banned for use and/or sale.
		WHO comment: Chlorphentermine, a sympathomimetic phenethylamine derivative, was introduced over twenty years ago for the treatment of obesity. Concern that its use was associated with cases of pulmonary hypertension led to its withdrawal in several countries. However, it remains available in some other countries.

Product name **Cianidanol**

C.A.S. number **154-23-4**

Scientific and common names, and synonyms

(+)-CATECHOL
CIANIDOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ITA	5 Sep. 1985	Provisionally withdrawn by the Pharmaceutical Division of the Ministry of Health.
@WD	6 Sep. 1985	Marketing of cianidanol was temporarily suspended worldwide by the manufacturer.
EGY	22 Oct. 1985	Cianidanol has been withdrawn from the market and importation temporarily prohibited.

...(Continued)

Legislative or regulative action

Product name **Cianidanol** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	26 June 1987	Subsequent to its decision to suspend the marketing authorization of products containing cianidanol, the Federal Health Office has definitively withdrawn registration of these products. (Reference: (FRGGH) Bundesgesundheitsamt Pressedienst,,, June 1987)
CHE	30 June 1988	The Intercantonal Office for Drug Control has withdrawn the marketing license for cianidanol.
@WD	30 June 1988	Cianidanol was definitively withdrawn worldwide by the manufacturer.
AUT		Use of preparations containing cianidanol has been prohibited until further notice.
		WHO comment: Cianidanol, which is extracted from the tropical plant Uncaria gambir, was introduced in 1976 as an adjunct in the treatment of liver disorders. Following a cluster of cases of haemolytic anaemia reported in 1985 from Naples, Italy, four of which were fatal, the company suspended sales worldwide. Although subsequently reintroduced in Switzerland and France for the treatment of acute and chronic hepatitis-B, it was later definitively withdrawn in Switzerland on detailed reassessment and the manufacturer has now withdrawn the product worldwide.

Product name **Cinchophen**

C.A.S. number **132-60-5**

Scientific and common names, and synonyms

CINCHONINIC ACID, 2-PHENYL-
2-PHENYLCINCHONINIC ACID
2-PHENYLQUINOLINE-4-CARBOXYLIC ACID.

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	June 1991	Products containing cinchophen were withdrawn, because of the associated risks of hepatic toxicity, including jaundice, hepatitis and cirrhosis and a greater incidence of gastric ulceration than is associated with other nonsteroidal antiinflammatory agents. (Reference: (FRGGH) Bundesgesundheitsamt Pressedienst,,, 7 June 1991)
ITA		Withdrawn from the market owing to an unfavourable risk-benefit ratio and the lack of substantial evidence of efficacy.
		WHO comment: Cinchophen, an analgesic and antipyretic, was formerly available in preparations for the treatment of gout. Its use was associated with adverse effects including hepatitis, cirrhosis, skin lesions and angioneurotic oedema. WHO has no information to suggest that preparations containing cinchophen remains commercially available.

Product name **Cinepazide**

C.A.S. number **23887-46-9**

Scientific and common names, and synonyms

1-((1-PYRROLIDINYLCARBONYL)METHYL)-4-(3,4,5-TRIMETHOXYCINNAMOYL) PIPERAZINE

...(Continued)

Legislative or regulative action

Product name **Cinepazide** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
EGY	1988	Registration of products containing cinepazide was refused, having regard to international reports of blood dyscrasias associated with their use. (Reference: (EGYDI) Drug Information, 6(4), 1, 1988)
ESP	1988	In agreement with the Ministry of Health, products containing cinepazide have been withdrawn by the manufacturers. (Reference: (ESPOR) Ministerio de Sanidad y Consumo,,, 13 Feb. 1991) **WHO comment:** Cinepazide, a vasodilating agent, was first introduced into medicine in 1974. It is used in the treatment of peripheral and cerebral vascular disorders. Following reports of blood dyscrasias, including agranulocytosis and thrombocytopenia, associated with the use of the drug, the Spanish Committee on Drug Surveillance has recommended its withdrawal. In other countries, the approved product information of preparations containing cinepazide has been amended to include a relevant warning on these adverse effects.

Product name **Cinnarizine**

C.A.S. number **298-57-7**

Scientific and common names, and synonyms

PIPERAZINE,1-(DIPHENYLMETHYL)-4-(3-PHENYL-2-PROPENYL)
1-CINNAMYL-4-(DIPHENYLMETHYL) PIPERAZINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ESP	Aug. 1989	Having regard to their potential to induce extrapyramidal symptoms, products containing cinnarizine may no longer be indicated for cerebral and peripheral arterial insufficiency, including loss of memory, insomnia, intermittent claudication, rest pain or vasospastic disturbances. The approved indications are restricted to vestibular disturbances, vertigo, prophylaxis of vascular headache and prevention of motion sickness. (Reference: (ESPINS) Información Terapéutica de la Seguridad Social, 13(8), 176, 1989) **WHO comment:** Cinnarizine, an antihistaminic and vasodilator agent, was introduced into medicine in 1962. It is indicated for the treatment of labyrinthine disturbances and vascular disorders, although its effectiveness in the latter indication has not been convincingly demonstrated.

Product name **Clemastine**

C.A.S. number **15686-51-8**

Scientific and common names, and synonyms

PYRROLIDINE, 2-((1-(4-CHLOROPHENYL)-1-PHENYLETHOXY)ETHYL)-1-METHYL-,(R-(R*,R*))-
(+)-(2R)-2-(-(((R)-p-CHLORO-alpha-METHYL-alpha-PHENYLBENZYL)OXY)ETHYL)-1-METHYLPYRROL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GBR	1991	Products containing clemastine were disallowed in children under one year of age, because of their possible association with sleep apnoea. (Reference: (GBRPHJ) The Pharmaceutical Journal,,, 24 Aug. 1991) **WHO comment:** See WHO comment for H1-antihistamines.

Legislative or regulative action

Product name **Clioquinol (see also halogenated hydroxyquinoline derivatives)**

C.A.S. number **130-26-7**

Scientific and common names, and synonyms

CHINOFORM
CHLOROIODOQUIN
IODOCHLORHYDROXYQUIN
IODOCHLORHYDROXYQUINOLINE
5-CHLORO-7-IODOQUINOLINOL
5-CHLORO-7-IODO-8-QUINOLINOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
JPN	Sep. 1970	The Ministry of Heath and Welfare prohibited the sale of clioquinol and broxyquinoline, and preparations containing them, following reports that clioquinol might be one of the causes of subacute myelo-optic neuropathy (SMON).
NOR	Jan. 1974	Withdrawn from the market.
SWE	June 1975	Withdrawn by the manufacturer after mutual discussions due to neurological adverse reactions. It remains on the market for external use.
BEL	1976	Following cases of subacute myelo-optic neuropathy (SMON) in Japan, manufacturers of clioquinol in Belgium have limited the indications for use and duration of treatment. Since 1975 clioquinol has been available only on prescription.
DEU	1 Jan. 1977	Preparations containing clioquinol intended for internal use have been placed under prescription control because of a propensity to cause neurological disorders.
DNK	1978	Products have been withdrawn from the market. (Reference: (UGLAAD) Ugeskrift for Laeger, 140, 1181, 1978)
FRA	3 Nov. 1978	Clioquinol has been placed under Schedule A of the Poisonous Substances Regulations.
ARE	9 June 1981	Pharmaceutical preparations containing clioquinol are banned. (Reference: (UAEMD) Ministry of Health Decree, No.694,, 1981)
NGA	1982	Importation, sale and manufacture of clioquinol and clioquinol-containing products for oral administration have been prohibited, because of evidence of neurological disorders, including SMON, associated with their use. (Reference: (NGAPN) Pharmanews, 10(11), 15, 1988)
BGD	June 1982	Banned as a single ingredient or in combination due to its implication in subacute myelo-optic neuropathy.
PHL	Aug. 1982	This drug, used to treat infectious diarrhea, has been withdrawn from the domestic market due to reports of neurological disorders (SMON) associated with its use in Japan.
ITA	1983	Withdrawn from the market.
NPL	1983	All preparations containing this substance have been banned.
DOM	Feb. 1983	Prohibited for use and/or sale after authorities were informed of the manufacturer's intent to gradually replace this ingredient in all preparations currently marketed worldwide.
ZWE	Feb. 1983	Use of clioquinol is prohibited because of its propensity to cause neurological disorders. (Reference: (ZWDCC) Drugs Control Council, News Bulletin, 1,, 1983)
ESP	29 July 1983	The Ministry of Health and Consumer Protection has withdrawn approval for clioquinol. (Reference: (ESPMC) Programa Selectivo de Revisión de Medicamentos, (I),, Sep. 1983)
ZMB	7 Dec. 1983	Preparations of clioquinol for internal use may only be imported or exported on a licence issued by the Director of Medical Services. (Reference: (ZMBSI) Statutory Instrument, 166-167,, Dec. 1983)
DDR	1984	Registration has been withdrawn. (Reference: (DDRMH) Regulation of Ministry of Health,,, Jan. 1984)

...(Continued)

Product name **Clioquinol (see also halogenated hydroxyquinoline derivatives)** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
HKG	1 Jan. 1984	The Pharmacy and Poisons Committee no longer allows the registration, sale or distribution of products containing clioquinol.
ETH	7 Sep. 1984	Prohibited due to its association with sub-acute myelo-optic neuropathy.
HND	24 Oct. 1985	The importation, manufacture and sale of products containing clioquinol have been prohibited having regard to the drug's potential to cause SMON. (Reference: (HNDSP) Circular, 10-85,, 1985)
OMN	Mar. 1987	Import and marketing of oral and parenteral preparations containing clioquinol and related substances intended for the treatment of diarrhoea in children were prohibited. Topical preparations remain on the market. (Reference: (OMNCR) Circular, 11/87,, Mar. 1987)
PAK	1988	Oral preparations containing clioquinol were withdrawn. (Reference: (PAKMH) Ministry of Health, Special Education and Social Welfare,,, 3 Aug. 1988)
GHA	1 Sep. 1989	Products containing clioquinol have been banned. (Reference: (GHAPDR) Pharmacy and Drugs (Banned Drugs) Regulations, Legislative Instruments, 1484,, 1989)
LIY	21 May 1990	The General People's Health Committee banned the use of clioquinol in children. (Reference: (LIYRL) Resolution of the General People's Health Committee, 141,, May 1990)
BHR		Preparations containing clioquinol have been withdrawn.
CHE		Oral preparations of clioquinol have been subjected to prescription control and the approved indications restricted to intestinal amoebiasis and diarrhoea caused by sensitive organisms following cases of subacute myelo-optic neuropathy (SMON) in Switzerland.
CUB		Use restricted to treatment of parasitic infections.
NLD		Preparations containing clioquinol have been withdrawn from the market.
SAU		Following reports of subacute myelo-optic neuropathy (SMON) in patients treated with this drug, the Drug Committee has prohibited its import.
THA		The use of pharmaceutical preparations containing clioquinol is severely restricted.
VEN		Subject to restricted use and/or sale.
		WHO comment: Clioquinol, a halogenated hydroxyquinoline derivative, was introduced into medicine around 1900 as a topical antiseptic and in 1934 oral preparations for the treatment of amoebic dysentery and simple diarrhoea became available. By 1964 its use in Japan had been associated with cases of sub-acute myelo-optic neuropathy (SMON) which reached epidemic proportions resulting in its withdrawal there in 1970. Although relatively few cases of SMON were documented elsewhere, clioquinol was subsequently withdrawn from use in many countries and placed under prescription control in others. It was phased out worldwide by the major manufacturer between 1983 and 1985 on grounds of obsolescence. No adequately controlled evidence was ever generated to demonstrate that clioquinol is effective in bacterial or viral diarrhoea. However, products containing clioquinol and related halogenated hydroxyquinolines continue to be used in some tropical and subtropical countries where amoebiasis remains endemic. Other amoebocides are preferred in the WHO Model List of Essential Drugs. (Reference: (WHODI) WHO Drug Information, 77.1, 9, 1977)

Product name **Clofenotane**

C.A.S. number **50-29-3**

Scientific and common names, and synonyms

alpha,alpha-BIS(p-CHLOROPHENYL)-beta,beta,beta-TRICHLORETHANE
CHLOROPHENOTHANE

...(Continued)

Legislative or regulative action

Product name **Clofenotane** ...(Continued)

Scientific and common names, and synonyms

DDT
DICHLORODIPHENYLTRICHLOROETHANE
DICHLORODIPHENYLTRICHLOROETHANE (USA)
ETHANE, 1,1,1-TRICHLORO-2,2-BIS(P-CHLOROPHENYL)
p,p'-DICHLORODIPHENYLTRICHLOROETHANE
TRICHLOROBIS(4-CHLOROPHENYL)ETHANE
1,1,1-TRICHLOOR-2,2-BIS(4-CHLOOR FENYL)-ETHAAN (NLD)
1,1,1-TRICHLORO-2,2-BIS(p-CHLOROPHENYL)ETHANE
1,1,1-TRICHLORO-2,2-BIS(4-CHLOROPHENYL)ETHANE
1,1,1-TRICHLORO-2,2-DI(4-CHLOROPHENYL)-ETHANE
1,1,1-TRICHLOR-2,2-BIS(4-CHLOR-PHENYL)-AETHAN (DEU)
1,1,1-TRICLORO-2,2-BIS(4-CLORO-FENIL)-ETANO (ITA)
2,2-BIS(p-CHLOROPHENYL)-1,1,1-TRICHLOROETHANE
4,4'-DICHLORODIPHENYLTRICHLOROETHANE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	July 1972	The Environmental Protection Agency has cancelled all DDT products, except the following list of uses: the U.S. Public Health Service and other health service officials for control of vector diseases; the USDA or military for health quarantine; in drugs, for controlling body lice. (To be dispensed only by a physician). These compounds have been found to pose carcinogenic risk to humans and to be toxic to the ecosystem. (Reference: (FEREAC) Federal Register, 37, 13369, 1972)

Bibliographical references

IARC MONOGRAPH, 5, 83, 1974
IPCS ENVIRONMENTAL HEALTH CRITERIA, 9, , 1979
IARC MONOGRAPH, SUPPL.4, 105, 1982
FAO PLANT PRODUCTION & PROTECTION PAPER, 62, , 1984
WHO GUIDELINES FOR DRINKING WATER QUALITY, 2, , 1984

Product name **Clofibrate**

C.A.S. number **637-07-0**

Scientific and common names, and synonyms

ETHYL alpha-(4-CHLOROPHENOXY)-alpha-METHYLPROPIONATE
ETHYL CLOFIBRATE
ETHYL 2-(PARA-CHLOROPHENOXY)-2-METHYLPROPIONATE
ETHYL 2-(p-CHLOROPHENOXY)ISOBUTYRATE
PROPANOIC ACID,2-(p-CHLOROPHENOXY)-2-METHYL, ETHYL ESTER
PROPANOIC ACID, 2-(4-CHLOROPHENOXY)-2-METHYL, ETHYL ESTER

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1978	Although withdrawn following reports of increased mortality associated with its use, clofibrate was subsequently reinstated for treatment of high-risk patients in whom diet, weight reduction, exercise and control of diabetes had failed to elicit adequate control.
DNK	1979	Indications for use have been restricted.
ISR	1979	Withdrawn from the market following reports of increased mortality associated with use.
NOR	1979	Withdrawn from the market following reports of increased mortality associated with use.
FRA	2 Feb. 1979	The indications have been restricted, as for every hypolipidaemic drug, to the treatment of endogenous hypercholesterolaemia and hypertriglyceridaemia a) when a suitable and assiduously followed diet has proved inadequate; and b) when cholesterolaemia is still raised after dieting and/or there are associated risk factors present. (Reference: (FRAPC) Press Communiqué,,, Feb. 1979)

...(Continued)

Legislative or regulative action

Product name **Clofibrate** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	Aug. 1979	Indications are restricted to treatment of patients with hyperlipidaemia refractory to dietary measures. (Reference: (FDADB) FDA Drug Bulletin, 9(3), 14, 1979)
PHL	1980	Severely restricted in use to certain patients only. This compound has been shown to cause hepatic tumours in rodents. There is an increased risk of malignancy and cholelithiasis with use in humans. A warning statement is required to be placed on the labels of all products.
ITA	1981	Currently marketed in Italy with limited therapeutic indications (certain hyperproteinaemias with ascertained diagnoses; diabetic exudative retinopathy; xanthomes).
SWE	Jan. 1981	Used only in cases of severe hyperlipoproteinaemia due to increased mortality connected with long-term treatment.
BGD	1982	Under the provisions of the Drugs (Control) Ordinance, this drug has been banned since it increases the incidence of gallstones and cholecystitis, drug-induced cardiac arrhythmias, cardiomegaly, angina, claudication and thromboembolic phenomena. It also enhances the effects and toxicity of other acidic drugs and it is implicated in the incidence of various tumours. (Reference: (BGDCO) The Drugs (Control) Ordinance,,, 1982)
CHL	16 Dec. 1982	Indications are restricted to treatment of patients with high plasma lipid levels, resistant to dietary control. (Reference: (CHLRS) Resolution of the Minister of Health, 3261,, Dec. 1982)
CHE		Indications are restricted to treatment of patients with hyperlipidaemia refractory to dietary measures.
CUB		Indications are restricted to treatment of patients with hyperlipidaemia.
GBR		Indications are restricted to treatment of patients with hyperlipidaemia refractory to dietary measures.
GRC		Indications are restricted to treatment of patients with severe hyperlipidaemia.
IND		Currently available on the market. Precautionary information is required to be given with this drug.
SAU		Severely restricted for use and/or sale.
VEN		Subject to restricted use and/or sale.
		WHO comment: Clofibrate, an antihyperlipidaemic agent, was introduced in 1967 and was subsequently extensively studied in the primary and secondary prevention of ischaemic heart disease. Following reports, published in 1978, of increased mortality among patients receiving clofibrate in a WHO-sponsored cooperative trial concerned with the primary prevention of ischaemic heart disease, the drug was withdrawn in some countries and its approved indications were severely restricted in many others. These restrictions have become the norm for more recently developed analogues of clofibrate. (Reference: (WHODI) WHO Drug Information, 2, 6, 1979)

Product name **Cloforex**

C.A.S. number **14261-75-7**

Scientific and common names, and synonyms

CLOPHOREX
ETHYL(p-CHLORO-alpha,alpha-DIMETHYLPHENETHYL)-CARBAMATE
(p-CHLORO-alpha,alpha-DIMETHYLPHENETHYL)-CARBAMIC ACID
(2-(4-CHLOROPHENYL)-1,1-DIMETHYLETHYL)-CARBAMIC ACID

...(Continued)

Legislative or regulative action

Product name **Cloforex** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1969	The Ministry of Health withdrew preparations containing aminorex, cloforex and chlorphentermine as a precautionary measure pending scientific evidence of a relationship between their use and the development of pulmonary hypertension.
SWE	14 Feb. 1969	All antiobesity preparations containing cloforex were withdrawn from the market following several reports of pulmonary hypertension in patients treated with the related drug chlorphentermine in West Germany, and pre-existing knowledge of a relationship between pulmonary hypertension and the antiobesity drug aminorex.
VEN		Not approved for use and/or sale. **WHO comment:** Cloforex, a sympathomimetic phenethylamine derivative, was introduced over twenty years ago for the treatment of obesity. Concern that its use was associated with cases of pulmonary hypertension led to its withdrawal in several countries. WHO has no information to suggest that this drug remains commercially available.

Product name **Clometacin**

C.A.S. number **25803-14-9**

Scientific and common names, and synonyms

3-(P-CHLOROBENZOYL)-6-METHOXY-2-METHYLINDOLE-1-ACETIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
FRA	1990	All preparations containing clometacin were withdrawn, having regard to severe cases of hepatitis associated with their use. (Reference: (FRARP) La Revue Prescrire, 10(95), 148, 1990) **WHO comment:** Clometacin, an analogue of indometacin, was introduced on the market in 1971. Subsequently several cases of severe - in some cases fatal - hepatitis were reported, which led in 1987 to the withdrawal of a high-dosage tablet formulation, while the indications for a lower dosage tablet were restricted and duration of the treatment was limited. Eventually all tablet formulations were removed from the market. Clometacin is not widely registered in other countries.

Product name **Clomethiazole**

C.A.S. number **533-45-9**

Scientific and common names, and synonyms

CHLORETHIAZOL
CHLORETHIAZOLE
5-(2-CHLOROETHYL)-4-METHYLTHIAZOLE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DDR	1 June 1983	Due to the high abuse or dependence potential, clomethiazole is controlled by the Law on Dependence-Producing Pharmaceuticals. Single dose preparations of not more than 0.2g and packages of multiple dose preparations of not more than 5g are exempt from this restriction. (Reference: (DDRG) Gazette of the German Democratic Republic, 1(7)S.69,, Jan. 1983)

...(Continued)

Legislative or regulative action

Product name **Clomethiazole** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Clomethiazole, which has sedative, anxiolytic and anticonvulsant activity, was introduced in 1960 for the treatment of acute alcohol withdrawal, delirium tremens, status epilepticus, eclamptic toxaemia, sleep disturbances in the elderly and agitation in psychogeriatic patients. It is also used as a sedative in certain anaesthetic procedures. There is little evidence of primary dependence in man but secondary dependence can occur in patients with a history of abuse of other substances, particularly alcohol. Dependence of this type has been reported as a result of inappropriate, long-term prescribing to outpatient alcoholics. Clomethiazole should not be prescribed to alcoholics who continue to drink. Adverse interactions with alcohol have been fatal. Although not controlled under the 1971 Convention on Psychotropic Substances, clomethiazole is subject to analogous controls in some countries.

Product name **Clozapine**

C.A.S. number **5786-21-0**

Scientific and common names, and synonyms

5H-DIBENZO(B,E),(1,4)DIAZEPINE, 8-CHLORO-11-(4-METHYL-1-PIPERAZINYL)-
8-CHLORO-11-(4-METHYL-1-PIPERAZINYL)-5H-DIBENZO(B,E)(1,4)DIAZEPINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
FIN	1975	Withdrawn from general use and restricted to named patients subject to permission of the competent authority.
SGP	Aug. 1977	Importation prohibited.
DEU	1978	Clozapine is only available for use in exceptional cases under the full responsibility of the physician.
DDR	Apr. 1978	The use of clozapine has been restricted, with the establishment of permitted indications, dosage limitations and control measures, due to the risk of agranulocytosis. (Reference: (DDRIL) Information Letter of the Ministry of Health,,, Apr. 1978)
NOR	1986	Registration refused since the balance of safety and efficacy does not justify registration. (Reference: (NNSLM) Nytt fra Statens Legemiddelkontroll, 2, 15, 1986)
		WHO comment: Clozapine, a tricyclic neuroleptic, was introduced in 1972 for the treatment of psychosis. In 1975 its use was associated with cases of agranulocytosis, particularly in Finland. These cases, which included several fatalities, resulted in the withdrawal of the drug in some countries. However, clozapine remains available in at least 30 countries, in some cases only on special request, for the treatment of severe psychotic disorders unresponsive to other neuroleptics provided that close monitoring of the blood count is feasible. In 1989, it was introduced in the United States for the treatment of severe schizophrenia. Lately, the use of clozapine in the United Kingdom has been associated with convulsions. (Reference: (WHODI) WHO Drug Information, 2, 10, 1977)

Product name **Cobalt (non-radioactive forms)**

C.A.S. number **7440-48-4**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	July 1967	Withdrawn from the market and prohibited for export (non-radioactive forms only) by the Food and Drug Administration due to the lack of evidence of effectiveness in treating iron-deficiency anemia and on the basis of toxic effects in humans including liver damage, claudication, myocardial damage, thyroid hyperplasia, hypothyroidism, dermatitis, nausea and anorexia. (Reference: (FEREAC) Federal Register, 32, 7945, 1967)
KWT	26 Oct. 1967	Importation and marketing of preparations containing inorganic cobalt salts are prohibited. **WHO comment:** The World Health Organization has no information further to the above regarding preparations containing cobalt or to indicate that they are still commercially manufactured.

Product name **Codeine**

C.A.S. number **6095-47-8**

Scientific and common names, and synonyms

MORPHINAN-6-OL, 7,8-DIDEHYDRO-4,5-EPOXY-3-METHOXY-17-METHYL-,MONOHYDRATE,(5alpha,6alpha)
7,8-DIDEHYDRO-4,5-alpha-EPOXY-3-METHOXY-17-METHYLMORPHINAN-6-alpha-OL MONOHYDRATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BGD	Sep. 1985	Use of codeine in any dosage form has been banned due to liability for addiction and misuse. **WHO comment:** Codeine, which has antitussive, opioid analgesic and antidiarrhoeal activity, was first extracted from opium in 1832 and has since been widely used in medicine. The development of dependence and its potential for abuse resulted in the control of the substance under Schedule II of the 1961 Single Convention on Narcotic Drugs. Preparations containing codeine remain widely available and are included in the WHO Model List of Essential Drugs. (Reference: (WHTAC1) Model List of Essential Drugs, 2nd Report of the WHO Expert Committee, No.722,, 1985)

Product name **Cyclamates in drugs**

C.A.S. number **139-05-9**

Scientific and common names, and synonyms

CYCLOHEXANESULFAMIC ACID
SULFAMIC ACID, CYCLOHEXYL-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
PER	Oct. 1969	Banned in pharmaceuticals due to its carcinogenic effects in experimental animals.
PHL	Jan. 1971	Cyclamic acid (or its salts) used as a sweetening agent in drugs has been withdrawn due to evidence of its carcinogenicity in animals.
PAN	23 Nov. 1971	Cyclamates are no longer allowed in pharmaceutical preparations. (Reference: (PANMR) Ministry of Health Resolution, 534,, Nov. 1971)

...(Continued)

Product name **Cyclamates in drugs** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
THA	Dec. 1974	As pharmaceutical ingredients, cyclamate and its salts are restricted to dosages of 3.5 g/day in adults and 1.2 g/day in children.
BGD	June 1982	Use of cyclamate as a sweetening agent has been banned due to reported adverse effects.
GRC	1986	Registration not approved.
NGA	1988	Sodium cyclamate has been banned, because its use has been associated with carcinogenicity in experimental animals. (Reference: (NGAPN) Pharmanews, 10(11), 15, 1988)
		WHO comment: Cyclamates, non-nutritive sweetening agents, have been used as additives in food and drugs since 1950. They have been demonstrated to have a carcinogenic potential at very high and long-sustained dosage in experimental animals. Some countries have consequently banned their use as food additives, whereas in others they remain available for this purpose. Most countries, however, continue to allow their use in small quantities in pharmaceutical preparations. (Reference: (WHODI) WHO Drug Information, 77.2, 12, 1977)

Product name **Cyproheptadine**

C.A.S. number **129-03-3**

Scientific and common names, and synonyms

PIPERIDINE,4-(5H-DIBENZO(A,D)CYCLOHEPTEN-5-YLIDENE)-1-METHYL-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GHA	1979	Sale and use of preparations containing cyproheptadine have been severely restricted due to abuse of its appetite stimulant effect.
BGD	1982	Under the provisions of the Drugs (Control) Ordinance, cyproheptadine was banned following unacceptable promotion encouraging its use as an appetite stimulant. (Reference: (BGDCO) The Drugs (Control) Ordinance,,, 1982)
MYS	Nov. 1986	All products containing cyproheptadine marketed as an appetite stimulant have been withdrawn. (Reference: (MYSDC) Malaysian Drug Control Authority, No.4,, Nov. 1986)
		WHO comment: Cyproheptadine, an antihistamine with anticholinergic and serotonin-antagonist properties, was introduced in 1961 for the symptomatic relief of allergy and was subsequently used as an appetite stimulant. In 1982 the drug was prohibited in Bangladesh because of its misuse as an appetite stimulant due to inappropriate promotion. Cyproheptadine remains widely available and the current marketing policy of the major manufacturer requires that it should be used as an appetite stimulant only under the supervision of a physician who should be assured that adequate food is available.

Product name **Dalkon shield**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	1974	The Dalkon shield has not been marketed since 1974, when the manufacturer withdrew the product from distribution following reports of mid-trimester septic abortions. In September 1980 the manufacturer issued a letter to all doctors recommending removal of all Dalkon shields due to an increased risk of pelvic inflammatory disease caused by actinomyces israeli. The Food and Drug Administration has recently stated that due to an increased risk of pelvic inflammatory disease, the Dalkon shield intrauterine device should be removed from any woman still using one. Women using the Dalkon shield were shown to have a fivefold increased risk of pelvic inflammatory disease compared with women using other types of IUD. (Reference: (FDADB) FDA Drug Bulletin, 13(2),, 1983)
GBR	1985	The manufacturer of the device has written to all doctors reminding them that women still wearing the Dalkon shield should have the device removed. Marketing was discontinued in 1975 and a similar letter was distributed in 1980.
NZL	1985	The New Zealand Health Authorities have instituted a programme to ensure that all women still wearing a Dalkon shield IUD have their device removed. (Reference: (NZCSL) Clinical Services Letter, Department of Health, 234,, July 1985)

Product name **Dantron**

C.A.S. number **117-10-2**

Scientific and common names, and synonyms

DANTHRON
1,8-DIHYDROXYANTHRAQUINONE
9,10-ANTHRACENEDIONE,1,8-DIHYDROXY-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NOR	1987	The major manufacturer has discontinued production of products containing dantron. All other manufacturers in Norway have subsequently withdrawn such preparations. (Reference: (NNSLM) Nytt fra Statens Legemiddelkontroll, 3(6),, 1987)
DEU	31 Jan. 1987	The Federal Health Office no longer permits the use of dantron in pharmaceutical preparations.
JPN	Feb. 1987	The Ministry of Health and Welfare has requested manufacturers to discontinue production and marketing of laxatives containing dantron.
USA	30 Mar. 1987	The United States Food and Drug Administration advised manufacturers to discontinue production of laxatives containing dantron and to recall all such products from retail stores.
GBR	Apr. 1987	The Committee on Safety of Medicines advised that the licensed indications for those products containing dantron that remain on the market should be limited to: (1) constipation in geriatric practice and analgesic-induced constipation in the terminally ill and (2) constipation in cardiac failure and coronary thrombosis (conditions in which defaecation must be free of strain). The Committee also advised that these products should be subjected to prescription control as quickly as possible.
SGP	15 Jan. 1988	The Ministry of Health has prohibited the import and sale of dantron on the basis of potential carcinogenicity. (Reference: (SGPRD) The Sale of Drugs (Prohibited Drugs) Regulations, S9, 7, Jan. 1988)

...(Continued)

Product name **Dantron** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Dantron, an anthroquinone derivative, has been available for over twenty years and is widely used as a laxative. The results of two chronic toxicity studies in rodents, published in 1985 and 1986, have shown that administration of high doses is associated with the development of intestinal and liver tumours. Although there is no evidence that the drug is carcinogenic in the doses used in medicine, one major manufacturer has ceased marketing products containing dantron worldwide and several drug regulatory authorities no longer permit its use in pharmaceutical preparations.

Bibliographical references

IARC MONOGRAPH, 50, 265, 1990

Product name **Depot medroxyprogesterone acetate (DMPA)**

C.A.S. number **71-58-9**

Scientific and common names, and synonyms

DMPA
PREGN-4-ENE,3,20-DIONE, 17-(ACETYLOXY)-6-METHYL-,(6alpha)
17-HYDROXY-6alpha-METHYLPREGN-4-ENE-3,20-DIONE ACETATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1983	The use of injectable steroid preparations for contraceptive purposes has been restricted to use by women with a normal menstrual cycle who do not tolerate other forms of contraception. Pregnancy must be excluded before treatment is started and it is contraindicated during lactation. The label must bear a warning about adverse effects including menstrual disturbances and headaches.
GBR	1983	Approved for long-term contraception when other methods are unacceptable or inappropriate.
SWE	1983	Approved for long-term contraception when other methods have given rise to adverse reactions or otherwise been judged as inappropriate. Patients must accept that after conclusion of treatment return of fertility may be slow.
ZMB	7 Dec. 1983	The use of medroxyprogesterone acetate in injectable form as a contraceptive is prohibited. The drug may only be imported or exported on a licence issued by the Director of Medical Services. (Reference: (ZMBSI) Statutory Instrument, No.166-167,, Dec. 1983)
EGY	1984	Use of this drug was restricted to contraception in women with a normal menstrual cycle who do not tolerate other forms of contraception.
USA	1984	Approval for this product was not granted on the grounds that the available evidence did not provide a sufficient basis for determining that depot medroxyprogesterone acetate is safe for general marketing in the USA. However, multinational studies subsequently indicated that the risk of cancer associated with its use was minimal or absent and the drug was registered in 1992. (References: (FEREAC) Federal Register, 49, 43507, Oct. 1984; (HHSNS) HHS News: US Department of Health and Human Services,,, 29 Oct. 1992)

...(Continued)

Product name **Depot medroxyprogesterone acetate (DMPA)** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: A depot preparation containing 150 mg medroxyprogesterone acetate was introduced over 20 years ago for use as a long-acting injectable contraceptive. Subsequently, positive results of carcinogenicity studies carried out in beagle bitches led to refusal of registration in the United States. These findings were later considered irrelevant to contraceptive use in women and the drug was approved by the Food and Drug Administration. Menstrual irregularities are the most common adverse effect associated with depot medroxyprogesterone acetate. Risk-benefit judgements differ significantly from country to country, having regard to differing national circumstances. The preparation is, however, widely available and is included in the WHO Model List of Essential Drugs. (References: (WHTAC1) Model List of Essential Drugs, 2nd Report of the WHO Expert Committee, No.722,, 1985; (WHODI) WHO Drug Information, 2(1), 31, 1988; (WHTAC4) The Use of Essential Drugs, 4th Report of the WHO Expert Committee, Technical Report Series, No.796,, 1990)

Product name **Dequalinium chloride**

C.A.S. number **522-51-0**

Scientific and common names, and synonyms

1,1'-DECAMETHYLENEBIS (4-AMINOQUINALDINIUM CHLORIDE)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GRC	1984	Withdrawn from the market due to an unacceptable benefit to risk ratio (low efficacy/skin reactions). **WHO comment:** Skin reactions to dequalinium chloride, including necrotic lesions, have been reported. It remains available as a mouth and throat disinfectant in many countries.

Product name **Dexamfetamine**

C.A.S. number **51-64-9**

Scientific and common names, and synonyms

(+)-alpha-METHYLPHENETHYLAMINE
BENZENEETHANAMINE, alpha-METHYL-,(S)-
DEXAMPHETAMINE
DEXTROAMPHETAMINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	1973	Anorectic drugs containing dexamfetamine were withdrawn from the market by the Food and Drug Administration due to evidence of abuse and a high risk of dependence.
TUR	6 Sep. 1982	Banned for production, import, export, sale and use.
OMN	10 May 1982	Import and marketing of products containing dexamfetamine were prohibited. (Reference: (OMNCR) Circular, 11/82,, May 1982)
NGA	1988	All products containing dexamfetamine have been banned. (Reference: (NGAPN) Pharmanews, 10(11), 15, 1988)

...(Continued)

Product name **Dexamfetamine** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Dexamfetamine, an amfetamine derivative, is controlled under Schedule II of the 1971 Convention on Psychotropic Substances. See WHO comment for amfetamine. (Reference: (UNCPS2) United Nations Convention on Psychotropic Substances (II),,, 1971)

Product name **Dibenzepin hydrochloride**

C.A.S. number **315-80-0**

Scientific and common names, and synonyms

10-(2-DIMETHYLAMINO)ETHYL)-5,10-DIHYDRO-5-METHYL-11H-DIBENZO(B,E),(1,4)-DIAZEPIN-11-ONE MONOHYDROCHLORIDE
11H-DIBENZO(B,E)(1,4)-DIAZEPIN-11-ONE, 10-(2-DIMETHYLAMINO)-ETHYL)-5, 10-DIHYDRO-5-METHYL-, MONOHYDROCHLORIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	1 Jan. 1983	Dibenzepin hydrochloride was associated with an unexpectedly high number of fatal suicidal attempts. The drug was withdrawn following discussions between the company and the National Board of Health and Welfare. **WHO comment:** Dibenzepin hydrochloride, a tricyclic antidepressant, was introduced in 1968 for the treatment of depressive illness. By 1973 its use in Sweden had been associated with an unexpectedly high number of suicide attempts which led to its withdrawal in that country. Although its use has lapsed in several countries, it remains available in at least eight European countries.

Product name **Diclofenac sodium**

C.A.S. number **15307-79-6**

Scientific and common names, and synonyms

ACETIC ACID, o-(2,6-DICHLOROANILINO)PHENYL)-, MONOSODIUM SALT
BENZENEACETIC ACID, 2-((2,6-DICHLOROPHENYL)AMINO)-, MONOSODIUM SALT
SODIUM (O-(2,6-DICHLOROANILINO)PHENYL) ACETATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
PHL	Sep. 1983	Disapproved for use due to fear of exposure of young children to risks of agranulocytosis, leucopenia and thrombocytopenia.
NOR	1987	Diclofenac acid is not approved for registration because the results of carcinogenicity testing in rats were not clearly negative and testing in another species is required. **WHO comment:** The World Health Organization currently has no information to suggest that diclofenac is less safe than other widely available non-steroidal antiinflammatory substances of this type, or that children are particularly liable to react adversely. It is registered in many countries in several dosage forms, including a 12.5 mg suppository indicated for juvenile arthritis.

Product name **Dicycloverine**

C.A.S. number **77-19-0**

Scientific and common names, and synonyms

(BICYCLOHEXYL)-1-CARBOXYLIC ACID, 2-(DIETHYLAMINO)ETHYL ESTER
DICYCLOMINE
2-(DIETHYLAMINO)ETHYL (BICYCLOHEXYL)-1-CARBOXYLATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	1985	The Swedish Board of Drugs has recommended that dicycloverine be used only by specialists for the treatment of very severe cases of infantile colic. (Reference: (SSLMS) Information från Socialstyrelsens Läkemedelsavdelning, No.6,, Oct. 1985)
AUS	20 Feb. 1985	The manufacturer has warned against administration of dicycloverine to infants under six months of age and deleted colic from the indications.
NZL	18 Mar. 1986	The Department of Health has issued a statement that liquid dicycloverine preparations for the treatment of colic are no longer recommended for infants under six months of age. (Reference: (NZCSL) Clinical Services Letter, Department of Health, 242,, 1986)
BGD	Dec. 1986	Syrup and drop forms are being withdrawn to avoid possible misuse and adverse reactions in children.
GBR		The manufacturer has warned against administration of dicycloverine to infants under six months of age and deleted colic from the indications.
NOR		In view of its propensity to cause serious adverse reactions in infants under six months of age, the Drug Control Board has prohibited the import of dicycloverine. **WHO comment:** Dicycloverine, an anticholinergic agent with antispasmodic and local anaesthetic activity, was introduced in 1952 for treatment of functional conditions involving smooth muscle of the gastrointestinal tract. Its use in the treatment of colic in infants under six months of age has been associated with irritability and restlessness, convulsions and apnoea which has led the major manufacturer to issue revised global prescribing information in 1985 contraindicating the use of dicycloverine in this age group. Subsequently restrictive regulatory action directed to other available brands of this drug was taken in several countries. Preparations containing dicycloverine remain available in at least ten major markets.

Product name **Dienestrol**

C.A.S. number **84-17-3**

Scientific and common names, and synonyms

DIENOL
DINOVEX
PHENOL, 4,4'-(DIETHYLIDENEETHYLENE)DI-
4,4'-(1,2-DIETHYLIDENE-1,2-ETHANEDIYL)BIS-PHENOL,(E,E)-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
AUT	Feb. 1977	Pharmaceutical specialities containing dienestrol, diethylstilbestrol, hexestrol and their derivatives have been withdrawn following reports indicating an association between prenatal exposure to diethylstilbestrol and the subsequent development of adenocarcinoma in post pubertal girls and young women. The use of stilbene derivatives is only authorized for the treatment of cancer of the prostate.
ITA	1979	Withdrawn from the market due to suspected carcinogenicity in newborns following prenatal exposure.
KWT	Apr. 1980	Prohibited for import.

...(Continued)

Product name **Dienestrol** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SAU		Following reports indicating the development of adenocarcinoma in post-pubertal girls and young women exposed prenatally to preparations containing diethylstilbestrol, dienestrol and their derivatives, the Drug Committee prohibited the use of these products during pregnancy.
VEN		Subject to restricted use and/or sale. **WHO comment:** Dienestrol is a stilbene derivative. See WHO comment for diethylstilbestrol. Vaginal forms of dienestrol, which were introduced in 1947, are currently available in over 35 countries for the management of hypoestrogenic vaginal atrophy. (Reference: (WHODI) WHO Drug Information, 77.1, 16, 1977)

Product name **Diethylaminoethoxyhexestrol**

C.A.S. number **2691-45-4**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
JPN	Dec. 1970	This product for the treatment of angina pectoris was voluntarily withdrawn from production by the manufacturer due its effects on the liver. **WHO comment:** The World Health Organization has no information further to the above regarding preparations containing diethylaminoethoxyhexestrol, a coronary vasodilator, or to indicate that they are still commercially manufactured.

Product name **Diethylstilbestrol**

C.A.S. number **56-53-1**

Scientific and common names, and synonyms

alpha,alpha'-DIETHYL-(E)-4,4'-STILBENEDIOL
DIETHYLSTILBOESTROL
PHENOL, 4,4-'(1,2-DIETHYL-1,2-ETHENEDIYL)BIS-,(E)-
STILBOESTROL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
PAN	15 July 1973	Sale and use of diethylstilbestrol or its derivatives in subcutaneous implants is prohibited. (Reference: (PANMR) Ministry of Health Resolution, No.1A,, Jan. 1973)
USA	4 Aug. 1975	Because of a statistically significant association between maternal ingestion during pregnancy of diethylstilbestrol (and close congeners) and the occurrence of vaginal carcinoma in the offspring, the labelling of all such products has previously been required to state that their use in pregnancy is contraindicated. An additional warning is now required concerning the possible development of vaginal adenosis in postpubertal girls whose mothers received diethylstilbestrol during pregnancy. (Reference: (FEREAC) Federal Register, 40, 32773, Aug. 1975)
AUT	Feb. 1977	Pharmaceutical specialities containing diethylstilbestrol, dienestrol, hexestrol and their derivatives have been withdrawn following reports indicating an association between prenatal exposure to diethylstilbestrol and the subsequent development of adenocarcinoma in postpubertal girls and young women. The use of stilbene derivatives is only authorized for the treatment of cancer of the prostate.
DEU	Feb. 1977	Indications for use restricted to the treatment of carcinoma of the prostate.

...(Continued)

Legislative or regulative action

Product name **Diethylstilbestrol** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GRC	1980	Diethylstilbestrol is registered solely for the treatment of cancer of the prostate.
KWT	Jan. 1980	Importation of pharmaceutical preparations containing diethylstilbestrol and diethylstilbestrol diphosphate is prohibited.
TUN	May 1983	Prohibited for pregnancy-related uses in women; restricted to urological use only.
ITA		Withdrawn from the market owing to an unfavourable risk-benefit ratio and the lack of substantial evidence of efficacy.
SAU		Following reports indicating the development of adenocarcinoma in post-pubertal girls and young women exposed prenatally to preparations containing diethylstilbestrol, dienestrol and their derivatives, the Drug Committee prohibited the use of these products during pregnancy. **WHO comment:** Diethylstilbestrol, a synthetic estrogen which is a stilbene derivative, was introduced into obstetric practice in the late 1940s and subsequently widely used for the treatment of threatened abortion. This use was later shown to be associated with an increased risk of vaginal cancer in the offspring which resulted in restrictive regulatory action in several countries. Diethylstilbestrol and other stilbenes remain available in many countries, however, for the treatment of certain hormone-dependent neoplasms including carcinoma of the prostate and postmenopausal breast cancer. (Reference: (WHODI) WHO Drug Information, 77.1, 16, 1977)

Bibliographical references

IARC MONOGRAPH, 6, 55, 1974
IARC MONOGRAPH, 21, 173, 1979
IARC MONOGRAPH, SUPPL.4, 184, 1982

Product name **Difemerine**

C.A.S. number **80387-96-8**

Scientific and common names, and synonyms

2-(DIMETHYLAMINO)-1,1-DIMETHYLETHYL BENZILATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	Mar. 1986	Oral preparations of difemerine were withdrawn by the manufacturer on the grounds of exceptionally frequent adverse effects.

Product name **Difenoxin**

C.A.S. number **28782-42-5**

Scientific and common names, and synonyms

DIFENOXYLIC ACID
1-(3-CYANO-3,3-DIPHENYLPROPYL)-4-PHENYL-ISONIPECOTIC ACID
4-PIPERIDINECARBOXYLIC ACID, 1-(3-CYANO-3,3-DIPHENYLPROPYL)-4-PHENYL-

...(Continued)

Legislative or regulative action

Product name **Difenoxin** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
PAK	June 1990	Drop and syrup formulations of products containing difenoxin intended for the treatment of diarrhoea in children were banned.
OMN	Sep. 1990	Import and marketing of oral preparations intended for paediatric use containing difenoxin were prohibited. (Reference: (OMNMH) Ministry of Health,,, 29 Sep. 1990)
KOR	May 1991	Antidiarrhoeal products containing difenoxin were not accepted for registration. (Reference: (KRMHSA) Ministry of Health and Social Affairs - Communication to WHO,,, 13 Dec. 1991)
LBN	Aug. 1991	Use of products containing difenoxin in children under 5 years of age was discontinued and preparations for paediatric use were withdrawn. (Reference: (LBNMHD) Ministry of Health and Social Affairs Decree, 150/1,, Aug. 1991)
		WHO comment: Difenoxin is the principal metabolite of diphenoxylate. See WHO comment for diphenoxylate.

Product name **Difurazone**

C.A.S. number **804-36-4**

Scientific and common names, and synonyms

1,3-BIS(5-NITROFURFURYLIDEN)ACETONEGUANYLHYDRAZONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
JPN	July 1977	Withdrawn from all marketed preparations on the grounds that it has been superseded by safer and more effective preparations.
SAU		The withdrawal of nitrofuran compounds is under consideration since they have been superseded by safer and more effective preparations.
VEN		Not approved for use and/or sale.
		WHO comment: Difurazone, a nitrofuran derivative, was formerly used as an antiinfective agent. It has, however, been superseded by safer compounds and WHO has no information to suggest that it remains commercially available.

Product name **Dihydrostreptomycin**

C.A.S. number **128-46-1**

Scientific and common names, and synonyms

DHSM
DST

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	Sep. 1970	Withdrawn from the market (injectable form) and prohibited for export by the Food and Drug Administration on the grounds of an unfavourable benefit/risk ratio. This antibiotic is considered unsafe due to its ototoxic hazards.
PHL	1972	Dihydrostreptomycin and its salts, singly or in combination, were withdrawn from sale for human use. The drug can cause severe vestibular damage.

...(Continued)

Legislative or regulative action

Product name **Dihydrostreptomycin** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ESP	1 Oct. 1983	The Ministry of Health and Consumer Protection has withdrawn approval for dihydrostreptomycin except in oral preparations. (Reference: (ESPMC) Programa Selectivo de Revisión de Medicamentos,,, Sep. 1983)
DOM		Prohibited for use and/or sale since scientific studies have shown that it can cause deafness.
ITA		Withdrawn from the market owing to an unfavourable risk-benefit ratio and the lack of substantial evidence of efficacy.
PER		Prohibited for use in its injectable form. It has been found to cause permanent deafness.
		WHO comment: Dihydrostreptomycin, a derivative of the aminoglycoside antibiotic streptomycin with similar antibacterial activity, was first synthesized in 1947 and subsequently used in the treatment of tuberculosis and gram-negative infections. Preparations for systemic use have been widely withdrawn as a result of concern regarding their severe ototoxicity. Dihydrostreptomycin is poorly absorbed from the gastrointestinal tract. It remains available in oral preparations in some countries.

Product name **Dihydroxymethylfuratrizine**

C.A.S. number **794-93-4**

Scientific and common names, and synonyms

BIS(HYDROXYMETHYL)FURATRIZINE
(((6-2(5-NITRO-2-FURYL)VINYL)-AS-TRIAZIN-3-YL)IMIDO)DI-METHANOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
JPN	July 1977	Withdrawn from all marketed preparations on the grounds that it has been superseded by safer and more effective preparations.
SAU		The withdrawal of nitrofuran compounds is under consideration since they have been superseded by safer and more effective preparations.
VEN		Not approved for use and/or sale.
		WHO comment: Dihydroxymethylfuratrizine, a nitrofuran derivative, was formerly used as an antiinfective agent. It has, however, been superseded by safer compounds and WHO has no information to suggest that it remains commercially available.

Product name **Dilevalol**

C.A.S. number **75659-07-3**

Scientific and common names, and synonyms

BENZAMIDE,2-HYDROXY-5-(1-HYDROXY-2-((1-METHYL-3-PHENYLPROPYL)AMINO)ETHYL)-,(R-(R*,R*)-
(-)-5-((1R)-1-HYDROXY-2-(((1R)-1-METHYL-3-PHENYLPROPYL)AMINO)ETHYL) SALICYLAMIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
@WD	9 Aug. 1990	Products containing dilevalol hydrochloride have been voluntarily discontinued by the manufacturer, haveing regard to evolving evidence of isolated cases of liver toxicity. (Reference: (SPCNR) Schering-Plough Corporation news release,,, 9 Aug. 1990)

...(Continued)

Legislative or regulative action

Product name **Dilevalol** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Dilevalol, a beta-adrenoreceptor antagonist, was introduced into medicine in 1989 for the treatment of hypertension. Shortly afterwards, its use became associated with isolated cases of hepatic toxicity. Although few cases were reported, the manufacturer discontinued sales in Japan and Portugal, the only countries where the drug was marketed, and withdrew applications for registration elsewhere.

Product name **Dimazole**

C.A.S. number **95-27-2**

Scientific and common names, and synonyms

AMYCAZOL
BENZOTHIAZOL,6-(2-DIETHYLAMINOETHOXY)-2-DIMETHYLAMINO-
DIAMTHAZOLE DIHYDROCHLORIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	July 1977	Withdrawn from the market and prohibited for export by the Food and Drug Administration on the grounds that the drug was not shown to be safe for its indicated uses. Neurotoxic effects had been found in humans. Products containing this ingredient had been used for the prophylaxis and treatment of athletes' foot. (Reference: (FEREAC) Federal Register, 42, 37057, July 1977) **WHO comment:** Dimazole, an antifungal agent, was introduced in 1951 for the treatment of tinea infections. Although the major manufacturer subsequently discontinued marketing preparations in the United States, the US Food and Drug Administration formally withdrew marketing approval for such preparations in 1977 on the grounds of their association with severe neurotoxic reactions, their potential for misuse and the availability of safer alternative products. Topical preparations of dimazole remain available in some 40 countries.

Product name **Dinoprostone**

C.A.S. number **363-24-6**

Scientific and common names, and synonyms

(E,Z)-(1R,2R,3R)-7-(3-HYDROXY-2-((3S)-(3-HYDROXY-1-OCTENYL))-5-OXOCYCLOPENTYL)-5-HEPTENOIC ACID
PROSTAGLANDIN E2
PROSTA-5,13-DIEN-1-OIC ACID,11,15-DIHYDROXY-9-OXO-,(5Z,11alpha,13E,15S)-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GBR	19 July 1990	In consultation with the Department of Health, a controlled-release pessary containing dinoprostone has been withdrawn by the manufacturer, having regard to reports of an unacceptable incidence of uterine hypertonia and foetal distress. (Reference: (CRDDL) Communication from Roussel enclosing "Dear Doctor" letter,,, 19 July 1990) **WHO comment:** Dinoprostone, prostaglandin E2, was introduced into medicine in 1971 and is primarily used for cervical ripening during the induction of labour. It is available in various formulations for oral, parenteral and vaginal administration. Tablets, ampoules and vaginal dosage forms (tablets, pessaries, gel) remain registered in many countries.

Product name **Dionaea muscipula (extract)**

Scientific and common names, and synonyms
VENUS FLY TRAP

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	Jan. 1986	The Federal Health Office has suspended the sale of an injectable herbal anticancer drug prepared from the carnivorous plant Dionaea muscipula following hypersensitivity reactions in almost two-thirds of patients. **WHO comment:** The World Health Organization has no information further to the above regarding preparations containing Dionaea muscipula or to indicate that they are still commercially manufactured.

Product name **Diphenazine**

C.A.S. number **13838-14-7**

Scientific and common names, and synonyms
1,4-BIS(alpha-METHYLPHENETHYL)PIPERAZINE
1,4-BIS(1-PHENYLISOPROPYL)PIPERAZINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
HUN	1967	Withdrawn from the market on account of photosensitivity, and possibly cataract, associated with its use.
VEN		Not approved for use and/or sale. **WHO comment:** The World Health Organization has no further information regarding preparations containing diphenazine and is not aware that they are still commercially manufactured.

Product name **Diphenoxylate**

C.A.S. number **915-30-0**

Scientific and common names, and synonyms
ETHYL 1-(3-CYANO-3,3-DIPHENYLPROPY-4-PHENYLISONIPECOTATE
4-PIPERIDINECARBOXYLIC ACID, 1-(3-CYANO-3,3-DIPHENYLPROPYL)-4-PHENLY,-ETHYL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
LIY	21 May 1990	Use of products containing diphenoxylate in children was banned. (Reference: (LIYRL) Resolution of the General People's Health Committee, 141,, May 1990)
PAK	June 1990	Drop and syrup formulations of products containing diphenoxylate intended for the treatment of diarrhoea in children were banned.
MEX	Dec. 1990	Elixir formulations of products containing diphenoxylate intended for the treatment of diarrhoea in children were withdrawn. (Reference: (MEXMH) Communication from the Ministry of Health,,, 28 Nov. 1990)
NPL	1991	Liquid formulations of products containing diphenoxylate either alone or in combination, and intended forthe treatment of diarrhoea in children, were banned (Reference: (NPLDDA) Communication from the Department of Drug Administration,,, 27 Feb. 1992)

...(Continued)

Legislative or regulative action

Product name **Diphenoxylate** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
PHL	1991	Paediatric formulations of products containing diphenoxylate were withdrawn.
KOR	May 1991	Antidiarrhoeal products containing diphenoxylate were not accepted for registration. (Reference: (KRMHSA) Ministry of Health and Social Affairs - Communication to WHO,,, 13 Dec. 1991)
LBN	3 Aug. 1991	Use of products containing diphenoxylate in children under 5 years of age was discontinued and preparations for paediatric use were withdrawn. (Reference: (LBNMHD) Ministry of Health and Social Affairs Decree, 150/1,, Aug. 1991)
THA	27 May 1992	The Ministry of Public Health, withdrew the registration of products containing diphenoxylate formulated as either syrup or drop formulation. (Reference: (THAMH) Ministry of Public Health,,, 27 May 1992)
		WHO comment: Diphenoxylate, a derivative of pethidine without analgesic activity, is used in the symptomatic treatment of acute and chronic diarrhoea to reduce intestinal motility. There is no clear evidence that it has any beneficial effect in diminishing fluid losses and it has been associated with central nervous system toxicity, particularly in children, which results in anorexia, nausea and vomiting, headache, drowsiness, confusion, insomnia, dizziness, restlessness, euphoria and depression. The World Health Organization recommends that diphenoxylate should not be used for the management of diarrhoea in children and many countries have since withdrawn products containing this compound indicated for paediatric use. (Reference: (WHORUD) The Rational Use of Drugs,,, 1990)

Product name **Dithiazanine iodide**

C.A.S. number **514-73-8**

Scientific and common names, and synonyms

3-ETHYL-2-(5-(3-ETHYL-2-BENZOTHIAZOLINYLIDENE)-1,3-PENTADIENYL) BENZOTHIAZOLIUM IODIDE
3-ETHYL-2-(5-(3-ETHYL-2(3H)-BENZOTHIAZOLYLIDENE)-1,3-PENTADIENYL)- BENZOTHIAZOLIUM IODIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	1964	Reports of death associated with the use of dithiazanine iodide led the Food and Drug Administration to limit the indications for its use to trichuris trichuria and strongyloides stercoralis infestations of a clinically severe nature.
FRA	Nov. 1964	Withdrawn from the market in agreement with the manufacturer following reports of death associated with its use.
TCD	1965	Following reports of fatal incidents associated with the use of dithiazanine iodide, the Ministry of Foreign Affairs prohibited importation and marketing of this drug.
ITA	1979	Withdrawn from the market owing to an unfavourable risk/benefit balance.
CUB		Withdrawn from use on grounds of adverse effects on the gastrointestinal tract. This drug has been superseded by more effective and less toxic products.
		WHO comment: Dithiazanine iodide, an anthelminthic, was introduced in 1959 for the treatment of strongyloid worms and whipworms. Between 1961 and 1964 its use was associated with eight fatal cases of severe acidosis and shock. Although the drug is not significantly absorbed from the gut, in normal circumstances it was assumed that these fatalities were due to atypically high uptake from inflamed intestinal mucosa. Dithiazanine iodide has been superseded by safer and more effective drugs; however, it may remain available in some countries.

Product name **Domperidone(injectable)**

C.A.S. number **57808-66-9**

Scientific and common names, and synonyms

2H-BENZIMIDAZOL-2-ONE, 5-CHLORO-1-(1-(3-(2,3-DIHYDRO-2-OXO-1H- BENZIMIDAZOL-1-YL)PROPYL)-4-PIPERIDINYL)1,3-DIHYDRO-5-CHLORO-1-(1-(3-(2-OXO-1-BENZIMIDAZOLINYL)PROPYL)-4-PIPERIDYL)-2- BENZIMIDAZOLINONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
@WD	31 Jan. 1985	The manufacturer has informed the World Health Organization that injectable dosage forms of the antiemetic domperidone have been voluntarily withdrawn from all markets following reports of cases of cardiotoxicity associated with intravenous administration. Suppositories remain available and injectable forms will continue to be supplied for a named patient at the written request of a doctor. **WHO comment:** Domperidone, a peripheral dopaminergic antagonist, was introduced in 1979 for the symptomatic relief of acute nausea and vomiting. The major manufacturer became aware that the injectable formulation was being used in some countries in much higher doses than those recommended to combat nausea and vomiting in cancer patients treated with cytostatic agents. Such use - which was not in conformity with the approved indications - was associated with cardiotoxicity, which in some cases was fatal, and the manufacturer decided to withdraw the injectable dosage form from the market worldwide in January 1985. Suppositories, tablets and a suspension remain available and the manufacturer continues to supply the injection for the treatment of a named patient at the written request of a doctor on the understanding that the appropriate dosage recommendations will be followed.

Product name **Doxepin**

C.A.S. number **1668-19-5**

Scientific and common names, and synonyms

3-(DIBENZ(b,e)OXEPIN-11-YLIDENE)PROPYL-DIMETHYLAMINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NOR	1992	The Medicines Control Authority has decided that the 50 mg tablet formulation of doxepin may be prescribed only in hospitals and specialized clinics because of the toxic potential of this product and the risk of overdosage and suicide with the high dose formula. (Reference: (NNSLM) Nytt fra Statens Legemiddelkontroll, 1, 9, 1992) **WHO comment:** Doxepin, a tricyclic antidepressant was introduced in 1964 for the management of endogenous depression. Much of the adverse effects are caused by its antimuscarinic actions. These include dry mouth, cardiac arrhythmias, central nervous system disturbances, blood disorders and risk of suicide. The risk of suicide and dangers related to overdosage led the Norwegian Medicines Control Authority to put the higher strength formulation under prescribing restriction in 1992. The risk of death following overdosage is apparently higher for products containing tricyclic compounds as compared with nontricyclic products.

Product name **Doxycycline hyclate(injectable)**

C.A.S. number **24390-14-5**

Scientific and common names, and synonyms

2-NAPHTACENECARBOXAMIDE,4-(DIMETHYLAMINO)-1,4,4a,5,5a,6,11,12a-OCTAHYDRO-3,5,10,12,12a-PENTAHYDROXY-6-METHYL-1, 11-DIOXO-,MONOHYDROCHLORIDE, compd. with ETHANOL(2:1),MONOHYDRATE,(4S-(4alpha,4aalpha,5alpha,5aalpha, 6alpha,12aalpha))-

6-DEOXY-5beta-HYDROXYTETRACYCLINE HYDROCHLORIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
FRA	1989	The use of injectable preparations containing doxycycline hyclate has been restricted exclusively to hospitals, on the grounds that cases of anaphylactic shock and bronchospasm, some of which have been fatal, have occurred during intravenous administration of the product. Furthermore, these preparations should only be prescribed to patients unable to take medicines orally and should always be administered by slow intravenous infusion and under close supervision. (Reference: (FRAMH) Ministry of Solidarity, Health and Social Protection,,, 17 Feb. 1989) **WHO comment:** Doxycycline, a semi-synthetic tetracycline derivative, was first introduced into medicine in 1960 for the treatment of bacterial, rickettsial and amoebic infections. Although allergic manifestations are uncommon, injectable preparations have occasionally resulted in severe anaphylactoid reactions. Clinical features and the fact that asthmatic patients seemed to be particularly at risk lead to suspect a sulfite preservative in the formulation more than doxycycline itself. Rapid administration may also be a factor. Injectable preparations of doxycycline hyclate are included in the WHO Model List of Essential Drugs. (Reference: (WHTAC4) The Use of Essential Drugs, 4th Report of the WHO Expert Committee, Technical Report Series, No.796,, 1990)

Product name **Emetine**

C.A.S. number **483-18-1**

Scientific and common names, and synonyms

EMETAN, 6',7',10,11-TETRAMETHOXY

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
MUS	9 Mar. 1982	Under the Pharmacy and Poisons (Prohibitions of Harmful Drugs) Regulations, this drug is deemed "harmful" by the Ministry of Health and is prohibited for import, manufacture, storage, distribution, sale, possession, use, export or other transaction. (Reference: (MPPHD) Pharmacy & Poisons (Prohibitions of Harmful Drugs) Regulations,,, Mar. 1982) **WHO comment:** Emetine, an alkaloid obtained from ipecacuanha, was first used rationally as an amoebocide in 1912. It was subsequently widely used and was included in earlier editions of the WHO Model List of Essential Drugs but has now been replaced by the less cardiotoxic synthetic derivative dehydroemetine. Although it is valuable in the treatment of systemic amoebic hepatitis it has now been largely superseded by considerably less toxic drugs, and in particular by metronidazole.

Product name **Encainide**

C.A.S. number **37612-13-8**

Scientific and common names, and synonyms

BENZAMIDE,4-METHOXY-N-(2-(2-(1-METHYL-2-PIPERIDINYL)ETHYL)-PHENY)-,(±)-
(±)-2'-(2-(1-METHYL-2-PIPERIDYL)ETHYL)-p-ANISANILIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
MYS	July 1980	Products containing encainide will only be considered for registration if the indications are restricted to the treatment of life-threatening arrhythmias only. (Reference: (MYSDN) Berita Ubat-Ubatan (Drug Newsletter), 3(3), 3, 1989)
SWE	26 Oct. 1990	The indications for products containing encainide are restricted to prophylaxis and treatment of life-threatening ventricular tachyarrhythmia such as ventricular tachycardia in patients unresponsive to conventional treatment. (Reference: (SWEILS) Information från Läkemedelsverket, 1(3),, 1990) **WHO comment:** The membrane-stabilizing antiarrhythmic agent encainide was introduced into medicine in the mid-1980's. The decision to delete the indications for patients with asymptomatic and less severe symptomatic ventricular arrhythmias was taken on the basis of the results of a trial (CAST study) that showed a two-fold increase in deaths in post-myocardiac patients taking encainide compared with the placebo group. (See also WHO comment for flecainide).

Product name **Epinephrine**

C.A.S. number **51-43-4**

Scientific and common names, and synonyms

ADRENALINE
2-BENZENEDIOL, 4-(1-HYDROXY-2-(METHYLAMINO)ETHYL)-,(R)-
(-)-3,4-DIHYDROXY-alpha-((METHYLAMINO)METHYL)BENZYL ALCOHOL
3,4-DIHYDROXY-alpha-((METHYLAMINO)METHYL)-BENZYL ALCOHOL
4-(1-HYDROXY-2-(METHYLAMINO)-ETHYL)-1,2-BENZENEDIOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
IRL	1973	The National Drugs Advisory Board has withdrawn from the market all local anesthetic preparations intended for infiltration anesthesia containing epinephrine 1:50,000 and norepinephrine 1:50,000 alone or in combination. This decision, reached in agreement with the Irish Dental Association, followed reports of serious cardiovascular and cerebrovascular reactions.
VEN		Epinephrine is not approved for use for infiltration anaesthesia, either alone or in combination. **WHO comment:** Epinephrine, first isolated in 1899, is the main hormone secreted by the adrenal medulla. It is widely used as a vasoconstrictor substance and in the treatment of anaphylactic shock. Its use in combination with local anaesthetics to prolong infiltration anaesthesia has been associated with systemic reactions including serious cardiovascular and cerebrovascular incidents. Regulations restricting the concentrations permitted in such preparations have been introduced in many countries but combination products containing epinephrine or levarterenol in concentrations of 1:80,000 or less remain widely available. Representative preparations are included in the WHO Model List of Essential Drugs. (Reference: (WHTAC1) Model List of Essential Drugs, 2nd Report of the WHO Expert Committee, No.722,, 1985)

Product name **Erythromycin estolate**

C.A.S. number **3521-62-8**

Scientific and common names, and synonyms

ERYTHROMYCIN PROPIONATE LAURYL SULPHATE
ERYTHROMYCIN 2'-PROPANOATE DODECYL SULPHATE
ERYTHROMYCIN, 2'PROPIONATE, DODECYL SULPHATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SGP	Nov. 1976	Banned for importation.
GRC	1977	Withdrawn from the market.
SDN	1982	The Ministry of Health no longer allows registration of preparations containing erythromycin estolate.
MUS	9 Mar. 1982	Under the Pharmacy and Poisons (Prohibitions of Harmful Drugs) Regulations, this drug is deemed "harmful" by the Ministry of Health and is prohibited for import, manufacture, storage, distribution, sale, possession, use, export or other transaction. (Reference: (MPPHD) Pharmacy & Poisons (Prohibitions of Harmful Drugs) Regulations,,, Mar. 1982)
BGD	1983	Banned due to its reported hepatotoxicity.
BHR		Preparations containing erythromycin estolate are not approved for registration.
DNK		Registration has been cancelled. (Reference: (UGLAAD) Ugeskrift for Laeger, 136, 2093, Sep. 1974)
PER		The package and/or label for this product requires a warning regarding the possibility of liver damage with this drug; and, in cases of repeated use, possible side effects including fever, nausea, vomiting, jaundice, and eosinophilia. It also warns pregnant women that no safe level for administration during pregnancy has yet been determined.
SWE		This product has been banned for use and/or sale for domestic purposes due to cases of severe cholestatic hepatitis and jaundice. **WHO comment:** Erythromycin estolate, a macrolide antibiotic, was introduced in 1958 for the treatment of gram-positive infections. By the early 1970s its use had been associated with a higher incidence of hepatic toxicity than that seen with other salts and esters of erythromycin. This led to its withdrawal by some regulatory authorities whereas others required the addition of a warning in the product information. Evidence that the estolate ester is more hepatotoxic than other salts or esters has subsequently been disputed. It has been claimed to be the most effective ester for treatment of Legionnaire's disease and preparations remain widely available. (Reference: (BMJOAE) British Medical Journal, 286, 1954, 1983)

Product name **Estrogens**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	Sep. 1989	Products containing estrogens may no longer be indicated for suppression of lactation and prevention of breast engorgement in mothers who elect not to breastfeed. (Reference: (FDATP) Food and Drug Administration Talk Paper, T89-56,, 27 Sep. 1989)
DEU	Jan. 1992	The use of estrogens for substitution therapy was restricted to the treatment of post-menopausal women who have undergone hysterectomy. (Reference: (DEUPZ) Pharmazeutische Zeitung, 136(3), 85, 1992)

...(Continued)

Legislative or regulative action

Product name **Estrogens** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Estrogens have been used for the prevention of postpartum breast pain and engorgement. However, because ofan increased risk of puerperal thromboembolism and a risk of rebound effect, and since only 10% of women benefit therapeutically from such intervention, the United States Food and Drug Administration has requested manufacturers to no longer indicate preparations containing estrogens for this purpose. The World Health Organization is not aware of similar action having been taken elsewhere.

Product name **Ethanol**

C.A.S. number **64-17-5**

Scientific and common names, and synonyms
ALCOHOL
ETHYL ALCOHOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
KWT	1966	The permissible limit of ethanol in liquid oral dosage forms should not exceed 10%. (Reference: (KTMD) Ministerial Decree, 71/66,, 1966)
CHL	1 Sep. 1985	The Institute of Public Health has prohibited the use of ethanol in oral pharmaceutical products. Exemptions from this decision will be allowed when use of ethanol is essential for galenic reasons, provided that it is used for this purpose at the lowest effective concentration. (Reference: (CHLRS) Resolution of the Minister of Health, No.3102,, Apr. 1985)
IRQ	1989	The Ministry of Health has approved the restriction of the inclusion of ethanol in pharmaceutical preparations. (Reference: (IRQMH) Resolution of the Arab Ministers of Health 13th Meeting, 9-13,, 1986)
LKA	1 Jan. 1992	The Ministry of Health withdrew from sale, all paediatric oral liquid formulations of pharmaceutical products containing ethanol, and all formulations for adults containing more than 5% of ethanol. (Reference: (LKADIB) Drug Information Bulletin, University of Peradeniya and Ministry of Health, 4(1),, 1992)
ARE		Pharmaceutical preparations containing high concentrations of ethanol are banned. **WHO comment:** Ethanol has been used throughout recorded history both in a medicinal and social context. It is currently included in pharmaceutical preparations either as an active or inactive ingredient. At pharmacologically active doses ethanol is both a powerful cerebral depressant and a drug of addiction. Its use in pharmaceutical preparations has been severely restricted in several countries and in 1986 the 39th World Health Assembly adopted a Resolution to prohibit such use except when ethanol is an essential ingredient which cannot be replaced by an appropriate alternative.

Product name **Ethyl nitrite (spirit)**

C.A.S. number **109-95-5**

Scientific and common names, and synonyms
NITROUS ETHER SPIRIT
SWEET NITRE SPIRIT

...(Continued)

Legislative or regulative action

Product name **Ethyl nitrite (spirit)** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	26 June 1980	Withdrawn from the market and prohibited for export by the Food and Drug Administration (FDA) due to the lack of scientific evidence for its effectiveness for any use. This drug was used in infants and children as a diuretic, a diaphoretic and an intestinal antispasmodic. The FDA has found evidence of a risk of fatal methaemoglobinaemia and poisoning in some infants. (Reference: (FEREAC) Federal Register, 45(126), 43400, 1980) **WHO comment:** Ethyl nitrite was formerly available in over-the-counter preparations for use as a diaphoretic, a diuretic and an intestinal antispasmodic. In the 1970s its use was associated with cases of methaemoglobinaemia, some of which were fatal. This led to its withdrawal in 1980 by the United States Food and Drug Administration. WHO has no information regarding its current availability in pharmaceutical preparations.

Product name **Ethylene dichloride**

C.A.S. number **107-06-2**

Scientific and common names, and synonyms

BROCIDE
DUTCH LIQUID
1,2-DICHLOROETHANE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1978	Two topical prescription preparations for rheumatic complaints containing ethylene dichloride were withdrawn. These preparations were implicated in a number of cases of acute poisoning following accidental ingestion and investigations by the National Cancer Institute in the USA demonstrated a possible carcinogenic effect.
DDR	1979	Use of ethylene dichloride in pharmaceutical products is no longer permitted due to its carcinogenic potential and hepatotoxicity.
SAU		Prohibited due to reports demonstrating carcinogenic effects in experimental animals. **WHO comment:** Ethylene dichloride was formerly used as an excipient in some pharmaceutical preparations. It has been reported to be carcinogenic in experimental animals and its accidental ingestion has resulted in liver and kidney damage. Although ethylene dichloride continues to be used as an industrial solvent, WHO has no information to suggest that it remains commercially available in pharmaceutical products or as a food additive. (Reference: (WHTAC3) 23rd Report of Joint FAO/WHO Expert Committee on Food Additives, 648,, 1980)

Bibliographical references

IARC MONOGRAPH, 20, 429, 1979
WHO GUIDELINES FOR DRINKING WATER QUALITY, 2, , 1984
FAO PLANT PRODUCTION & PROTECTION PAPER, 72/1, , 1985
IPCS ENVIRONMENTAL HEALTH CRITERIA, 62, , 1986

Product name **Ethylestrenol**

C.A.S. number **965-90-2**

Scientific and common names, and synonyms

ETHYLOESTRENOL
19-NORPREGN-4-EN-17-OL,(17-alpha)
19-NOR-17-alpha-PREGN-4-EN-17-beta-OL

...(Continued)

Legislative or regulative action

Product name **Ethylestrenol** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BGD	1982	Under the provisions of the Drugs (Control) Ordinance, low-strength preparations were banned following unacceptable promotion encouraging their use in children suffering from malnutrition. (Reference: (BGDCO) The Drugs (Control) Ordinance,,, 1982) **WHO comment:** Ethylestrenol, an anabolic steroid, was introduced in 1964. In 1982, low dosage preparations were prohibited in Bangladesh due to inadmissible promotion of products containing anabolic steroids for malnourished children. Higher dosage preparations of ethylestrenol remain available in many countries, including Bangladesh, for several highly specific but limited indications that apply to patients with chronic debilitating and emaciating diseases, particularly associated with neoplasia and some types of aplastic anaemia. Ethylestrenol is additionally used for its fibrinolytic activity.

Product name **Etomidate**

C.A.S. number **33125-97-2**

Scientific and common names, and synonyms

(+)-ETHYL 1-(alpha-METHYLBENZYL)IMIDAZOLE-5-CARBOXYLATE
1H-IMIDAZOLE-5-CARBOXYLIC ACID, 1-(1-PHENYLETHYL)-, ETHYL ESTER(+)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GBR	1985	Use of etomidate is restricted to induction of anaesthesia having regard to reports of reduced serum cortisol levels unresponsive to adrenocorticotropic hormone (ACTH) injections. **WHO comment:** Etomidate, a potent hypnotic agent, was introduced in 1977 for use as an intravenous anaesthetic. Its prolonged use can inhibit adrenal steroidogenesis and, following reports of reduced serum cortisol levels unresponsive to ACTH injection, the manufacturer suspended promotion of etomidate for sedation in intensive care in 1983. In 1985 regulatory action taken only in the United Kingdom further restricted use of the drug to induction of anaesthesia. Etomidate remains widely available and is currently registered for induction of anaesthesia in 34 countries and for maintenance of anaesthesia in 17 countries. It has never been registered for sedation.

Product name **Etretinate**

C.A.S. number **54350-48-0**

Scientific and common names, and synonyms

ETHYL (ALL-E)-9-(4-METHOXY-2,3,6-TRIMETHYLPHENYL)-3,7-DIMETHYL-2,4,6,8- NONATETRAENOATE
2,4,6,8-NONATETRAENOIC ACID, 9-(4-METHOXY-2,3,6-TRIMETHYLPHENYL)-, ETHYL ESTER, (ALL-E)-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
OMN	24 Dec. 1985	Having regard to its teratogenicity, etretinate may only be used under the supervision and control of a hospital dermatologist. (Reference: (OMNMH) Ministry of Health, 5,, 1985)
SWE	1987	The National Board of Health and Welfare has decided that contraception is essential during treatment of women of child-bearing age and that contraceptive measures must be continued for at least two years after discontinuation of treatment.

...(Continued)

Legislative or regulative action

Product name **Etretinate** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
MYS	1988	The Drug Control Authority has decided that the labelling of preparations containing etretinate should contain a distinct warning regarding teratogenicity, emphasizing that contraceptive measures must be instituted throughout treatment and for at least twelve months thereafter, and additional reference is also required to the following adverse effects: symptoms of hypervitaminosis-A; transient and reversible elevation of transaminases and alkaline phosphatases; bone changes after long-term high dosage; benign intracranial hypertension. (Reference: (MYSDN) Berita Ubat-Ubatan (Drug Newsletter), 2(1), 3, Feb. 1988)
BEL	1 Jan. 1988	Preparations containing etretinate have been placed in List IV of the 'Arrêté du Régent' of 2 June 1946 and as such can be administered only on prescription. They must be kept in a poisons cabinet and carry the skull and cross-bones label. They must bear a warning regarding the embryotoxicity and teratogenicity of the drug which contraindicates its use during pregnancy. (Reference: (BELAR) Arrêté Royal,,, June 1987)
NOR	Dec. 1992	The Medicines Control Authority has withdrawn etretinate from the market. (Reference: (NORMCA) Norwegian Medicines Control Authority,,, 2 May 1995)
ESP		Contraindications to etretinate must include a boxed paragraph stating that the drug may be used in women of child-bearing age only when an effective method of contraception assures protection during and for at least one year after discontinuation of treatment. Pregnancy must be excluded before initiation of treatment.
ITA		Having received reports of two deaths among patients taking etretinate, the Ministry of Health has decided to restrict the product to hospital use only for the treatment of particularly serious and/or diffuse forms of psoriasis causing evident psychological stress.
		WHO comment: Etretinate, a retinol derivative, was introduced in 1981 for the treatment of psoriasis. Its use in pregnant women has resulted in major foetal abnormalities. The manufacturer's information emphasizes that the drug is teratogenic and must not be given to women who are pregnant, and that contraceptive measures must be maintained for at least two years after discontinuation of treatment. In some countries, blood banks are advised not to accept as donors persons who have taken etretinate within the previous year.

Product name **Factor IX**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE		A manufacturer of Factor IX concentrate has withdrawn the product from the market following reports of infections with HIV (the AIDS virus) in three patients known to have been treated with the product. (Reference: (SSLMS) Information från Socialstyrelsens Läekemedelsavdelning, 3, 8, 1986)
		WHO comment: Factor IX, a naturally occurring plasma protein fraction, is a vital component of the normal blood clotting mechanism which is deficient in haemophiliacs who require replacement therapy for both the treatment and prevention of bleeding. Factor IX is extracted from the pooled plasma of a large number of donors and is presented as a concentrate. It has been recognized since 1984 that some viruses, and particularly the HIV (AIDS virus) could be transmitted to haemophiliacs from such preparations. As a result many regulatory authorities have issued new directives for the manufacture of blood products that avert this danger, by requiring the introduction of specific antiviral treatment measures during the manufacturing process. Manufacturers have withdrawn pre-existing preparations.

Product name **Factor VIII**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	June 1984	Having regard to the transfer of AIDS and other viral diseases, changes in the manufacturing process of Factor VIII preparations are required. These include selection of donors, monitoring for viral contamination, limiting the donor-pool as well as the inclusion of warnings in the product information.
GBR	Oct. 1986	A manufacturer of Factor VIII products has agreed voluntarily to surrender product licences for these products following concern about the ability of the heat treatment procedure used to inactivate HIV (the AIDS virus). **WHO comment:** Factor VIII, a naturally occurring plasma protein fraction, is a vital component of the normal blood clotting mechanism which is deficient in haemophiliacs who require replacement therapy for both the treatment and prevention of bleeding. Factor VIII is extracted from the pooled plasma of a large number of donors and is presented as a concentrate. It has been recognized since 1984 that some viruses, and particularly the HIV (AIDS virus) could be transmitted to haemophiliacs from such preparations. As a result many regulatory authorities have issued new directives for the manufacture of blood products that avert this danger, by requiring the introduction of specific antiviral treatment measures during the manufacturing process. Manufacturers have withdrawn pre-existing preparations.

Product name **Fenclofenac**

C.A.S. number **34645-84-6**

Scientific and common names, and synonyms

BENZENEACETIC ACID, 2-(2,4-DICHLOROPHENOXY)-
(o-(2,4-DICHLOROPHENOXY)PHENYL)ACETIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GBR	1985	Withdrawn from the market.
NOR	1985	Not approved for registration having regard to its propensity to cause skin reactions which are not considered to be counter-balanced by any apparent advantage over other non-steroidal anti-inflammatory drugs. (Reference: (NNSLM) Nytt fra Statens Legemiddelkontroll, 1,, 1985) **WHO comment:** Fenclofenac, a nonsteroidal anti-inflammatory agent, was introduced in 1978 for the treatment of rheumatic disorders. By 1984 its use in the United Kingdom was associated with serious adverse effects, predominantly skin rashes, some of which were fatal. This led to the UK Committee on Safety of Medicine's refusal to renew the product licence and to the subsequent withdrawal of the drug by the manufacturer in all countries in which it was marketed.

Product name **Fenetylline**

C.A.S. number **3736-08-1**

Scientific and common names, and synonyms

AMFETYLINE
FENETHYLLINE
1H-PURINE-2,6-DIONE,3,7-DIHYDRO-1,3-DIMETHYL-7-(2-((1-METHYL-2-PHENYLETHYL)AMINO)ETHYL)-
7-(2-(alpha-METHYLPHENETHYL)AMINO)ETHYL)THEOPHYLLINE

...(Continued)

Legislative or regulative action

Product name **Fenetylline** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
OMN	May 1991	Import and marketing of products containing fenetylline were prohibited. (Reference: (OMNCR) Circular, 16/91,, May 1991)
BGR	9 Apr. 1992	Manufacture, use, storage, trade, import, and export of the central stimulant fenetylline were no longer permitted. (Reference: (BGRNDI) Communication from National Drug Institute,,, 9 Apr. 1992)

WHO comment: Fenetylline, a theophylline derivative of amfetamine, was introduced in 1966 as a central nervous stimulant. It is subject to abuse and is therefore controlled under Schedule II of the 1971 Convention on Psychotropic Substances. Fenetylline is not widely marketed. (Reference: (UNCPS2) United Nations Convention on Psychotropic Substances (II),,, 1971)

Product name **Fenoterol**

C.A.S. number **13392-18-2**

Scientific and common names, and synonyms

1,3-BENZENEDIOL,5-(1-HYDROXY-2-((2-(4-HYDROXYPHENYL-1-METHYLETHYL)AMINO)ETHYL)-
3,5-DIHYDROXY-alpha-((p-HYDROXY-alpha-METHYLPHENYLETHYL)AMINO)METHYL)BENZYL ALCOHOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
AUS	27 Mar. 1990	The indications of products containing fenoterol have been restricted to the treatment of mild to moderate asthma, having regard to reports from New Zeland of an increased risk of death when fenoterol is used in patients with severe asthma. (Reference: (AUSTGA) Therapeutic Goods Administration, Department of Community Services and Health,,, 27 Mar. 1990)

WHO comment: Fenoterol, a beta 2-adrenoreceptor agonist with bronchodilator activity, was introduced in 1971 for the management of asthma. In the 1960's, the use of other sympathomimetics in pressurised aerosols had already been associated with an increase in mortality due to asthma. However, it was not clear whether patients died from the severity of the asthma attack or from its treatment.

Product name **Feprazone**

C.A.S. number **30748-29-9**

Scientific and common names, and synonyms

PHENYLPRENAZONE
PRENAZONE
4-(3-METHYLBUT-2-ENYL)-1,2-DIPHENYLPYRAZOLIDONE-3,5-DIONE
4-(3-METHYL-2-BUTENYL)-1,2-DIPHENYL-3,5-PYRAZOLIDINEDIONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GBR	30 Mar. 1984	Voluntarily withdrawn from the market after concern was expressed over its risk-benefit ratio by the Committee on Safety of Medicines.
DEU	Nov. 1984	Marketing authorization for the sale of feprazone was withdrawn at the request of the manufacturer having regard to the frequency of reported adverse reactions, particularly involving the skin, and demonstration of a carcinogenic potential in rats. The manufacturer had never exercised its option to market feprazone in the Federal Republic of Germany.

...(Continued)

Legislative or regulative action

Product name **Feprazone** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GRC	1985	Withdrawn from the market.
EGY	26 Feb. 1985	Preparations containing feprazone are not approved for registration.
OMN	May 1987	Products intended for internal use containing feprazone were subjected to prescription control and a certificate from the Ministry of Health was required for their importation. (Reference: (OMNCR) Circular, 26/87,, May 1987)
AUT		Indications restricted to exacerbations of gout and other arthritic conditions. Treatment should not exceed seven days and doctors are advised not to prescribe this drug to children under 14 years of age or elderly patients. (Reference: (WIMAM) Wichtige Mitteilung ueber Arzneimittel, (1),, 1984) **WHO comment:** Feprazone, a pyrazolone derivative with antiinflammatory, analgesic and antipyretic activity, was introduced in 1978 for the treatment of rheumatic disorders. As it is structurally related to phenylbutazone it is subjected to rigorously restricted indications by some national regulatory authorities. See WHO comment for phenylbutazone. WHO has been informed that to date feprazone is only available in some 7 countries.

Product name **Fipexide**

C.A.S. number **34161-24-5**

Scientific and common names, and synonyms

1-((p-CHLOROPHENOXY)ACETYL)-4-PIPERONYLPIPERAZINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
FRA	1990	Products containing fipexide were contraindicated in children, because their use had been associated withpneumopathy, neuropsychological disorders and rare cases of agranulocytosis. In 1991, the manufacturer decided to withdraw all preparations from the market. (Reference: (FRAMHH) Ministry of Health and Humanitarian Action,,, 11 Dec. 1992) **WHO comment:** Fipexide, a stimulant of the central nervous system, was introduced in 1973 for the treatment of depression and memory defects. Following its association with hepatic and hemopoietic disorders, particularly in children, the drug was withdrawn in France. Although not widely marketed, it may still remain registered elsewhere.

Product name **Flecainide**

C.A.S. number **54143-55-4**

Scientific and common names, and synonyms

BENZAMIDE, N-(2-PIPERIDINYLMETHYL)-2,5-bis(2,2,2-TRIFLUOROETHOXY)-
N-(2-PIPERIDYLMETHYL)-2,5-bis(2,2,2-TRIFLUOROETHOXY)BENZAMIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	31 May 1989	The indications for products containing flecainide are restricted to prophylaxis and treatment of life-threatening tachyarrhythmia, supraventricular tachyarrhythmia unresponsive to conventional treatment and Wolf-Parkinson-White syndrome. (Reference: (SSLMS) Information från Socialstyrelsens Läekemedelsavdelning, 14(3), 60, 1989)

...(Continued)

Legislative or regulative action

Product name **Flecainide** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
FRA	July 1989	The indications for flecainide have been restricted to the treatment of potentially life-threatening ventricular arrhythmias, particularly ventricular tachycardia, and symptomatic arrhythmias (except those resulting from myocardial infarction) with unchanged left ventricular function. Flecainide is now contraindicated in non-persistent ventricular arrhythmia after myocardial infarction. (Reference: (FRARP) La Revue Prescrire, 9(87), 292, 1989)
MYS	July 1989	The indications of products containing flecainide have been restricted to the treatment of life-threatening arrhythmias only. (Reference: (MYSDN) Berita Ubat-Ubatan (Drug Newsletter), 3(3), 3, 1989)
@EC	Nov. 1989	Having regard to the CAST (Cardiac Arrhythmia Suppression Trial) study carried out in the USA, the Committee for Proprietary Medicinal Products has issued the following statement on products containing flecainide: 1) myocardial infarction as a precondition must be a contraindication for use except for life-threatening ventricular arrhythmias 2) asymptomatic and non severe symptomatic ventricular arrhythmias are contraindications 3) life-threatening ventricular arrhythmias may be treated provided that treatment is started in hospital under specific monitoring; 4) supraventricular arrhythmias may be treated provided that there is a definite need for treatment and in the absence of left ventricular function impairment. Patients on safe and effective long-term treatment with flecainide already before publication of the results of the CAST study may continue to take the drug. (Reference: (CECC) Communication from CEC,,, 21 June 1990)
ITA	1990	The indications for products containing flecainide are restricted to some forms of supraventricular tachycardias and to persistent life-threatening hyperkinetic ventricular arrhythmia. In the latter indication, patients should be hospitalized when treatment is commenced and remain under specialized medical supervision throughout therapy. Use is contraindicated in cases of cardiac block, cardiogenic shock, cardiac insufficiency, known hypersensitivity and in patients with a history of myocardial infarction, except for the treatment of life-threatening ventricular arrhythmias. (Reference: (BIFTI) Bollettino d'Informazione sui Farmaci, 14(1), 2, 1990)
NOR	1990	The indications for products containing flecainide were restricted to life-threatening ventricular tachycardia and to treatment and prophylaxis of severe incapacitating supraventricular arrhythmia. Treatment was required to be instituted in a hospital after full cardiological assessment of the patient. (Reference: (NNSLM) Nytt fra Statens Legemiddelkontroll, 4, 7, 1990)
DEU	Jan. 1990	The approved indications of flecainide are restricted to supraventricular and severe ventricular arrhythmias. It is contraindicated in recent myocardial infarction and impaired ventricular function, except in patients with life-threatening arrhythmias. (Reference: (DAZ) Deutsche Apotheker Zeitung, 130(5), 10, 1990) **WHO comment:** The membrane-stabilizing antiarrhythmic agent flecainide was introduced into medicine in 1982. The decision to delete the indications for patients with asymptomatic and less severe symptomatic ventricular arrhythmias was taken on the basis of the results of a trial (CAST study) that showed a two-fold increase in deaths in post-myocardiac patients taking flecainide compared with the placebo group.

Product name **Floctafenine**

C.A.S. number **23779-99-9**

Scientific and common names, and synonyms

BENZOIC ACID, 2-((8-(TRIFLUOROMETHYL)-4-QUINOLINYL)AMINO)-,2,3-DIHYDROXYPROPYL ESTER
2,3-DIHYDROXYPROPYL-N-(8-TRIFLUOROMETHYL-4-)QUINOLYL)ANTHRANILATE

...(Continued)

Legislative or regulative action

Product name **Floctafenine** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BEL	26 June 1987	Having regard to the potential of floctafenine to cause severe anaphylactic shock, products containing floctafenine may now only be obtained on medical prescription. (Reference: (BELAR) Arrêté Royal,,, June 1987) **WHO comment:** See WHO comment for glafenine.

Product name **Flunarizine**

C.A.S. number **52468-60-7**

Scientific and common names, and synonyms

(E)-1-(bis-(p-FLUOROPHENYL)METHYL)-4-CINNAMYLPIPERAZINE
PIPERAZINE,1-(bis(4-FLUOROPHENYL)METHYL)-4-(3-PHENYL-2-PROPENYL)-,(E)-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ESP	Aug. 1989	Having regard to their potential to induce extrapyramidal symptoms, products containing flunarizine may no longer be indicated for cerebral and peripheral arterial insufficiency, including loss of memory, insomnia, intermittent claudication, rest pain or vasospastic disturbances. The approved indications are restricted to vestibular disturbances, vertigo, prophylaxis of vascular headache and prevention of motion sickness. (Reference: (ESPINS) Información Terapéutica de la Seguridad Social, 13(8), 176, 1989)
DEU	Jan. 1991	The indications for products containing flunarizine were restricted to the treatment of vestibular dysfunction, having regard to association of the compound with Parkinsonism, extrapyramidal symptoms and depression and to insufficient proof of efficacy in other indications. Doctors were advised not to continue treatment for longer than is necessary to obtain an effective response, and in no circumstances for longer than 3 months. (Reference: (BGHBL) Bundesgesundheitsblatt, 2/91, 81, Feb. 1991)
@EC	12 Mar. 1991	The Committee for Proprietary Medicinal Products advised that the indications for products containing flunarizine should be restricted to the prophylaxis of severe refractory migraine and to the treatment of functional vestibular vertigo, having regard to the risks associated with their use. In 1989 the Committee had recommended that the approved product information should: 1) state that the product is contraindicated in patients with a history of extrapyramidal symptoms, Parkinsonism, Alzheimer's disease and depression; 2) warn that it may induce extrapyramidal signs and depression and unmask Parkinsonism, particularly in the elderly; 3) provide a description of the signs of extrapyramidal and depressive reactions. (Reference: (CPMPPO) Pharmacovigilance Opinion, 6,, 13 Sep. 1989)
JPN	July 1991	The approved labelling of products containing flunarizine was amended to indicate that reversible extrapyramidal disturbances and, less frequently, depression have been associated with their use, particularly in the elderly. (Reference: (JPNARD) Information on Adverse Reactions to Drugs, 109,, July 1991) **WHO comment:** Flunarizine, an antihistaminic and vasodilator agent, was introduced into medicine in 1970. It is indicated for the treatment of central and peripheral vascular disorders. However, its effectiveness in these conditions has not been convincingly demonstrated, and its use has been associated with adverse reactions involving the central nervous system, including extrapyramidal disturbances and depression. This has led several regulatory authorities to restrict the approved indications for products containing flunarizine.

Product name **Flunitrazepam**

C.A.S. number **1622-62-4**

Scientific and common names, and synonyms

2H-1,4-BENZODIAZEPIN-2-ONE, 5-(2-FLUOROPHENYL)-1,3-DIHYDRO-1-METHYL-7- NITRO-
5-(O-FLUOROPHENYL)-1,3-DIHYDRO-1-METHYL-7-NITRO-2H-1,4-BENZODIAZEPIN-2- ONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
TUR	1986	The Ministry of Health and Social Assistance has subjected flunitrazepam to controls equivalent to those applied to drugs in Schedule II of the 1971 Convention on Psychotropic Drugs in view of its frequent abuse by drug addicts. **WHO comment:** Flunitrazepam, a benzodiazepine derivative with sedative and hypnotic activity, was introduced in 1974 for the management of insomnia. Although it is subject to international control under Schedule IV of the 1971 Convention on Psychotropic Substances, its potential for abuse by drug addicts has led at least one country to apply controls equivalent to those of Schedule II. (Reference: (UNCPS4) United Nations Convention on Psychotropic Substances (IV),,, 1971)

Product name **Fluvoxamine**

C.A.S. number **54739-18-3**

Scientific and common names, and synonyms

5-METHOXY-4'-(TRIFLUOROMETHYL)VALEROPHENONE (E)-O-(2-AMINOETHYL)OXIME

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ISL		The Committee on Pharmaceuticals has refused to approve fluvoxamine for registration because animal experiments have shown teratogenicity and a potential to cause renal damage. (Reference: (ISLCP) Notification,,, Feb. 1987)

Product name **Furazolidone**

C.A.S. number **67-45-8**

Scientific and common names, and synonyms

NIFURAZOLIDONUM
2-OXAZOLIDINONE, 3-(((5-NITRO-2-FURANYL)METHYLENE)AMINO)-
3-((5-NITROFURFURYLIDENE)AMINO)-2-OXAZOLIDINONE
3-((5-NITROFURFURYLIDENE)AMINO)-2-OXAZOLIDONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
JPN	July 1977	Withdrawn from all marketed preparations on the grounds that it has been superseded by safer and more effective preparations.
PHL	1980	Approved for restricted use only. Animal tests have shown that this drug has carcinogenic potential. A warning statement is required to be placed on the labels of all products.
ITA	1982	The following warning has been inserted on the label taking into account experimental data on animals: "To be used systemically only for short periods and under the physician's guidance".
IRQ	1986	The National Board for the Selection of Drugs has withdrawn furazolidone form the market.

...(Continued)

Legislative or regulative action

Product name **Furazolidone** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
MYS	Mar. 1987	All products containing furazolidone have been withdrawn. (Reference: (MYSDC) Malaysian Drug Control Authority, No.8,, Dec. 1986)
KOR	Dec. 1988	All products containing furazolidone were banned, because there are many preparations which are safer and more effective. (Reference: (KRMHSA) Ministry of Health and Social Affairs - Communication to WHO,,, 13 Dec. 1991)
LBN	3 Aug. 1991	Products containing furazolidone intended for the treatment of diarrhoea in children were withdrawn. (Reference: (LBNMHD) Ministry of Health and Social Affairs Decree, 150/1,, Aug. 1991)
		WHO comment: Furazolidone, a nitrofuran derivative with antibacterial and antiprotozoal activity, was introduced in 1954. In the 1970s it was shown to have a carcinogenic potential following long-term administration to experimental animals. However, the relevance of this to short-term therapy in man has not been established. The risk-benefit assessment varies and furazolidone remains widely available in many countries for the treatment of diarrhoea and enteritis.

Bibliographical references

WHO FOOD ADD., 31, 85, 1993

Product name **Gangliosides**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	31 Aug. 1992	The Federal Health Office extended the suspension period for the injectable preparation of mixed bovine brain gangliosides at least until 30 September 1994. The product was first suspended in 1989 because of a possible association with Guillian-Barré syndrome. (Reference: (DEUFHO) Communication from Federal Health Office,,, 31 Aug. 1992)
		WHO comment: Gangliosides are a glycolipid extract of bovine cerebral cortex claimed to ameliorate peripheral neuropathies of various types, including post-herpetic neuropathy, tobacco-alcohol amblyopia, toxic acoustic injuries, and traumatic facial paralysis. Its use has been associated with cases of Guillain-Barré syndrome characterized by mixed polyneuropathy and in some instances, flaccid paralysis.

Product name **Gemfibrozil**

C.A.S. number **25812-30-0**

Scientific and common names, and synonyms

PENTANOIC ACID, 5-(2,5-DIMETHYLPHENOXY)-2,2-DIMETHYL
2,2-DIMETHY-5-(2,5-XYLYLOXY)VALERIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NOR	1987	The Medicines Control Authority has refused registration of gemfibrozil on the grounds that the risk of adverse effects is not balanced by therapeutic benefit. (Reference: (NNSLM) Nytt fra Statens Legemiddelkontroll, 4, 10, 1987)

...(Continued)

Legislative or regulative action

Product name **Gemfibrozil** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Gemfibrozil, an antihyperlipidaemic derivative of clofibrate, was introduced in the early 1980's. It is registered in several countries for the treatment of hyperlipidaemia unresponsive to dietary measures. (See also the WHO comment for clofibrate).

Product name **Germander**

Scientific and common names, and synonyms
TEUCRIUM CHAMAEDRYS

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1992	The Federal Health Office withdrew the marketing authorization for herbal medicines containing germander based on reports of hepatotoxicity generated within France by the drug regulatory agency. (Reference: (DAZ) Deutsche Apotheker Zeitung, 132(12):20,, 1992)
FRA	1992	The Ministry of Health and Humanitarian Action suspended the marketing authorization for medicinal products containing the plant germander having regard to 26 cases of liver necrosis associated with the use of these products. (Reference: (FRARP) La Revue Prescrire, 12(114):17,, 1992)
BEL	4 Aug. 1992	The Minister of Social Integration, Public Health and the Environment decided to suspend for a period of one year all medicines containing germander having regard to concerns relating to hepatotoxicity generated within France. This suspension has been prolonged for another year from 20 July 1993 by order of the Ministry. (References: (BELMD) Ministerial Decree,,, 4 Aug. 1992; (BELMB) Moniteur Belge,, 20542, 25 Sep. 1992)
		WHO comment: Germander has been tradionally used as a diet aid, a treatment for light diarrhoea, or locally as an analgesic for oral pain. In 1991, the first cases of hepatitis associated with the use of these products were reported to the National System of Pharmacovigilance in France. It is yet uncertain whether contamination possible by pesticides or fungi, may be implicated or whether these cases result from toxic or immuno-allergic reactions to constituents of Germander.

Product name **Glafenine**

C.A.S. number **3820-67-5**

Scientific and common names, and synonyms
GLAPHENINE
2,3-DIHYDROXYPROPYL-N-(7-CHLORO-4-QUINOLYL) ANTHRANILATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1984	Following reports of frequent severe allergic reactions, this analgesic was withdrawn from the market by the manufacturer.
ITA	Oct. 1987	Having regard to adverse reactions reported in Italy and other countries, the General Directorate of the Pharmaceutical Service of the Ministry of Health has revoked the marketing authorization for suppositories containing 1 mg of glafenine. This preparation contained a higher dosage of the active principle than others available on the market. (Reference: (BIFTI) Bolletino d'Informazione sui Farmaci, 10(10), 2, 1987)

...(Continued)

Product name **Glafenine** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BEL	1 Jan. 1991	In agreement with the manufacturers, the Ministry of Health suspended the marketing authorization for all products containing glafenine, including extemporaneous preparations, following reports of anaphylactic shock, acute tubulo-interstitial renal insufficiency and immunoallergic hepatitis. In 1992, glafenine was withdrawn by the major manufacturer. (Reference: (BELGPI) General Pharmaceutical Inspectorate,,, 12 Dec. 1991)
@EC	14 Jan. 1992	The Committee for Proprietary Medicinal Products of the European Communities recommended the withdrawal of products containing glafenine, because the risk of serious anaphylactic reactions associated with their use is greater than with other analgesics. (Reference: (CPMPPO) Pharmacovigilance Opinion, 8/2,, 14 Jan. 1992)
CHE	Mar. 1992	The marketing authorization for products containing glafenine was suspended and later withdrawn by the company. (Reference: (CHBCM) Bulletin Mensuel,,, 6 Mar. 1992)
FRA	Mar. 1992	In agreement with the manufacturer, the Ministry of Health withdrew the marketing authorization for products containing glafenine, having regard to the risk of anaphylactic reactions. (Reference: (FRAMS) Ministry of Social Affairs and Integration,,, 2 Apr. 1992)
PRT	Mar. 1992	The marketing authorization for monocomponent and combination products containing glafenine was suspended. (Reference: (PRTMH) Ministry of Health,,, 6 Mar. 1992)
OMN	3 Mar. 1992	Import and marketing of products containing glafenine were prohibited, and they will not be considered for registration. (Reference: (OMNCR) Circular, 5/92,, Mar. 1992)
@WD	May 1992	Upon agreement of regulatory authorities, products containing glafenine were withdrawn worldwide by the major manufacturer. (Reference: (CRU) Communication to WHO from Roussel Uclaf,,, 21 May 1992) **WHO comment:** Glafenine, a quinolylanthranilate derivative, was introduced in 1965 for use as an analgesic. By the late 1970s its use had been associated with severe allergic responses, including anaphylactoid reactions, which led to its withdrawal in one country whereas in others a warning to this effect is required in the product information. In 1992, on the advice of the Committee for Proprietary Medicinal Products of the European Communities, glafenine was eventually withdrawn worldwide by the major manufacturer.

Product name **Glucosamine sulfate**

C.A.S. number **3416-24-8**

Scientific and common names, and synonyms

CHITOSAMINE SULFATE
D-GLUCOSE, 2-AMINO-2-DEOXY-, SULFATE
2-AMINO-2-DEOXY-beta-D-GLUCOPYRANOSE SULFATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1986	Following reports of local hypersensitivity reactions, preparations containing glucosamine sulfate are no longer approved for intra-articular administration.
EGY	1987	Preparations of glucosamine sulfate for intra-articular injection will not be considered for registration because of an unacceptable potential to cause allergic reactions. (Reference: (EGYDI) Drug Information, 5(3), 1, 1987) **WHO comment:** Glucosamine is found in chitin, mucoproteins and mucopolysaccharides. It is used as a pharmaceutical aid. Glucosamine sulfate has been used in the treatment of rheumatic disorders though it is not widely marketed for this purpose.

Product name **Glutethimide**

C.A.S. number **77-21-4**

Scientific and common names, and synonyms

GLUTEMIDE
2-ETHYL-2-PHENYLGLUTARIMIDE
2,6-PIPERIDINEDIONE, 3-ETHYL-3-PHENYL-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NOR	1980	Withdrawn from the market.
ZWE	Nov. 1984	Prohibited for use. (Reference: (ZWESI) Statutory Instrument, 366,, Nov. 1984)
PAK	1988	Products containing glutethimide were withdrawn. (Reference: (PAKMH) Ministry of Health, Special Education and Social Welfare,,, 3 Aug. 1988)
		WHO comment: Glutethimide, a piperidine derivative, was introduced in 1955 for use as a sedative-hypnotic drug. Its addiction liability and severity of withdrawal symptoms are equal to those of the barbiturates and it is controlled under Schedule III of the 1971 Convention on Psychotropic Substances. (Reference: (UNCPS3) United Nations Convention on Psychotropic Substances (III),,, 1971)

Product name **Griseofulvin**

C.A.S. number **126-07-8**

Scientific and common names, and synonyms

SPIRO(BENZOFURAN-2(3H), 1'-(2)CYCLOHEXENE)-3,4'-DIONE, 7-CHLORO-2',4,6- TRIMETHOXY-6'-METHYL-,(1'S-TRANS)-
7-CHLORO-2',4,6-TRIMETHOXY-6'beta-METHYLSPIRO(BENZOFURAN-2(3H),1'-(2) CYCLOHEXENE)-3,4'-DIONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GBR	1986	Having regard to recently evaluated reports of carcinogenicity, fetotoxity and teratogenicity in rodents administered very high doses of griseofulvin, the Committee on the Review of Medicines has recommended that all products containing griseofulvin should be restricted in their use to the treatment of dermatophyte infections of the skin, scalp, hair and nails when topical therapy has failed or is considered inappropriate. It also recommends that such products should not be used during pregnancy or for prophylactic treatment.
DEU	1992	Following reports of teratogenicity in experimental animals, the approved product information for products containing griseofulvin was amended to contraindicate their use during pregnancy, except in life-threatening conditions, and lactation. The need for contraceptive measures to be maintained throughout treatment and, for men, for 6 months thereafter was emphasized. (Reference: (DAZ) Deutsche Apotheker Zeitung, 32(12):XII,, 1992)
		WHO comment: Griseofulvin, isolated from a penicillin producing mould, has been widely used as a systemically administered antifungal agent in man for over 20 years. It is effective in dermatophyte infections (including tinea barbae and tinea capitis) but it is inactive against yeasts and bacteria. Evidence that very high doses of griseofulvin are carcinogenic, teratogenic and fetotoxic in laboratory animals has led to an acceptance that it should not be used to treat trivial infections that respond to topical therapy. Oral formulations of griseofulvin are included in the WHO Model List of Essential Drugs. (Reference: (WHTAC1) Model List of Essential Drugs, 2nd Report of the WHO Expert Committee, 722,, 1985)

Product name **Guanofuracin**

C.A.S. number **300-25-4**

Scientific and common names, and synonyms

5-NITROFURFURYLIDENAMINOGUANIDINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
JPN	July 1977	Withdrawn from all marketed preparations on the grounds that it has been superseded by safer and more effective preparations.
VEN		Not approved for use and/or sale.
		WHO comment: Guanofuracin, a nitrofuran derivative, was formerly used as an antiinfective agent. It has, however, been superseded by safer compounds and WHO has no information that it remains commercially available.

Product name **Halogenated hydroxyquinoline derivatives**

C.A.S. number **148-24-3**

Scientific and common names, and synonyms

OXINE
OXYQUINOL
OXYQUINOLINE
8-QUINOLINOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DNK	1978	All halogenated hydroxyquinoline derivatives intended for oral administration have been withdrawn from use. (Reference: (UGLAAD) Ugeskrift for Laeger, 140, 1181, 1978)
CYP	1980	The Drug Council withdrew all products containing halogenated hydroxyquinoline derivatives intended for internal use due to the possible risk of occurrence of sub-acute myelo-optic neuropathy (SMON) in treated patients.
PHL	Aug. 1980	Withdrawn from the domestic market due to reports of neurological disorders (SMON) with their use in Japan.
BGD	1982	Under the provisions of the Drugs (Control) Ordinance, these preparations have been banned. Clioquinol is implicated in sub-acute myelo-optic neuropathy (SMON), manifested by pain and persistent diarrhoea and proceeding to bilateral sensory disturbances, paraesthesias and dysaesthesias. Similar toxic effects have been observed with other halogenated hydroxyquinolines. (Reference: (BGDCO) The Drugs (Control) Ordinance,., 1982)
GHA	1982	All preparations containing halogenated hydroxyquinoline derivatives for oral administration have been withdrawn from use.
TUR	20 Dec. 1982	Banned for production and sale having regard to severe adverse reactions.
ITA	1983	Withdrawn from the market.
GRC	Mar. 1984	Pharmaceutical products containing halogenated hydroxyquinolines have been withdrawn having regard to experimental and clinical evidence of toxicity.
OMN	Mar. 1987	Import and marketing of oral and parenteral preparations containing oxyquinoline and its halogenated derivatives intended for the treatment of diarrhoea in children were prohibited. Topical preparations remained on the market. (Reference: (OMNCR) Circular, 11/87,, Mar. 1987)
ARE		The following halogenated hydroxyquinoline derivatives used for intestinal amoebiasis are banned: broxyquinoline, clioquinol and diiodohydroxyquinoline.

...(Continued)

Legislative or regulative action

Product name **Halogenated hydroxyquinoline derivatives** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
IND		Currently available on the market. Precautionary information is required to be given with this drug.
VEN		Subject to restricted use and/or sale. **WHO comment:** Halogenated hydroxyquinoline is structurally related to clioquinol. See WHO comment for clioquinol. (Reference: (WHODI) WHO Drug Information, 77.1, 9, 1977)

Product name **Halogenated salicylanilides**

Scientific and common names, and synonyms

DIBROMSALAN
METABROMSALAN
TETRACHLOROSALICYLANILIDE
TRIBROMSALAN

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	1 Dec. 1975	Withdrawn from the market and prohibited for export in drugs and cosmetic products by the Food and Drug Administration due to the risks of disabling skin disorders and photosensitivity in humans. (Reference: (FEREAC) Federal Register, 40(210), 50527, 1975)
JPN	Jan. 1976	Banned by the Pharmaceutical Affairs Bureau due to potential for photosensitivity reactions. **WHO comment:** Halogenated salicylanilides, including dibromsalan, metabromsalan, tribromsalan and tetrachlorosalicylanilide, which have antibacterial and antifungal activity, have been used both as active ingredients for antimicrobial purposes and as inactive ingredients (preservatives) in drug and cosmetic products. Their use has been associated with photosensitive eruptions and disabling skin disorders which has resulted in their withdrawal by some national drug regulatory authorities.

Product name **Heptabarb**

C.A.S. number **509-86-4**

Scientific and common names, and synonyms

HEPTABARBITONE
HEPTAMALUM
5-(CYCLOHEPT-1-ENYL)-5-ETHYLBARBITURIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	July 1984	Withdrawn following discussions between the manufacturer and the National Board of Health and Welfare. Fatal intoxications and abuse are associated with use of preparations containing heptabarb. **WHO comment:** Heptabarb is an intermediate-acting barbiturate. See WHO comment for barbiturates.

Product name **Herpes simplex vaccines**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	Aug. 1984	Sale of Herpes simplex vaccines has not been approved by the National Control Authority having regard to their potential hazards.
SAU		Preparations containing Herpes simplex vaccines have been withdrawn from the market.
VEN		Not approved for use and/or sale.
		WHO comment: Preparations containing Herpes simplex vaccine have been available for at least 15 years. As a result of a review of unlicensed products marketed in the Federal Republic of Germany in 1984 the National Control Authority banned the use of such preparations having regard to their potential harmfulness. Preparations remain available elsewhere, however.

Product name **Hexachlorophene**

C.A.S. number **70-30-4**

Scientific and common names, and synonyms

HEXACHLOROPHANE
2,2'-METHYLENEBIS(3,4,6-TRICHLOROPHENOL)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
PHL	1972	All talcum powders for infant use containing more than 0.75% hexachlorophene were withdrawn. All other products with greater concentration shall be available on prescription basis only.
JPN	Mar. 1972	Banned by the Pharmaceutical Affairs Bureau in preparations such as nursing powder, since edema of the brain is observed with test animals. Export is prohibited.
TUR	1981	Withdrawn from all toothpaste formulations by the Ministry of Health due to published evidence of its harmful effects. Export of this product is prohibited.
DDR	Apr. 1983	Hexachlorophene has been replaced in pharmaceutical and cosmetic preparations. (Reference: (DDRMH) Regulation of Ministry of Health,,, Apr. 1983)
COE	1984	The Committee of Experts on Cosmetics of the Council of Europe has reclassified hexachlorophene in the list of preservatives published in the second edition 1984 of "Cosmetic Products and their Ingredients" from class A (recommended) to class D (not recommended). Hexachlorophene is now considered an ingredient which, on the basis of information provided, presents a health hazard and which therefore is not recommended for use in cosmetic products. (Reference: (COECI) Cosmetic products and their ingredients 2nd edition,,, 1984)
SUN	25 Aug. 1988	Pharmaceutical products containing hexachlorophene are prohibited for production and use on grounds of teratogenicity, embryotoxicity, neurotoxicity, photosensitizing and allergic potential.
PER		Prohibited for use in hygienic preparations with the exception of deodorants, which may contain as much as 0.1%, and antiseptic soaps, which may contain 0.2% of hexachlorophene.
THA		The use of pharmaceutical preparations containing hexachlorophene is severely restricted.

...(Continued)

Product name **Hexachlorophene** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Hexachlorophene, an antimicrobial agent, was introduced in 1948 in proprietary liquid preparations and powders and was subsequently used extensively as a topical antiseptic. By the early 1970s its use in infants had been conclusively demonstrated to cause encephalopathy as a result of transdermal absorption. More recently it has been suggested that the drug has a teratogenic potential. Many regulatory authorities have placed rigorous restrictions on the medicinal use of hexachlorophene, particularly in preparations intended for infants. However, its use still commonly remains permissible at low concentrations as a preservative in toiletries and cosmetics. (Reference: (WHODI) WHO Drug Information, 3, 6, 1978)

Bibliographical references

IARC MONOGRAPH, 20, 241, 1979

Product name **Hexestrol**

C.A.S. number **5635-50-7**

Scientific and common names, and synonyms

DIHYDROSTILBOESTROL
HEXOESTROL
SYNESTROL
4,4'-(1,2-DIETHYLETHYLENE)DIPHENOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
AUT	Feb. 1977	Pharmaceutical specialities containing diethylstilbestrol, dienestrol, hexestrol and their derivatives have been withdrawn following reports indicating an association between prenatal exposure to diethylstilbestrol and the subsequent development of adenocarcinoma in postpubertal girls and young women. The use of stilbene derivatives is only authorized for the treatment of cancer of the prostate.
ITA	1979	This product has been withdrawn from the market due to suspected carcinogenicity in newborns following prenatal exposure.
KWT	Jan. 1980	Prohibited for import.
SAU		Following reports indicating the development of adenocarcinoma in post-pubertal girls and young women exposed prenatally to preparations containing diethylstilbestrol, dienestrol and their derivatives, the Drug Committee prohibited the use of these products during pregnancy.
VEN		Not approved for use and/or sale.
		WHO comment: Hexestrol is a stilbene derivative. See WHO comment for diethylstilbestrol. (Reference: (WHODI) WHO Drug Information, 77.1, 16, 1977)

Product name **Hexobarbital**

C.A.S. number **56-29-1**

Scientific and common names, and synonyms

HEXOBARBITONE
2,4,6(1H,3H,5H)-PYRIMIDINETRIONE, 5-(1-CYCLOHEXEN-1-YL)-1,5-DIMETHYL-
5-(CYCLOHEX-1-ENYL)-1,5-DIMETHYLBARBITURIC ACID

...(Continued)

Legislative or regulative action

Product name **Hexobarbital** ...(Continued)

Scientific and common names, and synonyms
5-(1-CYCLOHEXEN-1-YL)-1,5-DIMETHYLBARBITURIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	Oct. 1984	Withdrawn following discussions between the manufacturer and the National Board of Health and Welfare. Fatal intoxications and abuse are associated with use of preparations containing hexobarbital. **WHO comment:** Hexobarbital is a short-acting barbiturate. See WHO comment for barbiturates.

Product name **Hydroquinone**

C.A.S. number **123-31-9**

Scientific and common names, and synonyms
HYDROCHINONUM, BENZENE-1,4-DIOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1991	The Federal Health Office has restricted the use of products containing hydroquinone to pathological hyperpigmentation. Children under 12 years of age should not be treated. (Reference: (DAZ) Deutsche Apotheker Zeitung, 132(42),, 1991) **WHO comment:** Hydroquinone was introduced in 1965 as a topical depigmenting agent for hyperpigmentation. At high concentrations hydroquinone is corrosive and in most countries has been restricted to the level of approximately 2% and limited to the period of less than 2 months. Additional consideration for restrictive action is that animal experiments have also demonstrated carcinogenic and mutagenic potential of hydroquinone.

Product name **Hyoscine methonitrate**

C.A.S. number **6106-46-3**

Scientific and common names, and synonyms
HYOSCINE METHYLNITRATE
METHYLSCOPOLAMINE NITRATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	June 1981	Hyoscine methonitrate, an antimuscarinic agent, has been withdrawn from appetite suppressant preparations. **WHO comment:** Hyoscine methonitrate, a quaternary ammonium anticholinergic agent, was introduced in 1947 for use as a gastrointestinal antispasmodic. The action taken in Sweden relates to the use of this compound in preparations for suppressing the appetite. Preparations may remain available elsewhere.

Product name **H1-Antihistamines**

Scientific and common names, and synonyms
HISTAMINE H1 RECEPTOR ANTAGONISTS

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1987	Products containing histamine H1 receptor antagonists indicated for vomiting during pregnancy may only be dispensed on medical prescription, because they have been associated with an increased risk of neonatal pyloric stenosis. H1-antihistamines labelled for other indications should mention pregnancy as a contraindication. (Reference: (BGHBL) Bundesgesundheitsblatt, 30, 186, 1987)
CHE	28 Mar. 1990	Over-the-counter preparations containing phenothiazine antihistamines indicated for children under one year of age may only be dispensed on medical prescription. The product information directed to physicians must carry a warning stating that caution is recommended in treating children of less than one year of age and that the use of the preparation is clearly contra-indicated under the following circumstances: neonates (particularly premature births), history of apnoeic crises (near-miss-SIDS), SIDS in brothers and sisters and cardiorespiratory problems. The information intended for patients must carry a warning that a doctor is to be consulted before children of less than one year of age are treated. (Reference: (CHEAZ) Schweizer Apotheker Zeitung, 128(11), 311, 1990)
@EC	13 May 1991	The Committee for Proprietary Medicinal Products advised that products containing phenothiazines, including alimemazine, mequitazine, oxomemazine and promethazine indicated for the treatment of cough, allergic reactions, motion sickness and for sedation, should not be used in children below the age of one year, having regard to their possible association with sudden infant death syndrome. (Reference: (CPMPDP) Draft Position Statement on Phenothiazines and sudden infant death syndrome,,, 13 May 1991)
BEL		The approved information of products containing histamine H1 receptor antagonists must warn in the section"Precautions" against their administration to children aged less than one year without medical advice, because their sedative effect may be associated with episodes of sleep apnoea. The package leaflets of preparations containing of phenothiazine antihistamine must bear an idential warning in the section "Contra-indications". (Reference: (BELGPI) General Pharmaceutical Inspectorate,,, 18 June 1987) **WHO comment:** Histamine H1 receptor antagonists were introduced in 1937 as over-the-counter medicines for the treatment of allergies of the upper respiratory tract and skin. They are also widely used to reduce the symptoms of the common cold, although there is little evidence of their effectiveness in this condition. The sedative and antiemetic effects of antihistamines are of value in the treatment of sleep disorders, motion sickness and vomiting. In 1979, the possibility was raised that the use of phenothiazine antihistamines, particularly promethazine, could be associated with sleep aapnoea in young children and with sudden infant death syndrome (SIDS). Studies carried out subsequently, although they have not established a causal relationship, have led some drug regulatory authorities to subject products containing phenothiazine antihistamines to prescription control and/or to caution against their use in young children. In some countries, similar warnings have also been included in the package leaflets of other H1-antihistamines.

Product name **Ibuprofen**

C.A.S. number **15687-27-1**

Scientific and common names, and synonyms
2-(4-ISOBUTYLPHENYL)PROPIONIC ACID

...(Continued)

Legislative or regulative action

Product name **Ibuprofen** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	Feb. 1992	The Federal Health Office has amended the approved product information for a tropical formation of the non-steroidal anti-inflammatory agent, ibuprofen. The contraindications were extended to include patients with a history of allergy and children under 6 years of age. (Reference: (BGHBL) Bundesgesundheitsblatt, 2/92, 109, Feb. 1992) **WHO comment:** Ibuprofen, a non-steroidal anti-inflammatory agent, was introduced in 1969. It was approved for sale without prescription in packages containing no more than 400 mg, in the United Kingdom in 1983. This action was followed by the USA, Canada and several European countries. Since this time reports of suspected adverse effects have increased. Most of these relate to gastro-intestinal disturbances, hypersensitivity reactions but aseptic meningitis, skin rashes and renal damage have been recorded.

Product name **Indalpine**

C.A.S. number **63758-79-2**

Scientific and common names, and synonyms

2-(3-(4-PIPERIDYL)ETHYL)INDOLE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
FRA	13 July 1985	Following reports of agranulocytosis and severe neutropenia associated with the use of indalpine, the major manufacturer in consultation with the French health authorities decided to suspend the marketing of this drug. (Reference: (FMOPL) Le Moniteur des Pharmacies et des Laboratoires, 1666,, June 1985) **WHO comment:** Indalpine, an antidepressant with serotoninergic action, was introduced in 1983 and marketed exclusively in France. In 1984 its use was associated with cases of leucopenia and agranulocytosis which led to the voluntary suspension of clinical trials in the USA. In 1985 the major manufacturer voluntarily withdrew the drug from the market.

Product name **Indoprofen**

C.A.S. number **31842-01-0**

Scientific and common names, and synonyms

BENZENEACETIC ACID, 4-(1,3-DIHYDRO-1-OXO-2H-ISOINDOL-2-YL)-alpha-METHYL
P-(1-OXO-2-ISOINDOLINYL)HYDRATROPIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
CYP	Dec. 1983	Withdrawn from the market following reports of serious adverse gastrointestinal reactions.
GBR	Dec. 1983	Withdrawn from the market following reports of serious adverse gastrointestinal reactions.
@WD	1984	The nonsteroidal anti-inflammatory drug, indoprofen, was voluntarily withdrawn worldwide by the manufacturer following the demonstration of tumours in a carcinogenicity study undertaken in rats.
CHL	July 1984	Voluntarily withdrawn by the manufacturer.

...(Continued)

Legislative or regulative action

Product name **Indoprofen** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	July 1984	The Federal Health Office, in agreement with the manufacturer, withdrew products containing indoprofen on an interim basis pending an evaluation of the results of a recently undertaken carcinogenicity study.
ITA	July 1984	The manufacturer withdrew all formulations of indoprofen following decisions by the Ministry of Health to suspend promotion and disallow repeat prescriptions pending further evaluation of the safety of the drug. **WHO comment:** Indoprofen, a nonsteroidal anti-inflammatory agent, was introduced in 1976 for the treatment of rheumatic disorders. By 1983 its use had been associated with serious adverse effects, some of which were fatal. This led to its withdrawal in the United Kingdom and Cyprus. In 1984 reports of intestinal tumours in rats led to the drug's temporary withdrawal in Germany and Italy. This was followed immediately by the suspension of marketing worldwide by the major manufacturer.

Product name **Iodinated casein strophanthin (neo-barine)**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	Oct. 1964	Withdrawn from the market and prohibited for export by the Food and Drug Administration due to the risk of thyrotoxic side effects. This drug was marketed as an appetite suppressant. **WHO comment:** The World Health Organization has no information further to the above regarding preparations containing iodinated casein strophanthin or to indicate that they are still commercially manufactured.

Product name **Iproniazid**

C.A.S. number **54-92-2**

Scientific and common names, and synonyms

ISONICOTINIC ACID 2-ISOPROPYLHYDRAZIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ITA		Withdrawn from the market owing to an unfavourable risk-benefit ratio and the lack of substantial evidence of efficacy. **WHO comment:** Iproniazid, a monoamine oxidase inhibitor (MAOI), was introduced in 1952 for the treatment of depressive illness. Subsequently concern regarding potentially serious interactions between MAOIs and foods containing tyramine inspired much restrictive regulatory action. However, MAOIs still retain a place in the treatment of serious depressive illness although there is no international consensus on which compounds should be preferred. Thus iproniazid remains available in several countries.

Product name **Isaxonine phosphate**

C.A.S. number **4214-72-6**

Scientific and common names, and synonyms

2-(ISOPROPYLAMINO)PYRIMIDINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
FRA	25 June 1983	Isaxonine phosphate has been withdrawn following the occurrence of toxic hepatitis associated with its use.
TUN		Not approved for registration on grounds of safety.
		WHO comment: Isaxonine phosphate was introduced in 1981 and marketed exclusively in France for the treatment of peripheral neuropathy. In January 1983 indications for use were restricted following its association with cases of toxic hepatitis. It was subsequently withdrawn in June 1983.

Product name **Isocarboxazid**

C.A.S. number **59-63-2**

Scientific and common names, and synonyms

3-ISOXAZOLECARBOXYLIC ACID, 5-METHYL-, 2-(PHENYLMETHYL)HYDRAZIDE
5-METHYL-3-ISOXAZOLECARBOXYLIC ACID 2-BENZYLHYDRAZIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
JPN	Nov. 1974	The Ministry of Health and Welfare has withdrawn all products containing isocarboxazid and nialamide on the grounds that they lack substantial evidence of efficacy and safety.
CUB		Prohibited from use by the National Formulary Commission (1982) on grounds of reported toxicity and in view of the availability of other less toxic drugs.
SAU		Products now controlled by the authorities.
VEN		Not approved for use and/or sale.
		WHO comment: Isocarboxazid, a monoamine oxidase inhibitor (MAOI), was introduced in 1959 for the treatment of depressive illness. Subsequently concern regarding potentially serious interactions between MAOIs and foods containing tyramine inspired much restrictive regulatory action. However, MAOIs still retain a place in the treatment of serious depressive illness although there is no international consensus on which compounds should be preferred. Thus isocarboxazid remains available in several countries and is cited in the British National Formulary as a relatively safe example of this class of compound.

Product name **Isoprenaline**

C.A.S. number **7683-59-2**

Scientific and common names, and synonyms

ISOPROPYLARTERENOL
ISOPROPYLNORADRENALINE
ISOPROTERENOL
1-(3,4-DIHYDROXYPHENYL)-2-ISOPROPYLAMINOETHANOL

...(Continued)

Legislative or regulative action

Product name **Isoprenaline** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
LKA	1 Jan. 1992	The Ministry of Health withdrew from sale inhalers containing the beta-adrenoreceptor agonist, isoprenaline, because of its potential to induce serious cardiovascular adverse effects. (Reference: (LKADIB) Drug Information Bulletin, University of Peradeniya and Ministry of Health, 4(1),, 1992) **WHO comment:** Isoprenaline, a beta-adrenoreceptor agonist, was introduced in 1949 as treatment for a number of cardiac disorders and as a bronchial dilator for the symptomatic treatment of asthma. There is evidence that regular inhalation of bronchodilator drugs is associated, in some cases with exacerbation of the disease and with increased fatality rates. The underlying causes are disputed, but an increasing body of opinion now advocates regular maintenance therapy with inhaled, corticosteroids coupled with supplementary use as required of bronchial drugs to suppress exacerbations.

Product name **Isotretinoin**

C.A.S. number **4759-48-2**

Scientific and common names, and synonyms

RETINOIC ACID, 13-CIS
3,7-DIMETHYL-9-(2,6,6-TRIMETHYL-1-CYCLOHEXEN-1-YL)2-CIS-4-TRANS-6- TRANS-8-TRANS-NONATETRAENOIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
AUS	1984	Isotretinoin is approved only for the treatment of severe cystic acne unresponsive to conventional therapy. In most states the availability of products is restricted to prescription by specialist physicians. Labels and product literature carry a warning that "This product causes birth defects". Warning letters have been circulated to doctors and pharmacists concerning necessary precautions. Government approved patient information leaflets and patient consent forms have been issued. (Reference: (AUDEC) Report of the Australian Drug Evaluation Committee, No.116,, Nov. 1984)
USA	Aug. 1985	Having regard to its teratogenicity, isotretinoin should be used only for severe cystic acne refractory to conventional therapies. (Reference: (FDADB) FDA Drug Bulletin, (2),, 1985)
OMN	24 Dec. 1985	Having regard to its teratogenicity, isotretinoin may only be used under the supervision and control of a hospital dermatologist. (Reference: (OMNMH) Ministry of Health, 5,, 1985)
MYS	1988	The Drug Control Authority has decided that the labelling of preparations containing isotretinoin should bear a distinct warning regarding teratogenicity, emphasizing that effective contraceptive measures must be instituted throughout treatment and for at least four weeks thereafter, and additional reference is also required to the following adverse effects: symptoms of hypervitaminosis-A; transient and reversible elevation of transaminases and alkaline phosphatases; bone changes after long-term high dosage; benign intracranial hypertension. (Reference: (MYSPR) Ministry of Health Press Release, 2, 3, 1988)
BEL	1 Jan. 1988	Preparations containing isotretinoin have been placed in List IV of the 'Arrêté du Régent' of 2 June 1946 and as such can be administered only on prescription. They must be kept in a poisons cabinet and carry the skull and crossbones label. They must bear a warning regarding the embryotoxicity and teratogenicity of the drug which contraindicates its use during pregnancy. (Reference: (BELAR) Arrêté Royal,,, June 1987)
EGY		The Technical Committee for Drug Controls has issued a statement that preparations containing isotretinoin should not be used during pregnancy. Product information must include a warning that paronychia can develop during treatment.

...(Continued)

Product name **Isotretinoin** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ESP		Contraindications to isotretinoin must include a boxed paragraph stating that the drug may only be used in women of child-bearing age when an effective method of contraception assures protection during and for at least four weeks after discontinuation of treatment. Pregnancy must be excluded before initiation of treatment.
NLD		The Ministry of Welfare, Public Health and Culture has stressed that isotretinoin should be prescribed only for serious forms of acne resistant to other treatment. Pregnancy should be excluded prior to treatment and conception prevented during treatment. (Reference: (GENMB) Geneesmiddelenbulletin, 18(9),, 1984)
NZL		Having regard to its teratogenicity, isotretinoin is indicated only in severe nodulo-cystic acne resistant to other forms of therapy. (Reference: (NZCSL) Clinical Services Letter, Department of Health, 232,, Feb. 1985)
TUN		Having regard to its teratogenicity, isotretinoin should be used only for its recommended indications under the strict supervision of the prescribing doctor. **WHO comment:** Isotretinoin, a retinol derivative, was introduced in 1982 exclusively for the treatment of severe acne. Its use in pregnant women has resulted in major foetal abnormalities. The manufacturer's information emphasizes that the drug is teratogenic and must not be given to women who are pregnant, and that contraceptive measures must be maintained for at least four weeks after discontinuation of treatment. In some countries, blood banks are advised not to accept as donors persons who have taken isotretinoin within the previous four weeks.

Product name **Isoxicam**

C.A.S. number **34552-84-6**

Scientific and common names, and synonyms

2H-1,2-BENZOTHIAZINE-3-CARBOXIMIDE, 4-HYDROXY-2-METHYL-N-(5-METHYL-3- ISOXAZOLYL)-, 1,1-DIOXIDE
4-HYDROXY-2-METHYL-N-(5-METHYL-3-ISOXAZOLYL)-2H-1,2-BENZOTHIAZINE-3- CARBOXAMIDE 1,1-DIOXIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	Oct. 1985	The Federal Health Office has suspended approval of preparations containing isoxicam pending further evaluation of reported adverse reactions.
ITA	Oct. 1985	Following discussions with the National Health Council, the manufacturer has withdrawn all preparations containing isoxicam pending further evaluation of the reported adverse reactions.
FRA	11 Oct. 1985	The French Health Authorities have suspended marketing of products containing isoxicam following reports of rare but severe dermatological reactions.
@WD	31 Oct. 1985	Marketing of the nonsteroidal antiinflammatory drug isoxicam was suspended worldwide by the major manufacturer in October 1985 after it had been withdrawn in France on 11 October 1985 following reports of severe skin reactions, some of which were fatal.
OMN	8 Jan. 1986	Import and sale of isoxicam have been prohibited. (Reference: (OMNMH) Ministry of Health, 1,, 1986) **WHO comment:** Isoxicam, a nonsteroidal anti-inflammatory agent, was introduced in 1983 for the treatment of rheumatic disorders. By 1985 its use had been associated with serious adverse effects, including four deaths from rare skin reactions. This led to its withdrawal in France followed immediately by the voluntary suspension of marketing worldwide by the major manufacturer.

Product name **Kaolin**

C.A.S. number **1332-58-7**

Scientific and common names, and synonyms

ALBA
BOLUS

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
IND	11 Feb. 1991	The Central Government banned the manufacture and sale of combinations of fixed doses of kaolin with any other drug. (Reference: (INDC) Drugs Controller,,, Mar. 1992)
LKA	1 Jan. 1992	The Ministry of Health withdrew from sale all liquid preparations containing kaolin. Kaolin has doubtful efficacy and its use may lead to increased salt and water loss. (Reference: (LKADIB) Drug Information Bulletin, University of Peradeniya and Ministry of Health, 4(1),, 1992)
		WHO comment: Kaolin, a hydrated aluminium silicate, is an absorbent and has been used to treat diarrhoea because of its ability to bind and inactivate bacterial toxins. However, it has been shown to induce only a slight change in stool consistency and there is no evidence that it can reduce the duration or the severity of diarrhoeal disease. It does not reduce fluid and electrolyte losses. It cannot be recommended in the treatment of diarrhoea.

Product name **Kebuzone**

C.A.S. number **853-34-9**

Scientific and common names, and synonyms

4-(3-OXOBUTYL)-1,2-DIPHENYL-3,5-PYRAZOLIDINEDIONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DDR	Sep. 1984	Indications are restricted to acute inflammatory exacerbations of rheumatic disease and acute attacks of gout. (Reference: (DDRIL) Information Letter of the Ministry of Health,,, Sep. 1984)
DEU	1985	Indications are restricted to inflammatory degenerative rheumatism, chronic polyarthritis, ankylosing spondylitis, arthroses, neuritis and neuralgia such as lumbago and sciatica, acute gout, soft tissue rheumatism, painful bruising or post-traumatic inflammation and thrombophlebitis. A single course of treatment should not exceed three months. Preparations are contraindicated in children under six years of age.
OMN	Sep. 1986	The Ministry of Health has prohibited the import of preparations containing kebuzone except those intended for topical use.
AUT		Indications restricted to exacerbations of gout and other arthritic conditions. Treatment should not exceed seven days and doctors are advised not to prescribe this drug to children under 14 years of age or elderly patients. (Reference: (WIMAM) Wichtige Mitteilung ueber Arzneimittel, (1),, 1984)
		WHO comment: Kebuzone, a pyrazolone derivative with anti-inflammatory, analgesic and antipyretic activity, was introduced in 1973 for the treatment of rheumatic disorders. As it is structurally related to phenylbutazone it is subjected to rigorously restricted indications by some national regulatory authorities. See WHO comment for phenylbutazone.

Product name **Ketoconazole**

C.A.S. number **65277-42-1**

Scientific and common names, and synonyms

(+/-)-cis-1-ACETYL-4-(p-((2-(2,4-DICHLORPHENYL)-2-(IMIDAZOL-1-YLMETHYL)-1,3-DIOX-OLAN-4-YL)METHOXYLPHENYL)PIPERAZINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
OMN	4 Apr. 1988	Products containing ketoconazole were allowed to be used only under the supervision of a hospital physician. (Reference: (OMNCR) Circular, 11/88,, Apr. 1988) **WHO comment:** Ketoconazole, an imidazole antifungal agent, was introduced in 1978 for the topical and systemic treatment of a wide variety of fungal infections. Its use by mouth has been associated with hepatotoxicity, including cases of hepatitis, which have usually been reversible on discontinuation of the drug, but some fatalities have also occurred. Ketoconazole is widely marketed.

Product name **L-Tryptophan**

C.A.S. number **73-22-3**

Scientific and common names, and synonyms

L-2-AMINO-3-(INDOL-3-YL) PROPIONIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	17 Nov. 1989	The marketing authorization for over-the-counter dietary supplements containing L-tryptophan as the sole or major ingredient has been withdrawn. (Reference: (HHSNS) HHS News: US Department of Health and Human Services, P89-49,, 17 Nov. 1989)
CHE	Dec. 1989	The marketing authorization for all pharmaceuticals containing L-trytophan has been suspended. (Reference: (CHBCM) Bulletin Mensuel,,, 27 Dec. 1989)
GBR	Dec. 1989	Non-prescription dietary supplements containing L-tryptophan as the sole or major ingredient and medicinesindicated for the treatment of depression have been withdrawn. Multivitamin and multi-aminoacid supplements where tryptophan is a minor ingredient, parenteral nutrition fluids and preparations for the treatment of phenylketonuria remain on the market. (References: (GBRCSM) Committee on Safety of Medicines, Current problems, 27,, Dec. 1989; (GBRPHJ) The Pharmaceutical Journal, 244, 486, 1990)
SWE	6 Dec. 1989	Products containing L-tryptophan have been prohibited. An exemption has been granted for parenteral nutrition preparations and oral low dose combinations. (Reference: (SSLMS) Information från Socialstyrelsens Läekemedelsavdelning, 14(6), 181, 1989)
AUT	1990	The marketing authorization for all products containing L-tryptophan, including high and low-dose formulations for oral administration, combination products and solutions for infusion has been suspended. (Reference: (AUTGB) Bundesgesetzblatt für die Republik Oesterreich,,, 18 Oct. 1990)
BEL	1990	Food supplements containing L-tryptophan as the major ingredient have been withdrawn from sale. All other products containing L-tryptophan, including extemporaneous preparations, have been subjected to prescription control. (References: (BELAP) Annales Pharmaceutiques belges, 11, 64, 1990; (BELAP) Annales Pharmaceutiques belges, 2, 31, 1990)
DEU	1990	The marketing authorization for all products intended for oral use containing L-tryptophan has been suspended until 30 September 1991. An exemption has been granted for nutritional preparations intended for patients eith severely impaired digestion and absorption who are unresponsive to other therapy. (References: (DEUPZ) Pharmazeutische Zeitung, 145(40), 2629, 1990; (DEUPZ) Pharmazeutische Zeitung, 145(41), 2735, 1990; (DEUPZ) Pharmazeutische Zeitung, 145(44), 2951, 1990; (DAZ) Deutsche Apotheker Zeitung, 131(15), VI, 1991)

...(Continued)

Legislative or regulative action

Product name **L-Tryptophan** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ESP	1990	Products containing L-tryptophan intended for oral use were withdrawn, following their association with cases of eosinophilia-myalgia syndrome. Products intended for parenteral use were allowed to remain on the market. (Reference: (ESPITS) Informacion de la Terapeutica del Sistema Nacional de Salud, 14(12), 349, 1990)
NOR	1990	Products containing L-tryptophan as the therapeutic ingredient may noly be prescribed for patients alreadyunder treatment and at the special request of a psychiatrist. Preparations containing tryptophan at natural levels, such as products for parenteral nutrition, are exempted from this restriction. (Reference: (NNSLM) Nytt fra Statens Legemiddelkontroll, 3, 7, 1990)
NZL	Feb. 1990	Capsules and tablets which result in a daily intake of 100 mg or more of L-tryptophan have been recalled from retail outlets. Companies may continue to provide preparations containing L-tryptophan to patients. (Reference: (NZCSL) Clinical Services Letter, Department of Health, 257,, 15 Mar. 1990)
FRA	11 Mar. 1990	The manufacture, import, sale and distribution of all dietary supplements and extemporaneous medicinal preparations containing L-tryptophan has been suspended. This measure does not refer to other medicines or to special dietary preparations, including dietary products for nursing infants and for young children with metabolic and nutritional problems, hypoallergenic dietary products for infants and nutritive mixtures for special liquid nourishment. (References: (FMOPL) Le Moniteur des Pharmacies et des Laboratoires, 1892, 18, 1990; (JORF) Journal Officiel de la Republique Francaise,,, 13 May 1990; (JORF) Journal Officiel de la Republique Francaise,,, 11 Apr. 1991)
OMN	May 1990	Following reports of cases of eosinophilia-myalgia syndrome in the United States, import and marketing of monocomponent and multi-ingredient medicinal preparations containing L-tryptophan were prohibited. A certificate from the Ministry of Health was required for the importation of dietary supplements. (Reference: (OMNCR) Circular, 9/90,, May 1990)
JPN	14 May 1990	As a result of the epidemic of eosinophilia-myalgia syndrome reported from the USA, L-tryptophan and all drugs and food products in which it is a constituent have been withdrawn. (Reference: (JPNPH) Pharma Japan, 1204, 1, 14 May 1990)
MYS	July 1990	The marketing authorization for dietary supplements and medicines containing L-tryptophan has been withdrawn. The decision does not apply to preparations intended for parenteral nutrition or to enteral feed preparations used under medical supervision in patients with specific conditions. (Reference: (MYSDC) Malaysian Drug Control Authority,,, 26 July 1990)
		WHO comment: L-tryptophan, an essential aminoacid and precursor of serotonin, was introduced into medicine in 1963 for the treatment of depression and sleep disorders. Its effectiveness in these conditions has, however, never been convincingly demonstrated. It is also widely used in dietary supplenents, parenteral nutrition preparations and dietary products for children with phenylketonuria. In 1989, reports from the USA showed an association between the consumption of L-tryptophan containing preparations and the development of eosiniphilia-myalgia syndrome (EMS), a condition characterized by intense eosinophilia, severe muscle and joint pain, swelling of the arms and legs, skin rashes and possible fever. Some of the reported cases have been fatal. Since it is not yet clear whether L-tryptophan itself or an unidentified contaminant is the cause of the EMS, many drug regulatory authorities have suspended the marketing authorization of products containing tryptophan pending further investigation, whereas others have withdrawn these products or restricted their use.

Product name **Laetrile**

C.A.S. number **29883-15-6**

Scientific and common names, and synonyms

AMYGDALIN
(O-(6-O-beta-D-GLUCOPYRANOSYL-beta-D-GLUCOPYRANOSIDE)-D-MANDELONITRILE

...(Continued)

Legislative or regulative action

Product name **Laetrile** ...(Continued)

Scientific and common names, and synonyms
VITAMIN B17

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
AUS	20 Feb. 1986	The Australian Drug Evaluation Committee has recommended that import of preparations containing laetrile for use in cancer therapy be prohibited due to lack of efficacy, definite serious toxicity and absence of knowledge of metabolism, excretion and serum levels. Its use on an individual basis is under review. (Reference: (AUDEC) Report of the Australian Drug Evaluation Committee, 122, 13, 1986)
USA	24 Mar. 1987	Preparations containing laetrile have the same status as other unapproved drugs and as such importation is prohibited. **WHO comment:** Laetrile, which consists mainly of amydgalin, a glycoside extracted from the kernels of apricots, peaches and other fruits, has been available for over 30 years in preparations purporting to be beneficial in the treatment of cancer. Although there is no evidence that these are efficacious, preparations continued to be widely used and, until the late 1970s, they were considered to be harmless. However, oral dosage forms, which may be broken down in the gut to hydrogen cyanide, have subsequently been shown to be potentially lethal. This has resulted in restrictive regulatory measures in several countries.

Product name **Latamoxef**

C.A.S. number **64952-97-2**

Scientific and common names, and synonyms
LAMOXACTAM
MOXALACTAM
5-OXA-1-AZABICYCLO(4.2.0)OCT-2-ENE-2-CARBOXYLIC ACID,7-((CARBOXY(4-HYDROXYPHENYL)ACETYL)AMINO)-7-METHOXY-3-((1-METHYL-1H-TETRAZOL-5-YL)THIO)METHYL)-8-OXO-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1 July 1984	Following reports of spontaneous bleeding and death in patients receiving preparations containing latamoxef, indications will be restricted to serious and life threatening infections such as sepsis and meningitis. **WHO comment:** Latamoxef, a cefamycin antibiotic, was introduced in 1982 for the treatment of serious infections. Its use has subsequently been associated with reports of clinically important haemorrhage, sometimes fatal, and in some countries routine co-administration of vitamin K is advised to minimize this risk.

Product name **Lead oxide and lead salts**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
FRA	21 Feb. 1980	Lead oxide and lead salts have been withdrawn from cosmetics and topically administered medicinal products having regard to the danger of percutaneous absorption and their possible contribution to encephalopathy.
DNK	30 June 1983	As a result of recorded cases of lead poisoning caused by excessive topical application, all pharmaceutical products containing lead compounds have been withdrawn.

...(Continued)

Product name **Lead oxide and lead salts** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SAU		Prohibited for use in cosmetics and other topical uses, having regard for the danger of percutaneous absorption.
VEN		Not approved for use and/or sale in topical pharmaceutical products.
		WHO comment: Lead oxides and other lead salts were formerly available in topical preparations which had soothing astringent properties. The toxicity of lead salts by inhalation, ingestion and percutaneous absorption is now conclusively established and the medicinal use of preparations containing lead salts is no longer permitted in many countries.

Product name **Levamfetamine**

C.A.S. number **156-34-3**

Scientific and common names, and synonyms

(-)-alpha-METHYLBENZENEETHANAMINE
(-)-alpha-METHYLPHENETHYLAMINE
LEVAMPHETAMINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	1973	Anorectic drugs containing levamfetamine were withdrawn from the market by the Food and Drug Administration due to evidence of abuse and high risk of dependence.
OMN	May 1991	Import and marketing of products containing levamfetamine were prohibited. (Reference: (OMNCR) Circular, 16/91,, May 1991)
ARE		Pharmaceutical preparations containing levamfetamine are banned.
		WHO comment: Levamfetamine, an amfetamine derivative, is controlled under Schedule II of the 1971 Convention on Psychotropic Substances. See WHO comment for amfetamine. (Reference: (UNCPS2) United Nations Convention on Psychotropic Substances (II),,, 1971)

Product name **Levarterenol**

C.A.S. number **51-41-2**

Scientific and common names, and synonyms

NORADRENALINE
NOREPINEPHRINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
IRL	1973	The National Drugs Advisory Board has withdrawn from the market all local anesthetic preparations intended for infiltration anesthesia containing epinephrine 1:50,000 and norepinephrine 1:50,000 alone or in combination. This decision, reached in agreement with the Irish Dental Association, followed reports of serious cardiovascular and cerebrovascular reactions.
SAU		Following published reports of serious cardiovascular and cerebrovascular adverse reactions, preparations for infiltration anaesthesia which contain epinephrine and levarterenol, alone or in combination, are now under review.
VEN		Not approved for use and/or sale for infiltration anesthesia, alone or in combination.

...(Continued)

Legislative or regulative action

Product name **Levarterenol** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Vasoconstrictor agents have been in use for many years to prolong duration of action of local anaesthetics, particularly in dentistry. Combination products containing epinephrine or levarterenol in concentrations of 1:80,000 or less remain widely available. See also WHO comment for epinephrine.

Product name **Lindane**

C.A.S. number **58-89-9**

Scientific and common names, and synonyms

BENZENE HEXACHLORIDE, gamma
CYCLOHEXANE, 1,2,3,4,5,6-HEXACHLORO-,(1alpha,2alpha,3beta,4alpha,5alpha,6beta)-
gamma-1,2,3,4,5,6-HEXACHLOROCYCLOHEXANE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NLD	17 Jan. 1984	Products containing lindane are no longer accepted for the treatment of head-lice infestation because of widespread development of resistant strains. They remain available for the treatment of scabies and body or pubic lice.
DEU	18 July 1986	Use is limited to 0.3% with the exception of shampoo, which may contain up to 1% since exposure time is limited to 4 minutes.
EGY	1987	The Technical Committee for Drug Control has restricted the use of lindane to topical treatment of lice and scabies. Products should not contain concentrations greater than 0.3%. (Reference: (EGYDI) Drug Information, 5(2),, 1987)
OMN	May 1991	Import and marketing of external preparations containing lindane in concentrations greater then 0.3% were prohibited. Use of more concentrated preparations is considered to be less safe and no more effective. (Reference: (OMNCR) Circular, 9,, Mar. 1991)
		WHO comment: Lindane has been available for more than 25 years and is widely used as an agricultural and household pesticide.

Product name **Lobelia**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BGD	1982	Under the provisions of the Drugs (Control) Ordinance, this drug has been prohibited for use. All prescription chemicals and galenical preparations not included in the latest edition of the British Pharmacopeia or British Pharmaceutical Codex have been prohibited for use. (Reference: (BGDCO) The Drugs (Control) Ordinance,,, 1982)
ITA		Withdrawn from the market owing to an unfavourable risk-benefit ratio and the lack of substantial evidence of efficacy.
		WHO comment: Lobelia comprises the dried aerial parts of lobelia species, the activity of which is due chiefly to the alkaloid lobeline. Although preparations containing lobelia were formerly available for use in the symptomatic treatent of asthma, they are now largely obsolescent as a result of their irritant properties and the availability of more effective preparations.

Product name **Loperamide**

C.A.S. number **53179-11-6**

Scientific and common names, and synonyms

1-PIPERIDINEBUTANAMIDE, 4-(4-CHLOROPHENYL)-4-HYDROXY-N,N-DIMETHYL-alpha, alpha-DIPHENYL
4-(P-CHLOROPHENYL)-4-HYDROXY-N,N-DIMETHYL-alpha,alpha-DIPHENYL-1- PIPERIDINEBUTYRAMIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
PHL	Nov. 1982	Restricted for use as an antidiarrhoeal drug. Contraindicated in children below two years of age due to the risk of central nervous system damage.
@WD	1990	Drop formulations containing loperamide have been voluntarily withdrawn by the major manufacturer. (Reference: (LJJ) Letter to WHO from Johnson & Johnson,,, 21 June 1990)
LIY	May 1990	Use of products containing loperamide in children was banned. (Reference: (LIYRL) Resolution of the General People's Health Committee, 141,, May 1990)
PAK	June 1990	Drop and syrup formulations of products containing loperamide were banned.
OMN	July 1990	Drop and syrup formulations of products intended for paediatric use containing loperamide were voluntarily withdrawn by the manufacturer. (Reference: (OMNCR) Circular, 13/90,, July 1990)
PER	Oct. 1990	Registration of drop formulations of loperamide intended for paediatric use was withdrawn. Syrup formulations of loperamide were required to carry a warning stating that they should not be administered to children under 5 years of age. (Reference: (PERMH) Ministry of Health,,, 27 Oct. 1990)
IDN	Nov. 1990	Syrup and liquid formulations of products containing loperamide intended for the treatment of diarrhoea in children were banned. (Reference: (IDMH) Ministry of Health,,, 19 Nov. 1990)
MEX	Dec. 1990	Registration of products containing loperamide intended for paediatric use was withdrawn. (Reference: (MEXMH) Communication from the Ministry of Health,,, 28 Nov. 1990)
FRA	18 Dec. 1990	The approved information for paediatric formulations of the antidiarrhoeal substance loperamide was amended to indicate that these products should not be administered, on grounds of safety, to children less than two years of age. (Reference: (FRARP) La Revue Prescrire, 11(108), 293, 1991)
NPL	1991	Liquid formulations of products containing loperamide either alone or in combination, and intended for the treatment of diarrhoea in children, were banned. (Reference: (NPLDDA) Communication from the Department of Drug Administration,,, 27 Feb. 1992)
PHL	1991	Registration of products containing loperamide intended for paediatric use was withdrawn.
KOR	May 1991	Solid oral dosage forms of products containing loperamide were disallowed for use in children under 7 years of age and syrup formulations were prohibited in infants under 24 months due to the severe toxic effects on the central nervous system. (Reference: (KRMHSA) Ministry of Health and Social Affairs - Communication to WHO,,, 13 Dec. 1991)
LBN	3 Aug. 1991	Use of products containing loperamide in children under 5 years of age was discontinued and registration of paediatric preparations was withdrawn. (Reference: (LBNMHD) Ministry of Health and Social Affairs Decree, 150/1,, Aug. 1991)
TUR	Sep. 1991	Drop and syrup formulations of products containing loperamide were banned. (Reference: (TURMH) Communication from the Ministry of Health,,, 6 Nov. 1991)
LKA	Nov. 1991	Manufacture, import or sale of drop and syrup formulations of loperamide were prohibited. (Reference: (LKAGAZ) The Gazette of the Democratic Socialist Republic of Sri Lanka (Extraordinary), 688/29, Part I-1, 15 Nov. 1991)

...(Continued)

Product name **Loperamide** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Loperamide, an inhibitor of intestinal peristalsis, was introduced in 1975 for the treatment of acute and chronic diarrhoea. In many countries its use was discouraged in young children. In late 1989, treatment of infants in Pakistan was associated with 19 cases of paralytic ileus, 6 of which have been fatal. This has subsequently led the major manufacturer to withdraw all drop formulations of the drug worldwide as well as the lower dose syrup forms from countries where there is a programme for the control of diarrhoeal diseases. The WHO Control of Diarrhoeal Diseases Programme recommends that loperamide should not be used in children below five year of age. (Reference: (LJJ) Letter to WHO from Johnson & Johnson,,, 21 June 1990)

Product name **Lynestrenol**

C.A.S. number **52-76-6**

Scientific and common names, and synonyms

LYNENOL
LYNOESTRENOL
19 NORPREGN-4-EN-20-YN-17-OL, (17alpha)-
19-NOR-17-alpha-PREGN-4-EN-20-YN-17-OL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
AUS	1980	High dosage (2.5mg) lynestrenol products were withdrawn following demonstration of a dose-related incidence of mammary tumours in the beagle bitch. It is acknowledged, however, that this species may not offer a reliable model for predicting possible carcinogenicity of progestogens in humans. (Reference: (AUDEC) Report of the Australian Drug Evaluation Committee, No.90)
SAU		Products now controlled by the authorities. **WHO comment:** Lynestrenol, a synthetic progestogen, was introduced in the early 1960s as a component in oral contraceptive preparations. In 1967, as a result of new regulations required by the United States Food and Drug Administration, lynestrenol was submitted to long-term toxicity studies and by the early 1970s it was shown to be associated with an increased incidence of mammary tumours in beagle bitches which led to its withdrawal by at least one regulatory authority. Subsequently the validity of the beagle bitch model as a predictor of carcinogenicity of steroid contraceptives has been contested by many national regulatory authorities and lynestrenol remains available in some countries for contraceptive and other purposes. (Reference: (WHODI) WHO Drug Information, 1-3, 5-7, 1984)

Product name **Mazindol**

C.A.S. number **22232-71-9**

Scientific and common names, and synonyms

5-(p-CHLOROPHENYL)-2,5-DIHYDRO-3H-IMIDAZOL(2,1-a)ISOINDOL-5-OL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
OMN	11 Jan. 1987	Import and marketing of products containing mazindol were prohibited. (Reference: (OMNCR) Circular, 2/87,, Jan. 1987)

...(Continued)

Legislative or regulative action

Product name **Mazindol** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Mazindol, an anorectic agent, was introduced into medicine in 1970 as an aid to weight reduction. It is controlled under Schedule IV of the 1971 Convention on Psychotropic Substances. It remains available in many countries with highly evolved drug regulatory authorities. (Reference: (UNCPS4) United Nations Convention on Psychotropic Substances (IV),,, 1971)

Product name **Meclozine**

C.A.S. number **569-65-3**

Scientific and common names, and synonyms

MECLIZINE
PIPERAZINE, 1-((4-CHLOROPHENYL)PHENYLMETHYL)-4-((3-METHYLPHENYL)METHYL)-
1-(P-CHLORO-alpha-PHENYLBENZYL)-4-(M-METHYLBENZYL)PIPERAZINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
IDN	1 Jan. 1963	The Ministry of Health has prohibited the importation, production, sale and distribution of this drug. (Reference: (IDMHD) Ministerial Decree, 682-PH-63B,, June 1963) **WHO comment:** Meclozine, an antihistamine with antiemetic activity, was introduced in 1953 for the treatment of nausea. The action taken in Indonesia in 1963 resulted from concern regarding its possible teratogenic potential. Subsequent epidemiological studies have been widely accepted, however, as dispelling this suspicion. Meclozine remains widely available in both prescription only and over-the-counter preparations and in some countries the licensed indications include management of nausea of pregnancy.

Product name **Megestrol acetate**

C.A.S. number **3562-63-8**

Scientific and common names, and synonyms

PREGNA-4,6-DIENE-3,20-DIONE, 17-(ACETYLOXY)-6-METHYL
17-HYDROXY-6-METHYLPREGNA-4,6-DIENE-3,20-DIONE ACETATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GRC	1976	Preparations for oral use have been withdrawn from the market.
NOR	1 Jan. 1976	Oral contraceptives containing this substance have been withdrawn from the market and use is now restricted to anti-cancer treatment.
DEU	1977	Following the discovery of increased incidence of breast tumours in beagle bitches during long-term toxicity studies, contraceptive preparations containing megestrol acetate were voluntarily withdrawn by the manufactuer. The drug remains available for treatment of endometrial carcinoma.
GBR	1982	This substance is licensed only for the treatment of certain hormone-dependent neoplasms but not for use in contraceptive preparations. This restriction was applied because of reports of dose dependent mammary tumours in beagles. Such lesions have not been reported in rats and monkeys.
NZL		Voluntarily withdrawn from the market.

...(Continued)

Legislative or regulative action

Product name **Megestrol acetate** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Megestrol acetate, a synthetic progestogen, was introduced in the early 1960s as a component in oral contraceptive preparations. In 1967, as a result of new regulations required by the United States Food and Drug Administration, megestrol acetate was submitted to long-term toxicity studies and by the early 1970s it was shown to be associated with an increased incidence of mammary tumours in beagle bitches which led to its withdrawal by several regulatory authorities. Subsequently the validity of the beagle bitch model as a predictor of carcinogenicity of steroid contraceptives has been contested by many national regulatory authorities and megestrol remains available in some countries for contraceptive purposes. In other countries its use is restricted to anticancer treatment. (Reference: (WHODI) WHO Drug Information, 1-3, 5-7, 1984)

Product name **Mephenesin**

C.A.S. number **59-47-2**

Scientific and common names, and synonyms

3-(o-METHYLPHENOXY)-1,2-PROPANEDIOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
JPN	July 1976	This compound, promoted as a muscle relaxant, has been withdrawn because of lack of substantial evidence of efficacy and safety.
SAU		Registration of this drug has been postponed, and its distribution is prohibited.
		WHO comment: Mephenesin, a centrally acting muscle relaxant and sedative, was introduced in 1948 and its use has subsequently been associated with some of the undesirable features of barbiturate use. It is of limited efficacy since it is short-acting and does not relieve the spasticity associated with chronic neurological disorders. It has therefore been largely superseded by benzodiazepines but it remains available in some countries.

Product name **Meprobamate**

C.A.S. number **57-53-4**

Scientific and common names, and synonyms

1,3-PROPANEDIOL, 2-METHYL-2-PROPYL-, DICARBAMATE
2-METHYL-2-PROPYL-1,3-PROPANEDIOL DICARBAMATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	Jan. 1981	Meprobamate-containing appetite suppressants have been withdrawn from the market. There is a lack of evidence of their value in long-term management of obesity, they have the potential for abuse and despite warnings they are frequently used over unacceptably prolonged periods.
		WHO comment: Meprobamate, a bis-carbamate ester, was introduced in 1955 for the treatment of anxiety and was subsequently used as a sedative-hypnotic drug. Psychological and physical dependence can occur and abuse has been reported. Meprobamate is controlled under Schedule IV of the 1971 Convention on Psychotropic Substances. (Reference: (UNCPS4) United Nations Convention on Psychotropic Substances (IV),,, 1971)

Product name **Mercuric derivatives (topical)**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
JPN	July 1969	Aminomercuric chloride was banned by the Pharmaceutical Affairs Bureau due to skin disorders associated with long-term use.
BRA	15 July 1980	Products containing mercuric derivatives, with the exception of merbromin and thiomersal, are prohibited. (Reference: (BRAPT) Portaria do Servico Publico Federal, No.10,, July 1980)
PHL	Nov. 1983	Mercury-based products for topical use are being phased out due to dubious efficacy and safety.
FRA	19 Dec. 1986	The Ministry of Health has decided to withdraw dermatological preparations containing ammoniated mercury following a warning that such products may produce allergic reactions and mercury intoxication. (Reference: (FRAPC) Press Communiqué,,, Dec. 1986)
NGA	1988	All soaps containing mercury compounds have been banned. (Reference: (NGAPN) Pharmanews, 10(11), 15, 1988)
GHA	1 Sep. 1989	All mercury based soaps have been banned. (Reference: (GHAPDR) Pharmacy and Drugs (Banned Drugs) Regulations, Legislative Instruments, 1484,, 1989)
ITA		Withdrawn from the market owing to an unfavourable risk-benefit ratio and the lack of substantial evidence of efficacy. **WHO comment:** Mercuric derivatives were formerly widely available in topical anti-infective preparations. The hazards associated with their use, including hypersensitivity and allergy, outweigh any therapeutic benefit and such preparations have been withdrawn in many countries. Systemic absorption has resulted in chronic mercury poisoning and acrodynia (pink disease) in children.

Product name **Mesna**

C.A.S. number **19767-45-4**

Scientific and common names, and synonyms

ETHANESULFONIC ACID, 2-MERCAPTO-, MONOSODIUM SALT
SODIUM 2-MERCAPTOETHANESULFONATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	Apr. 1991	Oral liquid dosage forms of preparations containing mesna were voluntarily withdrawn by the manufacturer because their use had been associated with hypersensitivity reactions of different degrees, including slight skin eruptions up to more serious anaphylactic reactions, in patients with autoimmune conditions. (Reference: (DAZ) Deutsche Apotheker Zeitung, 131(17), VI, 1991) **WHO comment:** Mesna, an antidote used to protect patients treated with cyclophosphamide or ifosfamide from haemorrhagic vesiculitis, was introduced on the market in 1984. Shortly afterwards, its use became associated with allergic reactions, which occurred mainly in patients treated with the oral solution. This led to the withdrawal of this formulation in Germany, the only country where it was marketed. An oral liquid dosage form is still registered, but not marketed, in the Netherlands and products for intravenous injection remain available elsewhere.

Product name **Metamfetamine**

C.A.S. number **537-46-2**

Scientific and common names, and synonyms

METAMPHETAMINE
METHYLAMPHETAMINE
(+)-2-METHYLAMINO-1-PHENYLPROPANE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
TUR	6 Sep. 1982	Banned for production, import, export, sale and use.
OMN	10 May 1982	Import and marketing of products containing metamfetamine and its racemic form were prohibited. (Reference: (OMNCR) Circular, 11/82,, May 1982)
NGA	1988	All products containing metamfetamine have been banned. (Reference: (NGAPN) Pharmanews, 10(11), 15, 1988)
		WHO comment: Metamfetamine, an amfetamine derivative, is controlled under Schedule II of the 1971 Convention on Psychotropic Substances. See WHO comment for amfetamine. (Reference: (UNCPS2) United Nations Convention on Psychotropic Substances (II),,, 1971)

Product name **Metamizole sodium**

C.A.S. number **68-89-3**

Scientific and common names, and synonyms

ANALGIN
DIPYRON
DIPYRONE
METHAMPYRONE
METHANESULFONIC ACID
METHANESULFONIC ACID, ((2,3-DIHYDRO-1,5-DIMETHYL-3-OXO-2-PHENYL-1H-PYRAZOL-4-YL)METHYLAMINO)-,SODIUM SALT
NORAMIDOPYRINE METHANESULFONATE SODIUM
SULPYRIN
SULPYRINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
AUS	1965	The Department of Health has prohibited the importation of noramidopyrine methanesulfonate sodium (metamizole sodium). (Reference: (AUDEC) Report of the Australian Drug Evaluation Committee, No.9)
NOR	July 1976	Withdrawn from the market.
PHL	1977	Used only as a last resort in serious and life-threatening situations when other less toxic antipyretic drugs and other measures have failed and are not tolerated, and only with proper supervision and monitoring. The package inserts are required to carry extensive warning information, especially regarding the risk of fatal agranulocytosis with the usage of this drug. The drug is available only on prescription. (Reference: (PHADO) Administrative Order, 330,, 1977)
USA	27 June 1977	An analgesic, antipyretic drug, found to be effective at reducing fever but withdrawn from the market and prohibited for export by the Food and Drug Administration on the basis of reports of agranulocytosis, a sometimes fatal blood condition, associated with its use. The Director of the Bureau of Drugs found that agranulocytosis cannot be effectively prevented by frequent examination of treated patients since this condition can occur within a few hours following administration of the drug to a sensitive individual. In its decision, the FDA cited the availability of effective orally administered drug products (e.g. acetylsalicylic acid or paracetamol) and concluded that the risks associated with this drug far outweigh any benefit derived from its use, including use in Hodgkin's disease and similar malignant diseases. (Reference: (FEREAC) Federal Register, 42(117), 30893, 1977)

...(Continued)

Legislative or regulative action

Product name **Metamizole sodium** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
KWT	Dec. 1978	All dosage forms are no longer allowed with the exception of injectable preparations which may be used only in an emergency. (Reference: (KTMD) Ministerial Decree, 556/78,, 1978)
ITA	1979	Injectable preparations with dosages higher than 1 gram and intravenous preparations in combination with other compounds have been withdrawn. The label for currently marketed preparations now carries a warning regarding fatal accidents due to hypersensitivity.
DNK	Apr. 1979	Preparations containing metamizole were banned for systemic use due to the potential risk of fatal agranulocytosis. (Reference: (UGLAAD) Ugeskrift for Laeger, 873,, Mar. 1979)
SAU	1980	All preparations containing metamizole were prohibited due to several reports of anaphylactic shock.
ARE	9 June 1981	Pharmaceutical preparations containing metamizole sodium are banned. (Reference: (UAEMD) Ministry of Health Decree, No.694,, 1981)
SDN	1982	The Ministry of Health no longer allows registration of metamizole sodium with the exception of parenteral preparations for limited use.
BGD	June 1982	Banned in oral drops and tablet form due to high incidence of adverse effects and availability of safer alternatives. A single ingredient injection remains available for terminal care as a restricted drug for specialized use.
EGY	July 1983	Following reports of anaphylactic shock, no registration licence is to be granted for injectable preparations containing more than 1 gram of this compound.
ISR	1 Dec. 1985	Fixed dose combinations of metamizole sodium are not approved for registration. Parenteral preparations of metamizole sodium (single-dose product) may be administered only in hospitals and clinics where there are suitable facilities for resuscitation (in cases of anaphylactic shock). Enteral preparations of metamizole sodium (single-dose product) may be dispensed without prescription.
BEL	1987	Preparations containing metamizole sodium have been placed in List IV of the 'Arrêté du Régent' of 2 June 1946 and as such can be administered only on prescription. They must be kept in a poisons cabinet and carry the skull and crossbones label. Metamizole in combination with a spasmolytic may be dispensed a maximum of five times against a renewable prescription for a period of six months. (Reference: (BELAR) Arrêté Royal,,, June 1987)
MYS	Jan. 1987	All products containing metamizole sodium have been withdrawn. (Reference: (MYSDC) Malaysian Drug Control Authority, No.6,, Oct. 1986)
DEU	27 Apr. 1987	Subsequent to the regulatory action taken in January 1983 (see Pyrazolones) the Federal Health Office has further restricted the use of preparations containing metamizole sodium. As from 1 January 1987 all preparations have been subjected to prescription control and combination products have been withdrawn. (Reference: (FRGGH) Bundesgesundheitsamt Pressedienst, 18,, Apr. 1987)
PAK	1988	All combination products containing metamizole sodium were withdrawn. (Reference: (PAKMH) Ministry of Health, Special Education and Social Welfare,,, 3 Aug. 1988)
ESP	1989	The indications of products containing metamizole sodium have been restricted to acute post-traumatic or post-surgical pain, abdominal colic and high fever unresponsive to other antipyretics. All fixed combination products containing metamizole have been withdrawn, except those in which it is associated with a spasmolytic. (Reference: (ESPINS) Información Terapéutica de la Seguridad Social, 13(1), 6, 1989)
GHA	1 Sep. 1989	Products containing metamizole sodium of its salts have been banned. (Reference: (GHAPDR) Pharmacy and Drugs (Banned Drugs) Regulations, Legislative Instruments, 1484,, 1989)
NLD	1990	Having regard to reports of agranulocytosis, the manufacturers have agreed to the voluntary withdrawal of metamizole sodium from combination preparations. (Reference: (NPHWB) Pharmaceutisch Weekblad, 125(3), 82, 1990)

...(Continued)

Product name **Metamizole sodium** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
CHE	1 Jan. 1992	Products containing metamizole sodium were subjected to prescription control. (Reference: (CHBCM) Bulletin Mensuel, 10, 686, 1991)
LKA	1 Jan. 1992	The Ministry of Health withdrew from sale pharmaceutical products containing metamizole sodium (injectable formulation). This action was based on the potential of these products to induce suppression of the bone marrow. (Reference: (LKADIB) Drug Information Bulletin, University of Peradeniya and Ministry of Health, 4(1),, 1992)
BHR		Preparations containing metamizole sodium have been withdrawn.
GRC		Preparations containing metamizole have been withdrawn from the market, with the exception of injectable preparations containing up to 1 gram, because of concern about agranulocytosis associated with the drug's use.
IRL		Products containing metamizole have been withdrawn.
MEX		Due to toxicity, not accepted for use in pediatric preparations (elixir, solution, suspension, suppositories). Alternatives must be sought.
PER		The package and/or label for this product advises that the drug is intended for prescription use only and may cause agranulocytosis.
SGP		Metamizole sodium and related salts have been banned for importation.
SWE		Preparations containing metamizole sodium were withdrawn from the market by the manufacturers after mutual discussions due to adverse reactions such as agranulocytosis.
VEN		Not approved for use and/or sale.
		WHO comment: Metamizole sodium, a pyrazolone derivative with analgesic, antipyretic and anti-inflammatory activity, was introduced in 1921 and has since been widely available in over-the-counter preparations. By the early 1970s its use had been associated, as with some other pyrazolones, with serious and sometimes fatal adverse reactions, notably cases of blood dyscrasias including agranulocytosis, which led to its withdrawal by some regulatory authorities. The incidence of these reactions has been disputed. The results of a large international collaborative study, published in 1986, confirmed the existence of a causal relationship with agranulocytosis but not with aplastic anaemia. The apparent incidence of cases of agranulocytosis varied from country to country, and although metamizole emerged as a demonstrable cause of drug-induced dyscrasias, the original estimate of incidence was shown to be too high. Although preparations of metamizole sodium are prohibited in certain countries they remain widely available in others and, in some cases, in over-the-counter preparations.

Product name **Methanol**

C.A.S. number **67-56-1**

Scientific and common names, and synonyms

METHYL ALCOHOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
THA		Products containing this ingredient may not be registered.
		WHO comment: Methanol has been subjected to abuse by consumption as a substitute for ethanol. Its toxic metabolites cause irreversible blindness and severe metabolic acidosis, and are ultimately fatal. Methanol continues to be used as an industrial solvent.

Product name **Methapyrilene**

C.A.S. number **91-80-5**

Scientific and common names, and synonyms

1,2-ETHANEDIAMINE, N,N-DIMETHYL-N'-2-PYRIDINYL-N'-(2-THIENYLMETHYL)
2((2-(DIMETHYLAMINO)ETHYL)-2-THENYLAMINO)PYRIDINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1979	Withdrawn following experimental evidence of carcinogenicity in rodents.
DOM	1979	Withdrawn following experimental evidence of carcinogenicity in rodents.
GBR	1979	Withdrawn following experimental evidence of carcinogenicity in rodents.
ITA	1979	Withdrawn from the market owing to suspected carcinogenicity.
CAN	28 June 1979	Approval for registration of products containing methapyrilene, or any of its salts was withdrawn. Action was based on data received by the Health Protection Branch identifying methapyrilene as a potent carcinogen in rats. (Reference: (CANGZ) Canada Gazette, 113/II(13), 2530, 1979)
SGP	Oct. 1979	Medicinal products containing methapyrilene and/or its salts have been banned for importation.
HKG	17 Dec. 1979	The Pharmacy and Poisons Committee no longer allows the registration, sale or distribution of products containing methapyrilene.
AUS	1980	All preparations withdrawn following demonstration of carcinogenic potential in rats.
EGY	1980	Products containing methapyrilene were withdrawn having regard to its carcinogenic potential.
PAN	9 May 1980	The Ministry of Health has banned the sale of pharmaceuticals and cosmetics containing methapyrilene. (Reference: (PANMR) Ministry of Health Resolution, 882,, May 1980)
BRA	30 June 1980	Products containing methapyrilene are prohibited. (Reference: (BRAPT) Portaria do Servico Publico Federal, No.08,, 1980)
PHL	Sep. 1980	This compound has been banned in antihistamines. It has been found to be carcinogenic in animals.
ARE	9 June 1981	Pharmaceutical preparations containing methapyrilene hydrochloride are banned. (Reference: (UAEMD) Ministry of Health Decree, No.694,, 1981)
IND	1983	Prohibited for manufacture and sale for reasons of health risks associated with use and/or questionable therapeutic value. (Reference: (GAZIE) The Gazette of India: Extraordinary, II-3i,, 23 July 1986)
OMN	27 July 1992	Marketing of products containing methapyrilene was prohibited. (Reference: (OMNCR) Circular, 28/92,, July 1992)
CHL		Withdrawn following experimental evidence of carcinogenicity in rodents.
NZL		Voluntarily withdrawn from the market.
USA		This antihistamine was withdrawn in the United States of America, and subsequently in several other countries, following experimental evidence of carcinogenicity in rodents.
VEN		Withdrawn from market.
		WHO comment: Methapyrilene, an antihistamine with moderate sedative activity, was introduced in 1947 for the treatment of various allergic conditions and was subsequently incorporated in many over-the-counter sleeping aids. In the early 1970s it was identified as a carcinogen in rats and, although there was no direct evidence that it constitutes a health hazard to man, it was withdrawn in many countries. (Reference: (WHODI) WHO Drug Information, 2, 4, 1979)

Product name **Methaqualone**

C.A.S. number **72-44-6**

Scientific and common names, and synonyms

2-METHYL-3-o-TOLYL-4(3H)-QUINAZOLINONE
4(3H)-QUINAZOLINONE, 2-METHYL-3-(2-METHYLPHENYL)-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GRC	1979	Withdrawn from the market.
TUR	6 Sep. 1982	Banned for production, import, export, sale and use.
OMN	10 May 1982	Import and marketing of products containing methaqualone were prohibited. (Reference: (OMNCR) Circular, 11/82,, May 1982)
ZWE	Nov. 1984	Prohibited for use. (Reference: (ZWESI) Statutory Instrument, 366,, Nov. 1984)
PAK	1988	Products containing methaqualone were withdrawn. (Reference: (PAKMH) Ministry of Health, Special Education and Social Welfare,,, 3 Aug. 1988)
GHA	1 Sep. 1989	Products containing methaqualone or its salts have been banned. (Reference: (GHAPDR) Pharmacy and Drugs (Banned Drugs) Regulations, Legislative Instruments, 1484,, 1989)
ARE		Pharmaceutical preparations containing methaqualone are banned.
		WHO comment: Methaqualone, a quinazolone derivative, was introduced in 1965 for use as a sedative-hypnotic drug. It is widely abused and is associated with severe withdrawal symptoms. Methaqualone is controlled under Schedule IV of the 1971 Convention of Psychotropic Substances. (Reference: (UNCPS4) United Nations Convention on Psychotropic Substances (IV),,, 1971)

Product name **Methiodal sodium**

C.A.S. number **126-31-8**

Scientific and common names, and synonyms

METHANESULFONIC ACID, IODO-, SODIUM SALT
SODIUM IODOMETHANESULFONATE
SODIUM IODOMETHANE SULPHONATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	1 Jan. 1975	Methiodal sodium was reported to have induced muscle spasms in some patients subjected to myelography, presumably because of an irritant action on motor nerve roots. Registration was withdrawn when a safer X-ray contrast medium was introduced on the market.
		WHO comment: Methiodal sodium, a radio-opaque medium, was formerly used for the examination of the urinary tract. Its use was associated with muscle spasms presumed to result from irritation of motor nerve roots in the spinal canal. This led to its withdrawal in Sweden in 1975 when a safer alternative became available. Preparations containing methiodal sodium were subsequently withdrawn worldwide by the manufacturer.

Product name **Methylphenidate**

C.A.S. number **113-45-1**

Scientific and common names, and synonyms

METHYL alpha-PHENYL-2-PIPERIDINEACETATE
2-PHENYL-2-(2-PIPERIDYL)ACETIC ACID, METHYL ESTER
2-PIPERIDINEACETIC ACID, alpha-PHENYL-, METHYL ESTER, (R*,R*)-(+/-)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
TUR	6 Sep. 1982	Banned for production, import, export, sale and use.
OMN	10 May 1982	Import and marketing of products containing methylphenidate were prohibited. (Reference: (OMNCR) Circular, 11/82,, May 1982)
NGA	1988	All products containing methylphenidate have been banned. (Reference: (NGAPN) Pharmanews, 10(11), 15, 1988)
		WHO comment: Methylphenidate, a piperidine derivative with mild central stimulant activity, was introduced in 1956. Its pharmacological properties resemble those of amfetamines and it shares their abuse potential. Methylphenidate retains a place as an adjunct in the treatment of hyperkinetic syndromes in both children and adults. It is controlled under Schedule II of the 1971 Convention on Psychotropic Substances. (Reference: (UNCPS2) United Nations Convention on Psychotropic Substances (II),,, 1971)

Product name **Methyprylon**

C.A.S. number **125-64-4**

Scientific and common names, and synonyms

PIPERIDINEDIONE
2,4-PIPERIDINEDIONE, 3,3-DIETHYL-5-METHYL-
3,3-DIETHYL-5-METHYL-2,4-PIPERIDINEDIONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ZWE	Nov. 1984	Prohibited for use. (Reference: (ZWESI) Statutory Instrument, 366,, Nov. 1984)
		WHO comment: Methyprylon, a piperidine derivative, was introduced in 1955 for use as a sedative-hypnotic drug. Habituation, tolerance, physical dependence and addiction can occur and methyprylon is controlled under Schedule IV of the 1971 Convention on Psychotropic Substances. (Reference: (UNCPS4) United Nations Convention on Psychotropic Substances (IV),,, 1971)

Product name **Metofoline**

C.A.S. number **2154-02-1**

Scientific and common names, and synonyms

ISOQUINOLINE,1-(2-(4-CHLOROPHENYL)ETHYL)-1,2,3,4-TETRAHYDRO-6,7-DIMETHOXY-2-METHYL-
METHOPHOLINE
1-(p-CHLOROPHENETHYL)-1,2,3,4-TETRAHYDRO-6,7-DIMETHOXY-2- METHYLISOQUINOLINE

...(Continued)

Legislative or regulative action

Product name **Metofoline** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	Mar. 1965	Withdrawn from the market and prohibited for export by the Food and Drug Administration on the basis of findings of eye changes and corneal opacities in chronic-toxicity studies in dogs. **WHO comment:** Metofoline, an analgesic, was introduced in the early 1960s for the treatment of mild to moderate acute and chronic pain. It was never available outside the USA.

Product name **Mianserin**

C.A.S. number **24219-97-4**

Scientific and common names, and synonyms

DIBENZO(C,F)-PYRAZINO(1,2-a)AZEPINE, 1,2,3,4,10,14B-HEXAHYDRO-2- METHYL
1,2,3,4,10,14B-HEXAHYDRO-2-METHYLDIBENZO(C,F)-PYRAZINO(1,2-a)AZEPINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
OMN	27 Nov. 1986	Having regard to reported adverse effects, the Central Drug Committee has prohibited import and marketing of pharmaceutical products containing mianserin. **WHO comment:** Mianserin, a serotonin antagonist with antidepressant and antihistaminic activity, was introduced in 1975 for the treatment of depressive illness. Its use has since been associated with cases of severe blood dyscrasias, particularly in elderly patients, including agranulocytosis, leucopenia and granulocytopenia. Several drug regulatory authorities have reacted by stipulating that blood counts should be monitored regularly during the first few months of treatment and that administration should be discontinued immediately should any signs possibly indicative of dyscrasia develop.

Product name **Mifepristone**

C.A.S. number **84371-65-3**

Scientific and common names, and synonyms

11beta-(p-(DIMETHYLAMINO)PHENYL)-17beta-HYDROXY-17-(1-PROPYNYL)ESTRA-4,9-DIEN-3-ONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
FRA	Apr. 1991	Following reports of cardiovascular adverse effects, the approved product information for mifepristone was amended to contraindicate its use, in conjunction with a prostaglandin, as an abortifacient in women who have smoked regularly for more than 2 years and in all women over 35 years of age. (Reference: (FRAMSS) Ministry of Social Affairs and Solidarity,,, 19 Apr. 1991) **WHO comment:** Mifepristone, an antiprogesterone used in combination with a prostaglandin for the termination of early pregnancy, was introduced in 1990. Use of the combination has been associated with episodes of coronary spasm that are attributed to administration of the prostaglandin and which have resulted in several cases of cardiac infarction and ventricular fibrillation. At least one of these incidents has been fatal.

Product name Minocycline

C.A.S. number 10118-90-8

Scientific and common names, and synonyms

2-NAPHTACENECABOXAMIDE,4,7-bis(DIMETHYLAMINO)-1,-4,4a,5,5a,6,11,12a-OCTAHYDRO-3,10,12,12a-TETRAHYDROXY-1,-11-DIOXO,(4S-(4alpha,4aalpha,5aalpha,12aalpha)-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NOR	1989	Products containing minocycline have been refused for registration, on the grounds that the associated adverse reactions tend to be more severe than those resulting from other tetracycline antibiotics. (Reference: (NNSLM) Nytt fra Statens Legemiddelkontroll, 1, 13, 1989) **WHO comment:** Minocycline, a semi-synthetic tetracycline derivative was introduced in 1967. It is used today in the treatment of bacterial, rickettsial and amoebic infections. Symptoms described as dizziness or vertigo have been recognized in association with minocycline administration, however, these symptoms are usually not severe. Minocycline is registered in many countries and the World Health Organization is not aware that registration has been refused elsewhere.

Product name Mofebutazone

C.A.S. number 2210-63-1

Scientific and common names, and synonyms

4-BUTYL-1-PHENYL-3,5-PYRAZOLIDINEDIONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1985	Indications are restricted to symptomatic treatment of acute exacerbations of arthroses including chronic articular rheumatism, periarthritis, tendinitis, ankylosing spondylitis and superficial thrombophlebitis.
OMN	Sep. 1986	The Ministry of Health has prohibited the import of preparations containing mofebutazone except those intended for topical use.
AUT		Indications restricted to exacerbations of gout and other arthritic conditions. Treatment should not exceed seven days and doctors are advised not to prescribe this drug to children under 14 years of age or elderly patients. (Reference: (WIMAM) Wichtige Mitteilung ueber Arzneimittel, (1),, 1984) **WHO comment:** Mofebutazone, a pyrazolone with anti-inflammatory, analgesic and antipyretic activity, was introduced in 1962 for the treatment of rheumatic disorders. As it is structurally related to phenylbutazone it is subjected to rigorously restricted indications by some national regulatory authorities. See WHO comment for phenylbutazone.

Product name Mucopolysaccharide polysulfuric acid ester

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
CHE	May 1988	The Intercantonal Office for Drug Control has suspended indefinitely the marketing authorization for products containing mucopolysaccharide polysulfuric acid ester.

...(Continued)

Product name **Mucopolysaccharide polysulfuric acid ester** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
FRA	1992	Acting on the advice of the National Commission for Pharmacovigilance, the Ministry of Health suspended for one year the marketing authorization for a mixture of aqueous calf cartilage and bone marrow extract indicated as a chondroprotective agent. The decision was taken having regard to reports of allergic reactions. (Reference: (FRARP) La Revue Prescrire, 12(121), 415, 1992)
PRT	2 July 1992	The Ministry of Health suspended the marketing authorization for a product containing mucopolysaccharide polysulfuric acid ester indicated as a chondroprotective agent pending a thorough evaluation of reported adverse reactions. (Reference: (PRTMH) Ministry of Health,,, 2 July 1992)
AUT	7 July 1992	The Ministry of Health suspended a product indicated as a chondroprotective agent and containing mucopolysaccharide polysulfruic acid ester (Ateparon(R): Luitpold) pending the results of further investigations. The decision was taken after two deaths associated with the use of this product were reported in Germany. The product containing mucopolysaccharide polysulfuric acid ester was initially suspended at the begining of 1988 after reports of serious adverse reactions including cerebral bleeding which gave rise to concern about its safety. It was reintroduced in 1989 since results did not confirm a causal relationship at the time. (Reference: (AUTMH) Ministry of Health,,, 7 July 1992)
DEU	28 July 1992	The Federal Health Office amended the product information for a topical mucopolysaccharide polysulfuric acid ester indicated as treatment for thrombophlebitis, varicose veins, haematoma, and oedema to alert prescribers to cases of skin irritation and allergy. The contraindications have been extended to patients known to be hypersensitive to any component of the product. The manufacturer of a product containing mucopolysaccharide polysulfuric acid ester and indicated as a chondroprotective agent voluntarily withdrew the product from the market. (References: (DEUBGL) Bundesgesund Leitsblatt, 2/92, 109, Feb. 1992; (DEUDC) Drugs Commission,,, 28 July 1992)
		WHO comment: Mucopolysaccharide polysulfuric acid ester is a heparinoid used in the treatment of rheumatoid arthritis.Those formulations of mucopolysaccharide polysulfuric acid esters indicated for topical application have been associated with adverse drug reactions in the form of skin irritations. In 1992 contraindications for the topical mucopolysaccharide polysulfuric acid ester (Huridoid R) were altered to include all patients known to be hypersensitive to any component of the product.

Product name **Muzolimine**

C.A.S. number **55294-15-0**

Scientific and common names, and synonyms

3-AMINO-1-(3,4-DICHLORO-alpha-METHYLBENZYL)-2-PYRAZOLIN-5-ONE
3H-PYRAZOL-3-ONE, 5-AMINO-2-(1-(3,4-DICHLOROPHENYL)ETHYL)-2,4-DIHYDRO-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1987	Following discussions with the Federal Health Office, the manufacturer has voluntarily suspended the sale of products containing muzolimine.
FRA	1987	Following discussions with the Directorate of Pharmacy and Medicines, the manufacturer has voluntarily suspended the sale of products containing muzolimine. (Reference: (FMOPL) Le Moniteur des Pharmacies et des Laboratoires, 1762(10),, 1987)
NOR	1987	Muzolimine is not approved for registration on grounds of positive carcinogenicity tests and because the risk of carcinogenic effect in man is not excluded.

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Product name **Noscapine** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Noscapine, a centrally-acting cough suppressant and one of several alkaloids present in papaveretum (opium concentrate) was introduced into medicine many years ago. Subsequently, it was shown to increase the number of chromosomes in mammalian cell lines maintained in vitro. Although the clinical significance of this finding is uncertain, restrictive action was taken in a few countries since the possibility of a genotoxic effect cannot be excluded. On 4 December 1992 the European Committee on Proprietary Medicinal Products concluded that the available evidence does not indicate that use of noscapine holds any significant hazard. The Swedish Medical Products Agency also concluded that there is no justification to restrict the use of noscapine in women of childbearing age.

Product name **Novobiocin**

C.A.S. number **303-81-1**

Scientific and common names, and synonyms

BENZAMIDE,N-(7-((3-O-(AMINOCARBONYL)-6-DEOXY-5-C-METHYL-4-O-METHYL-beta-L-LYXO-HEXOPYRANOSYL)OXY)-4-HYDROXY-8-METHYL-2-OXO-2H-1-BENZOPYRAN-3-YL)-4-HYDROXY-3-(3-METHYL-2-BUTENYL)-

STRETONOVICIN

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
MYS	July 1987	All products containing novobiocin may not be registered. (Reference: (MYSDC) Malaysian Drug Control Authority, No.11,, July 1987)
		WHO comment: Novobiocin, an antibiotic with a narrow spectrum of activity, was introduced in 1956. Its use was subsequently associated with serious adverse effects including blood dyscrasias. In view of its toxicity there are no current valid indications for its use. Although preparations containing novobiocin may remain available in some countries it has largely lapsed into disuse.

Product name **Opium in antitussive preparations**

C.A.S. number **8008-60-4**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BGD	June 1982	Banned in tincture and spirit form due to its liability for addiction and misuse.
ITA		This substance for use as an antitussive has been removed from the market owing to an unfavourable risk-benefit ratio and lack of substantial evidence of efficacy.
		WHO comment: Opium, which is extracted from the unripe seed capsules of the poppy plant, has been used throughout recorded history both in a medicinal and recreational context. Of the pharmacologically active constituents, several alkaloids, including morphine, codeine, papaverine and noscapine, have wide clinical use. Opium produces both physical and psychological dependence and is controlled under Schedule I of the 1961 Single Convention on Narcotic Drugs. (Reference: (UNSND) United Nations Single Convention on Narcotic Drugs I,,, 1972)

Product name **Oral rehydration salts**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NPL	2 July 1986	Import, sale and distribution of oral rehydration salts which do not comply with WHO recommendations are prohibited.
OMN	1 Aug. 1988	Import and marketing of oral rehydration salts which do not comply with the WHO/UNICEF formula were prohibited. (Reference: (OMNCR) Circular, 21/88,, June 1988)

Product name **Orgotein**

C.A.S. number **9016-01-7**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
CHE	May 1990	The marketing authorization for products containing orgotein has been withdrawn, on the grounds that a great number of anaphylactic reactions associated with their use has been reported, particularly in the Federal Republic of Germany, and that they are of questionable efficacy in some of the indications claimed by the manufacturers. (Reference: (CHBCM) Bulletin Mensuel, 8,, 24 Sep. 1990) **WHO comment:** Orgotein, bovine superoxide dismutase with anti-inflammatory activity, was introduced in 1968 for the management of rheumatic disorders and for the amelioration of side-effects of radiotherapy. Although not widely registered, it remains available in other countries.

Product name **Oxyphenbutazone**

C.A.S. number **129-20-4**

Scientific and common names, and synonyms

BUTANOVA
HYDROXYPHENBUTAZONE
HYDROXYPHENYLBUTAZONE
OXAZOLIDIN
3,5-PYRAZOLIDINEDIONE, 4-BUTYL-1-(4-HYDROXYPHENYL)-2-PHENYL-
4-BUTYL-1-(p-HYDROXYPHENYL)-2-PHENYL-3,5-PYRAZOLIDINEDIONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
JPN	July 1977	Indications are restricted to acute exacerbations of rheumatoid arthritis and osteoarthritis. Doctors are advised to prescribe this drug only to adults and for periods of no longer than one week.
AUT	1984	Indications are restricted to exacerbations of gout and other arthritic conditions. Treatment should not exceed seven days and doctors are advised not to prescribe this drug to children under 14 years of age or elderly patients. (Reference: (WIMAM) Wichtige Mitteilung ueber Arzneimittel, (1),, 1984)
CYP	1984	Withdrawn from the market due to the potential to cause serious adverse reactions. Exemption applies for products intended for local ophthalmic use.
FIN	1984	Oral and rectal preparations have been withdrawn from the market.

...(Continued)

Product name **Oxyphenbutazone** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
IRL	1984	Approved indications for phenylbutazone and oxyphenbutazone revised: now restricted to cases of acute gout, ankylosing spondylitis, and chronic arthritis in patients unsuited to alternative therapy. Treatment of acute gout should not extend beyond 7-10 days and the lowest effective dose should be used. Treated arthritic patients should remain under regular surveillance and specialist supervision. Doctors are advised not to prescribe these drugs for children or pregnant women and to reduce the dose in elderly patients. Certain contraindications include previous or existing gastrointestinal disease, blood dyscrasias, hepatic or renal dysfunction, cardiac or pulmonary insufficiency, thyroid or salivary gland disorders or hypersensitivity. Combination products with other active ingredients have been withdrawn from use.
TUN	1984	All preparations of oxyphenbutazone have been banned for use.
ARE	19 Mar. 1984	Pharmaceutical preparations containing oxyphenbutazone are banned. (Reference: (UAEMD) Ministry of Health Decree, No.480,, 1984)
KWT	Apr. 1984	Approved indications have been restricted to ankylosing spondylitis and acute gout and oxyphenbutazone should not be dispensed without a prescription. (Reference: (KTMD) Ministerial Decree, 160/84,, 1984)
BRB	25 June 1984	Indications for oxyphenbutazone are limited to active ankylosing spondylitis, gout and pseudo-gout. It may also be used to treat acute exacerbations of rheumatoid arthritis and osteoarthritis and acute non-articular rheumatoid disease unresponsive to other non-steroidal anti-inflammatory drugs.
ZWE	July 1984	The Drugs Control Council requested manufacturers to withdraw preparations containing oxyphenbutazone from the market and to exhaust stocks by June 1985. (Reference: (ZWDCC) Drugs Control Council, News Bulletin,,, 1985)
ESP	15 July 1984	Approved indications have been restricted to inflammatory arthritic conditions, active ankylosing spondylitis and other inflammatory spondylopathies, acute attacks of gout and pseudogout, acute exacerbations of rheumatoid arthritis and other polyarthritic conditions. Parenteral preparations have been restricted to hospital use only.
JOR	1 Oct. 1984	Registration of all pharmaceutical products containing oxyphenbutazone has been withdrawn. (Reference: (JORMH) Ministry of Health Resolution, No.4/2/1559,, Apr. 1984)
BGD	Nov. 1984	Use has been banned due to reported severe adverse reactions.
DEU	1985	Indications are restricted to severe exacerbations of rheumatism and acute gout. Duration of oral treatment should not exceed one week. Parenteral preparations are indicated only for initiating therapy. A single injection only is recommended because local tissue damage may occur. Preparations are contraindicated in children under 14 years of age.
ETH	1985	Banned from the market due to reported serious adverse reactions.
GRC	1985	Withdrawn from the market.
NLD	1 Jan. 1985	Parenteral dosage forms and combination products containing oxyphenbutazone have been withdrawn from the market. The approved indications have been restricted to the treatment of spondyloarthritis unresponsive to other non-steroidal anti-inflammatory agents. (Reference: (NETJAN) Nederlands Tijdschrift voor Geneeskunde, 128(50),, 1984)
SWE	1 Jan. 1985	Withdrawn from the market after joint discussions between the National Board of Health and Welfare and the importer on the grounds of serious blood dyscrasias associated with its use.
NZL	Apr. 1985	Voluntarily withdrawn from the market.
CHL	4 June 1985	Preparations containing oxyphenbutazone have been prohibited. (Reference: (CHLRS) Resolution of the Minister of Health, No. 2660,, Apr. 1984)
GHA	1986	Use of oxyphenbutazone has been banned.
OMN	1986	Oxyphenbutazone for internal use (tablets, injections, syrups and suppositories) should neither be imported nor marketed after the stock in the local market has been used.

...(Continued)

Product name **Oxyphenbutazone** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
TUR	1 Mar. 1986	The Ministry of Health has prohibited the manufacture and sale of preparations containing oxyphenbutazone for oral, rectal and topical use.
MYS	Jan. 1987	All products containing oxyphenbutazone have been withdrawn. (Reference: (MYSDC) Malaysian Drug Control Authority, No.6,, Oct. 1986)
HKG	1 Sep. 1987	The Pharmacy and Poisons Committee no longer allows the registration, sale or distribution of products containing oxyphenbutazone.
BEL	1 Jan. 1988	Preparations containing oxyphenbutazone have been placed in List IV of the Arrêté du Régent of 2 June 1946 and as such can be administered only on prescription. They must be kept in a poisons cabinet and carry the skull and cross-bones label. (Reference: (BELAR) Arrêté Royal,,, June 1987)
LKA	1 Jan. 1992	The Ministry of Health withdrew from sale pharmaceutical products containing oxyphenbutazone (tablet formulation). This action was based on the potential of these products to induce suppression of the bone marrow. (Reference: (LKADIB) Drug Information Bulletin, University of Peradeniya and Ministry of Health, 41(1),, 1992)
BHR		Preparations containing oxyphenbutazone have been withdrawn.
COG		Injectable preparations have been withdrawn from the market. Oral preparations have indications restricted to the treatment of ankylosing spondylitis, gout and periarticular rheumatism.
GBR		All product licences for preparations containing oxyphenbutazone have been revoked with the exception of those for eye ointments.
HUN		Indications are restricted to ankylosing spondylitis and related diseases, acute gout attacks, acute exacerbations of rheumatoid arthritis and inflamed osteoarthritis. The duration of treatment is restricted to 14 days. There is only one registered preparation containing oxyphenbutazone; its dispensing is restricted to individual cases authorized by the Ministry of Health at special request.
ISR		The pharmaceutical administration of the Ministry of Health withdrew from use all preparations containing oxyphenbutazone.
		WHO comment: Oxyphenbutazone, a pyrazolone derivative with anti-inflammatory, analgesic and antipyretic activity, was introduced in 1955 for the treatment of rheumatic disorders. It is one of the active metabolites of phenylbutazone and has a similar spectrum of activity including an association with serious and sometimes fatal adverse reactions, notably cases of aplastic anaemia and agranulocytosis. Many national drug regulatory authorities consider that more recently introduced drugs offer a safer alternative for most, if not all, patients requiring antiinflammatory agents. Although oxyphenbutazone has been widely withdrawn it remains available in some countries.

Product name **Oxyphenisatine acetate**

C.A.S. number **115-33-3**

Scientific and common names, and synonyms

ACETPHENOLISATIN
BISATIN
DIACETOXYDIPHENYLISATIN
DIACETYLDIPHENOLISATIN
DIASATIN
DIPHESATIN
ISAPHENIN
OXYPHENISATIN DIACETATE
PHENLAXINE
2H-INDOL-2-ONE,3,3-BIS(4-ACETYLOXY)PHENYL)-1,3-DIHYDRO-
3,3-BIS(P-HYDROXYPHENYL)-2-INDOLINONE DIACETATE

...(Continued)

Legislative or regulative action

Product name **Oxyphenisatine acetate** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
CUB	1970	Banned for use following reports of hepatotoxicity.
AUS	1972	The Department of Health of the Commonwealth withdrew from the market all preparations containing oxyphenisatine acetate (diacetoxydiphenolisatin) and triacetyldiphenolisatin. This recommendation was based on an increasing number of reports, including one fatality, implicating these compounds as a cause of acute and chronic liver disease.
USA	Feb. 1972	Preparations for oral or rectal use withdrawn by the Food and Drug Administration (oral preparations withdrawn 2/72; rectal preparations withdrawn 3/73) on grounds of safety considerations. After a review of the clinical evidence, the FDA concluded that in view of the hazards associated with the use of these drugs, including hepatitis and jaundice, and the availability of alternative drugs having a wider margin of safety, the benefit/risk ratio did not justify their continued marketing. (Reference: (FEREAC) Federal Register, 38, 6419, Mar. 1973)
JPN	Mar. 1972	Banned by the Pharmaceutical Affairs Bureau in over-the-counter drugs, due to hepatic damage (e.g. jaundice) observed with long-term use.
NOR	1974	Withdrawn from the market.
DNK	Oct. 1975	Registration for these products has been cancelled. (Reference: (DENBH) Danish National Board of Health, Circular Letter,,, July 1985)
DEU	1976	Withdrawn following a review of published cases of acute and chronic liver disease.
ITA	1976	Preparations for oral, rectal and topical use have been withdrawn from the market due to the risk of sensitization.
AUT	Mar. 1977	Withdrawn by the Federal Ministry of Health and Environmental Protection following reports of cases of acute and chronic liver disease associated with this drug.
GBR	1978	All products containing this substance have been withdrawn except for rectal suppositories for single-dose use.
CAN	1 July 1978	All preparations containing this substance have been withdrawn from sale. (Reference: (CANGZ) Canada Gazette, 113/(10),, 1979)
FRA	30 Mar. 1979	The Commission on Drug Monitoring of the Ministry of Health has called for the exclusion of oxyphenisatine from proprietary laxative products, having regard to the established relationship between this substance and chronic hepatic damage.
KWT	Jan. 1980	The importation of oxyphenisatine and related compounds is prohibited.
BEL	14 Jan. 1981	Pharmaceutical preparations containing oxyphenisatine acetate are prohibited. (Reference: (BELAR) Arrêté Royal,,, Jan. 1981)
DDR	Dec. 1981	Registration approval has been withdrawn due to proven hepatotoxicity. (Reference: (DDCI) Regulation of the Drug Control Institute,,, Nov. 1981)
MUS	9 Mar. 1982	Under the Pharmacy and Poisons (Prohibitions of Harmful Drugs) Regulations, this drug is deemed "harmful" by the Ministry of Health and is prohibited for import, manufacture, storage, distribution, sale, possession, use, export or other transaction. (Reference: (MPPHD) Pharmacy & Poisons (Prohibitions of Harmful Drugs) Regulations,,, Mar. 1982)
ESP	1 Mar. 1985	Products containing oxyphenisatine have been withdrawn from the market because of its potential to induce hepatitis. (Reference: (ESPMC) Programa Selectivo de Revisión de Medicamentos,,, 1985)
CYP		Products containing oxyphenisatine acetate have been withdrawn having regard to the risk of liver damage in patients receiving this drug.
NLD		Products containing oxyphenisatine have been withdrawn from the market.
NZL		Voluntarily withdrawn from the market.
VEN		Not approved for use and/or sale.

...(Continued)

Product name **Oxyphenisatine acetate** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Oxyphenisatine acetate was widely used as a laxative after its cathartic activity was first described in 1925. In 1969 its use was first associated with cases of acute and chronic liver disease. This association is considered by some, but not all, national drug regulatory authorities to warrant the withdrawal from the market of preparations containing oxyphenisatine and its derivatives.

Product name **Pangamic acid**

C.A.S. number **13149-68-3**

Scientific and common names, and synonyms

GLUCONIC ACID 6-BIS(N-DI-ISOPROPYLAMINO)ACETATE
VITAMIN B15

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GRC	1984	Withdrawn from the market having regard to its low benefit to risk ratio (mutagenicity). **WHO comment:** Pangamic acid, which is extracted from apricot kernels and rice bran, has been described as Vitamin-B15. Although there is no evidence that it is a vitamin, it remains available in some preparations sold in health food stores.

Product name **Pargyline**

C.A.S. number **555-57-7**

Scientific and common names, and synonyms

BENZENEMETHANAMINE, N-METHYL-N-2-PROPYNYL-
N-METHYL-N-2-PROPYNYLBENZYLAMINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DDR	Dec. 1979	Registration approval has been withdrawn due to an unfavourable risk/benefit relationship. (Reference: (DDCI) Regulation of the Drug Control Institute,,, Oct. 1979) **WHO comment:** Pargyline, a non-hydralazine monoamine oxidase inhibitor (MAOI), was introduced in 1965 for the treatment of hypertension. Severe toxic reactions may occur if the drug is taken concurrently with foods containing tyramine. As safer antihypertensive agents have subsequently been introduced, at least one country now considers the risk-benefit ratio to be unfavourable and has withdrawn the drug. However, it remains available in other countries for the treatment of selected patients with severe hypertension unresponsive to other drugs.

Product name **Paromomycin**

C.A.S. number **7542-37-2**

Scientific and common names, and synonyms

D-STREPTAMINE,O-2-AMINO-2-DEOXY-alpha-D-GLUCOPYRANOSYL-1(1->4)-O-(O-2,6-DIAMINO-2,6-DIDEOXY-beta-L-IDOPYRANOSYL-(1->3)-beta-D-RIBOFURANOSYL-(1->5))-2-DEOXY-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ESP	1989	All parenteral forms of preparations containing paromomycin have been withdrawn, having regard to their unacceptably high toxicity. (Reference: (ESPINS) Información Terapéutica de la Seguridad Social, 13(1), 7, 1989) **WHO comment:** Paromomycin, an aminoglycoside antibiotic was introduced into medicine in 1959 for the treatment of protozoal, helminthic and bacterial infections. It has been associated, particularly when used by parenteral route, with severe adverse effects including renal damage, neuromuscular blockage and ototoxicity, possibly leading to deafness in some patients. This route of administration is now considered obsolete. However, parenteral dosage forms of paromomycin may still remain available in certain countries.

Product name **Pectin**

C.A.S. number **9000-69-5**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
LIY	May 1990	The use of pectin for children was banned. (Reference: (LIYRL) Resolution of the General People's Health Committee, 141,, 21 May 1990)
IND	11 Feb. 1991	The Central Government banned the manufacture and sale of combinations of fixed doses of pectin with any other drug. (Reference: (INDC) Drugs Controller,,, Mar. 1992)
LKA	1 Jan. 1992	The Ministry of Health withdrew from sale all liquid preparations containing pectin. Pectin is of doubtful efficacy in the management of diarrhoea and its use may lead to increased salt and water loss. (Reference: (LKADIB) Drug Information Bulletin, University of Peradeniya and Ministry of Health, 4(1),, 1992) **WHO comment:** Pectin is a purified carbohydrate product isolated from the rinds of citrus fruits or green apples. Its major constituent is polygalacteronic acid, and it is almost completely digested and absorbed in the intestine. Pectin became popular as a simple remedy for diarrhoea in the early 1900s. It does not affect the frequency of stool or stool weight. Use of such products diverts attention away from more important aspects of treatment, such as rehydration, proper nutrition and in the case of cholera and dysentery, appropriate antibiotics.

Product name **Pentazocine**

C.A.S. number **359-83-1**

Scientific and common names, and synonyms

(2R*,6R*,11R*)-1,2,3,4,5,6-HEXAHYDRO-6,11-DIMETHYL-3-(3-METHYL-2- BUTENYL)-2,6-METHANO-3-BENZAZOCIN-8-OL
2,6-METHANO-3-BENZAZOCIN-8-OL, 1,2,3,4,5,6-HEXAHYDRO-6,11-DIMETHYL-3-(3-METHYL-2-BUTENYL)-, (2alpha,6alpha-11R*)-

...(Continued)

Legislative or regulative action

Product name **Pentazocine** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
AUT		Subjected to control at national level analogous to that provided by Schedule I of the 1961 Single Convention on Narcotic Drugs. **WHO comment:** Pentazocine, which has both agonist and weak opioid antagonist activity, was introduced in 1967 for the treatment of moderate and severe pain. The risk of drug dependence is lower with pentazocine than with morphine-like drugs and pentazocine has been controlled under Section III of the 1971 Convention on Psychotropic Substances since 1984. The risk of dependence is now widely acknowledged to exist in vulnerable individuals and at least one country has applied controls analogous to those of Schedule I of the 1961 Single Convention on Narcotic Drugs. (Reference: (UNCPS3) United Nations Convention on Psychotropic Substances (III),,, 1971)

Product name **Pentobarbital**

C.A.S. number **76-74-4**

Scientific and common names, and synonyms

PENTOBARBITONE
2,4,6(1H,3H,5H)-PYRIMIDINETRIONE, 5-ETHYL-5-(1-METHYLBUTYL)-
5-ETHYL-5-(1-METHYLBUTYL)BARBITURIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	July 1985	Withdrawn following discussions between the manufacturer and the National Board of Health and Welfare. Fatal intoxications and abuse are associated with use of preparations containing pentobarbital. **WHO comment:** Pentobarbital is a short-acting barbiturate which is controlled under Schedule III of the 1971 Convention on Psychotropic Substances. See WHO comment for barbiturates. (Reference: (UNCPS3) United Nations Convention on Psychotropic Substances (III),,, 1971)

Product name **Phenacetin**

C.A.S. number **62-44-2**

Scientific and common names, and synonyms

ACETAMIDE, N-(4-ETHOXYPHENOL)-
ACETOPHENETHIDINE
ACETOPHENETIDIN
N-(4-ETHOXYPHENYL) ACETAMIDE
P-ACETOPHENETIDIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
FIN	1965	Prohibited due to the well-documented association between its long-term use and nephropathy.
CAN	1973	No manufacturer or importer shall sell a drug that contains phenacetin in combination with any salt or derivative of salicylic acid. (Reference: (CANGZ) Canada Gazette,,, June 1973)
ITA	1973	Withdrawn from the market due to suspected liver and kidney toxicity.

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Legislative or regulative action

Product name **Phenacetin** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
KWT	1973	Preparations containing phenacetin in combination with salicylates are no longer allowed. (Reference: (KTMD) Ministerial Decree, No.53,, 1973)
NZL	1974	Phenacetin was scheduled as a prescription drug in 1974, and was subsequently voluntarily withdrawn.
NGA	Mar. 1978	Prohibited for import, distribution and sale based on a survey and review of the literature, and clinical and experimental data regarding toxic effects on the kidney and liver.
CYP	1979	The Drug Council decided to withdraw all products containing phenacetin and its derivatives having regard to the risk of liver damage in patients receiving this drug.
YEM	1979	Preparations containing phenacetin have been withdrawn.
PHL	June 1980	Phenacetin-containing drugs are no longer registrable due to the risk of developing methaemoglobinaemia.
GBR	27 Mar. 1980	The Phenacetin Prohibition Order has prohibited the sale, supply or importation of any medicinal product containing phenacetin. Certain exemptions may apply. (Reference: (GBPHA) Phenacetin Prohibition Order, 1181,, 1979)
ISR	1981	The sale of analgesic combination products containing phenacetin has been prohibited. Paracetamol has been recommended as a substitute for phenacetin.
NOR	1981	Withdrawn from the market.
ARE	9 June 1981	Pharmaceutical preparations containing phenacetin are banned. (Reference: (UAEMD) Ministry of Health Decree, No.694,, 1981)
BRA	27 Nov. 1981	Products containing phenacetin are prohibited. (Reference: (BRAPT) Portaria do Servico Publico Federal, No.23,, Nov. 1981)
ROM	1982	The Minister of Health has recommended the gradual reduction in the use of this product until it has been phased out of use completely.
TUR	1982	Preparations containing phenacetin in combination with analgesics and antipyretics have been withdrawn by the Ministry of Health with the recommendation that such formulations be changed, due to the risk of nephropathy from long-term use. Export of this product is prohibited.
BGD	Mar. 1982	Under the provisions of the Drugs (Control) Ordinance, this product has been banned, since the phenacetin component is toxic and liable to be abused. (Reference: (BGDCO) The Drugs (Control) Ordinance,,, 1982)
MUS	9 Mar. 1982	Under the Pharmacy and Poisons (Prohibitions of Harmful Drugs) Regulations, this drug is deemed "harmful" by the Ministry of Health and is prohibited for import, manufacture, storage, distribution, sale, possession, use, export or other transaction. (Reference: (MPPHD) Pharmacy & Poisons (Prohibitions of Harmful Drugs) Regulations,,, Mar. 1982)
SWE	July 1982	Banned for use and/or sale for domestic purpose due to the risk of carcinogenicity and renal damage on long-term use and the presence of alternative therapy. Although Sweden has no legal powers to prohibit export, no export of this product occurs.
HKG	1 July 1982	The Pharmacy and Poisons Committee no longer allows the registration, sale or distribution of products containing phenacetin.
JPN	Aug. 1982	The Ministry of Health and Welfare banned phenacetin in proprietary drugs because of its propensity to cause renal damage and its carcinogenicity.
IND	1983	Prohibited for manufacture, sale and import for reasons of health risks associated with use and/or questionable therapeutic value. (Reference: (GAZIE) The Gazette of India: Extraordinary, II-3i,, 23 July 1986)
NPL	1983	Preparations containing phenacetin have been banned from use.

...(Continued)

Product name **Phenacetin** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
THA	Feb. 1983	Registration permit has been revoked for pharmaceutical preparations containing this ingredient.
RWA	1 Oct. 1983	Products containing phenacetin have been banned following established evidence of adverse effects of these preparations.
USA	4 Nov. 1983	Withdrawn from the market and prohibited for export by the Food and Drug Administration due to its high potential for abuse and its unfavourable benefit-to-risk ratio with excessive chronic use. Risks cited include kidney damage and the possibility of haemolytic anaemia and methaemoglobinaemia resulting from abuse. (Reference: (FEREAC) Federal Register, 48(194), 45466, 1983)
CHL	1984	Products containing phenacetin have been withdrawn from the market in view of the risk of renal damage and methaemoglobinaemia with use.
ETH	1984	Withdrawn from the market due to the association of long-term use and nephropathy.
GRC	1984	Withdrawn from the market.
DNK	31 Dec. 1984	Products containing phenacetin have been withdrawn from the market due to their potential risks of carcinogenicity and nephrotoxicity. (Reference: (UGLAAD) Ugeskrift for Laeger, 3769,, Nov. 1984)
PAN	16 Sep. 1985	The Ministry of Health has banned the import and sale of pharmaceuticals containing phenacetin. (Reference: (PANMR) Ministry of Health Resolution, No.7-DG,, June 1985)
DEU	1 Apr. 1986	Preparations containing phenacetin have been withdrawn from the market and will no longer be considered for registration.
MYS	Nov. 1986	All products containing phenacetin have been withdrawn. (Reference: (MYSDC) Malaysian Drug Control Authority, No.4,, Aug. 1986)
OMN	1 Jan. 1987	The Ministry of Health has prohibited the import and marketing of products containing phenacetin.
AUT	1 Jan. 1988	The distribution and use of medicines containing phenacetin are prohibited. (Reference: (AUTGB) Bundesgesetzblatt für die Republik Oesterreich, No.284,, 1987)
BEL	1 Jan. 1988	Preparations containing phenacetin have been placed in List IV of the 'Arrêté du Régent' of 2 June 1946 and as such can be administered only on prescription. They must be kept in a poisons cabinet and carry the skull and crossbones label. (Reference: (BELAR) Arrêté Royal,,, June 1987)
BHR		Preparations containing phenacetin have been withdrawn.
EGY		The Technical Committee for Drug Control has instructed manufacturers to reformulate products to exclude this substance due to its potential to cause cumulative kidney damage.
IRL		Products containing phenacetin have been withdrawn.
NLD		Products containing phenacetin have been banned.
SAU		Not approved, having regard to the risk of liver damage as well as nephropathy.
SUR		Registration of all pharmaceutical products containing phenacetin has been withdrawn.
		WHO comment: Phenacetin, an aniline derivative, was introduced into medicine as an antipyretic over a century ago. It subsequently gained recognition as an analgesic and was available in many proprietary analgesic preparations. However, in the 1940s its habitual use was first implicated as the cause of methaemoglobinaemia and chronic haemolysis. Since 1950 there have been many reports published indicating that abusive use is associated with cumulative renal damage. Evidence also exists to suggest that it may have a carcinogenic potential. The drug has been withdrawn in many countries but may remain available in others. (Reference: (WHODI) WHO Drug Information, 1, 5, 1980)

Product name **Phenazone**

C.A.S. number **60-80-0**

Scientific and common names, and synonyms

ANTIPYRINE
AZOPHENUM
1,2-DIHYDRO-1,5-DIMETHYL-2-PHENYL-3H-PYRAZOLE-3-ONE
2,3-DIMETHYL-1-PHENYL-3-PYRAZOLIN-5-ONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ARE	9 June 1981	Pharmaceutical preparations containing phenazone are banned. (Reference: (UAEMD) Ministry of Health Decree, 694,, 1981)
DDR	Dec. 1983	Phenazone has been eliminated from combination preparations intended for the treatment of asthma. (Reference: (DDCI) Regulation of the Drug Control Institute,,, Dec. 1983)
MYS	Nov. 1986	All products containing phenazone have been withdrawn. (Reference: (MYSDC) Malaysian Drug Control Authority, No.4,, Nov. 1986)
BHR		Preparations containing phenazone have been withdrawn. **WHO comment:** Phenazone is a pyrazolone derivative chemically related to aminophenazone. Some regulatory authorities have imposed restrictions on its use on these grounds. However, a recent international study showed no statistically-based evidence of an association with agranulocytosis or aplastic anaemia. Nor does it share with aminophenazone the propensity to produce potentially carcinogenic nitrosamines.

Product name **Phenazopyridine**

C.A.S. number **94-78-0**

Scientific and common names, and synonyms

2,6-DIAMINO-3-(PHENYLAZO)PYRIDINE
2,6-PYRIDINEDIAMINE, 3-(PHENYLAZO)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GRC	1984	Withdrawn from the market having regard to its unacceptable benefit to risk ratio (carcinogenic potential). **WHO comment:** Phenazopyridine, an azo dye, was introduced in the 1950s as a urinary antiseptic. It was withdrawn in Greece in 1984 on grounds that it has a carcinogenic potential but it remains available in other countries, most frequently as a constituent of combination products.

Product name **Phendimetrazine**

C.A.S. number **634-03-7**

Scientific and common names, and synonyms

MORPHOLINE, 3,4-DIMETHYL-2-PHENYL-, (2S-TRANS)-
PHENIMETHOXAZINE
(2S,3S)-3,4-DIMETHYL-2-PHENYLMORPHOLINE
(+)-3,4-DIMETHYL-2-PHENYLMORPHOLINE

...(Continued)

Legislative or regulative action

Product name **Phendimetrazine** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
TUR	6 Sep. 1982	Banned for production, import, export, sale and use. **WHO comment:** Phendimetrazine, a sympathomimetic amine, was introduced in 1961 for use as an anorexic agent. It retains a place in the treatment of obesity. However, since it has been subject to abuse and because dependence can occur, phendimetrazine is controlled under Schedule IV of the 1971 Convention on Psychotropic Substances. (Reference: (UNCPS4) United Nations Convention on Psychotropic Substances (IV),,, 1971)

Product name **Phenformin**

C.A.S. number **114-86-3**

Scientific and common names, and synonyms

IMIDODICARBONIMIDIC DIAMIDE, N-(2-PHENYLETHYL)-
PHENFORMIN HYDROCHLORIDE
1-PHENETHYLBIGUANIDE
1-PHENETHYLBIGUANIDE HCL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
TUR	1970	Due to published evidence of occasional fatal cases of lactic acidosis from this substance, the Ministry of Health has withdrawn all products containing phenformin and used metformin as a replacement. Export of this product is prohibited.
CAN	1977	Voluntarily withdrawn from sale as a result of concern regarding lactic acidosis. Metformin remains available for use.
CHE	1977	Withdrawn following reports of occasional but sometimes fatal cases of lactic acidosis among diabetics receiving biguanides.
NOR	1977	Phenformin was withdrawn following a review of the published evidence relating to the development of lactic acidosis in diabetics treated with this drug. In the view of the specialities board adequate alternative treatment is available that does not involve a comparable risk.
NZL	1977	Voluntarily withdrawn from the market.
SGP	Aug. 1977	Banned for importation.
BRA	14 Dec. 1977	Combination products containing phenformin are prohibited. (Reference: (BRAPT) Portaria do Servico Publico Federal, No.30,, Dec. 1977)
DNK	1978	Withdrawn following reports of occasional but sometimes fatal cases of lactic acidosis among diabetics receiving biguanides. (Reference: (UGLAAD) Ugeskrift for Laeger, 140, 181, 1978)
FIN	1978	Withdrawn from the market by the manufacturers since it has been shown to cause lactic acidosis among diabetics receiving biguanides.
ITA	1978	Warnings and contraindications have been added to currently marketed products with this ingredient. It has been recommended that dosages lower than 100 mg/day be followed due to the risk of lactic acidosis.
DEU	Mar. 1978	Withdrawn from the market because of occurrence of lactic acidosis.
FRA	31 May 1978	Withdrawn following reports of occasional but sometimes fatal cases of lactic acidosis among diabetics receiving biguanides.

...(Continued)

Product name **Phenformin** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
AUT	Sep. 1978	In conformity with the decision taken in several other countries, and following reports of occasional lactic acidosis, all products containing phenformin and buformin have been withdrawn. Metformin remains available for limited indications.
SWE	Oct. 1978	Withdrawn from domestic use due to several cases of lactic acidosis, some of which have been fatal. This product is no longer manufactured in Sweden. Although Sweden has no legal powers to prohibit export, no export of this product occurs.
THA	Nov. 1978	Registration permit has been revoked for pharmaceutical preparations containing this ingredient.
USA	15 Nov. 1978	Withdrawn from the market and prohibited for export by the Food and Drug Administration following reports of cases of lactic acidosis. Special arrangements have been made to allow doctors to obtain, on request, supplies of phenformin for the treatment of specific patients in whom the "benefits of the drug are considered to outweigh the risks.". (Reference: (FEREAC) Federal Register, 44(68), 20966, 1979)
CYP	1979	The Drug Council withdrew all products containing phenformin following a review of published literature relating to the development of fatal acidosis in diabetics treated with this drug.
ETH	1979	Withdrawn from the market following reports of fatal lactic acidosis.
IRL	1979	Phenformin and buformin were withdrawn from the market as a result of concern regarding lactic acidosis. (Reference: (IRDAB) National Drugs Advisory Board Annual Report, 14,, 1979)
YEM	1979	Withdrawn following reports of fatal lactic acidosis.
KWT	Jan. 1980	Prohibited for import.
GBR	1982	Withdrawn from the market by the manufacturer owing to evidence of lactic acidosis with its use.
HKG	14 Oct. 1985	The Pharmacy and Poisons Committee no longer allows the registration, sale or distribution of products containing phenformin.
IND		Currently available on the market. Precautionary information is required to be given with this drug.
MUS		The Committee on Safety of Drugs has issued a circular letter to all doctors informing them of contraindications to phenformin and the precautions to be observed when the drug is used.
NLD		Withdrawn from the market.
SAU		Prohibited following reports of lactic acidosis.
VEN		Subject to restricted use and/or sale.
		WHO comment: Phenformin, a biguanide with oral hypoglycaemic activity, was introduced in 1957 for the management of diabetes mellitus. By 1970 its use had been associated with incidences of lactic acidosis and by 1976 clinical studies had conclusively demonstrated that the hazards of phenformin treatment outweighed the benefits. Preparations containing phenformin were withdrawn in several countries and their use restricted in others. Elsewhere, however, proprietary preparations containing this drug may remain available. The related biguanide, buformin, has been also associated with lactic acidosis and has been subjected to similar restrictions as phenformin, whereas there is some evidence that metformin is less liable to induce lactic acidosis. (Reference: (WHODI) WHO Drug Information, 2, 4, 1977)

Product name **Phenicarbazide**

C.A.S. number **103-03-7**

Scientific and common names, and synonyms

1-PHENYLSEMICARBAZIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
IRL		Having regard to the serious nature of the adverse effects, products containing phenicarbazide have been withdrawn. **WHO comment:** Phenicarbazide, which has analgesic and antipyretic activity, was introduced in the 1970s. It has been withdrawn in at least one country on grounds of its adverse effect profile and it appears to have fallen into disuse in others.

Product name **Phenmetrazine**

C.A.S. number **134-49-6**

Scientific and common names, and synonyms

MORPHOLINE, 3-METHYL-2-PHENYL
3-METHYL-2-PHENYLMORPHOLINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
TUR	6 Sep. 1982	Banned for production, import, export, sale and use.
OMN	10 May 1982	Import and marketing of products containing phenmetrazine were prohibited. (Reference: (OMNCR) Circular, 11/82,, May 1982)
NGA	1988	All products containing phenmetrazine have been banned. (Reference: (NGAPN) Pharmanews, 10(11), 15, 1988) **WHO comment:** Phenmetrazine, a sympathomimetic amine, was introduced in 1956 for use as an anorexic agent. Although preparations remain available, the use of phenmetrazine is no longer indicated for the treatment of obesity. Moreover, since it has been subject to abuse, and because dependence can occur, it is now controlled under Schedule II of the 1971 Convention on Psychotropic Substances. (Reference: (UNCPS2) United Nations Convention on Psychotropic Substances (II),,, 1971)

Product name **Phenobarbital**

C.A.S. number **50-06-6**

Scientific and common names, and synonyms

PHENEMALUM
PHENOBARBITONE
2,4,6(1H,3H,5H)-PYRIMIDINETRIONE, 5-ETHYL-5-PHENYL-
5-ETHYL-5-PHENYLBARBITURIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	July 1985	Withdrawn following discussions between the manufacturer and the National Board of Health and Welfare. Fatal intoxications and abuse are associated with use of preparations containing phenobarbital.

...(Continued)

Legislative or regulative action

Product name **Phenobarbital** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Phenobarbital is a long-acting barbiturate which is controlled under Schedule IV of the 1971 Convention on Psychotropic Substances. Phenobarbital is of value in the treatment of epilepsy and preparations for such use are included in the WHO Model List of Essential Drugs. See also WHO comment for barbiturates. (Reference: (UNCPS4) United Nations Convention on Psychotropic Substances (IV),,, 1971)

Product name **Phenol**

C.A.S. number **108-95-2**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DOM	1983	Domestic manufacturers and importers have been requested to eliminate this ingredient from their marketed products since studies worldwide have shown that its antiseptic benefits do not outweigh the risks associated with use. **WHO comment:** Phenol became widely used as an antiseptic following demonstration of its germicidal activity in 1867. It is an intensely corrosive substance and percutaneous absorption can produce serious systemic toxicity. It has been withdrawn from pharmaceutical preparations by at least one national regulatory authority. However, it is still used widely in concentrations of the order of 1.4% in proprietary preparations for the relief of soreness of the mouth and throat.

Product name **Phenolphthalein**

C.A.S. number **77-09-8**

Scientific and common names, and synonyms

1(3H)-ISOBENZOFURANONE, 3,3-BIS(4-HYDROXYPHENYL)
3,3-BIS-(p-HYDROXYPHENYL)PHTHALIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NOR	1979	Withdrawn from the market.
YEM	1979	All products containing phenolphthalein have been withdrawn.
BGD	1982	Under the provisions of the Drugs (Control) Ordinance, this product has been banned due to evidence of insufficient therapeutic value. (Reference: (BGDCO) The Drugs (Control) Ordinance,,, 1982)
GRC	1985	Withdrawn from the market.
BHR		Preparations containing phenolphthalein have been withdrawn. **WHO comment:** Phenolphthalein has been widely used as a laxative since its cathartic activity was first described in 1902. Because it undergoes enterohepatic circulation it is eliminated slowly and it has been associated with adverse effects, notably skin reactions, potassium loss and atonia. This has led to the withdrawal of phenolphthalein from pharmaceutical preparations in several countries. Elsewhere, it remains available, often in over-the-counter preparations.

Product name **Phenoxybenzamine**

C.A.S. number **59-96-1**

Scientific and common names, and synonyms

BENZENEMETHANAMINE, N-(2-CHLOROETHYL)-N-(1-METHYL-2-PHENOXYETHYL)
N-(2-CHLOROETHYL)-N-(1-METHYL-2-PHENOXYETHYL)BENZYLAMINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
AUS	July 1984	The Australian Drug Evaluation Committee has recommended that phenoxybenzamine should be restricted to use in phaeochromocytoma and neurogenic retention of urine having regard to reported carcinogenicity and mutagenicity in animal studies. (Reference: (AUDEC) Report of the Australian Drug Evaluation Committee, 114,, July 1984) **WHO comment:** Phenoxybenzamine, a long-acting alpha-adrenoreceptor antagonist, was introduced in 1953 and has been used in a variety of peripheral vascular disorders. In 1982 it was shown to have mutagenic activity and in 1985 it was found to be carcinogenic in the rat. Its approved use was subsequently restricted by several regulatory authorities and phenoxybenzamine is currently used to manage hypertensive episodes associated with phaeochromocytoma, as an adjunct to the short-term management of urinary retention due to neurogenic bladder, in the short-term treatment of benign prostatic hypertrophy in patients awaiting surgery, and in inoperable benign prostatic hypertrophy.

Product name **Phentermine**

C.A.S. number **122-09-8**

Scientific and common names, and synonyms

alpha,alpha-DIMETHYLPHENETHYLAMINE
BENZENEETHANAMINE, alpha,alpha-DIMETHYL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	Jan. 1981	Phentermine-containing appetite suppressants have been withdrawn from the market. There is a lack of evidence of their value in long-term management of obesity, they have the potential for abuse and despite warnings they are frequently used over unacceptably prolonged periods.
ARE	9 June 1981	Pharmaceutical preparations containing phentermine are banned. (Reference: (UAEMD) Ministry of Health Decree, No.694,, 1981)
MUS	9 Mar. 1982	Under the Pharmacy and Poisons (Prohibitions of Harmful Drugs) Regulations, this drug is deemed "harmful" by the Ministry of Health and is prohibited for import, manufacture, storage, distribution, sale, possession, use, export or other transaction. (Reference: (MPPHD) Pharmacy & Poisons (Prohibitions of Harmful Drugs) Regulations,,, Mar. 1982)
TUR	6 Sep. 1982	Banned for production, import, export, sale and use.
OMN	11 Jan. 1987	Import and marketing of products containing phentermine were prohibited. (Reference: (OMNCR) Circular, 2/87,, Jan. 1987)
VEN		Phentermine is not approved for use and/or sale. **WHO comment:** Phentermine, a sympathomimetic amine, was introduced in 1959 for use as an anorexic agent. It retains a place in the treatment of obesity. However, since it has been subject to abuse and because dependence can occur, phentermine is controlled under Schedule IV of the 1971 Convention on Psychotropic Substances. (Reference: (UNCPS4) United Nations Convention on Psychotropic Substances (IV),,, 1971)

Product name **Phenylbutazone**

C.A.S. number **50-33-9**

Scientific and common names, and synonyms

BUTADIONE
3,5-PYRAZOLIDINEDIONE, 4-BUTYL-1,2-DIPHENYL-
4-BUTYL-1,2-DIPHENYL-3,5-PYRAZOLIDINEDIONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
JPN	July 1977	Indications are restricted to acute exacerbations of rheumatoid arthritis, ankylosing spondylitis and acute gout. Doctors are advised to prescribe these drugs only to adults and for periods of no longer than one week.
HUN	1984	Indications are restricted to ankylosing spondylitis and related diseases, acute gout attacks, acute exacerbations of rheumatoid arthritis and inflamed osteoarthritis. The duration of treatment is restricted to 14 days. (Reference: (BNIPH) Bulletin of the National Institute of Pharmacy, 34(6), 186, 1984)
IRL	1984	Approved indications for phenylbutazone and oxyphenbutazone revised: now restricted to cases of acute gout, ankylosing spondylitis, and chronic arthritis in patients unsuited to alternative therapy. Treatment of acute gout should not extend beyond 7-10 days and the lowest effective dose should be used. Treated arthritic patients should remain under regular surveillance and specialist supervision. Doctors are advised not to prescribe these drugs for children or pregnant women and to reduce the dose in elderly patients. Certain contraindications include previous or existing gastrointestinal disease, blood dyscrasias, hepatic or renal dysfunction, cardiac or pulmonary insufficiency, thyroid or salivary gland disorders or hypersensitivity. Combination products with other active ingredients have been withdrawn from use.
TUN	1984	Injectable and topical preparations are prohibited. Tablets and suppositories are restricted to the treatment of ankylosing spondylitis and gout.
ARE	19 Mar. 1984	Pharmaceutical preparations containing phenylbutazone are banned. (Reference: (UAEMD) Ministry of Health Decree, No.480,, 1984)
KWT	Apr. 1984	Approved indications have been restricted to ankylosing spondylitis and acute gout and phenylbutazone should not be dispensed without a prescription. (Reference: (KTMD) Ministerial Decree, No.160,, 1984)
BRB	25 June 1984	Indications for phenylbutazone are limited to active ankylosing spondylitis, gout and pseudogout. It may also be used to treat acute exacerbations of rheumatoid arthritis and osteoarthritis and acute non-articular rheumatoid disease unresponsive to other non-steroidal antiinflammatory drugs.
ZWE	July 1984	Approved indications are restricted to ankylosing spondylitis. The duration of therapy should not exceed seven days. Labelling must contain a warning that adverse haematological effects may occur and that the blood count should be monitored before and during therapy. Topical products have been withdrawn. (Reference: (ZWDCC) Drugs Control Council, News Bulletin,,, Aug. 1985)
ESP	15 July 1984	Approved indications have been restricted to inflammatory arthritic conditions, active ankylosing spondylitis and other inflammatory spondylopathies, acute attacks of gout and pseudogout, acute exacerbations of rheumatoid arthritis and other polyarthritic conditions. Parenteral preparations have been restricted to hospital use only.
COG	1 Aug. 1984	Indications for phenylbutazone have been restricted to ankylosing spondylitis.
DDR	Sep. 1984	Indications are restricted to acute inflammatory exacerbations of rheumatic disease and acute attacks of gout. (Reference: (DDCI) Regulation of the Drug Control Institute,,, Sep. 1984)
JOR	1 Oct. 1984	Registration of all pharmaceutical products containing phenylbutazone has been withdrawn. (Reference: (JORMH) Ministry of Health Resolution, 4/2/1559,, Apr. 1984)
BGD	Nov. 1984	Use has been banned due to reported severe adverse reactions.

...(Continued)

Product name **Phenylbutazone** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1985	Indications have been restricted to exacerbations of rheumatism and acute gout. Duration of oral treatment should not exceed one week. Parenteral preparations are indicated only for initiating therapy. A single injection only is recommended because local tissue damage may occur. Preparations are contraindicated in children under 14 years of age.
ETH	1985	Banned from the market due to reported serious adverse reactions.
GRC	1985	Indications have been restricted.
NLD	1 Jan. 1985	Parenteral dosage forms and combination products containing phenylbutazone have been withdrawn from the market. The approved indications have been restricted to the treatment of spondyloarthritis unresponsive to other non-steroidal antiinflammatory agents. (Reference: (NETJAN) Nederlands Tijdschrift voor Geneeskunde, 128(50),, 1984)
SWE	Feb. 1985	Indications for use have been restricted to acute gout and morbus Bechterew on the grounds of serious blood dyscrasias associated with its use.
NZL	Apr. 1985	Indications for phenylbutazone have been restricted.
CHL	4 June 1985	Preparations containing phenylbutazone have been prohibited. (Reference: (CHLRS) Resolution of the Minister of Health, No.2660,, Apr. 1984)
OMN	22 Sep. 1985	Phenylbutazone is available in small quantities only in government hospitals for the treatment of patients unresponsive to other therapy. The Ministry of Health has prohibited import of preparations containing phenylbutazone except combinations containing phenylbutazone and clofexamide (clofezone) intended for topical use. (Reference: (OMNMH) Ministry of Health, 3,, 1985)
HKG	2 Oct. 1985	The use of preparations containing phenylbutazone has been restricted.
PAN	1 Jan. 1986	The Ministry of Health has suspended the import and sale of pharmaceuticals containing phenylbutazone with the exception of parenteral preparations for which use will be confined to hospitals. (Reference: (PANMR) Ministry of Health Resolution, No.9/III-DG)
TUR	12 Mar. 1986	Production and sale of preparations containing phenylbutazone have been banned with the exception of topical preparations.
MYS	Jan. 1987	All products containing phenylbutazone have been withdrawn. (Reference: (MYSDC) Malaysian Drug Control Authority, No.6,, Oct. 1986)
BEL	1 Jan. 1988	Preparations containing phenylbutazone have been placed in List IV of the 'Arrêté du Régent' of 2 June 1946 and as such can be administered only on prescription. They must be kept in a poisons cabinet and carry the skull and crossbones label. (Reference: (BELAR) Arrêté Royal,,, June 1987)
GHA	1 Sep. 1989	Products containing phenylbutazone, its salts or derivatives have been banned. (Reference: (GHAPDR) Pharmacy and Drugs (Banned Drugs) Regulations, Legislative Instruments, 1484,, 1989)
LKA	1 Jan. 1992	The Ministry of Health withdrew from sale pharmaceutical products containing phenylbutazone. This action was based on the potential of these products to induce suppression of the bone marrow. (Reference: (LKADIB) Drug Information Bulletin, University of Peradeniya and Ministry of Health, 4(1),, 1992)
AUS		Indications are restricted to seronegative spondyloarthropathies, acute gout and rheumatoid arthritis not responding to other non-steroidal anti-inflammatory drugs.
AUT		Indications are restricted to exacerbations of gout and other arthritic conditions. Treatment should not exceed seven days and doctors are advised not to prescribe this drug to children under 14 years of age or elderly patients. (Reference: (WIMAM) Wichtige Mitteilung ueber Arzneimittel, (1),, 1984)
BHR		Preparations containing phenylbutazone have been withdrawn.

...(Continued)

Product name **Phenylbutazone** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
CYP		All combination products withdrawn from the market due to the potential to cause serious adverse reactions. The indications for monocomponent products have been restricted to ankylosing spondylitis.
GBR		Approved indications are restricted to ankylosing spondylitis. Use is restricted to hospitals.
ISR		The Pharmaceutical Administration of the Ministry of Health has notified the World Health Organization of its intention to withdraw from use all preparations containing oxyphenbutazone and to restrict the approved indication for preparations containing phenylbutazone to ankylosing spondylitis.
ITA		Indications have been restricted to the acute phase of ankylosing spondylitis, acute gout and the acute phase of pelvispondylitis and psoriatic polyarthritis. Use should only be considered when alternative treatment is ineffective or inappropriate. No course of treatment should exceed seven to ten days.
PHL		Due to its risk of toxicity, phenylbutazone is recommended for use only when other agents fail.
		WHO comment: Phenylbutazone, a pyrazolone derivative with anti-inflammatory, analgesic and antipyretic activity, was introduced in 1949 for the treatment of rheumatic disorders. Its use was subsequently associated with serious and sometimes fatal adverse reactions, notably cases of aplastic anaemia and agranulocytosis. Many national drug regulatory authorities consider that more recently introduced drugs offer a safer alternative for most, if not all, patients requiring anti-inflammatory agents. Phenylbutazone has thus been either withdrawn at the national level or retained with rigorously restricted indications for patients unresponsive to other therapy. These restrictions also apply, in general, to combination products containing phenylbutazone.

Product name **Phenylephrine**

C.A.S. number **59-42-7**

Scientific and common names, and synonyms

BENZENEMETHANOL, 3-HYDROXY-alpha-((METHYLAMINO)METHYL)
(-)-M-HYDROXY-alpha-((METHYLAMINO)METHYL)BENZYL ALCOHOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GBR	June 1987	The Department of Health and Social Security has refused to extend the product licence for eyedrops containing phenylephrine having regard to the possibility that use in the eye may result in delayed healing, reactive hyperaemia and the precipitation of closed angle glaucoma.

Product name **Phenylpropanolamine**

C.A.S. number **14838-15-4**

Scientific and common names, and synonyms

BENEZENEMETHANOL, ALPHA-(1-AMINOETHYL)-,(R*,S*)-, (+/-)
(+/-)-NOREPHEDRINE

...(Continued)

Legislative or regulative action

Product name **Phenylpropanolamine** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GBR	Nov. 1985	The Committee on the Review of Medicines has recommended that preparations containing phenylpropanolamine for treatment of cough and cold (other than nasal sprays and drops) should be subjected to prescription control if the recommended dosage exceeds, for slow-release forms, 50 mg (single dose), 100 mg (daily dose); or for immediate release dosage forms, 25 mg (single dose), 100 mg (daily dose). Slow-release preparations are contraindicated in children and all formulations are contraindicated in hypertensive patients and those currently receiving (or within two weeks of stopping) therapy with monoamine oxidase inhibitors. (Reference: (GBMIL) Medicines Act Information Letter, 45,, Nov. 1985)
HKG	Nov. 1985	The Pharmacy and Poisons Committee has issued guidelines restricting the use of phenylpropanolomine.
DEU	1987	Approval of products containing phenylpropanolamine as appetite suppressants and for the symptomatic treatment of the common cold was withdrawn, because of their association with hypertensive episodes in susceptible individuals, particularly when taken together with coffee, alcohol, antihistamines or neuroleptics. (Reference: (BGHBL) Bundesgesundheitsblatt, 30(5), 187, 1987) **WHO comment:** Phenylpropanolamine, a symopathomimetic amine, has been widely available in over-the-counter preparations since 1941. It is one of the most frequently used nasal decongestants and it is a common ingredient in preparations for weight reduction, although doubts have been raised about its usefulness in this indication. It is also used in stress incontinence. Its use has been associated with occasional excessive elevation of blood pressure, especially in hypersensitive individuals.

Product name **Phthalylsulfathiazole**

C.A.S. number **85-73-4**

Scientific and common names, and synonyms

BENZOIC ACID, 2-(((4-((2-THIAZOLYLAMINO)SULFONYL)PHENYL)AMINO)-CARBONYL)-
4'-(2-THIAZOLYLSULFAMOYL)PHTHALANILIC ACID
6'-(THIAZOLYLAMINOSULFAMOYL)PHTHALANILIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BGD	1982	Under the provisions of the Drugs (Control) Ordinance, this product has been banned. It has been found to be of little or no therapeutic value, its side effects can be harmful, and it is subject to misuse. (Reference: (BGDCO) The Drugs (Control) Ordinance,,, 1982) **WHO comment:** Phthalylsulfathiazole, a sulfonamide anti-infective agent, was introduced in 1946 for the treatment of bacterial infections. The importance of sulfonamides has subsequently decreased as a result of increasing bacterial resistance and their replacement by antibiotics which are generally more active and less toxic. Although phthalylsulfathiazole, which is poorly absorbed from the gastrointestinal tract, is no longer recommended in some countries, it continues to be used in others for the treatment of local intestinal infections, including bacterial dysentery, and for pre-operative bowel preparation.

Product name **Pipamazine**

C.A.S. number **84-04-8**

Scientific and common names, and synonyms

10-(3-(4-CARBAMOYLPIPERIDINO)PROPYL)-2-CHLOROPHENOTHIAZINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	July 1969	Withdrawn from the market and prohibited for export by the Food and Drug Administration due to the lack of proof of efficacy and safety for use as an antinauseant and antiemetic for pregnant women. **WHO comment:** Pipamazine, which is pharmacologically similar to chlorpromazine, was introduced in 1959 for the treatment of nausea and vomiting. Although it was withdrawn in 1969 by the United States FDA on grounds of lack of proof of efficacy and safety, it remains available in some countries.

Product name **Pipenzolate**

C.A.S. number **13473-38-6**

Scientific and common names, and synonyms

1-ETHYL-3-HYDROXY-1-METHYLPIPERIDINIUM BENZILATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
PAK	June 1990	Paediatric formulations of antidiarrhoeal products containing pipenzolate were banned. **WHO comment:** Pipenzolate, an anticholinergic agent, was introduced in 1960 for the treatment of spastic conditions of the gastro-intestinal tract. It has never been widely used for the treatment of diarrhoea, and WHO is not aware of any such preparations that remain available.

Product name **Piperazine**

C.A.S. number **110-85-0**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ITA	1977	Products with anthelminthic indications have been withdrawn due to an unfavourable risk/benefit balance. Since 1975, warnings have been added to the labels concerning the possibility of neurotoxic effects with high dosages. In 1979, the label was revised to advise use on an empty stomach and for short periods of time with long intervals, in order to avoid interaction with nitrites.
SWE	1983	In the light of the carcinogenic and mutagenic potential of piperazine demonstrated in recent studies, discussions between the manufacturers and the Department of Drugs have led to the withdrawal of registration for this drug.
DNK	2 July 1984	Following recent evidence leading to the possibility that carcinogenic nitroso-derivatives may be generated in vivo, preparations containing piperazine have been placed under prescription control. (Reference: (UGLAAD) Ugeskrift for Laeger, 1949,, June 1984)

...(Continued)

Product name **Piperazine** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NLD	1 Jan. 1985	The Board of Evaluation of Drugs has concluded that other anthelminthics have a more favourable risk-benefit ratio than piperazine, which may also give rise to potentially carcinogenic nitroso-derivatives. Manufacturers have been requested to withdraw products containing piperazine. (Reference: (NETJAN) Nederlands Tijdschrift voor Geneeskunde, 128(41),, 1984)
THA		The use of pharmaceutical preparations containing piperazine is severely restricted.
		WHO comment: Piperazine was first used as a treatment for gout earlier this century and its anthelminthic activity was discovered in 1949. It continues to retain a place in the WHO Model List of Essential Drugs because it is widely available, effective and apparently safe when used on an occasional basis for the treatment of ascariasis infections. It is also considerably cheaper than other anthelminthic drugs. In some countries where ascariasis is not endemic and where piperazine was used predominantly for the treatment of pinworm it has been withdrawn from use on the grounds that other more effective and less toxic drugs are now available. In other such countries, however, piperazine remains available in over-the-counter preparations. Clinical dosages occasionally induce transient neurological signs and concern has been expressed that in some circumstances the drug may generate small amounts of nitrosamine in the stomach. However, it is widely considered that these trace doses are unlikely to give rise to a significant carcinogenic potential. (Reference: (WHODI) WHO Drug Information, 1, 5, 1983)

Product name **Pipradrol**

C.A.S. number **467-80-7**

Scientific and common names, and synonyms

alpha,alpha-DIPHENYL-2-PIPERIDINEMETHANOL
1,1-DIPHENYL-1-(2-PIPERIDYL)-METHANOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
TUR	6 Sep. 1982	Banned for production, import, export, sale and use.
DNK		Withdrawn from the market by the manufacturer.
VEN		Not approved for use and/or sale.
		WHO comment: Pipradrol, a central nervous system stimulant, was introduced in 1955 for use as an anorexic agent. Pipradrol is controlled under Schedule IV of the 1971 Convention on Psychotropic Substances. (Reference: (UNCPS4) United Nations Convention on Psychotropic Substances (IV),,, 1971)

Product name **Pirprofen**

C.A.S. number **31793-07-4**

Scientific and common names, and synonyms

BENZENEACETIC ACID,3-CHLORO-4-(2,5-DIHYDRO-1H-PYRROL-1-YL)-alpha-METHYL-
2-(3-CHLORO-4-(3-PYOLIN-1-YL)PHENYL) PROPIONIC ACID
3-CHLORO-4-(3-PYRROLIN-1-YL) HYDRATROPIC ACID

...(Continued)

Legislative or regulative action

Product name **Pirprofen** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
@WD	30 Sep. 1990	Products containing pirprofen have been voluntarily discontinued by the manufacturer. (Reference: (CGPR) Press release from Ciba-Geigy,,, 15 Mar. 1990) **WHO comment:** Pirprofen, a nonsteroidal anti-inflammatory agent, was introduced in 1982 primarily for the treatment of rheumatic diseases, as well as for use in post-traumatic and post-operative inflammatory conditions, acute gout and dysmenorrhoea. Reports of serious adverse effects, in particular cases of liver toxicity, some of which were fatal, led the manufacturer, in 1985 and in 1989, to amend the approved product information of the drug, limiting duration of treatment and lowering the recommended doses. In the light of these successive restrictions, which have considerably reduced the field of application of pirprofen and in view of available alternatives, the manufacturer has decided to discontinue the drug worldwide.

Product name **Pituitary-chorionic gonadotropin (injectable)**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	July 1972	Gonadotropins of animal origin have been withdrawn from use and prohibited for export by the Food and Drug Administration on grounds of safety and efficacy. In its decision the FDA cited the risk of eliciting antibodies to animal protein, leading to allergic reactions, and the availability of safer and more effective alternatives. (Reference: (FEREAC) Federal Register, 37(130), 13284, 1972) **WHO comment:** The World Health Organization has no information further to the above regarding preparations containing pituitary chorionic gonadotropin or to indicate that preparations are still commercially manufactured.

Product name **Placental tissue derived medicine**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
FRA	23 July 1992	The Directorate of Pharmacy has suspended the marketing authorization of certain medicinal products derived from human placental tissue: Placentafil, injectable and tipical formulations and Placenta Soca, ointment (Laboratoire gerda). This does not necessarily include other products made from placental tissue. (Reference: (FRAMHH) Ministry of Health and Humanitarian Action,,, 23 July 1992) **WHO comment:** Placental derived products, both topical and injectable, have been used to treat arthritis, eczema, acne vulgaris and numerous other ailments. In 1989 the European Community raised concerns regarding the risk of viral infection and it was this that stimulated restrictive regulatory action. Other placental products including some preparations of albumin remain on the market. Indeed, worldwide, placental tissue continues to be a prime source of albumin.

Product name **Podophyllum resin**

Scientific and common names, and synonyms
PODOPHYLLIN

...(Continued)

Legislative or regulative action

Product name **Podophyllum resin** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ITA	1970	Withdrawn from the market owing to the risk of teratogenicity.
FRA	30 Mar. 1979	Having regard to the presumed teratogenic risk, the Commission on Drug Monitoring of the Ministry of Health recommended that podophyllin be removed from all medicinal products intended for internal use.
EGY	1984	Preparations containing podophyllum will not be considered for registration, having regard to the potential risk of teratogenicity.
CUB		Restricted to hospital use for the treatment of cutaneous lesions only. Oral and parenteral preparations are banned.
SAU		Available medicinal products containing this drug are intended for topical use only.
		WHO comment: Podophyllum resin, which is extracted from Indian podophyllum, is highly irritant to the skin and mucous membranes and its use in purgatives is now obsolescent. However, topical preparations remain available for the treatment of venereal and other warts and the drug is included in the WHO Model List of Essential Drugs for this purpose. Podophyllin extracts have been demonstrated to have a teratogenic potential which has led to their withdrawal in some countries and restriction of use in others. They are best avoided during pregnancy. (Reference: (WHTAC1) Model List of Essential Drugs, 2nd Report of the WHO Expert Committee, 722,, 1985)

Product name **Polidexide sulfate**

C.A.S. number **56227-39-5**

Scientific and common names, and synonyms

DEAE-SEPHADEX
DEXTRAN 2-(DIETHYLAMINO)ETHYL 2-((2-(DIETHYLAMINO)ETHYL)DIETHYLAMMONIO) ETHYL ETHER SULFATE, EPICHLOROHYDRIN CROSSLINKED
PDX-CHLORIDE
POLY(2-(DIETHYLAMINO)ETHYL)POLYGLYCERYLENE)DEXTRAN

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GBR	1977	This substance, except for the intravenous preparation, has been withdrawn by the company following evidence of oculo-mucocutaneous syndrome.
		WHO comment: Polidexide sulfate, an anion-exchange resin, was formerly used in the treatment of hypercholesterolaemia. The drug, which was marketed only in the United Kingdom, was withdrawn in the mid-1970s on the basis of new safety findings.

Product name **Polyoxyethylated castor oil**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ITA	1984	The Italian Ministry of Health has suspended the marketing authorization of two anaesthetic preparations containing polyoxyethylated castor oil.
@WD	June 1984	The manufacturer of an anaesthetic agent containing polyoxyethylated castor oil has withdrawn the product worldwide.

...(Continued)

Product name **Polyoxyethylated castor oil** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
EGY	26 Mar. 1985	Preparations containing polyoxyethylated castor oil will no longer be approved for registration and the substance should be withdrawn from all pharmaceutical and cosmetic products. **WHO comment:** Polyoxyethylated castor oil is a non-ionic emulsifying agent produced by reacting ethylene oxide with castor oil. It has been used for over 20 years to prepare stable injectable liquid preparations of drugs with low aqueous solubility. By the mid-1970s, its use had been associated with cases of severe anaphylactoid reactions and haematological changes including hyperlipidaemia, altered blood viscosity and erythrocyte aggregation. For the formulation of certain lipophilic substances such as ciclosporin there is currently no viable alternative to this pharmaceutical aid. It continues to be approved in some countries whereas its use is restricted or banned in others. One manufacturer has withdrawn worldwide all products containing polyoxyethylated castor oil.

Product name **Polyvidone**

C.A.S. number **9003-39-8**

Scientific and common names, and synonyms

POLYVINYLPYRROLIDONE
POVIDONE
PVP
1-VINYL-2-PYRROLIDINONE POLYMER
2-PYRROLIDINONE, 1-ETHENYL-, HOMOPOLYMER

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1983	All injectable products containing PVP with a molecular weight of approximately 12000 have been reformulated or withdrawn. PVP content of remaining products and an appropriate warning regarding their risks must be widely displayed on the labelling. PVPs have been widely used as stabilisers in injectable products, but the Federal Health Office considers that safer substances are now available for this purpose. It is now recognized that PVPs of high molecular weight are sequestered in the body. Their accumulation may cause pain at the site of injection and granulomatous lesions have developed that have been mistaken for neoplastic tumors.
PAK	1988	Plasma expanders containing polyvidone were withdrawn. (Reference: (PAKMH) Ministry of Health, Special Education and Social Welfare,,, Aug. 1988)
EGY		Registration of injectable preparations containing polyvidone with a molecular weight greater than 12000 are not approved because such preparations can cause painful granulomatous lesions at the site of administration. Currently registered products were reformulated to exclude this product. **WHO comment:** Polyvidone, a polymer of vinylpyrrolidinone, is an excipient used as a suspending and dispersing agent. Injectable preparations containing polymers with a molecular weight in the order of 12,000 have caused painful local granulomatous lesions. This has led to the withdrawal of polyvidone from such preparations in some countries. Polyvidone was formerly also used as a plasma expander but, because it was sequestered within the liver and spleen, this use has been discontinued. However, it remains widely used as a vehicle for ophthalmic preparations, and as the major component of artificial tears.

Product name **Potassium canrenoate**

C.A.S. number **2181-04-6**

Scientific and common names, and synonyms

ALDADIENE POTASSIUM
POTASSIUM 17-HYDROXY-3-OXO-17alpha-PREGNA-4,6-DIENE-21-CARBOXYLATE
PREGNA-4,6-DIENE-21-CARBOXYLIC ACID, 17-HYDROXY-3-OXO, POTASSIUM SALT (17alpha)-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	Sep. 1986	The indications for preparations containing potassium canrenoate are restricted having regard to the possible carcinogenic risk associated with long-term use. All combination products containing potassium canrenoate have been withdrawn. (Reference: (DEUAB) Deutsches Aertzteblatt, 83,, 1986) **WHO comment:** Potassium canrenoate, which has no intrinsic aldosterone antagonist activity, owes its therapeutic effect to the enzymatic interconversion in the body to canrenone. Evidence that long-term administration of high doses are tumorigenic in the rat has recently led to restriction of its use by some national regulatory authorities. See also WHO comments for canrenone and spironolactone.

Product name **Potassium chloride**

C.A.S. number **7447-40-7**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BEL	1982	Having regard to their association with ulceration of the gastrointestinal tract, fast-acting tablet formulations of potassium salts, including potassium chloride, are prohibited. Sustained-release tablets, tablets intended to be dissolved and liquid formulations remain available.
FRA	31 Mar. 1989	Fast-acting tablets containing potassium chloride have been withdrawn, in the light of evidence that rapid release of potassium can induce intestinal perforation. (References: (FRARP) La Revue Prescrire, 8(80), 492, 1988; (FRARP) La Revue Prescrire, 9(82), 59, 1989) **WHO comment:** Potassium chloride has been used for many years to correct potassium deficiency. The use of fast-acting tablets has been associated with lesions of the gastro-intestinal mucosa, which have led to their general withdrawal.

Product name **Potassium nitrate**

C.A.S. number **7757-79-1**

Scientific and common names, and synonyms

NITRE
SALTPETRE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
FRA	Jan. 1981	Having regard to their obsolescence in clinical medicine and the potential carcinogenic risk attached to excessive use of nitrates, medicinal preparations of potassium nitrate were withdrawn from the market.
EGY	Mar. 1984	No registration licence is to be granted for oral pharmaceutical preparations containing potassium nitrate to avoid any carcinogenic risk resulting from excessive use of nitrates.
VEN		Not approved for use and/or sale.

...(Continued)

Legislative or regulative action

Product name **Potassium nitrate** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Potassium nitrate was formerly used as a diuretic. Its use for this purpose is now considered obsolete but it is still available in at least one country for the correction of potassium deficiency. It is aslo widely permitted at concentrations of the order of 5% in proprietary toothpastes. In some countries the drug has been banned due to a potential carcinogenic risk arising from the excessive use of nitrates and their transformation to nitrosamines.

Product name **Practolol**

C.A.S. number **6673-35-4**

Scientific and common names, and synonyms

ACETAMIDE, N-(4-(2-HYDROXY-3-((1-METHYLETHYL)AMINO)PROPOXY)PHENYL)-
4'-(2-HYDROXY-3-(ISOPROPYLAMINO)-PROPOXY)ACETANILIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
FIN	1975	Restricted for use only in cases of cardiac dysrhythmias due to the oculo-mucocutaneous syndrome. The only available preparation is a solution for intravenous use.
GRC	1975	Withdrawn from the market.
TUR	1975	Withdrawn from the market by the Ministry of Health due to published evidence of its harmful effects on hearing and on the eyes and skin. Export of this product is prohibited.
NZL	Mar. 1975	Voluntarily withdrawn from the market.
SWE	1 May 1975	An intravenous preparation remains on the market for treatment of selected cardiac dysrhythmias.
DNK	1 July 1975	Registration has been cancelled for the product in tablet form. Administration by injection is allowed. (Reference: (UGLAAD) Ugeskrift for Laeger, 137, 1016, Apr. 1975)
THA	Dec. 1975	Products containing this ingredient have been banned.
SGP	July 1976	Banned for importation.
GBR	1977	This substance except for the intravenous preparation has been withdrawn from use by the company following evidence of oculo-mucocutaneous syndrome.
MUS	9 Mar. 1982	Under the Pharmacy and Poisons (Prohibitions of Harmful Drugs) Regulations, this drug is deemed "harmful" by the Ministry of Health and is prohibited for import, manufacture, storage, distribution, sale, possession, use, export or other transaction. (Reference: (MPPHD) Pharmacy & Poisons (Prohibitions of Harmful Drugs) Regulations,,, Mar. 1982)
IND	1983	Prohibited for manufacture and sale for reasons of health risks associated with use and/or questionable therapeutic value. (Reference: (GAZIE) The Gazette of India: Extraordinary, II-3i,, 23 July 1986)
DEU	25 Mar. 1994	The Federal Health Office has suspended the marketing authorization for pharmaceutical products containing orgotein on the grounds that unjustifiable risk outweighs the benefits. The Agency has received about 400 reports of adverse reactions - 90 of these repors describe serious hypersensitivity reactions, some of which were fatal. (Reference: (DEUPD) BGA Pressedienst, 19/1994,, 30 Mar. 1994)
NOR	1995	Preparations for oral use were withdrawn from the market in 1975. Preparations for parenteral use have been withdrawn from the market.
VEN		Banned due to undesirable effects.

...(Continued)

Legislative or regulative action

Product name **Practolol** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Practolol, a beta-adrenoreceptor antagonist, was introduced in 1970 for the treatment of angina and cardiac dysrhythmias. By 1974 long-term use had been associated with serious delayed idiosyncratic reactions (oculo-mucocutaneous syndrome) and this led to the withdrawal of oral preparations by the major manufacturer on a worldwide basis. There is no evidence to suggest that other beta-adrenoreceptor antagonist are associated with this risk. Intravenous preparations of practolol remain available in many countries for the emergency treatment of selected cardiac dysrhythmias.

Product name **Prasterone**

C.A.S. number **53-43-0**

Scientific and common names, and synonyms

DEHYDROANDROSTERONE
DEHYDROEPIANDROSTERONE
DHEA
3beta-HYDROXYANDROST-5-EN-17-ONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	1985	The Food and Drug Administration has withdrawn products containing prasterone on grounds of lack of information on efficacy and safety of long-term use. These products, which were available without prescription, were promoted for weight reduction, enhanced sexual function and extension of life. (Reference: (HHSNS) HHS News: US Department of Health and Human Services,,, Apr. 1985) **WHO comment:** The World Health Organization has no information further to the above regarding preparations containing prasterone or to indicate that such preparations remain available.

Product name **Prenylamine**

C.A.S. number **390-64-7**

Scientific and common names, and synonyms

BENZENEPROPANAMINE, N-(1-METHYL-2-PHENYLETHYL)-GAMMA-PHENYL-N-(3,3-DIPHENYLPROPYL)-ALPHA-METHYLPHENETHYLAMINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
@WD	31 Mar. 1989	Following reports of polymorphic ventricular tachycardia that led to withdrawal of prenylamine in the United Kingdom and the Federal Republic of Germany, the manufacturer has decided to withdraw the product from the market worldwide from 31 March 1989. **WHO comment:** Prenylamine is a calcium-channel blocking agent which was introduced in 1960. It has been widely used for the prophylaxis of angina pectoris and long-term treatment of coronary heart disease. Concern about its propensity to induce dangerous cardiac dysrhythmias led the company to withdraw it from the market.

Product name **Progabide**

C.A.S. number **62666-20-0**

Scientific and common names, and synonyms

BUTANAMIDE, 4-(((4-CHLOROPHENYL)(5-FLUORO-2-HYDROXYPHENYL)METHYLENE) AMINO)-
4-((alpha-(P-CHLOROPHENYL)-5-FLUOROSALICYLIDENE)AMINO)BUTYRAMIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
FRA	17 Mar. 1986	Following the development of icteric hepatitis in patients taking progabide, the major manufacturer advised doctors that its use should be restricted to patients unresponsive to other anticonvulsants. **WHO comment:** Progabide, an anticonvulsant, was introduced in France in 1985 for the treatment of epilepsy. Its use has occasionally been associated with clinically evident signs of icteric hepatitis developing within the first six months of treatment. These signs are generally reversible on withdrawal of the drug but continuation of treatment has been associated with three reported fatalities (two of which are doubtfully related to the drug). The manufacturer revised the data sheet in March 1986 advising that use of progabide should be reserved for patients unresponsive to other anticonvulsants.

Product name **Propafenone**

C.A.S. number **54063-53-5**

Scientific and common names, and synonyms

1-PROPANONE, 1-(2-(2-HYDROXY-3-(PROPYLAMINO)PROPOXY)PHENYL)-3-PHENYL-
2'-(HYDROXY-3-(PROPYLAMINO)PROPOXY)-3-PHENYLPROPIOPHENONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
JPN	Sep. 1990	Products containing propafenone were restricted to the treatment of patients unsuitable for or unresponsive to other antiarrhythmic agents, on the grounds that they had been associated with cases of ventricular tachycardia and fibrillation, some of which were fatal. (Reference: (JPNARD) Information on Adverse Reactions to Drugs, 104,, Sep. 1990)
MYS	Feb. 1991	The indications for products containing propafenone were restricted to the suppression of life-threatening ventricular arrhythmias, including sustained ventricular tachycardia, on the grounds that their potential to induce adverse effects must be assumed to be similar to that of encainide and flecainide. (Reference: (MYSDN) Berita Ubat-Ubatan (Drug Newsletter), 5(1):2,, 1991) **WHO comment:** Propafenone, a membrane-stabilizing antiarrhythmic agent, was introduced into medicine in the mid 1980s. Shortly afterwards, its use became associated with cases of severe cardiac arrhythmias, which led to notable restrictions in the drug's indications in at least two countries. See also WHO comment for flecainide.

Product name **Propionic acid**

C.A.S. number **79-09-4**

Scientific and common names, and synonyms

PROPANOIC ACID

...(Continued)

Product name **Propionic acid** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1987	Having regard to proliferative lesions associated with administration of high dosages of propionic acid to experimental animals, the Federal Health Office restricted its use as a preservative and prohibited its use in bread. (Reference: (BGHBL) Bundesgesundheitsblatt, 30(10), 370, 1987)

Product name **Propofol**

C.A.S. number **2078-54-8**

Scientific and common names, and synonyms

DISOPROFOL
2,6-BIS(1-METHYLETHYL)PHENOL
2,6-DI-ISOPROPYLPHENOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ISR	1992	The Ministry of Health has not approved propofol for use in children. (Reference: (ISRMH) Ministry of Health, Israel,,, 29 June 1992)
NOR	6 Apr. 1992	The use of propofol for long term sedation in children was not approved in Norway. The drug authorities in Norway strongly advised Norwesgian hospitals not to use propofol in children. (Reference: (NORMCA) Norwegian Medicines Control Authority,,, 6 Apr. 1992)
GBR	June 1992	The Committee on Safety of Medicines reminded doctors that the use of propofol for sedation in children has not been evaluated and, in light of serious and sometimes fatal reactions, such use is not recommended. (Reference: (GBRCSM) Committee on Safety of Medicines, Current problems, 34,, June 1992) **WHO comment:** Propofol, a short acting injectable anaesthetic, was introduced in 1987. In April 1992, the Norwegian Medicines Control Board reported that prolonged use of propofol had been associated with two fatalities in children characterized by metabolic acidosis, liver enlargement, and cerebral oedema. The UK Committee on the Safety of Medicines has received 5 reports of deaths occurring in children who had received propofol while in intensive care.

Product name **Propylhexedrine**

C.A.S. number **3595-11-7**

Scientific and common names, and synonyms

CYCLOHEXANEETHANAMINE, N,alpha-DIMETHYL-(+/-)
(+/-)-N,alpha-DIMETHYLCYCLOHEXANEETHYLAMINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	July 1981	Administration of centrally active appetite inhibiting preparations containing propylhexedrine has been restricted to four weeks. A warning concerning the risk of dependence has been included in the package leaflet.

...(Continued)

Legislative or regulative action

Product name **Propylhexedrine** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Propylhexedrine, a sympathomimetic amine, has been widely available since 1949 in over-the-counter inhalants for nasal decongestion and in oral anorexic preparations. As dependence can occur and because abuse has been reported, propylhexedrine was subjected in 1986 to control under Schedule IV of the 1971 Convention on Psychotropic Substances. (Reference: (WHTAC2) 2nd Expert Committee on Drug Dependence (IV),,, 1971)

Product name **Propyphenazone**

C.A.S. number **479-92-5**

Scientific and common names, and synonyms

ISOPROPYLANTIPYRINE
4-ISOPROPYL-2,3-DIMETHYL-1-PHENYL-3-PYRAZOLIN-5-ONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
TUR	Jan. 1986	Banned for production and sale having regard to severe adverse reactions.
ITA	1989	Having regard to the adverse effects associated with their long-term use, products containing propyphenazone may now be indicated only for the short-term treatment of severe pain or pyrexia. (Reference: (BIFTI) Bolletino d'Informazione sui Farmaci, 13(2), 5, 1989)
ARE		Pharmaceutical preparations containing propyphenazone are banned.
BHR		Preparations containing propyphenazone have been withdrawn.
IRL		Following the occurrence of a case of fatal aplastic anaemia in a patient taking a propyphenazone-containing product for a prolonged period, the regulatory authority requested that the product be reformulated to exclude this ingredient.
		WHO comment: Propyphenazone, a pyrazolone derivative with anti-inflammatory, analgesic and antipyretic activity, was introduced in 1951 for the treatment of rheumatic disorders. As it is structurally related to aminophenazone it has been associated with severe blood dyscrasias. However, it cannot be transformed into potentially carcinogenic nitrosamines and has therefore been widely used as a replacement drug for aminophenazone. In certain countries, products containing propyphenazone have now been restricted in their indications, whereas in others they are still available, sometimes as over-the-counter preparations. See also WHO comment for aminophenazone.

Product name **Pyritinol**

C.A.S. number **1098-97-1**

Scientific and common names, and synonyms

PYRITHIOXINE
3,3'-(DITHIODIMETHYLENE)BIS(5-HYDROXY-6-METHYL-4-PYRIDINEMETHANOL)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BGD	1982	Under the provisions of the Drugs (Control) Ordinance, this product has been banned due to evidence of insufficient therapeutic value and risk of misuse. (Reference: (BGDCO) The Drugs (Control) Ordinance,,, 1982)

...(Continued)

Legislative or regulative action

Product name **Pyritinol** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Pyritinol, which is claimed to promote the uptake of glucose in the brain, is used in the treatment of cerebrovascular disorders. However, WHO is not aware of controlled experimental data to show that it has any therapeutic effect.

Product name **Pyrrolizidine**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1992	The Federal Health Office has decided to withdraw certain medicines containing pyrrolizidine alkaloids with a 1,2 unsaturated necine structure which occur in the cells of many plant species on the grounds that they are potentially carcinogenic and hepatotoxic. (Reference: (DEUPZ) Pharmazeutische Zeitung, 137(32):2400,, 1992)
BEL	2 Sep. 1992	The Minister of Social Integration, Public Health and the Environment decided to prohibit the use of medicinal products derived from plants containing pyrrolizidine alkaloids having regard to the potential of these substances to induce veno-occlusive liver disease, pulmonary and central nervous system toxicit, as well as their potential carcinogenicity, mutagenicity and teratogenicity. (Reference: (BELMD) Ministerial Decree,,, 2 Sep. 1992)
GBR	20 Mar. 1993	Tablet and capsule formulations of comfrey containing pyrrolizidine alkaloids have been voluntarily withdrawn from the market following reports of liver toxicity. (Reference: (GBRPHJ) The Pharmaceutical Journal, 377,, 20 Mar. 1993)
		WHO comment: Plants containing pyrrolizidine alkaloids have traditionally been made into teas in the Caribbean and South-East Asia and several of these active substances have been incorporated into medicines for use in treatment for a variety of illnesses. The decision to prohibit use of these products was based on their association with a variety of adverse effects and on their hepatotoxic and carcinogenic potential as seen in both laboratory animals and in communities that commonly use plants containing these compounds to prepare teas and other beverages.

Product name **Remoxipride**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
@WD	1994	The manufacturer of the antipsychotic dopamine antagonist, remoxipride, has decided to withdraw the product licence worldwide following concern about an association with its use and aplastic anaemia. It will, however, remain available on a compassionate basis for named patients.

Product name **Retinol**

C.A.S. number **68-26-8**

Scientific and common names, and synonyms

AXEROPHTHOCUM
VITAMIN A
3,7-DIMETHYL-9-(2,6,6-TRIMETHYL-1-CYCLOHEXEN-1-YL)-2,4,6,8-NONATETRAEN-1-OL

...(Continued)

Legislative or regulative action

Product name **Retinol** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1 Apr. 1989	Oral dosage forms of products containing vitamin A (retinol) are required to bear the following warnings: 1) preparations bearing a maximum recommended daily dosage of more than 25000 IU: "Because of danger of congenital malformations, not allowed during pregnancy nor for women of childbearing age." 2) preparations bearing a maximum recommended daily dosage of 10000 IU to 25000 IU: "Contraindicated during pregnancy because of danger of congenital malformations." 3) preparations bearing a maximum recommended daily dosage of 10000 IU: "Pregnant women should not exeed the recommended daily dosage except on medical advice." (References: (DAZ) Deutsche Apotheker Zeitung, 128(41), 85, 1988; (DAZ) Deutsche Apotheker Zeitung, 129(2), 4, 1989) **WHO comment:** Vitamin A, a fat-soluble vitamin, is used in the treatment and prevention of vitamin A deficiency resulting from inadequate dietary intake. It has been demonstrated to be teratogenic at high doses (more than 25000 IU per day). Daily dosages of less than 10000 IU seem to be free of this risk.

Product name **Rubiae tinctorum radix**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	29 Apr. 1992	The Federal Health Office has decided to revoke the marketing authorization of all medicinal products containing derivatives of Rubiae tinctorum radix, including lucidin and other derivatives of anthraquinone. (Reference: (DEUFHO) Communication from Federal Health Office,,, 29 Apr. 1992) **WHO comment:** Extracts of Rubiae tinctorum radix have traditionally been used as treatment for a variety of diseases. Regulatory action has been taken because insufficient evidence has been gathered about its efficacy. Lucidin (1,2-dihydroxyanthraquinone), a component of Rubia tinctorum, has been shown in animal experiments to induce both benign and malignant tumours in the gastric and intestinal mucosa. Lucidin is positive for the Ames test indicating possible genotoxicity.

Product name **Santonin**

C.A.S. number **481-06-1**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SGP	Oct. 1978	Importation prohibited. **WHO comment:** Santonin, a crystalline lactone obtained from flowerheads of species of Artemisia, was formerly used as an anthelminthic. Its use was associated with a range of adverse effects, mainly involving the sense organs and the central nervous system, some of which were fatal. It has been superseded by other less toxic and more effective anthelminthics.

Product name **Scopolamine**

C.A.S. number **51-34-3**

Scientific and common names, and synonyms

BENZENEACETIC ACID, alpha-(HYDROXYMETHYL)-,9-METHYL-3-OXA-9-AZATRICYCLO(3.3.1.0.???)NON-7-YL ESTER,(7(S)-(1alpha, 2beta,4beta,5alpha,7beta)-
HYSOCINE
6beta,7beta-EPOXY-1alphaH,5alphaH-TROPAN-3alpha-OL(-)-TROPATE (ESTER)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NOR	1 Mar. 1988	Depot plasters containing scopolamine have been subjected to prescription control, on the grounds of adverse effects including visual disturbances, hallucinations and glaucoma. (Reference: (NNSLM) Nytt fra Statens Legemiddelkontroll, 2, 8, 1988) **WHO comment:** Scopolamine, an alkaloid with anticholinergic activity extracted from solanaceous plants, was introduced into medicine in 1888. It is used as a mydriatic, as an antiemetic for the control of motion sickness, and for premedication in general anaesthesia. Shortly after their introduction in the early 1980's, transdermal delivery systems containing scopolamine that were indicated for the prevention of motion sickness were associated with visual disorders (e.g. mydriasis, glaucoma) and hallucinations. The action taken in Norway is in accordance with the legislation in several other countries where these preparations have always been subjected to prescription control.

Product name **Secobabital**

C.A.S. number **76-73-3**

Scientific and common names, and synonyms

QUINALBARBITONE
2,4,6(1H,3H,5H)-PYRIMIDINETRIONE, 5-(1-METHYLBUTYL)-5-(2-PROPENYL)-
5-ALLYL-5-(1-METHYLBUTYL) BARBITURIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GHA	1 Sep. 1989	Products containing secobarbital have been banned. (Reference: (GHAPDR) Pharmacy and Drugs (Banned Drugs) Regulations, Legislative Instruments, 1484,, 1989)
NZL	1990	In agreement with the Department of Health, products containing secobarbital sodium have been withdrawn bythe manufacturer. (Reference: (NZCSL) Clinical Services Letter, Department of Health, 258,, 16 July 1990)
OMN	May 1991	Import and marketing of products containing secobarbital were prohibited. (Reference: (OMNCR) Circular, 16/91,, May 1991) **WHO comment:** Secobarbital is a short to intermediate-acting barbiturate which is controlled under Schedule III of the 1971 Convention on Psychotropic Substances. See WHO comment for barbiturates. (Reference: (UNCPS3) United Nations Convention on Psychotropic Substances (III),,, 1971)

Product name **Silver acetate**

C.A.S. number **563-63-3**

Scientific and common names, and synonyms

ARGENTI ACETATE

...(Continued)

Legislative or regulative action

Product name **Silver acetate** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
CYP	23 Oct. 1992	The Drugs Council rejected a marketing application for a lozenge preparation containing silver acetate intended as a smoking deterrent. (Reference: (CYPPS) Pharmaceutical Services, Ministry of Health,,, 23 Oct. 1992) **WHO comment:** Silver acetate has been used as a disinfectant and as an anti-smoking aid. It was refused registration in Cyprus on the grounds that prolonged use of silver salts can cause permanent argyria and that no well-controlled trials have been performed to establish the safety and efficacy of the preparation. It remains registered as an aid to stopping smoking in Canada and the United States.

Product name **Sodium dibunate**

C.A.S. number **14992-59-2**

Scientific and common names, and synonyms

SODIUM 2,6-DI-TERT-BUTYL-1(OR 3)-NAPHTHALENESULFONATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
PHL	Apr. 1982	Withdrawn from use as an antitussive following demonstration of central nervous system toxicity in experimental mice. Prolonged administration in humans results in reduction in granular leukocytes.

Product name **Somatropin (pituitary-derived)**

C.A.S. number **12629-01-5**

Scientific and common names, and synonyms

GROWTH HORMONE, HUMAN
HGH
SOMATOTROPHIN
SOMATOTROPIN
STH

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
CYP	1985	Voluntarily withdrawn by Kabi Vitrum following reports of deaths associated with its use.
IRL	1985	Some preparations containing growth hormone derived from human pituitary have been withdrawn while use of others is severely restricted.
ISR	1985	The Ministry of Health has decided that no patients should be newly placed on growth hormone therapy unless they are suffering from associated hypoglycaemia. (Reference: (ISRDB) Israel Drug Information Bulletin,,, Feb. 1987)
NZL	1985	Preparations of somatropin (growth hormone) extracted from human pituitary glands have been withdrawn by the Department of Health following reports of Creutzfeldt-Jakob disease associated with their use. (Reference: (NZCSL) Clinical Services Letter, Department of Health)
BEL	May 1985	The National Commission for Pituitary Dwarfism has advised doctors not to prescribe somatropin (human growth hormone) following reports of Creutzfeldt-Jakob disease associated with their use. (Reference: (BFOLP) Folia Pharmacotherapeutica, 12(6), 46, 1985)
GBR	May 1985	Withdrawn following reports of deaths associated with its use.

...(Continued)

Legislative or regulative action

Product name **Somatropin (pituitary-derived)** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NLD	May 1985	The use of products containing pituitary-derived human growth hormone (somatropin) was discontinued following reports of Creutzfeldt-Jakob disease associated with their use.
DDR	July 1985	Preparations of somatropin (growth hormone) have been withdrawn following reports of death in the USA associated with their use. (Reference: (DDRMH) Regulation of Ministry of Health,,, July 1985)
EGY	9 July 1985	Withdrawn from the market.
USA	Aug. 1985	The Food and Drug Administration has withdrawn the licence of the National Pituitary Agency for manufacture of human growth hormone preparations following reports of death associated with their use. (Reference: (FDADB) FDA Drug Bulletin, 15(2), 17-18, 1985)
DEU	Sep. 1985	The Federal Health Office has informed doctors to restrict the use of human somatropin (growth hormone) to the treatment of pituitary dwarfism with hypoglycaemic reactions or before the end of the growth period. Preparations must bear a warning that some patients contracted Creutzfeldt-Jakob disease after treatment. No more than three batches should be used for each patient.
TUR	Oct. 1985	Banned for production, import, export, sale and use having regard to severe adverse reactions.
OMN	16 Jan. 1986	Import of pharmaceutical preparations containing somatropin (human growth hormone) has been prohibited following reports of Creutzfeldt-Jakob disease associated with their use. (Reference: (OMNMH) Ministry of Health, 2,, 1986)
ITA		The manufacture and use of somatropin (human growth) hormone have been restricted following reports of Creutzfeldt-Jakob disease associated with its use.
THA		Preparations containing somatropin are not approved for use.
		WHO comment: Somatropin, a pituitary-derived human growth hormone, has been used in the treatment of hypopituitary dwarfism for over twenty years. In 1985 it became known that Creutzfeldt-Jakob disease, a potentially fatal form of brain degeneration resulting from a slow neurotropic viral infection, had developed in several patients who had received preparations of somatropin in the late 1960s/early 1970s. This led to the withdrawal of these preparations in many countries. An international collaborative effort was maintained to identify newly-diagnosed cases. By 1990 a total of 30 such cases had been notified. More efficient purification procedures introduced during the 1970s greatly reduced the risk of viral contamination, but products containing pituitary-derived somatropin have been superseded by biosynthetically-manufactured preparations produced using recombinant techniques.

Product name **Spironolactone**

C.A.S. number **52-01-7**

Scientific and common names, and synonyms

PREGN-4-ENE-21-CARBOXYLIC ACID, 7-(ACETYLTHIO)-17-HYDROXY-3-OXO,gamma- LACTONE, (7alpha,17alpha)-17-HYDROXY-7alpha-MERCAPTO-3-OXO-17alpha-PREGN-4-ENE-21-CARBOXYLIC ACID, gamma-LACTONE ACETATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GBR	Oct. 1986	Having regard to the possible carcinogenic risk associated with long-term use of spironolactone, the approved indications of products containing spironolactone are now restricted to cirrhosis with ascites and oedema, malignant ascites, nephrotic syndrome, the diagnosis and treatment of primary hyperaldosteronism, and congestive heart failure.

...(Continued)

Product name **Spironolactone** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Spironolactone, an aldosterone antagonist, has been widely used for over 25 years in the treatment of hypertension and in the management of refractive oedema. Evidence that long-term administration of high doses are tumorigenic in the rat has recently led to restriction of its use by some national regulatory authorities although the significance of this finding with respect to clinical use is not certain. In 1987 spironolactone was transferred from the main list to the complementary list of the WHO Model List of Essential Drugs. (See also WHO comments for canrenone and potassium canrenoate). (Reference: (WHODI) WHO Drug Information, 2(1),, 1988)

Product name **Streptomycin**

C.A.S. number **57-92-1**

Scientific and common names, and synonyms

D-STREPTAMINE, O-2-DEOXY-2-(METHYLAMINO)-alpha-L-GLUCOPYRANOSYL-(1->2)-O-5-DEOXY-3-C-FORMYL-alpha-L-LYXOFURANOSYL-(1->4)-N,N'-BIS(AMINOIMINOMETHYL)-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
KOR	May 1991	Antidiarrhoel products containing streptomycin were not accepted for registration. (Reference: (KRMHSA) Ministry of Health and Social Affairs - Communication to WHO,,, 13 Dec. 1991)
LBN	3 Aug. 1991	Liquid formulations of products containing streptomycin indicated for the treatment of diarrhoea in children were withdrawn. (Reference: (LBNMHD) Ministry of Health and Social Affairs Decree, 150/1,, Aug. 1991)
		WHO comment: Oral preparations of streptomycin, an aminoglycoside antibiotic isolated from streptomyces griseus in 1944, were formerly widely used to treat intestinal infections. There is no evidence that streptomycin is effective in this indication and its widespread use promotes the emergence of resistant strains of bacteria. The World Health Organization recommends that streptomycin should not be used for the treatment of diarrhoea. (Reference: (WHORUD) The Rational Use of Drugs,,, 1990)

Product name **Strychnine and salts**

C.A.S. number **57-24-9**

Scientific and common names, and synonyms

STRICNINA (ITA)
STRYCHNIDIN-10-ONE
STRYCHNIN (DEU)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
CAN	1979	The Health Protection Branch has considered the value of strychnine in drugs for human use and concluded that this substance has no established therapeutic significance. S.C. 01.038 of the Food and Drug Act states that "A drug for human use is adulterated if it contains: a) strychnine or any of its salts, b) extracts or tinctures of 1) Strychnos nux-vomica 2) Strychnos ignatii or 3) Strychnos species containing strychnine, other than those species mentioned in sub paragraph 1) and 2)".

...(Continued)

Legislative or regulative action

Product name **Strychnine and salts** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BRA	17 July 1980	Products containing strychnine are prohibited. (Reference: (BRAPT) Portaria do Servico Publico Federal, (12),, 1980)
BGD	Mar. 1982	Under the provisions of the Drugs (Control) Ordinance, this product has been banned. Authorities feel that "Strychnine should only be used as a rodenticide". (Reference: (BGDCO) The Drugs (Control) Ordinance,,, 1982)
JPN	1987	Preparations containing strychnine have been withdrawn.
PAK	Jan. 1987	The Registration Board of the Ministry of Health has directed manufacturers to reformulate all preparations containing strychnine so as to delete this ingredient.
ARE		Pharmaceutical preparations containing strychnine are banned.
PHL		Products containing strychnine are banned for use and sale.
		WHO comment: Strychnine, the principal alkaloid present in nux vomica, was first used in medicine several centuries ago. However, it has no demonstrated therapeutic value and there is no current justification for its presence in any medication. It continues to be used as a rodenticide though such use is severely restricted in many countries since accidental ingestion can be lethal.

Product name **Sulfacarbamide**

C.A.S. number **547-44-4**

Scientific and common names, and synonyms

SULFANILYLUREA

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1992	The Federal Health Office withdrew products containing sulfacarbamide from the market. This decision is based on a review carried out by the Advisory Panel for the Evaluation of Medicines which concluded that the benefit/risk ratio for these products is negative. (References: (DAZ) Deutsche Apotheker Zeitung, 132(11),, 1992; (DWM) Wichtige Mitteilungen, 18,, 1992)
		WHO comment: Sulfacarbamide, a sulfonamide anti-infective agent, was introduced in the 1940's for the treatment of bacterial infections. The importance of sulfonamides has subsequently decreased as a result of increasing bacterial resistance and their replacement by antibiotics which are generally more active and less toxic. The Sulfacarbamide are known to cause serious adverse effects such as renal toxicity, sometimes fatal exfoliative dermatitis and erythema multiforma and dangerous adverse reactions affecting blood formation such as agranulocytosis and haemolytic or aplastic anaemia. Sulfacarbamide still remains available in at least one country for the treatment of urinary infections.

Product name **Sulfadicramide**

C.A.S. number **115-68-4**

Scientific and common names, and synonyms

3-METHYL-N-SULPHANILYLCROTONAMIDE

...(Continued)

Legislative or regulative action

Product name **Sulfadicramide** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1992	The Federal Health Office has withdrawn products containing sulfanilamide from the market. This decision is based on a review carried out by the Advisory Panel for the Evaluation of Medicines which concluded taht the benefit/risk ratio for these products is negative. (References: (DAZ) Deutsche Apotheker Zeitung, 132(11),, 1992; (DWM) Wichtige Mitteilungen, 18,, 1992) **WHO comment:** Sulfadicramide, a sulfonamide anti-infective agent, was introduced in 1942 for the treatment of bacterial infections. The importance of sulfonamides has subsequently decreased as a result of increasing resistance and their replacement by antibiotics which are generally more active and less toxic. The sulfonamides are known to cause serious adverse effects such as renal toxicity, sometimes fatal exfoliative dermatitis and erythema multiforma and dangerous adverse reactions affecting blood formation such as agranulocytosis and haemolytic or aplastic anaemia. Sulfadicramide is still used in some countries as a 15% ointment for application to the eye.

Product name **Sulfadimidine**

C.A.S. number **57-68-1**

Scientific and common names, and synonyms

SULFADIMERAZINE
SULFADIMETHYLPYRIMIDINE
SULFADIMEZINIUM
SULFADIMIDINUM
SULFAMETHAZINE
4-(4,6-DIMETHYLPRIMIDINE-2-YL)SULPHANILIMIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1992	The Federal Health Office has withdrawn products containing sulfadimidine from the market. This decision is based on a review carried out by the Advisory Panel for the Evaluation of Medicines which concluded that the benefit/risk ratio for these products is negative. (References: (DAZ) Deutsche Apotheker Zeitung, 132(11),, 1992; (DWM) Wichtige Mitteilungen, 18,, 1992) **WHO comment:** Sulfadimidine, a sulfonamide anti-infective agent, was introduced in 1942 for the treatment of bacterial infections. The importance of sulfonamides has subsequently decreased as a result of increasing resistance and their replacement by antibiotics which are generally more active and less toxic. The sulfonamides are known to cause serious adverse effects such as renal toxicity, sometimes fatal exfoliative dermatitis and erythema multiforma and dangerous adverse reactions affecting blood formation such as agranulocytosis and haemolytic or aplastic anaemia. Sulfadimidine is still used in some countries as a injectable or oral antimicrobial for susceptible infections.

Product name **Sulfaguanidine**

C.A.S. number **57-67-0**

Scientific and common names, and synonyms

BENZENESULFONAMIDE, 4-AMINO-N-(DIAMINOMETHYLENE)-
N-AMIDINOSULPHANILAMIDE MONOHYDRATE
N1-(DIAMINOMETHYLENE)SULFANILAMIDE
SULFAMIDINUM
SULGINUM

...(Continued)

Legislative or regulative action

Product name **Sulfaguanidine** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DOM	June 1971	Prohibited for import, manufacture, distribution, storage, sale or medical prescription. It has been found to be ineffectual in the treatment of acute bacterial dysentery and in therapeutic use with colon surgery in reducing hospitalization. Furthermore, it has been shown that most strains of Shigella have developed a resistance against this drug in vivo.
IRN	1972	The Ministry of Health has prohibited the importation and production of all drugs containing sulfaguanidine.
THA	Jan. 1975	May only be used in the treatment of diarrhoea.
TUR	4 Mar. 1985	Banned for production and sale having regard to severe adverse reactions.
PAK	1988	Tablets containing sulfaguanidine were withdrawn. (Reference: (PAKMH) Ministry of Health, Special Education and Social Welfare,,, 3 Aug. 1988)
NPL	1991	Products containing sulfaguanidine either alone or in combination, and intended for the treatment of diarrhoea in children, were banned. (Reference: (NPLDDA) Communication from the Department of Drug Administration,,, 27 Feb. 1992)
DEU	1992	The Federal Health Office has withdrawn products containing sulfaguanidine from the market. This decision is based on a review carried out by the Advisory Panel for the Evaluation of Medicines which concluded that the benefit/risk ratio for these products in negative. (References: (DAZ) Deutsche Apotheker Zeitung, 132(11),, 1992; (DWM) Wichtige Mitteilungen, 18,, 1992)
DNK		Withdrawn from the market by the manufacturer.
VEN		Not approved for use and/or sale. Compound currently under study.

WHO comment: Sulfaguanidine, a sulfonamide anti-infective agent, was introduced in 1941 for the treatment of bacterial infections. The importance of sulfonamides has subsequently decreased as a result of increasing bacterial resistance and their replacement by antibiotics which are generally more active and less toxic. The sulfonamides are known to cause serious adverse effects such as renal toxicity sometimes fatal exfoliative dermatitis and erythema multiforma and dangerous adverse reactions affecting blood formation such as agranulocytosis and haemolytic or aplastic anaemia. Although sulfaguanidine, which is poorly absorbed from the gastrointestinal tract, is no longer recommended in some countries, it continues to be used in others for the treatment of local intestinal infections, including bacterial dysentery, and for pre-operative bowel preparation.

Product name **Sulfamerazine sodium**

C.A.S. number **127-58-2**

Scientific and common names, and synonyms

SOLUBLE SULPHERAMERAZINE
SULFAMERAZINUM NATRICUM

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1992	The Federal Health Office has withdrawn products containing sulfamerazine sodium from the market. This decision is based on a review carried out by the Advisory Panel for the Evaluation of Medicines which concluded that the benefit/risk ratio for these products is negative. (References: (DAZ) Deutsche Apotheker Zeitung, 132(11),, 1992; (DWM) Wichtige Mitteilungen, 18,, 1992)

...(Continued)

Product name **Sulfamerazine sodium** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Sulfamerazine sodium, a sulfonamide anti-infective agent, was introduced several decades ago for the treatment of bacterial infections. The importance of sulfonamides has subsequently decreased as a result of increasing resistance and their replacement by antibiotics which are generally more active and less toxic. The sulfonamides are known to cause serious adverse effects such as renal toxicity, sometimes fatal exfoliative dermatitis and erythema multiforma and dangerous adverse reactions affecting blood formation such as agranulocytosis and haemolytic or aplastic anaemia. Sulfamerazine is still used in some countries usually in combination with other sulfonamides.

Product name **Sulfamethizole**

C.A.S. number **144-82-1**

Scientific and common names, and synonyms

BENZENESULFONAMIDE, 4-AMINO-N-(5-METHYL-1,3,4-THIADIAZOL-2-YL)-
N1-(5-METHYL-1,3,4-THIADIAZOL-2-YL)-SULFANILAMIDE
N1-(5-METHYL-1,3,4-THIADIAZOL-2-YL)SULPHANILAMIDE
SULPHAMETHIZOLE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	1 Feb. 1984	Withdrawn following discussions between the manufacturer and the National Board of Health and Welfare. A combination of adverse reactions and low sales led to this decision. **WHO comment:** Sulfamethizole, a sulfonamide anti-infective agent, was introduced in 1953 for the treatment of bacterial infections. The importance of sulfonamides has subsequently decreased as a result of increasing bacterial resistance and their replacement by antibiotics which are generally more active and less toxic. However sulfamethizole, which is rapidly eliminated, retains a place in the treatment of urinary infections in some countries whereas in others its use has been discontinued.

Product name **Sulfamethoxypyridazine**

C.A.S. number **80-35-3**

Scientific and common names, and synonyms

N1-(6-METHOXYPYRIDAZIN-3-YL)SULPHANILAMIDE
N1-(6-METHOXY-3-PYRIDAZINYL)SULFANILAMIDE
SULPHAMETHOXYPYRIDAZINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	1 Feb. 1984	Withdrawn following discussions between the manufacturer and the National Board of Health and Welfare. A combination of adverse reactions and low sales led to this decision.
PAK	1988	Products containing sulfamethoxypyridazine were withdrawn. (Reference: (PAKMH) Ministry of Health, Special Education and Social Welfare,,, 3 Aug. 1988)
ARE		Pharmaceutical preparations containing sulfamethoxypyridazine are banned.

...(Continued)

Product name **Sulfamethoxypyridazine** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Sulfamethoxypyridazine, a sulfonamide anti-infective agent, was introduced in 1957 for the treatment of bacterial infections. The importance of sulfonamides has subsequently decreased as a result of increasing bacterial resistance and their replacement by antibiotics which are generally more active and less toxic. The sulfonamides are known to cause serious adverse effects such as renal toxicity, sometimes fatal exfoliative dermatitis and erythema multiforma and dangerous adverse reactions affecting blood formation such as agranulocytosis and haemolytic or aplastic anaemia. Commercial manufacture of the drug has been discontinued by at least one major manufacturer but supplies can still be obtained on special request, particularly for patients with dermatitis herpetiformis in which condition it has been claimed to be beneficial.

Product name **Sulfanilamide**

C.A.S. number **63-74-1**

Scientific and common names, and synonyms

SOLFAMMIDE
STREPTOCIDIN
SULFAMINUM
SULFANILAMIDUM
4-AMINOBENZENESULPHONAMIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1992	The Federal Health Office has withdrawn products containing sulfanilamide from the market. This decision is based on a review carried out by the Advisory Panel for the Evaluation of Medicines which concluded that the benefit/risk ratio for these products is negative. (References: (DAZ) Deutsche Apotheker Zeitung, 132(11),, 1992; (DWM) Wichtige Mitteilungen, 18,, 1992) **WHO comment:** Sulfanilamide, a sulfonamide anti-infective agent, was introduced in 1936 for the treatment of bacterial infections. The importance of sulfonamides has subsequently decreased as a result of increasing resistance and their replacement by antibiotics which are generally more active and less toxic. The sulfonamides are known to cause serious adverse effects such as renal toxicity, sometimes fatal exfoliative dermatitis and erythema multiforma and dangerous adverse reactions affecting blood formation such as agranulocytosis and haemolytic or aplastic anaemia. Sulfanilamide is still used in some countries as a pessaries or as vaginal cream.

Product name **Sulfathiazole**

C.A.S. number **72-14-0**

Scientific and common names, and synonyms

BENZENESULFONAMIDE, 4-AMINO-N-2-THIAZOLYL
NORSULFAZOLUM
N1-(THIAZOL-2-YL)SULPHANILAMIDE
N1-2-THIAZOLYLSULFANILAMIDE
SULFANILAMIDOTHIAZOLUM
SULFONAZOLUM

...(Continued)

Product name **Sulfathiazole** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	Sep. 1970	Sulfathiazole has been withdrawn as an ingredient in products for systemic use due to the known serious hazards associated with this compound. The Food and Drug Administration has determined that the benefit/risk ratio associated with this compound is unfavourable especially in the light of the availability of other sulfonamides with equivalent benefits and less risk. Prohibited for export. (Reference: (FEREAC) Federal Register, 35, 16190, Oct. 1970)
PHL	May 1971	The use of this drug as an antidiarrhoeal has been withdrawn due to the risk of crystalluria.
DOM	Mar. 1982	Preparations containing sulfathiazole or its sesquihydrate or monohydrate as the active ingredient have been prohibited for use and/or sale since they have been associated with serious side effects and shown to be of questionable efficacy. **WHO comment:** Sulfathiazole, a sulfonamide anti-infective agent, was introduced more than 25 years ago for the treatment of bacterial infections. The importance of sulfonamides has subsequently decreased as a result of increasing bacterial resistance and their replacement by antibiotics which are generally more active and less toxic. The sulfonamides are known to cause serious adverse effects such as renal toxicity, sometimes fatal exfoliative dermatitis and erythema multiforma and dangerous adverse reactions affecting blood formation such as agranulocytosis and haemolytic or aplastic anaemia. Although preparations remain available, use of the drug has been discontinued in many countries.

Bibliographical references

WHO FOOD ADD., 25, 95, 1991

Product name **Sulfisomidine**

C.A.S. number **515-64-0**

Scientific and common names, and synonyms

N-(2,6-DIMETHYLPYRIMIDIN-4-YL)SULPHANILAMIDE
SULFAISODIMIDINE
SULFASOMIDINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1992	The Federal Health Office has withdrawn products containing sulfisomide from the market. This decision isbased on a review carried out by the Advisory Panel for the Evaluation of Medicines which concluded that the benefit/risk ratio for these products is negative. (References: (DAZ) Deutsche Apotheker Zeitung, 132(11),, 1992; (DWM) Wichtige Mitteilungen, 18,, 1992) **WHO comment:** Sulfisomide, a sulfonamide anti-infective agent, was introduced several decades ago for the treatment of bacterial infections. The importance of sulfonamides has subsequently decreased as a result of increasing resistance and their replacement by antibiotics which are generally more active and less toxic. The sulfonamides are known to cause serious adverse effects such as renal toxicity, sometimes fatal exfoliative dermatitis and erythema multiforma and dangerous adverse reactions affecting blood formation such as agranulocytosis and haemolytic or aplastic anaemia. Sulfisomide is still used topically in some countries for vaginal infection.

Product name **Sulfonamides (topical preparations)**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
CHL		Pharmaceutical preparations for topical use containing sulfonamide and its derivatives are prohibited. (Reference: (CHLRS) Resolution of the Minister of Health, No.10154,, Oct. 1986)

Product name **Suloctidil**

C.A.S. number **54767-75-8**

Scientific and common names, and synonyms

BENZENEMETHANOL, 4-((1-METHYLETHYL)THIO)-alpha-(1-(OCTYLAMINO)ETHYL-, (R*,S*)-
ERYTHRO-P-(ISOPROPYLTHIO)-alpha-(1-(OCTYLAMINO)ETHYL)BENZYL ALCOHOL
1-(4-ISOPROPYLTHIOPHENYL)-2-OCTYLAMINOPROPAN-1-OL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
@WD	1985	Suloctidil, a vasodilator, was voluntarily withdrawn worldwide by the manufacturer following several reports of hepatitis associated with its use, some of which were fatal.
DEU	July 1985	The Federal Office of Health has not renewed its approval for suloctidil following reports of hepatitis. Meanwhile the manufacturer stopped the sale of this drug and recalled all distributed packages.
AUT	Oct. 1985	The Federal Ministry of Health and Environmental Protection prohibited the use of preparations containing suloctidil following reports of hepatotoxic effects.
CYP		Voluntarily withdrawn by the manufacturer following reports of hepatitis. **WHO comment:** Suloctidil, a peripheral vasodilator, was introduced in 1975 for the treatment of arterial disease. By 1985 its use had been associated with serious adverse effects, including deaths from hepatitis. In July 1985 renewal for approval was refused in the Federal Republic of Germany. This was followed by the voluntary withdrawal of the drug by the manufacturer firstly in several European countries and ultimately on a worldwide basis.

Product name **Sultopride**

C.A.S. number **53583-79-2**

Scientific and common names, and synonyms

N-((1-ETHYL-2-PYRROLIDINYL)METHYL)-5-(ETHYLSULFONYL)-O-ANISAMIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
FRA	Oct. 1991	The Ministry of Health extended the contraindications for products containing sultopride to patients withbradycardia and hypokalaemia; to those receiving drugs that may induce bradycardia, hypokalaemia, impairment of intracardiac conduction and ventricular arrhythmias; and to breastfeeding women. The association of sultopride with other phenothiazines was also discouraged. A warning was required in the product information stating that patients with severe cardiovascular disorders are at risk of hypotension and cardiac arrhythmias. These amendments to the approved product information were made following reports of ventricular arrhythmias in patients treated with sultopride. (Reference: (FRAMHH) Ministry of Health and Humanitarian Action,,, 11 Dec. 1992)

...(Continued)

Product name **Sultopride** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Sultopride, a neuroleptic indicated for the treatment of acute and chronic psychoses, was introduced on the market in 1976. In the early 1990s, its use was associated with cardiac arrhythmias, some of which were fatal. This led the regulatory authority in France to take restrictive action on the product. Sultopride continues to be marketed in several other countries.

Product name **Suprofen**

C.A.S. number **40828-46-4**

Scientific and common names, and synonyms

BENZENACETIC ACID, alpha-METHYL-4-(2-THIENYLCARBONYL)-
PARA-2-THENOYLHYDRATROPIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
@WD		The manufacturer has suspended sales worldwide. **WHO comment:** Suprofen, a nonsteroidal anti-inflammatory agent, was introduced in 1983 for use as an analgesic for the symptomatic relief of mild to moderate pain and for primary dysmenorrhoea. By 1986 it had become evident that its use was occasionally associated with flank pain sometimes accompanied by evidence of decreased renal function. The Arthritis Advisory Committee of the United States Food and Drug Administration met in December 1986 to review the situation and decided against withdrawing suprofen from the market. However, in May 1987 the Committee for Proprietary Medicinal Products of the European Community recommended that all marketing authorizations should be suspended. The manufacturer subsequently decided to suspend sale worldwide on the grounds that sales had diminished to the point where the product was no longer economically viable.

Product name **Suxibuzone**

C.A.S. number **27470-51-5**

Scientific and common names, and synonyms

4-BUTYL-(4-HYDROXYMETHYL)-1,2-DIPHENYL-3,5-PYRAZOLIDINEDIONE HYDROGEN SUCCINATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
JPN	July 1977	Indications are restricted to severe exacerbations of rheumatoid arthritis, osteoarthritis and ankylosing spondylitis. Doctors are advised to prescribe this drug only to adults and for periods of no longer than one week.
DEU	1985	Indications are restricted to severe exacerbations of rheumatism and acute gout. Duration of oral treatment should not exceed one week. Parenteral preparations are indicated only for initiating therapy. A single injection only is recommended because local tissue damage may occur. Preparations are contraindicated in children under 14 years of age.
OMN	Sep. 1986	The Ministry of Health has prohibited the import of preparations containing suxibuzone except those intended for topical use.
ITA		Withdrawn from the market owing to an unfavourable risk-benefit ratio and the lack of substantial evidence of efficacy.

...(Continued)

Legislative or regulative action

Product name **Suxibuzone** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Suxibuzone, a pyrazolone derivative with anti-inflammatory, analgesic and antipyretic activity, was introduced in 1974 for the treatment of rheumatic disorders. As it is structurally related to phenylbutazone, it is subjected to rigorously restricted indications by some national regulatory authorities. See WHO comment for phenylbutazone.

Product name **Tartrazine**

C.A.S. number **1934-21-0**

Scientific and common names, and synonyms

CI FOOD YELLOW 4
COLOUR INDEX NO. 19140
E 102
FD&C YELLOW NO.5
TARTRAZOL YELLOW
TRISODIUM 5-HYDROXY-1-(4-SULPHONATOPHENYL)-4-(4-SULPHONATOPHENYLAZO) PYRAZOLE-3-CARBOXYLATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GRC	1984	Not allowed in antihistamines and bronchodilators. All other products must bear a warning about allergic reactions.
NZL	Aug. 1984	The inclusion of tartrazine in medicines for internal use will be phased out over the next two years having regard to its allergenic potential. It can be used in products for external use. (Reference: (NZCSL) Clinical Services Letter, Department of Health, 224,, Jan. 1984)
IRL	1985	Products intended for the management of allergic states and for prolonged use should be reformulated to exclude tartrazine. Use of tartrazine should be discouraged in all other preparations and where it is present it should be declared on the label. (Reference: (IRDAB) National Drugs Advisory Board Annual Report,,, 1985)
HUN	31 Mar. 1990	Tartrazine is no longer accepted as a colouring agent in pharmaceutical products submitted for registration. In registered products it must be replaced by 31 December 1992 and, in the meantime, these products must bear the warning: "This preparation contains tartrazine which may cause allergic reactions in sensitized individuals". (Reference: (HUNIP) National Institute of Pharmacy,,, 8 Feb. 1990)
		WHO comment: Tartrazine is widely used as a permitted colouring agent in food and pharmaceutical preparations. Its use has been associated with allergic reactions some of which have been severe. Several national drug regulatory authorities now require a warning on labels of products containing tartrazine and some manufacturers have voluntarily withdrawn this compound from their products.

Product name **Temafloxacin**

C.A.S. number **108319-06-8**

Scientific and common names, and synonyms

(+/-)-(2,4-DIFLUOROPHENYL)-6-FLUORO-1,4-DIHYDRO-7-(3-METHYL-1-PIPERAZINYL)-4-OXO-3-QUINOLINECARBOXYLIC ACID

...(Continued)

Legislative or regulative action

Product name **Temafloxacin** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
@WD	June 1992	Products containing temafloxacin were withdrawn worldwide by the manufacturer, having regard to severe adverse reactions associated with their use, some of which were fatal. (Reference: (HHSNS) HHS News: US Department of Health and Human Services, P92-16,, 5 June 1992)
OMN	22 June 1992	Products containing temafloxacin will not be allowed for import and marketing. (Reference: (OMNCR) Circular, 25/92,, June 1992)

WHO comment: Temafloxacin, a quinolone antimicrobial, was introduced in 1991. Shortly afterwards, its use became associated with severe adverse effects, including hypoglycaemia, haemolytic anaemia, renal failure, hepatitis and anaphylactic reactions. This led to its worldwide withdrawal by the manufacturer.

Product name **Terconazole**

C.A.S. number **67915-31-5**

Scientific and common names, and synonyms

cis-1-(p-((2-(2,4-DICHLOROPHENYL)-2-(1H-1,2,4-TRIAZOL-1-YLMETHYL)-1,3-DIOXOLAN-4-YL)METHOXY)PHENYL)-4-ISOPROPYLPIPERAZINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	Dec. 1988	The marketing authorization of vaginal suppositories containing 160 mg terconazole has been suspended, having regard to reports of fever, shivering, headace and circulatory reactions associated with their use. Lower dose formulations remain available. (Reference: (BGHBL) Bundesgesundheitsblatt, 12, 492, 1988)
SWE	1 July 1991	The marketing authorization for vaginal suppositories containing 80 mg and 160 mg terconazole was withdrawn, after these preparations had been associated with febrile reactions, often accompanied by influenza-like symptoms. (Reference: (SWEILS) Information från Läkemedelsverket, 2(3), 158, 1991)

WHO comment: Terconazole, an antifungal agent, was introduced into medicine in 1980. It is indicated for the treatment of vaginal candidiasis. It is not yet clear whether the adverse effects associated with high dose formulations are due to terconazole itself, to an excipient in the preparation or to fungal constituent.

Product name **Terodiline**

C.A.S. number **15793-40-5**

Scientific and common names, and synonyms

BENZENEPROPANAMINE, N-(1,1-DIMETHYLETHYL)-alpha-METHYL-gamma-PHENYL-
N-TERT-BUTYL-1-METHYL-3,3-DIPHEYLPROPYLAMINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
@WD	1992	Products containing terodiline were withdrawn from the market worldwide by the manufacturer, following reports of cardiac adverse reactions, including ventricular tachycardia, heart block and bradycardia associated with their use. (Reference: (DCCKB) Drug company communication - Kabi Pharmacia,,, 26 Sep. 1991)

...(Continued)

Legislative or regulative action

Product name **Terodiline** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision

WHO comment: Terodiline, an anticholinergic and calcium-channel blocking agent, was first introduced into medicine in the mid 1960s for the treatment of angina pectoris. In 1986, it was registered for the indication of urinary incontinence. In 1991, its use in urinary incontinence was reported to be associated with severe cardiac arrhythmias. This led to a temporary withdrawal in a few Member States in 1991, followed by a final withdrawal by the manufacturer in 1992.

Product name **Testosterone propionate (injectable)**

C.A.S. number **57-85-2**

Scientific and common names, and synonyms

ANDROST-4-EN-3-ONE, 17-(1-OXOPROPOXY)-, (17beta)-
TESTOSTERONE PROPIONATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BGD	1982	Under the provisions of the Drugs (Control) Ordinance, low dosage forms (100mg ampoules) were banned on grounds of inadmissable promotion and misuse. Higher dosage forms (250mg ampoules) remain available for use in selected patients under medical supervision. (Reference: (BGDCO) The Drugs (Control) Ordinance,,, 1982)

WHO comment: In 1982, low dosage preparations of testosterone propionate, a synthetic ester of the naturally-occurring androgen, testosterone, were prohibited in Bangladesh following their inadmissable promotion as anabolic agents for use in malnourished children. Higher dosage preparations of testosterone propionate remain available in many countries, including Bangladesh, for several highly specific but limited indications including hypogonadism and the palliative treatment of inoperable breast cancer.

Product name **Tetracycline (paediatric)**

C.A.S. number **60-54-8**

Scientific and common names, and synonyms

2-NAPHTHACENECARBOXAMIDE, 4-(DIMETHYLAMINO)-1,4,4A,5,5A,6,11,12A- OCTAHYDRO-3,6,10,12,12A-PENTAHYDROXY-6-METHYL-1,11-DIOXO- (4S-(4alpha,4Aalpha,5Aalpha,6beta,12Aalpha))
4-(DIMETHYLAMINO)-1,4,4A,5,5A,6,11,12A-OCTAHYDRO-3,6,10,12,12A- PENTAHYDROXY-6-METHYL-1,11-DIOXO-2-NAPHTHACENECARBOXAMIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
JOR	1973	The Ministry of Health withdrew syrup formulations of tetracyclines (mixtures, suspension or drops) particularly intended for pediatric use on the grounds that tetracyclines interfere with the growth of bones and teeth in infants.
PER	1974	The package insert and/or label for this product requires a warning that its use may be dangerous in nursing infants, children under 3 years of age and pregnant women, due to the drug's well known effects on bone formation.
ITA	1975	Preparations for rectal use have been withdrawn from the market owing to their non-constant absorption. Since 1979, labels of concentrated liquid preparations have warned about possible dischromic effects on tooth enamel.

...(Continued)

Product name **Tetracycline (paediatric)** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
PHL	1978	Preparations containing chlortetracycline, oxytetracycline, tetracycline, demeclocycline, rolitetracycline, methacycline, doxycycline, minocycline, and other tetracycline derivatives in the form of syrup (mixture or suspension) or drops particularly intended for pediatric use are no longer acceptable. (Reference: (PHADO) Administrative Order, 342,, 1978)
USA	2 Jan. 1979	Tetracycline drops intended for pediatric use have been withdrawn from the market. Doctors have been advised that liquid preparations of tetracycline and its congeners should not be administered to pregnant women or children under 9 years of age. (Reference: (FEREAC) Federal Register, 43(211), 50676, 1978)
GHA	1980	Paediatric preparations have been banned.
ARE	9 June 1981	Tetracyclines in syrups and paediatric drops are banned. (Reference: (UAEMD) Ministry of Health Decree, No.694,, 1981)
BGD	1982	Under the provisions of the Drugs (Control) Ordinance, tetracycline syrups have been banned as they are harmful to children and pregnant mothers; they disturb bone growth of children up to 12 years of age and discolour teeth. (Reference: (BGDCO) The Drugs (Control) Ordinance,,, 1982)
SDN	1982	The Ministry of Health no longer allows registration of tetracycline syrups. Syrups will only be available to government health units for specific treatment.
IND	1983	Liquid oral dosage preparations have been prohibited for manufacture and sale for reasons of health risks associated with use and/or questionable therapeutic value. (Reference: (GAZIE) The Gazette of India: Extraordinary, II-3i,, 23 July 1986)
OMN	Sep. 1985	Tetracycline pediatric suspension has been prohibited for import, selling and marketing.
PAK	1988	Products containing tetracyclines for paediatric use, including tetracycline, oxytetracycline and doxycycline were withdrawn. (Reference: (PAKMH) Ministry of Health, Special Education and Social Welfare,,, 3 Aug. 1988)
CHL	31 Aug. 1990	All products containing tetracycline, demeclocycline, doxycycline, metacycline, exytetracycline or other tetracycline derivatives were required to bear a warning stating that they should not be administered to children under 8 years of age, or to pregnant or lactating women. (Reference: (BMCHL) Boletin Informativo Sobre Medicamentos, 8(1), 14, 1991)
NPL	1991	Liquid oral preparations containing tetracycline, and intended for the treatment of diarrhoea in children, were banned. (Reference: (NPLDDA) Communication from the Department of Drug Administration,,, 27 Feb. 1992)
AUS		The Australian Drug Evaluation Committee has recommended that all pediatric formulations of tetracyclines should be withdrawn from the market in view of their propensity to stain teeth and retard bone growth. (Reference: (AUDEC) Report of the Australian Drug Evaluation Committee, No.71)
BEL		Preparations containing tetracyclines intended for internal use must carry a warning stating that the preparation should not be administered to children under eight years of age or to pregnant women after the fourth month of pregnancy except on medical advice.
NZL		Pediatric preparations have been voluntarily withdrawn.
SAU		Following reports indicating interference with bone growth and teeth in infants the use of all tetracycline preparations is prohibited in pregnant women and children below twelve years of age.

...(Continued)

Product name **Tetracycline (paediatric)** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: The first tetracycline antibiotic, chlortetracycline, was introduced in 1948 and subsequently several semisynthetic derivatives have been used as antibacterial, antiamoebic and antirickettsial agents. All tetracyclines accumulate in the developing bones and teeth of the foetus and young children which can result in retarded bone growth and dental staining. Preparations intended specifically for children have been withdrawn in some countries, whereas in others warnings are required on the label advising against administration of tetracyclines to young children and pregnant women. Non-paediatric dosage forms of tetracycline remain in the WHO Model List of Essential Drugs. (Reference: (WHTAC1) Model List of Essential Drugs, 2nd Report of the WHO Expert Committee,, 722, 1985)

Product name **Thalidomide**

C.A.S. number **50-35-1**

Scientific and common names, and synonyms

alpha-(N-PHTHALIMIDO)GLUTARIMIDE
N-(2,6-DIOXO-3-PIPERIDYL)PHTHALIMIDE
1H-ISOINDOLE-1,3(2H)-DIONE, 2-(2,6-DIOXO-3-PIPERIDINYL)-

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BEL	1963	Pharmaceutical preparations containing thalidomide were prohibited in 1963. In 1983 they were reintroduced for limited use in special circumstances.
FIN	1963	Prohibited due to its well-known teratogenic effects.
IDN	1963	Prohibited for importation, production, sale and distribution by the Ministry of Health.
CAN	July 1984	Total ban under S.15 of the Food and Drugs Act has been revoked. Thalidomide is now available on a limited basis, upon specific authorization for emergency purposes only.
BRA	4 July 1994	The Ministry of Health has issued an Order prohibiting the prescription of thalidomide for women of childbearing age. This action has been taken in consideration of the risks of teratogenic effects of thalidomide associated with indiscriminate use of the product. (Reference: (BRACVS) Centro de Vigilancia Sanitaria, 63,, 4 July 1994)
DNK		Prohibited for import, production, sale and distribution by the Ministry of Health.
IND		Prohibited for import due to the lack of substantial evidence of safety and/or efficacy, except for specially authorized use in leprosy patients in leprosy hospitals excluding women patients of childbearing age.
NZL		This product is a controlled drug and is available on a very restricted basis.
SGP		Banned for importation.
VEN		Not approved for use and/or sale.
		WHO comment: Notwithstanding the highly potent teratogenic action of thalidomide, this drug retains a place in the treatment of reactional lepromatous leprosy and several serious dermatological conditions refractory to other treatment. In many countries, the competent authorities have granted exemption from licensing requirements to enable doctors to obtain limited supplies of thalidomide under strictly controlled circumstances for use in named patients. Arrangements have also been made by some national drug regulatory authorities for thalidomide to be used in institutions concerned with the treatment of leprosy.

Product name **Thenalidine**

C.A.S. number **86-12-4**

Scientific and common names, and synonyms

THENOPHENOPIPERIDINE
1-METHYL-4-N-2-THENYLANILINOPIPERIDINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	17 July 1958	Thenalidine was withdrawn in the United States of America after four cases of severe neutropenia, two of which were fatal, were reported in patients treated continuously over periods of several months.
GBR	1961	Thenalidine was withdrawn in the United States of America after four cases of severe neutropenia, two of which were fatal, were reported in patients treated continuously over periods of several months. It was subsequently withdrawn in the United Kingdom.
SWE	Apr. 1976	Withdrawn following reports of neutropenia associated with its use.
FRA	16 June 1978	Voluntarily withdrawn following reports of neutropenia associated with its use.
CYP	1980	Products containing thenalidine were withdrawn following reports of neutropenia associated with their use.
AUS		Voluntarily withdrawn following reports of neutropenia associated with its use.
FIN		Voluntarily withdrawn following reports of neutropenia associated with its use.
NOR		Withdrawn following reports of neutropenia associated with its use.
VEN		Not approved for use and/or sale.
		WHO comment: Thenalidine, a piperidine antihistamine, was introduced in 1953 for the management of dermatologic and allergic conditions. By 1958 its use had been associated with cases of severe neutropenia, two of them fatal, which led to its withdrawal in the United States of America and subsequently in the United Kingdom. Over the next fifteen years, continued reports of its association with cases of neutropenia resulted in further withdrawals in many countries. It is apparently still available, however, in some combination products. (Reference: (WHODI) WHO Drug Information, 1, 5, 1979)

Product name **Ticlopidine**

C.A.S. number **55142-85-3**

Scientific and common names, and synonyms

THIENO(3,2-C)PYRIDINE, 5-((2-CHLOROPHENYL)METHYL)-4,5,6,7-TETRAHYDRO-
5-(o-CHLOROBENZYL)-4,5,6,7-TETRAHYDROTHIENO-(3,2-C)PYRIDINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1983	Registered solely for the treatment of haemodialysis patients, with shunt complications, who are intolerant to acetylsalicylic acid. A full blood count should be made before treatment and every 14 days, then subsequently every month throughout treatment.
GRC	1984	Use is restricted to patients with severe renal damage who do not tolerate acetylsalicylic acid having regard to the occurrence of severe blood reactions.
ITA		Approved indications for use have been restricted to antithrombotic therapy in haemodialysis, peripheral obliterating arteriopathy, thrombosis of the central retinal vein, maintenance of extracorporeal circulation and aortic-coronary by-pass. Haematological monitoring is advised throughout treatment. (Reference: (BIFTI) Bolletino d'Informazione sui Farmaci, (3),, 1984)

...(Continued)

Legislative or regulative action

Product name **Ticlopidine** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Ticlopidine, an inhibitor of platelet aggregation, was introduced in 1978 for use as an antithrombotic agent. By 1982 its use had been associated with cases of agranulocytosis, severe leucopenia and impaired haemostasis. The drug remains available in most countries in which it was approved with appropriate warnings in the product information.

Product name **Tienilic acid**

C.A.S. number **40180-04-9**

Scientific and common names, and synonyms

ACETIC ACID, (2,3-DICHLORO-4-(2-THIENYLCARBONYL)PHENOXY)-
TICRYNAFEN
(2,3-DICHLORO-4-(2-THENOYL)-PHENOXY)ACETIC ACID
(2,3-DICHLORO-4-(2-THIENYLCARBONYL)PHENOXY)-ACETIC ACID
4-(2-THENOYL)-2,3-DICHLOROPHENOXYACETIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GRC	1980	The Ministry of Health and Welfare has withdrawn this product from domestic use. (Reference: (GRAGA) Ministry of Health Decision, 12946,, Dec. 1980)
PHL	Jan. 1980	Withdrawn by the manufacturer after reports from other countries that prolonged use in some patients resulted in deaths due to liver dysfunction.
USA	30 Jan. 1980	Withdrawn from the market following reports of liver toxicity.
BRA	31 Jan. 1980	Products containing tienilic acid are prohibited. (Reference: (BRAPT) Portaria do Servico Publico Federal, (01),, Nov. 1980)
DEU	Dec. 1980	Voluntarily withdrawn from the market following cases of hepatic failure some of which were fatal.
PAN	10 Apr. 1981	The Ministry of Health has banned the sale of pharmaceuticals and cosmetics containing tienilic acid. (Reference: (PANMR) Ministry of Health Resolution, 28,, Apr. 1981)
FRA	1991	Voluntarily withdrawn from the market by the manufacturer, following reports of hepatitis associated with its use. (Reference: (FRARP) La Revue Prescrire, 12(114), 28, 1992)
IND		Not approved for marketing after withdrawal in the United States following reports of liver toxicity.
VEN		Not approved for use and/or sale.
		WHO comment: Tienilic acid, a diuretic agent with uricosuric and antihypertensive activity, was introduced in 1976. By 1979 its use had been associated with cases of hepatic toxicity, some of which were fatal, which led to the withdrawal of the drug in most countries in which it was marketed. In France, however, precautions regarding the use of tienilic acid were issued by the Pharmacovigilance Commission and the drug remained available for another decade. In 1991, it was eventually also withdrawn there since cases of hepatitis, some of which were fulminant, had continued to occur.

Product name **Tocainide**

C.A.S. number **41708-72-9**

Scientific and common names, and synonyms

PROPANAMIDE, 2-AMINO-N-(2,6-DIMETHYLPHENYL)-
2-AMINO-2',6'-PROPIONOXYLIDIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
IRL	1985	Use of tocainide has been limited to named patients under the supervision of a consultant, having regard to cases of agranulocytosis associated with its use. (Reference: (IRDAB) National Drugs Advisory Board Annual Report,,, 1985)
NLD	1986	Having regard to reports of blood dyscrasias associated with its use, indications are restricted to the symptomatic treatment of ventricular dysrhythmias when other treatments fail or are contraindicated. (Reference: (NPHWB) Pharmaceutisch Weekblad, 121, 167, 1986) **WHO comment:** Tocainide, an antidysrhythmic agent, was introduced in 1981 for the treatment of ventricular dysrhythmias. By 1984 its use was associated with cases of agranulocytosis, aplastic anaemia and thrombocytopenia, some of which were fatal. This led some regulatory authorities to restrict the indications for its use. The major manufacturer has subsequently restricted its use on a worldwide basis to the treatment of symptomatic ventricular dysrhythmias not responding to other therapy, or when other therapy is contraindicated.

Product name **Tramadol**

C.A.S. number **27203-92-5**

Scientific and common names, and synonyms

CYCLOHEXANOL,2-((DIMETHYLAMINO)METHYL))-1-(3-METHOXYPHENYL)-, TRANS-(+/-)
(+/-)-TRANS 2-((DIMETHYLAMINO)METHYL)-1-(M-METHOXYPHENYL)CYCLOHEXANOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
AUT	1 Oct. 1985	The drug substance and finished preparations are subject to control at national level analogous to that provided by Schedules I and III of the 1961 Single Convention on Narcotic Drugs.

Product name **Tranylcypromine**

C.A.S. number **155-09-9**

Scientific and common names, and synonyms

CYCLOPROPANAMINE, 2-PHENYL-, TRANS-(+/-)-
TRANSAMINE SULPHATE
(+/-)-TRANS-2-PHENYLCYCLOPROPYLAMINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ITA	1964	Withdrawn from the market by the Ministry of Health.
BEL	1965	The Ministry of Health has withdrawn drugs containing tranylcypromine.
SAU		Products with this ingredient are now under strict control.

...(Continued)

Legislative or regulative action

Product name **Tranylcypromine** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
VEN		Not approved for use and/or sale. **WHO comment:** Tranylcypromine, a monoamine oxidase inhibitor (MAOI), was introduced in 1961 for the treatment of depressive illness. By 1964 its use had been associated with transient hypertensive crises and other adverse effects when taken together with certain cheeses and other foods containing tyramine. This led to the withdrawal of the drug in several countries and the suspension of marketing on a worldwide basis by the major manufacturer pending review of these adverse reactions. Subsequently, in response to requests from the medical profession, tranylcypromine was resubmitted for registration with appropriate warnings in the product information and it is now marketed in more than 30 countries.

Product name **Trazodone**

C.A.S. number **19794-93-5**

Scientific and common names, and synonyms

1,2,4-TRIAZOLO(4,3-A)PYRIDIN-3(2H)-ONE, 2-(3-(4-(3-CHLOROPHENYL)-1- PIPERAZINYL)PROPYL)-2-(3-(4-(m-CHLOROPHENYL)-1-PIPERAZINYL)PROPYL)-S-TRIAZOLO(4,3-A) PYRIDIN-3(2H)-ONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NOR	1985	Not approved for registration because the results of a two-year study in rats gave rise to suspicion of a carcinogenic effect, and carcinogenic studies in another animal species were not submitted. (Reference: (NNSLM) Nytt fra Statens Legemiddelkontroll, (1),, 1985) **WHO comment:** Trazodone, an antidepressant indicated for the treatment of a wide range of depressive illness, was introduced in 1973. Although it is registered for use in many countries with highly evolved regulatory authorities, approval for registration was not granted in Norway because of a suspicion of carcinogenicity in a two-year rat study.

Product name **Tretinoin**

C.A.S. number **302-79-4**

Scientific and common names, and synonyms

ALL-TRANS-RETINOIC ACID
RETINOIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
OMN	24 Dec. 1985	Having regard to its teratogenicity, tretinoin may only be used under the supervision and control of a hospital dermatologist. (Reference: (OMNMH) Ministry of Health, No.5,, 1985)
DEU	29 Mar. 1988	Tretinoin may no longer be included as an ingredient in cosmetic products, having regard to its teratogenic potential. (Reference: (DAZ) Deutsche Apotheker Zeitung, 128(21), 35, 1988) **WHO comment:** Tretinoin, a retinol derivative, was introduced in 1973 exclusively for the topical treatment of severe acne. Preparations of tretinoin are indicated for topical use only since oral administration has been associated with risk of toxicity from hypervitaminosis-A.

Product name **Triacetyldiphenolisatin**

C.A.S. number **18869-73-3**

Scientific and common names, and synonyms

PHENISATINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1976	Withdrawn following a review of published cases of acute and chronic liver disease. The action was consonant with decisions previously taken in a number of countries including Australia and the United States. Some other national authorities have chosen to place products containing this compound under prescription control.
ITA	1976	Preparations for oral, rectal and topical use have been withdrawn from the market due to the risk of sensitization.
CAN	1978	All preparations containing this substance were withdrawn from sale in Canada. (Reference: (CANGZ) Canada Gazette,,, May 1978)
CYP		Products containing triacetyldiphenolisatin have been withdrawn having regard to the risk of liver damage in patients receiving this drug.
NZL		Voluntarily withdrawn from the market.
VEN		Not approved for use and/or sale.
		WHO comment: Triacetyldiphenolisatin is a derivative of oxyphenisatine. See WHO comment for oxyphenisatine acetate.

Product name **Triazolam**

C.A.S. number **28911-01-5**

Scientific and common names, and synonyms

CLORAZOLAM
4H-(1,2,4)TRIAZOLO(4,3-A)(1,4)BENZODIAZEPINE, 8-CHLORO-6-(2- CHLOROPHENYL)-1-METHYL-
8-CHLORO-6-(O-CHLOROPHENYL)-1-METHYL-4H-S-TRIAZOLO(4,3-A)(1,4) BENZODIAZEPINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
MUS	9 Mar. 1982	Under the Pharmacy and Poisons (Prohibitions of Harmful Drugs) Regulations, this drug is deemed "harmful" by the Ministry of Health and is prohibited for import, manufacture, storage, distribution, sale, possession, use, export or other transaction. (Reference: (MPPHD) Pharmacy & Poisons (Prohibitions of Harmful Drugs) Regulations,,, Mar. 1982)
AUS	11 Apr. 1986	Tablets containing 0.50mg and 0.25mg triazolam were not approved by the Australian Drug Evaluation Committee, having regard to the risk of adverse effects due to inappropriate use. Tablets containing 0.125mg triazolam were approved for the treatment of insomnia. (Reference: (AUDEC) Report of the Australian Drug Evaluation Committee, 123,, Apr. 1986)
ITA	9 Mar. 1987	The marketing authorization of tablets containing 0.50 mg triazolam was withdrawn by Ministerial Decree on the basis of evidence that use of 0.50 mg tablets had caused incidents of anterograde amnesia, mental confusion and behavioural disorders. The package insert must state that the recommended dose of 0.25 mg should only be exceeded in very exceptional cases to treat particularly resistant insomnia. (Reference: (ITAMD) Ministerial Decree, No.7639/R,, Mar. 1987)
DEU	1 Apr. 1988	The Federal Health Office has decided to withdraw the registration of tablets containing 0.5 mg triazolam and the indications for tablets containing 0.25 mg have been restricted to short-term treatment of sleep disturbances.

...(Continued)

Product name **Triazolam** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
CHL	14 Mar. 1989	Products containing 0.125 mg and 0.250 mg triazolam have been subjected to prescription control and must carry the following warning: "This product may only be administered under strict medical control and supervision." These measures were taken on the grounds of reports of serious adverse psychiatric effects. (References: (BMCHL) Boletin Informativo Sobre Medicamentos, 6(1), 13, 1989; (CHLMS) Letter to WHO from the Ministerio de Salud,,, 5 Sep. 1990)
@EC	16 Oct. 1991	The Committee for Proprietary Medicinal Products recommended that the indications for products containing triazolam should be restricted to the treatment of severe disabling sleeping disorders or to insomnia causing extreme distress; duration of treatment should not exceed 2-3 weeks; the lowest effective dose should be used and a dose of 0.250 mg should not be exceeded; for the elderly, debilitated patients and patients with disturbed liver/kidney function, the dose should not exceed 0.125 mg; the compound should not be administered to patients with major psychiatric disorders; packs of not more than seven tablets should be made available. (Reference: (CPMPPS) Position Statement,,, Oct. 1991)
ESP	Dec. 1991	The marketing authorization for tablets containing 0.250 mg triazolam was suspended by the manufacturer, because of association with serious psychiatric adverse reactions, particularly anterograde amnesia.
FRA	30 Dec. 1991	The marketing authorization for tablets containing 0.250 mg triazolam was suspended, because this high dosage formulation was considered to present risks, especially amnesia, that outweigh the therapeutic benefits. Duration of treatment for tablets containing 0.125 mg was restricted to two weeks and the package size was limited to seven tablets. Tablets containing 0.5 mg triazolam had been withdrawn in the late 1980s. (Reference: (FRAMS) Ministry of Social Affairs and Integration,,, 30 Dec. 1991)
PAK	Jan. 1992	The Drug Registration Board decided that triazolam tablets should bear a warning that they are contraindicated in patients with a major psychiatric disorder. (Reference: (PAKDI) Pakistan Drug Information, 3,, Jan. 1992)
NOR	1 Feb. 1992	Following their initial suspension from the market on 4 October 1991, products containing triazolam were withdrawn because of their association with serious psychiatric adverse effects, including memory disturbances, anxiety, depression and agressivity. (Reference: (NORMCA) Norwegian Medicines Control Authority,,, 6 Oct. 1992)
JPN	Mar. 1992	The Pharmaceutical Affairs Bureau decided to reduce the recommended dosage regimen for triazolam. It is proposed that treatment should be initiated at a nightly dose of 0.125 mg or less, and that under no circumstances should the dose exceed 0.5 mg. (Reference: (JPNARD) Information on Adverse Reactions to Drugs, 113,, Mar. 1992)
BRA	5 June 1992	The Centre for Pharmacovigilance of the State of Sao Paulo prohibited the sale and use of pharmaceutical products containing triazolam. The National Secretariat for Pharmacovigilance suspended indefinitely the manufacture and marketing of such products with effect from 5 June 1992. (References: (BRAPT) Portaria do Servico Publico Federal, 59,, 5 June 1992; (BRACVS) Centro de Vigilancia Sanitaria,,, 8 June 1992; (BRADMS) Diario Oficial Ministerio da Saude,,, 8 June 1992)
CYP	23 Oct. 1992	The Drug Council withdrew the marketing licence for tablets containing 0.5 mg of triazolam and revised the product information for lower dose formulations. These products are now indicated exclusively for sleeping disorders that are "severe, disabling or cause extreme distress". (Reference: (CYPPS) Pharmaceutical Services, Ministry of Health,,, 23 Oct. 1992)
OMN	4 Nov. 1992	The Directorate General of Pharmaceutical Affairs and Drug Control has decided to suspend the sale of pharmaceutical products containing triazolam as a precautionary measure. This decision will be reviewed when further information concerning the safety of triazolam is available. (Reference: (OMNDGP) Directorate General of Phamaceutical Affairs,,, 4 Nov. 1992)
FIN	13 Jan. 1993	Following the initial suspension of registration of products containing triazolam pending a reassessment of their benefits and risks, these products were reintroduced to the market with restricted indications. Tablets of 0.125mg and 0.25mg and buccal tablets 0.2mg only are available. The indications are restricted to transient but disabling short-term insomnia. (Reference: (FINAWH) National Agency for Welfare and Health,,, 13 Jan. 1993)

...(Continued)

Product name **Triazolam** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GBR	9 June 1993	Products containing triazolam were withdrawn in 1991 because of their association with serious, though reversible psychiatric adverse effects, particularly loss of memory and depression. After several appeals to this decision, the United Kingdom Licensing Authority decided to uphold its decision to revoke the licence of all products containing triazolam. (Reference: (DCCUJC) Upjohn News Release,,, 9 June 1993) **WHO comment:** Triazolam, a benzodiazepine derivative with sedative and hypnotic activity, was introduced in 1978 for themanagement of insomnia. It is controlled under Schedule IV of the 1971 Convention of Psychotropic Substances. Concern regarding the psychotropic effects of triazolam was first raised in the Netherlands in 1979 when this compound was suspended for sale and subsequently withdrawn by the Committee for the Evaluation of Medicines on the basis of reports of a reversible complex of symptoms including paranoia, depersonalization, nightmares, suicidal tendency and hyperaesthesia in patients receiving the drug. The basis for this decision was later successfully contested by the manufacturer and the drug was reregistered in early 1990 with a revised product information. However, concern was renerated elsewhere that higher doses are associated with an unacceptable incidence of unwanted effects and the manufacturer has eventually withdrawn 0.5 mg tablets on a worldwide basis. In 1991 the issue of the safety of triazolam was again reopened by reports of retrograde amnesia and depression among patients taking the decreased recommended dosages. The product information has been revised by the United States FDA to include more rigorous cautions regarding dosage. In the Member States of the European Communities the products have been suspended pending further review by the EC Committee on Proprietary Medicinal Products. (Reference: (UNCPS4) United Nations Convention on Psychotropic Substances (IV),,, 1971)

Product name **Trimipramine**

C.A.S. number **739-71-9**

Scientific and common names, and synonyms

DIMETHYL-[3-(3-(10,11-DIHYDRO-5H-DIHENZ(B,F)AZEPIN-5-YL-2-METHYL)PROPYL]AMINE
TRIMEPRIMINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NOR	1992	The Medicines Control Authority has decided that the 50 mg tablet formulation of trimipramine may be prescribed only in hospitals and specialized clinics because of the toxic potential of these products and the risk of overdosage and suicide with the high dose formula. (Reference: (NNSLM) Nytt fra Statens Legemiddelkontroll, 1, 9, 1992) **WHO comment:** Trimipramine, a tricyclic antidepressant was introduced in 1961 for the management of endogenous depression. Much of the adverse effects are caused by its antimuscarinic actions. These include dry mouth, cardiac arrhythmias, central nervous system disturbances, blood disorders and risk of suicide. The risk of suicide and dangers related to overdosage led Norwegian Medicines Control Authority to put the higher strength formulation under prescribing restriction in 1992. The risk of death following overdosage is apparently higher for products containing tricyclic compounds as compared with nontricyclic products.

Product name **Trolamine**

C.A.S. number **102-71-6**

Scientific and common names, and synonyms

ETHANOL, 2,2',2"-NITRILOTRIS-
TRIETHANOLAMINE
2,2',2"-NITRILOTRIETHANOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
CHE	30 June 1992	Trolamine and its salts can no longer be contained in products intended for oral use, because under certain circumstances this emulsifying agent can be concerted in the stomach into carcinogenic N-nitrosamines. In products for external and parenteral use trolamine may still be used, but in strictly limited amounts. (Reference: (CHBCM) Bulletin Mensuel, 11, 760, 1990) **WHO comment:** Trolamine is widely used as an emulsifier in combination with fatty acids in pharmaceutical and cosmetic products. The World Health Organization is not aware of restrictive action having been taken elsewhere.

Product name **Urethane**

C.A.S. number **51-79-6**

Scientific and common names, and synonyms

CARBAMIC ACID, ETHYL ESTER
ETHYL CARBAMATE
ETHYLURETHANE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BRA	16 Sep. 1963	Products containing urethane are prohibited. (Reference: (BRAPT) Portaria do Servico Publico Federal, No.13,, Sep. 1963)
CUB	1964	The use of urethane both as a solvent and an antineoplastic agent was prohibited due to the availability of less toxic and more effective drugs.
DNK	1967	Registration has been cancelled. (Reference: (UGLAAD) Ugeskrift for Laeger, 136, 2093, Sep. 1974)
EGY	1975	Products containing urethane were withdrawn having regard to the carcinogenic potential of the drug.
JPN	July 1975	Banned as a co-solvent in drugs by Pharmaceutical Affairs Bureau, for reasons of carcinogenicity.
THA	Dec. 1975	Use as a stabilizer or solubilizer in drug preparations is prohibited.
USA	Mar. 1977	Withdrawn from use and/or sale by the Food and Drug Administration as an ingredient in pharmaceutical products due to its carcinogenic nature. Prohibited for export in pharmaceutical products.
ITA	1979	Withdrawn from the market owing to suspected carcinogenicity.
GRC	1980	Withdrawn as an excipient in pharmaceutical preparations.
DEU	Jan. 1982	Registration for all products containing urethane was cancelled due to the carcinogenic potential of the drug.
VEN		Not approved for use and/or sale in pharmaceutical products.

...(Continued)

Product name **Urethane** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Urethane was formerly used as an antineoplastic agent in the treatment of chronic myeloid leukaemia. It is also a mild hypnotic which has been used as an anaesthetic for veterinary practice. It has been reported to have both a carcinogenic and mutagenic potential. Although urethane continues to be used as an industrial solvent, WHO has no information to suggest that it remains commercially available in pharmaceutical preparations.

Bibliographical references

IARC MONOGRAPH, 7, 111, 1974

Product name **Vaccines for mumps, measles, and rubella**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
@WD	16 Sep. 1992	In agreement with regulatory agencies SmithKline Beecham decided to discontinue marketing all vaccines which contain the Urabe Am 9 strain of the mumps virus in those countries where an alternative vaccine containing other strains of the mumps virus is available. This decision is based on the reported incidence of meningeal reactions (1: 11,000) associated with this strain of virus. (Reference: (DCCSKB) Drug company communication - Smith Kline Beecham,,, 16 Sep. 1992)
GBR	19 Sep. 1992	The Department of Health restricted future purchasing of mumps, measles and rubella vaccine to MMR-II which is marketed by Wellcome Medical Division and contains the Jeryl Lynn (B level) strain of the mumps virus. (Reference: (GBRPHJ) The Pharmaceutical Journal, 358,, 19 Sep. 1992)
CYP	23 Oct. 1992	The Drug Council in Cyprus withdrew the marketing licence for SmithKline Beecham triple vaccine Pluserix,the mumps/measles vaccine Rimparix, the mumps vaccine Pariorix and two other MMR vaccines, Trimovax and Imovax (Pasteur Merieux). (Reference: (CYPPS) Pharmaceutical Services, Ministry of Health,,, 23 Oct. 1992)
		WHO comment: Mumpa, measles and rubella vaccine is a mixed preparation containing live attenuated strains of the measles, mumps and rubella virus. There are different strains of the mumps virus and it is suggested that meningitis may occur marginally more frequently with vaccine containing the Urabe Am 9 strain of the mumps virus than the Jeryl Lynn strain. However, a number of regulatory authorities still accept the Urabe Am 9 strain of the mumps virus on the grounds that no permanent damage arises from the aseptic meningitis.

Product name **Vigabatrin**

C.A.S. number **60643-86-9**

Scientific and common names, and synonyms

gamma-VINYL AMINOBUTYRIC ACID
gamma VINYL-GABA
4-AMINOHEX-5-ENOIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NOR	1991	The Medicines Control Authority has refused an application of registration of the anticonvulsant, vigabatrin, on grounds that the product is not medically justified. (Reference: (NNSLM) Nytt fra Statens Legemiddelkontroll, 1, 27, 1991)

...(Continued)

Product name **Vigabatrin** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Vigabatrin, an irreversible inhibitor of GABA-transaminase was introduced in 1989 as a anticonvulsant for management of epilepsy unresponsive to other antiepilepsy agents. In 1991 it was refused registration in Norway because it induced toxic changes, including microvacuolation in the brain of two animal species, at doses that are close to therapeutic dosage levels in man. It is still marketed in Seweden and the United Kingdom.

Product name **Vinbarbital**

C.A.S. number **125-42-8**

Scientific and common names, and synonyms

VINBARBITONE
5-ETHYL-5-(1-METHYLBUT-1-ENYL)BARBITURIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	July 1984	Withdrawn following discussions between the manufacturer and the National Board of Health and Welfare. Fatal intoxications and abuse are associated with use of preparations containing vinbarbital. **WHO comment:** Vinbarbital is an intermediate-acting barbiturate. See WHO comment for barbiturates.

Product name **Vincamine**

C.A.S. number **1617-90-9**

Scientific and common names, and synonyms

METHYL(3alpha,16alpha)-14,15-DIHYDRO-14beta-HYDROXYEBURNAMENINE-14- CARBOXYLATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
HUN	1980	Intravenous administration of preparations containing vincamine was prohibited, following association with cardia arrhythmias. (Reference: (HUNIP) National Institute of Pharmacy,,, 21 Aug. 1980)
DEU	1987	The Federal Health Office has withdrawn herbal preparations containing vincamine on grounds of inadequate evidence of efficacy and risk of blood dyscrasias. (Reference: (DEUPD) BGA Pressedienst, No.38,, July 1987) **WHO comment:** Vincamine, an alkaloid derived from Vinca minor, is claimed to increase cerebral circulation and utilization of oxygen. It is used in a variety of cerebral disorders and is widely marketed for this purpose.

Product name **Warfarin**

C.A.S. number **81-81-2**

Scientific and common names, and synonyms

2H-1-BENZOPYRAN-2-ONE,4-HYDROXY-3-(3-OXO-1-PHENYLBUTYL)-
3-(alpha-ACETONYLBENZYL)-4-HYDROXYCOUMARIN

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
EGY	1988	Products containing warfarin must bear a warning advising against the use during the first trimester of pregnancy, having regard to their teratogenic potential. (Reference: (EGYDI) Drug Information, 6(4), 1, 1988) **WHO comment:** Warfarin, a coumarin anticoagulant, was introduced into medicine in 1950 for the prevention and managementof thrombo-embolic disorders. Its use during the first trimester of pregnancy has been associated with birth malformations, particularly in relation to cranial and limb development, and there have been reports of foetal death due to haemorrhage following administration of the drug during the late stages of pregnancy. The decision of the Egyptian agency to requrie a warning regarding teratogenicity to be included in the approved information of products containing warfarin beings the text of the package insert in line with those approved in other countries. Warfarin is included in the WHO Model List of Essential Drugs. (Reference: (WHTAC4) The Use of Essential Drugs, 4th Report of the WHO Expert Committee, Technical Report Series, 796,, 1990)

Product name **Xenazoic acid**

C.A.S. number **1174-11-4**

Scientific and common names, and synonyms

P-((alpha-ETHOXY-P-PHENYLPHENACYL)AMINO)BENZOIC ACID
XENALAMINE
XENALMINE
4-(2-(BIPHENYL-4-YL)-1-ETHOXY-2-OXOETHYLAMINO)BENZOIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BEL	1965	The Ministry of Health has suspended the sale of drugs containing xenazoic acid.
FRA	1965	The Ministry of Health withdrew approval of xenazoic acid since liver damage had been noted during administration of this drug.
VEN		Not approved for use and/or sale. **WHO comment:** Xenazoic acid, an antiviral agent, was introduced in the early 1960s. Its use was associated with hepatic toxicity which resulted in its withdrawal from the market in at least two countries in 1965. WHO has no information to suggest that xenazoic acid remains commercially available.

Product name **Zimeldine**

C.A.S. number **56775-88-3**

Scientific and common names, and synonyms

(Z)-3-(1-p-BROMOPHENYL)-3-(DIMETHYLAMINO)PROPENYL)-PYRIDINE
2-PROPEN-1-AMINE, 3-(4-BROMOPHENYL)-N,N-DIMETHYL-3-(3-PYRIDINYL-, (Z)-

...(Continued)

Legislative or regulative action

Product name **Zimeldine** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
@WD	July 1983	This antidepressant drug was withdrawn worldwide by the manufacturer following consultations with the Swedish Department of Drugs. This action was taken in consequence of reports of hypersensitivity reactions which, in a few instances, were accompanied by neurological complications. **WHO comment:** Zimeldine, an inhibitor of serotonin uptake, was introduced in 1982 for the treatment of depressive illness. By 1983 its use had been associated with incidences of hypersensitivity of varying severity and serious neurological side effects including the Guillain-Barré syndrome. Following discussions with the National Board of Health and Welfare of Sweden, the major manufacturer decided to withdraw the drug on a worldwide basis.

Product name **Zipeprol**

C.A.S. number **34758-83-3**

Scientific and common names, and synonyms

alpha-(alpha-METHOXYBENZYL)-4-(beta-METHOXYPHENETHYL)-1- PIPERAZINEETHANOL
1-METHOXY 3-(4-(beta-METHOXYPHENETHYL)-PIPERAZIN-1-YL)-1-PHENYLPROPAN- 2-OL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
PHL	June 1982	Withdrawn from use as an antitussive since toxicological studies with rhesus monkeys have shown respiratory arrest after administration.

Product name **Ziperol**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BRA	Oct. 1993	The Brazilian Ministry of Health has withdrawn Ziperol from the market and prohibited its importation or production due to several cases of deaths among street children. (Reference: (BRASDP) Centro Brasileiro de Informacoes Sobre Drogas Psicotropicas,,, 5 Oct. 1993)

Product name **Zomepirac**

C.A.S. number **33369-31-2**

Scientific and common names, and synonyms

1H-PYRROLE-2-ACETIC ACID, 5-(4-CHLOROBENZOYL)-1,4-DIMETHYL-
5-(p-CHLOROBENZOYL)-1,4-DIMETHYLPYRROLE-2-ACETATE
5-(P-CHLOROBENZOYL)-1,4-DIMETHYLPYRROLE-2-ACETIC ACID

...(Continued)

Legislative or regulative action

Product name **Zomepirac** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
@WD	Mar. 1983	The US Food and Drug Administration has informed the World Health Organization that this non-steroidal anti-inflammatory drug has been withdrawn voluntarily from the market by the manufacturers following reports of serious allergic reactions, including five deaths from anaphylaxis. The drug was approved for marketing within the USA in October 1980. In April 1982 the labelling was revised to warn of the occurrence of allergic reactions, but because of the subsequent increase in the incidence of anaphylactoid reactions and reports of four deaths in the first three months of 1983, the company advised the FDA that it was temporarily withdrawing zomepirac worldwide pending further evaluation. **WHO comment:** Zomepirac, a nonsteroidal anti-inflammatory agent, was introduced in 1979 for the treatment of rheumatic disorders and the management of moderate to severe pain. By 1983 its use had been associated with serious allergic reactions, including five deaths from anaphylaxis. This led to voluntary withdrawal of the drug from markets worldwide by the major manufacturer.

Product name **Zopiclone**

C.A.S. number **43200-80-2**

Scientific and common names, and synonyms

4-METHYL-1-PIPERAZINECARBOXYLIC ACID ESTER WITH 6-(5-CHLORO-2-PYRIDYL)- 6,7-DIHYDRO-7-HYDROXY-5H-PYRROLO(3,4-B) PYRAZIN-5-ONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ISL	25 Feb. 1986	Zopiclone is not approved for registration on grounds of positive findings in carcinogenicity tests in animals and adverse effects in humans.
NOR	1987	Zopiclone is not approved for registration on grounds that animal studies have disclosed thyroid disorders and neoplasms. **WHO comment:** Zopiclone was introduced as a sedative in 1985. It remains registered in several countries and the World Health Organization is not aware of any other country that has refused registration.

PHARMACEUTICALS

COMBINATION PRODUCTS

Product name **Acetylsalicylic acid/codeine**

Scientific and common names, and synonyms
CODEINE/ACETYLSALICYLIC ACID

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	1 Jan. 1990	All fixed combination preparations containing acetylsalicylic acid 500 mg + codeine phosphate 10 mg have been withdrawn, on the grounds that the low dose of codeine in these preparations does not contribute to the analgesic effect, but may cause adverse effects and induce dependence. (Reference: (SSLMS) Information från Socialstyrelsens Läekemedelsavdelning, 15(2), 59, 1990)

Product name **Acetylsalicylic acid/phenacetin/caffeine (APC)**

Scientific and common names, and synonyms
APC
CAFFEINE/PHENACETIN/ACETYLSALICYLIC ACID
PHENACETIN/ACETYLSALICYLIC ACID/CAFFEINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
THA	1983	Banned for manufacture. Preparations must be reformulated to contain only acetylsalicylic acid.

Product name **Analgesics in combination**

Scientific and common names, and synonyms
ANALESICS/MEPROBAMATE
ANALGESICS/BENZODIAZEPINES

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1991	The marketing authorization for products containing analgesics in combination with benzodiazepines or neprobamate was withdrawn, because sedative components in analgesic preparations create unnecessary risks of abuse, dedation and subsequently adverse effects due to chronic misuse of the analgesics. (Reference: (DEUPZ) Pharmazeutische Zeitung, 136/8, 402, 1991)

Product name **Anorectic dugs in combinations**

Scientific and common names, and synonyms
AMFEPRAMONE,BENZFETAMINE,BENFLUOREX,FENFLURAMINE,PHENDIMETRAZINE,PHENTERMINE/TIRATRICOL/THYROID HORMONE/METFORMIN

...(Continued)

Legislative or regulative action

Product name **Anorectic dugs in combinations** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
ITA	26 May 1987	Extemporaneous preparation of products in which anorectic agents including amfepramone, benzfetamine, benfluorex, fenfluramine, phendimetrazine and phentermine are combined with tiratricol, thyroid hormone or metformin has been prohibited. Prohibition of manufacture of preparations containing anorectics in combination with other active principles. (Reference: (ITADMS) Decree of the Ministero della Sanita,,, 26 May 1987) **WHO comment:** Anotectics have been introduced many years ago for use as adjuncts to dietary control in the short-term management of obesity. Their use in combination with other drugs such as thyroid hormone, tiratricol or metformin to increase weight loss is considered inappropriate and dangerous. Although they may lead to weight loss, thyroid hormone and tiratricol should only be used in obese patients with a proven thyroid deficiency and metformin should only be administered to overweight patients suffering from diabetes. Moreover, all three drugs are associated with serious adverse effects. Extemporaneous preparations of products containing anorectics in combination with other active ingredients has been prohibited in Italy. In some other countries, although discouraged, it still remains a common practice.

Product name **Antidiarrhoeal combinations**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
OMN	1989	Import and marketing of antidiarrhoeal preparations containing antibiotics or antimicrobial agents were prohibited. (References: (OMNCR) Circular, 15/89,, 1989; (OMNCR) Circular, 31/89,, 1989)
LBN	3 Aug. 1991	Antidiarrhoeal combination preparations intended for the treatment of diarrhoea in children were not accepted for registration. (Reference: (LBNMHD) Ministry of Health and Social Affairs Decree, 150/1,, Aug. 1991)
IDN	Oct. 1991	Solid and liquid formulations of preparations containing streptomycin, kanamycin, neomycin, non-absorbable sulfonamides, hydroxyquinolines, antihistamines or vitamins intended for the treatment of diarrhoea in children were banned. (Reference: (IDMH) Ministry of Health,,, 19 Nov. 1991) **WHO comment:** The aminoglycoside antibiotics streptomycin, kanamycin and neomycin, non-absorbable sulfonamides (i.e. sulfaguanidine, succinylsulfathiazole, phthalyl- sulfathiazole) and halogenated hydroxyquinolines (e.g. clioquinol, broxyquinoline, chlorquinaldol) have been used as antidiarrhoeal agents. However, there is no satisfactory evidence that they are effective, they occasionally have been associated with severe adverse reactions and some promote the emergence of bacterial resistance. The World Health Organization recommends that they should not be used for the management of diarrhoea in children. (Reference: (WHORUD) The Rational Use of Drugs,,, 1990)

Product name **Antirheumatic combinations with glucocorticosteroids**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
AUT	Jan. 1986	Enteral preparations have been withdrawn and parenteral preparations may only be used for very limited indications and under strict medical supervision.
DEU	1 Jan. 1986	Fixed combinations have been withdrawn since concurrent administration of such drugs potentiates adverse effects without increasing benefit.

Product name **Atropine in combination**

C.A.S. number **51-55-8**

Scientific and common names, and synonyms

BENZENEACETIC ACID, ALPHA-(HYDROXYMETHYL)-8-METHYL-8-AZABICYLO(3.2.1)OCT-3-YL ESTER, ENDO(+/-)-
1ALPHA H, 5ALPHA H-TROPAN-3ALPHA-OL (+/-)-TROPATE (ESTER)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
PHL	Sep. 1976	Combinations of atropine sulfate with difenoxylate, furazolidone and dimethylpolysiloxane were withdrawn because of potential adverse reactions including dysuria (from atropine and furazolidone), tachycardia, palpitation and blurring of vision.
KOR	Dec. 1991	Products containing atropine indicated for the treatment of acute diarrhoea were banned because there are many preparations which are safer and more effective. (Reference: (KRMHSA) Ministry of Health and Social Affairs - Communication to WHO,,, 13 Dec. 1991) **WHO comment:** Atropine, an alkaloid with anticholinergic activity extracted from Atropa belladonna, has been widely used in medicines for centuries for its antispasmodic and mydriatic properties. It is also used for premedication prior to anaesthesia. Preparations containing atropine remain available and the substance is included in the WHO Model List of Essential Drugs. (Reference: (WHTAC4) The Use of Essential Drugs, 4th Report of the WHO Expert Committee, Technical Report Series, 796,, 1990)

Product name **Barbiturates in combination**

Scientific and common names, and synonyms

ANALGESICS/BARBITURATES
ANTACIDS/BARBITURATES
ANTIASTHMATICS/BARBITURATES
BARBITURATES/ANALGESICS
BARBITURATES/ANTACIDS
BARBITURATES/ANTIASTHMATICS

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
TUR	1982	Combination products with barbiturates and analgesics have been withdrawn by the Ministry of Health due to the lack of substantial evidence of efficacy and the risk of dependence. Export of these products is prohibited.
DEU	1 June 1986	The Federal Health Office has withdrawn approval for the inclusion of barbiturates in analgesic and antirheumatic preparations since their inclusion in such products serves no purpose and creates unnecessary risks of abuse and sedation.
MYS	Nov. 1986	All combination products containing barbiturates have been withdrawn. (Reference: (MYSDC) Malaysian Drug Control Authority, No.4,, Nov. 1986)
GBR		Barbiturates and antacids in combination have been withdrawn from the market by manufacturers, for general safety reasons in relation to barbiturates. Combination products with barbiturates and antiasthmatics have been withdrawn by manufacturers because barbiturates may depress respiration.

...(Continued)

Product name **Barbiturates in combination** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
		WHO comment: Barbiturates were introduced at the beginning of the 20th century and have been extensively used as sedative-hypnotic drugs. Their use in the treatment of sleep disorders and anxiety has been largely superseded by the benzodiazepines since the former have a greater liability for abuse and development of tolerance, a lower therapeutic index and a higher incidence of drug interactions and adverse effects. Although many preparations containing barbiturates remain available, some regulatory authorities have severely restricted their approved indications and withdrawn product licences for combination products containing these substances. Several are controlled under the 1971 Convention on Psychotropic Substances. The long-acting barbiturates phenobarbital and methylphenobarbital are of value in the treatment of epilepsy and several short-acting barbiturates are still used in anaesthesia. (Reference: (UNCPS) United Nations Convention on Psychotropic Substances,,, 1971)

Product name **Chloramphenicol in combination**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BEL	1980	Preparations containing chloramphenicol in combination with tetracyclines are prohibited having regard to the cumulative toxicity of the two antibiotics. (Reference: (BELAR) Arrêté Royal,,, Oct. 1980)
ESP	1 Mar. 1985	Registration of combination products containing chloramphenicol was disallowed because of the propensity of this drug to cause aplastic anaemia.
IND	3 Nov. 1988	Fixed dose oral and parenteral combination products containing chloramphenicol were banned. (Reference: (INDDHS) Directorate of Health Services,,, 11 Mar. 1992)
THA	Oct. 1989	Products containing chloramphenicol in combination with nitrofurantoin, sulfisoxazole and methylene blue have been withdrawn for reasons of increased risk of toxicity, especially blood dyscrasias, and lack of therapeutic advantage over products containing chloramphenicol only. (Reference: (THAMH) Ministry of Public Health,,, 15 Apr. 1991)

Product name **Chlormadinone acetate/mestranol (in oral contraceptives)**

Scientific and common names, and synonyms
MESTRANOL/CHLORMADINONE ACETATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	1970	Oral contraceptives containing this combination were voluntarily withdrawn from the market because of the development of breast nodules in beagle dogs administered 10 to 25 times the human dosage of active components. The beagle is especially prone to breast nodules, regularly developing these in later life. The naturally occurring nodules are generally accepted to be benign mixed tumours. However, in these studies, the treated dogs developed more nodules at an earlier age than did the control dogs which were not given the drug. Species difference in the metabolism of the chemicals and the large doses used also prevent direct transposition of these data to human beings.
SAU		Oral contraceptives with these and other ingredients are available only on a prescription basis.

...(Continued)

Legislative or regulative action

Product name **Chlormadinone acetate/mestranol (in oral contraceptives)** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
VEN		Not approved for use and/or sale as ingredients in oral contraceptives.

Product name **Cycloserine/isoniazid**

Scientific and common names, and synonyms
ISONIAZID/CYCLOSERINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DOM		This combination has been prohibited for use and/or sale since the benefits of treatment have not been found to outweigh the risks.

Product name **Dihydroergotamine/heparin**

C.A.S. number **511-12-6**

Scientific and common names, and synonyms
HEPARIN/DIHYDROERGOTAMINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	9 Feb. 1988	The approved indications of injectable preparations containing dihyroergotamine in combination with heparin have been amended to limit their use as follows: "post-operative prophylaxis against deep vein thromboses and lung embolism in pateints at high risk of thrombotic complications who have undergone elective non-traumatic surgery". This reflects the risk of vasospastic reations, some of which have necessitated limb amputation, in particular in treated patients who had undergone surgery for trauma. (In addition to the reference given, also see Farmaceutiska specialiteter i Sverige. Läkemedelsinformation AB, 23,635,1988). (References: (SSLMS) Information från Socialstyrelsens Läekemedelsavdelning, 13(4), 115, 1988; (SWEFSL) Farmaceutiska specialiteter i Sverige. Läkemedelsinformation AB, 23, 635-636, 1988)

Product name **Dihydrostreptomycin sulfate/streptomycin sulfate**

Scientific and common names, and synonyms
STREPTOMYCIN SULFATE/DIHYDROSTREPTOMYCIN SULFATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA		Combination withdrawn from the market and prohibited for export by the Food and Drug Administration on the grounds of an unfavourable benefit/risk ratio.

Product name **Dipotassium clorazepate/acepromazine/ acepromethazine**

Scientific and common names, and synonyms
ACEPROMAZINE/DIPOTASSIUM CLORAZEPATE/ACEPROMETAZINE
ACEPROMETAZINE/ACEPROMAZINE/DIPOTASSIUM CLORAZEPATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
PHL	Mar. 1983	Disapproved for use due to effects of liver toxicity and Parkinsonism. There is a lack of evidence of greater efficacy in the combination than with the component drugs given individually. Acepromazine is approved for veterinary use only.

Product name **Estrogen-progestogen preparations for secondary amenorrhea**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DNK	Oct. 1974	Use of high-dosage products has been cancelled.
DEU	1980	The Federal Health Office has withdrawn from the market relatively high-dosage combination products containing estrogens and progestogens indicated for the treatment of secondary amenorrhoea. An expert committee had emphasized the need to exclude pregnancy before such products are used, having regard to their propensity to induce abortion.
SAU		The Drug Committee has advised using these combination products only after pregnancy has been ruled out. Relatively high-dosage products are restricted for use.
VEN		Combinations for secondary amenorrhoea are not approved for use and/or sale.

Product name **Estrogens (in oral contraceptives)**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	Apr. 1988	Oral contraceptives containing more than 50 mcg of estrogen have been voluntarily withdrawn by the manufacturers, because they are associated with a higher risk of venous thrombo-embolism than low dose preparations. (Reference: (HHSNS) HHS News: US Department of Health and Human Services, P88-7,, 14 Apr. 1988) **WHO comment:** Preparations containing both an estrogen and a progestogen in fixed combination were introduced for oral contraception in 1960. In late 1960's, use of products containing more than 50 mcg of estrogen was demonstrated to be associated with an increased risk of thrombo-embolic disease. Such formulations, which offer no advantage in terms of efficacy have subsequently been largely abandoned.

Product name **Estrogens/testosterone**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BGD	1982	Under the provisions of the Drugs (Control) Ordinance, combinations of ethinyl estradiol and methyltestosterone have been banned. It has been found to be a highly misused preparation with carcinogenic properties and side effects include menstrual irregularities, increased blood pressure, uterine bleeding and others. (Reference: (BGDCO) The Drugs (Control) Ordinance,,, 1982)

Product name **Ethinylestradiol/methyltestosterone**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
BGD	1982	Combinations of ethinyl estradiol and methyltestosterone were banned under the provisions of the Drugs (Control) Ordinance. They were subject to misuse and had been associated with carcinogenic properties, menstrual irregularities, increased blood pressure and uterine bleeding. (Reference: (BGDCO) The Drugs (Control) Ordinance,,, 1982)

Product name **Etidocaine hydrocloride/epinephrine tartrate**

Scientific and common names, and synonyms

EPINEPHRINE TARTRATE/ETIDOCAINE HYDROCHLORIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
PHL	Mar. 1977	This combination, for use as an anesthetic and analgesic, has been disapproved. Hypertensive crisis may result when used on individuals with high blood pressure.

Product name **Guaifenesin/camphor/ether**

Scientific and common names, and synonyms

CAMPHOR/GUAIFENESIN/ETHER
ETHER/CAMPHOR/GUIFENESIN

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
PHL	Nov. 1983	Combinations of these ingredients mixed with an alcohol (e.g. phenol, cincol, eucalyptol, chlorobutanol) are being phased out of use since they are ineffective in cough relief and may cause lipodystrophy and lipoid pneumonia.

Product name **Hormonal pregnancy tests**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
NOR	1970	Withdrawn from the market.
USA	Feb. 1975	The combination of norethindrone acetate and ethinyl estradiol has been withdrawn from the market by the Food and Drug Administration as a presumptive test for pregnancy due to a lack of proof of safety for that use in view of the potential danger in the presence of pregnancy and the availability of accurate alternatives. Prohibited for export.
GBR	1977	Owing to evidence of congenital abnormalities, these products were withdrawn by the manufacturer.
AUT	1978	Withdrawn in view of their apparent association with birth defects.
BEL	1978	Withdrawn from the market following consideration of the evidence associating their use with birth defects.
DEU	1978	Withdrawn from the market.
ITA	1978	Withdrawn from the market.
SGP	Apr. 1978	Banned for importation.
ETH	1979	Estrogen/progestogen preparations should no longer be promoted for pregnancy testing. This use should be included among the contraindications listed in package inserts.
GRC	1980	All preparations containing estrogens and progestogens intended for pregnancy testing were withdrawn.
NZL		Voluntarily withdrawn from the market.
SAU		In view of their association with birth defects, all such estrogen/progestogen preparations are not recommended for use.
THA		Pregnancy tests with a combination of norethisterone and estradiol are prohibited.
VEN		Not approved for use and/or sale.
ZAF		Preparations for oral use are not indicated and may not be promoted for pregnancy testing, based on information received from the World Health Organization.

Product name **Hydrochlorothiazide/potassium**

Scientific and common names, and synonyms

POTASSIUM/HYDROCHLOROTHIAZIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DOM		Products with this combination of ingredients have been prohibited for use and/or sale since they have been shown to cause small bowl ulceration.

Bibliographical references

IARC MONOGRAPH, 50, 337, 1990

Product name **Medroxyprogesterone acetate/ethinylestradiol**

Scientific and common names, and synonyms
ETHINYLESTRADIOL/MEDROXYPROGESTERONE ACETATE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA		Withdrawn from the market and prohibited for export by the Food and Drug Administration after studies in dogs showed an increased incidence of mammary tumors from the medroxyprogesterone acetate component.

Product name **Meprobamate/diazepines**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GRC	1980	Withdrawn from the market since the combination is considered unacceptable having regard to the higher incidence of adverse reactions than reported with monocomponent preparations.

Product name **Mepyramine maleate/pamabrom**

Scientific and common names, and synonyms
PAMABROM/PYRILAMINE MALEATE
PYRILAMINE MALEATE/PAMABROM

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	1974	Combinations of pamabrom and mepyramine maleate (pyrilamine maleate) have been withdrawn from the market.

Product name **Metoclopramide/polidocanol**

Scientific and common names, and synonyms
POLIDOCANOL/METOCLOPRAMIDE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
PHL	Mar. 1983	Disapproved for use in gastrointestinal disturbances since marked liver toxicity limits its therapeutic use.

Product name **Neomycin sulfate/polymyxin bisulfate/nystatin/acetarsol**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
PHL	Sep. 1977	This combination, for use in trichomonal vaginitis, has been disapproved due to the irrational and potentially harmful nature of the combination, which is not shown to be more effective than its individual ingredients given separately in appropriate doses.

Product name **Penicillin/streptomycin**

Scientific and common names, and synonyms
STREPTOMYCIN/PENICILLIN

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GRC	1978	Withdrawn from the market having regard to an unacceptable benefit-to-risk ratio.

Product name **Penicillin/tetracycline**

Scientific and common names, and synonyms
TETRACYCLINE/PENICILLIN

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GRC	1975	Withdrawn from the market having regard to its low benefit-to-risk ratio.
ITA	1977	These products intended for general use have been withdrawn from the market owing to suspected liver toxicity.

Product name **Phenformin/chlorpropamide**

Scientific and common names, and synonyms
CHLORPROPAMIDE/PHENFORMIN

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GRC	1986	Withdrawn from the market having regard to its low benefit-to-risk ratio.

Product name **Pipradol/hesperidin**

Scientific and common names, and synonyms
HESPERIDIN/PIPRADOL

...(Continued)

Legislative or regulative action

Product name **Pipradol/hesperidin** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DOM		Products with this combination of ingredients have been prohibited for use and/or sale since they have been found to be harmful.

Product name **Prednisolone/phenobarbital**

Scientific and common names, and synonyms
PHENOBARBITAL/PREDNISOLONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
THA		Not permitted in combination for the treatment of asthma.

Product name **Promethazine in combination**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	Sep. 1989	Combination preparations containing promethazine, indicated for the symptomatic relief of upper respiratory infections, were subjected to prescription control because their use in children of less than two years of age had been associated with sudden infant death syndrome. Concern was also raised about their potential to induce extrapyramidal disorders. In the light of these concerns, two combination preparations were voluntarily withdrawn by the manufacturer in 1991. (References: (FEREAC) Federal Register, 54(227):4891, 48914, 1989; (FEREAC) Federal Register, 58(50), 10904, 1991) **WHO comment:** See WHO comment for H1-antihistamines.

Product name **Pyrazolones in combination (see also aminophenazone, metamizole sodium)**

Scientific and common names, and synonyms
AMIDOPYRINE
ISOPYRINE
METAMIZOLE SODIUM
NIFENAZONE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
JPN	Sep. 1977	The Central Pharmaceutical Affairs Council recommended that, because of their propensity to cause skin eruptions and shock, pyrazolones should no longer be included in proprietary cold medicines or in antipyretic-analgesic preparations available without a doctor's prescription.
PHL	May 1979	Several combination products containing pyrazolones have been disapproved for use.
GRC	Oct. 1980	The Ministry of Health and Welfare has severely restricted the use and sale of these products for domestic use. (Reference: (GRAGA) Ministry of Health Decision, No.7116,, July 1983)

...(Continued)

Product name

Pyrazolones in combination (see also aminophenazone, metamizole sodium) ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DEU	1982	Eighty analgesic preparations containing a pyrazolone in combination with another active compound were withdrawn from sale either: 1) because their indications were not consonant with those approved by the Federal Health Office, or 2) on suspicion that the other active constituent might potentiate the accepted known risk of the pyrazolone component. These actions were largely directed against drugs containing metamizole sodium, but products containing isopyrine and nifenazone were also implicated. The situation is complex, however, since preparations containing one or more active ingredient remain on the market.
DEU	1983	Labelling for certain pyrazolone-containing drugs was recently revised to limit indications for use. Substances affected include: metamizole, isopropylaminophenazone, nifenazone, propyphenazone, phenazone and morazone. Indications were limited to the treatment of acute severe pain, such as post-traumatic and post-operative pain and colic, and high fever unresponsive to other therapy. Specific contraindications include use in inflammatory arthroses, conditions predisposing to shock or bone marrow depression, known allergy to pyrazolones and phenylbutazone, and certain metabolic deficiencies such as hepatic porphyria. The importance of weighing the need for treatment against the slight but life-threatening risks of anaphylactic shock and agranulocytosis is stressed.
ISR	1983	The Pharmaceutical Administration of the Ministry of Health has suspended all combination products containing noramidopyrine methanesulfonate sodium (metamizole sodium).
ITA	1989	Having regard to the adverse effects associated with their long-term use, products containing pyrazolones may now be indicated only for the short-term treatment of severe acute pain or pyrexia. (Reference: (BIFTI) Bolletino d'Informazione sui Farmaci, 13(2), 5, 1989)
MEX		Combinations of pyrazolones with antihistamines, vasoconstrictors, decongestants, muscle relaxants, antibiotics or vitamins are prohibited due to the toxic properties of pyrazolones.
SAU		All pyrazolones are used only under prescription.
		WHO comment: Pyrazolone derivatives, which include aminophenazone, metamizole sodium, phenylbutazone and propyphenazone have been associated with serious adverse effects. Since safer alternatives are widely available some regulatory authorities have withdrawn or severely restricted all pharmaceutical preparations containing pyrazolone derivatives. See also WHO comments for aminophenazone, metamizole sodium, phenylbutazone and propyphenazone.

Product name

Sulfathiazole sodium with sodium lactate or sodium bicarbonate

Scientific and common names, and synonyms

SODIUM BICARBONATE/SULFATHIAZOLE SODIUM
SODIUM LACTATE/SULFATHIAZOLE SODIUM

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
DOM		Combinations of sulfathiazole sodium with sodium lactate or sodium bicarbonate or other sulfonamides have been prohibited for use and/or sale since they have been associated with serious side effects and recent studies have shown them to be of questionable efficacy. The risks of these combinations have not been found to outweigh the benefits and other sulfonamides are available that present much lower risk with use.

Product name **Superheporin**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
IDN	1980	Superheporin capsules, a traditional herbal mixture of angelica radix, ligustica rhizoma, salviae radix, pteropii excrementum and carthamic flos, has been withdrawn from sale following reports of congenital malformations in babies whose mothers had taken this compound in early pregnancy.
VEN		Not approved for use and/or sale.

Product name **Tetracycline in combination**

Scientific and common names, and synonyms
CHLORAMPHENICOL/TETRACYCLINE

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	1971	This combination, for oral and parenteral use, was withdrawn from the market.
DOM		Tetracycline in combination with oleandomycin or with novobiocin is prohibited for use and/or sale since studies have shown that this combination can be hazardous to health.
VEN		Banned for use and/or sale.

Product name **Theophylline/meprobamate/barbiturates**

Scientific and common names, and synonyms
BARBITURATES/MEPROBAMATE/THEOPHYLLINE
MEPROBAMATE/THEOPHYLLINE/BARBITURATES

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
GRC	1986	Withdrawn from the market having regard to its low benefit-to-risk ratio (respiratory depression).

Product name **Thiazides/potassium chloride**

Scientific and common names, and synonyms
POTASSIUM CHLORIDE/THIAZIDES

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
USA	Oct. 1971	The combination of these two compounds, alone or with reserpine or rauwolfia serpentina, has been withdrawn from the market and prohibited for export by the Food and Drug Administration on the grounds that no adequate data demonstrating safety and efficacy exist. These combinations were used as diuretics to treat certain edemas due to cardiac, renal and hepatic failure, and to treat specific cases of hypertension. In its decision, the FDA cited cases of small-bowel lesions that had developed with the administration of these drugs, for which a causal relationship had not been excluded by appropriate tests.

...(Continued)

Legislative or regulative action

Product name **Thiazides/potassium chloride** ...(Continued)

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SAU		Following reports of small bowel lesions resulting in ulcers, obstruction, haemorrhage and perforation, this combination was withdrawn.

Product name **Tiratricol/cyclovalone/retinol**

Scientific and common names, and synonyms

CYCLOVALONE/TIRATRICOL/RETINOL
RETINOL/CYCLOVALONE/TIRATRICOL

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
FRA	30 Oct. 1988	A preparation containing an association of tiratricol, cyclovalone and retinol has been withdrawn from themarket. (Reference: (FRARP) La Revue Prescrire, 9(81), 18, 1989) **WHO comment:** This combination product, indicated for the treatment of obesity, has not been demonstrated to possess anytherapeutic effect and has been associated with cases of cellular hepatitis, of which at least one was fatal. It is not yet known which of the constituents is the causative agent.

Product name **Trimethoprim/sulfamethoxazole**

C.A.S. number **8064-90-2**

Scientific and common names, and synonyms

CO-TRIMOXAZOLE
SULFAMETHOXAZOLE/TRIMETHOPRIM

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
SWE	1987	The approved indications for products containing trimethoprim and sulfamethoxazole were restricted to exclude the treatment of urinary tract infections, having regard to the association of these combination products with severe and even fatal adverse effects, including sensitivity reactions, mucocutaneous syndrome, blood dyscrasias and hepatic disorders. A similar restriction applies to products containing trimethoprim and sulfadiazine. (Reference: (SSLMS) Information från Socialstyrelsens Läekemedelsavdelning, 3(12), 48, 1987)
IRL	June 1987	Products containing trimethoprim and sulfamethoxazole may now be indicated only for respiratory and urinary tract infections, on the grounds that they are associated with a greater risk of adverse effects, in particular in the elderly, including potentially fatal cases of blood dyscrasias and erythema multiforme, than other commonly used anti-infectives. (Reference: (IRDAB) National Drugs Advisory Board Annual Report,, 26, 1987) **WHO comment:** The combination of sulfamethoxazole and trimethoprim (5:1) was introduced in 1971 for the treatment of a wide variety of bacterial infections. Its use has been associated with severe hypersensitivity reactions, particularly involving the skin, many of which have been attributed to the sulphonamide component. Elderly people seem to be more vulnerable. The World Health Organization has no information further to the above concerning restrictive action on this combination.

Product name **Tyrothricin/fomocaine/diphenhydramine**

Legislative or regulative action

Country	Effective Date	Description of action taken Grounds for decision
CYP	23 Oct. 1992	The Drugs Council decided to withdraw the marketing approval for a gel preparation containing tyrothricin0.1%, fomocaine hydrochloride 2.5% and diphenhydramine 1% used for the treatment of wounds and burns. The decision also applies to the powder formulation. (Reference: (CYPPS) Pharmaceutical Services, Ministry of Health,,, 23 Oct. 1992) **WHO comment:** Tyrothricin, fomocaine and diphenhydramine is a combination of antimicrobial, local anaesthetic and H1 receptor antagonist respectively. Tyrothricin, which is a mixture containing gramacidin and tyrocidine, is too toxic to be administered systematically because of liver and kidney toxicity. The product has been removed on the grounds that absorption of tyrothricin through broken skin may result in renal myelotoxicity.

CONSOLIDATED LIST OF PRODUCTS WHOSE CONSUMPTION AND/OR SALE HAVE BEEN BANNED, WITHDRAWN, SEVERELY RESTRICTED OR NOT APPROVED BY GOVERNMENTS

Sixth Issue

Pharmaceuticals

PART II

COMMERCIAL INFORMATION

PHARMACEUTICALS

MONOCOMPONENT PRODUCTS

Product name **Acetanilide**

C.A.S. number **103-84-4**

Trade and brand names

Acetanil
Capsula dr. knapf
Digiseb
Phenalgin

For regulatory information, see page 5

Product name **Acetarsol**

C.A.S. number **97-44-9**

Trade and brand names

Acetarsolum
Acetarsone
Acetphenarsine
Amarson
Amoebal
Arsabott
Arsaphen
Arsonine
Auryphan
Chrlich 594
Collarsin
Devegan
Disparicida
Dynarsan
Edoiacolo
Ehrlich 594
F 190
Fluryl
Fourneau 190
Ginarsol
Goyl
Gynoplix
Kharophen
Kubarsol
Limarsol
Monargan
Neo-vagipurin
Nilacid
Oralcid
Orarsan
Osarsal
Osarsol
Osarsole
Osvarsan
Pallacid
Paroxyl
Polygynax
Spirozid
Stovarsol
Stovarsolan
Svc
Trichovan
Ucb 630
Vagipurin
Vagisep
Vagival
Vagoflor
190 f

For regulatory information, see page 5

Product name **Acetylfuratrizine**

C.A.S. number **1789-26-0**

Trade and brand names

Panfuran
Panfuran-troche

For regulatory information, see page 5

Product name **Acitretin**

C.A.S. number **55079-83-9**

Trade and brand names

Etretin
Neotigason
Neotigason (r) 10
Neotigason roche 10 mg
Neotigason sauter kapsein 25 mg
Soriatane

For regulatory information, see page 8

Product name **Acridine derivatives**

C.A.S. number **260-94-6**

Trade and brand names

Euflavin
Proflavin

For regulatory information, see page 9

Product name Alclofenac

C.A.S. number 22131-79-9

Trade and brand names

Allopydin
Allopydinac
Alopidin
Alopydin
Argun
Darkeyfenac
Desintlam
Epinal
Medifenac
Mervan
Mirvan
Mirvan a
My 101
Neosten
Neoston
Prinalgin
Reufenac
Vanadian
W-7320
W7320
Zubirol
Zumaril

For regulatory information, see page 9

Product name Allergen extracts

Trade and brand names

A.d.l.
Alavac
Alavac-p
Alavac-s
Albay pure venom
Allpyral specific
Allpyral-d
Allpyral-g
Allpyral-mite fortified house dust
Bencard skin testin solutions
Bencard-a
Conjuvac two grass
Glycerinated skin testing solutions
Merck skin testin solutions
Migen
Norisen
Norisen grass
Pharmalgen
Pollinex
Rapifen
S.d.l.
Sdv specific desentistising caccine
Spectralgen
Spectralgen pollens
Suspal
Tyrivac

For regulatory information, see page 10

Product name Aloxiprin

C.A.S. number 9014-67-9

Trade and brand names

Aloxipirine tablets
Harbureta
Lyman tabs
Palaprin forte
Paloxin
Palprin
Rumatral
Shin-rheufen
Superpyrin
Tiatral

For regulatory information, see page 11

Product name Alprostadil

C.A.S. number 745-65-3

Trade and brand names

Coverject
Liple
Minprog
Minprog pad
Postivas
Prostadin
Prostalgin
Prostandin
Prostavasin
Prostin vr pediatric
Prostin-vr
Prostivas

For regulatory information, see page 11

Product name Amfepramone

C.A.S. number 90-84-6

Trade and brand names

Adipan
Adiposan
Adiposon
Amfepromone
Anfamon
Anorex
Bonumin
Brenalalit
Cegramine
D.i.p.n
Danylen
Delgamer
Derfon
Dietec
Dietil-retard
Dobesin
Frekentine
Lineal-plus
Lineal-valeas
Lipomin
Liposlim

...(Continued)

Product name Amfepramone ...(Continued)

Trade and brand names

Magrene
Menutil
Moderatan
Neobes
Nobesine
Nobesine-25
Nulobes
Obesitex
Prefamone
Propion
Regenon
Regibon
Slim-plus
Super emegrin
T-712
Tenuate
Tenucap
Tepanil
Tylinal

For regulatory information, see page 12

Product name Amfetamine

C.A.S. number 300-62-9

Trade and brand names

Actedron
Adipan
Allodene
Amfetasul
Amphamed
Amphedrine
Anorexine
Benzebar
Benzedrine
Benzolone
Centramina
Dexatrine
Durophet
Elastonon
Finam
Isoamyn
Isomyn
Mecodrin
Neoton
Norphedrane
Novydrine
Novydrinene
Obesin
Obesine
Obesitab
Oktadrin
Ortedrine
Percomon
Phenedrine
Phenopromin
Profamina
Propisamine
Raphetamine
Rhinalator
Simpamina
Simpatedrin
Sympamine
Sympatedrin
Sympatina
Synatan
Wekamine
Zedrine

For regulatory information, see page 13

Product name Aminoglutethimide

C.A.S. number 125-84-8

Trade and brand names

Ba-16038
C-16038-ba
Cytadren
Doredin
Elipten
Mamomit
Orimeten
16038

For regulatory information, see page 13

Product name Aminophenazone

C.A.S. number 58-15-1

Trade and brand names

Adexogan
Agevis
Algimicin anttitermico
Ambene
Amidazopen
Amidazophen
Amidazophene
Amidozen
Aminophenazonum
Amplisiex
Anafebrin
Anafebrina
Aneuxol
Anoixal
Antigripina
Areumal
Axiston
Balbion
Barsedan
Baukal
Bayer 1387 p
Bronchisan
Brufaneuseol
Brufaneuxol
Budirol
Butapyrine
Buto beta
Capsyka dr knapf
Capysal
Chinopyrin
Cibalgin
Ciclazon
Clinit
Coffan
Compral
Cor-asthmolyticum
Demolpas
Dentigoa
Depiral c
Dereuma
Dexa escopyrin
Dexa-attritin
Dha 51
Dialpyrin
Digisab
Dim-antos
Dimametten
Dimapyrin
Dimopyrin
Dipirin
Diprin
Dipyrin
Dipyrine
Dolo-attirin
Dolo-eupaco
Dolo-optineural
Dolorphen

...(Continued)

Product name Aminophenazone ...(Continued)

Trade and brand names

Dolovosano
Donobin
Duerin
Dysmensan
Escopyrin
Escopyrinus
Espasnatex
Eufibran
Eufibron
Eunalgit
Euprogan
Febren
Febrinina
Febron
Febrosolvin
Fenodon
Fever
Flivalgin
Flumil
Fortalidon
Ftalazon
Funapon
Galenopyrin
Glucopirina
Helvagit-f
Hemicraneal
Hisense-p
Hyparon
Influnal depot
Inst
Irgapyrine
Isoftal
Itamidone
Jovapyrin
Kalmine
Katareuma
Lagaflex
Latepyrine
Lauroanginol
Lidor
Mamallet-a
Manslu
Medispanmin
Melaforte
Meloka
Mepropyrin
Metapirazone
Naupax
Netsusarin
Neuro-demoplast
Nifedon
Nikartrone
Nostress
Novamidon
Novogen
Novospasmin
Optalidon
Optineural(analgesic)
Optipax
Osadrine
Osmotipax
P.s.b.p.
Paralgin
Piracodid
Piradenil
Piradol
Piramidon
Piramidone
Pirasco
Piraseptolo
Piridol
Piro rectal
Piromidina
Piroreumal
Pneumol
Polinalin
Premineat
Prontylin
Pyradon
Pyraelmedal
Pyramidon
Pyramidone
Pyrbutal
Pyrodin
Regitol
Remlomed
Reopin
Reu-bon
Reumanova
Reumasedina
Reumo termina
Reumoftal
Reumotranc
Revulex
Rheopyrin
Rini c
Rinoplex
Sanglin
Sapotera
Sedacoral
Sedafen
Sedopsic
Selbon-a
Sigma-elmedal
Somnopyrin
Spasmo-barbanub
Spasmo-deterex
Spasmo-dimonil
Spasmo-tropax
Spasmovalin
Spasmoverlgin
Spasmus
Stabilat
Supamidal
Suppnon
Teofedrin
Tonosan
Trabit
Trogal
Tropax
Tsefokon
Verodon
Viadol
Waudobuzon
Wofapyrin
Zirkonorm

For regulatory information, see page 14

Product name Aminophylline

C.A.S. number 317-34-0

Trade and brand names

Afonilum
Amino-slow
Aminocardol
Aminodrox
Aminodur
Aminomal
Aminophylline
Aminophylline injection
Aminophylline mudrane
Aminophylline oral
Amnivent
Asmafilin
Cardophyllin
Cardophylline
Carena
Carine
Colonofilin
Corfilamine
Corophyllin
Corophylline
Corphyllamin
Diaphylline
Duraphyllin
Escophylline
Ethophylline
Eudiamine
Eufilina
Euphyllin
Euphyllin retard
Euphyllin 0.48
Euphyllin cr
Euphyllina
Fadfilina
Godafilin
Inophylline
Jaa aminophylline
Mini-fix
Mudrane
Mudrane gg
Mundiphyllin
Palaran
Palaron
Pecram
Pecran
Peterphylin
Phyllocontin
Phyllotemp
Planphylline
Somophyllin
Somophyllin-12
Syntophyllin
Tefamin
Teophyllamin
Thodrox
Truphylline
Variaphylline

For regulatory information, see page 16

Product name Aminorex

C.A.S. number 2207-50-3

Trade and brand names

Aminoxafen
Aminoxaphen
Apiquel
Mcn 742
Menocil

For regulatory information, see page 17

Product name Amitriptyline

C.A.S. number 50-48-6

Trade and brand names

Adepril
Amavil
Ami-anelun
Amilent
Amilit-ifi
Amineurin
Aminiurin
Amitimid
Amitril
Amitrip
Amitriptol
Amyline
Amyzol
Annolytin
Apo-amitriptylline
Apo-pram
Deprelio
Deprestal
Diapatal
Domical
Elatrol
Elatrolet
Elavil
Elavil plus
Emitrip
Endep
Enovil
Entrafon-a
Entrafon-forte
Entrafon-2-10
Entrafon-2-25
Entrafon-210
Etarfon
Etrafon-a
Etrafon-forte
Euplit
Laroxal
Laroxyl
Larozyl
Lentizol
Levat
Levate
Limbatarail
Limbatral
Limbitryl
Limitrol
Longopax
Loxaryl
Mareline
Meravil
Muaban d
Mutaban a/d/f
Mutabase
Nobrital
Normaln
Novo-tryptin
Novotriptyn
Novotryptin
Pantrop
Parks-plus
Pms levazine
Prouvil
Redomex
Saratem
Saroten
Sarotena
Sarotex
Sedans
Sk-amitriptyline
Sylvemid
Tensorelax
Teperin
Trepiline
Trepulin
Triavil
Triptizol
Triptonal
Triptpane
Trivial
Trivial-4-10
Trivial-4-50

For regulatory information, see page 17

Product name Amobarbital

C.A.S. number 57-43-2

Trade and brand names

Altinal
Alupent-sed
Amal
Amasust
Ambese-la
Amital
Amobell
Amsal
Amsebarb
Amybal
Amycal
Amydorm
Amylbarb
Amylobeta
Amytal
Amytal sodium
Analgilasa
Anorexin
Appenil
Asthmin
Barbamyl
Beatol
Binoctal
Bludex
Calavon
Cuaot
Dexaspan
Dexital
Dorlotyn
Dorminal
Dormytal
Ergo-lonarid
Estimal
Etamyl
Eunoctal
Gardstat
Ifenin
Isoamitil sedante
Isobec
Isomyl
Isomytal
Isonal
Jalonac
Lonarid n
Medi-trol
Mudeka
Mylodorm
Mylodorm sustrel
N 8
Neur-amyl
Novambobarb
Novogen
Obe_slim
Pentymal
Placidel
Protasma
Robarb
Schiwanox
Sednotic
Sedo-rythmodan
Somnal
Somvit
Stadadorm
Sumital
Sy-dexam
Talamo
Tensophoril
Transital
Uno

For regulatory information, see page 18

Product name **Amodiaquine**

C.A.S. number **86-42-0**

Trade and brand names

Amodoquin tablets
Basoquin
Camoquin
Flavoquine

For regulatory information, see page 18

Product name **Aprobarbital**

C.A.S. number **77-02-1**

Trade and brand names

Allypropymal
Alurate
Alurate sodium
Apb
Aprozal
Escoderm
Isonal
Nervisal
Numal
Somnipron

For regulatory information, see page 21

Product name **Aristolochic acid**

C.A.S. number **313-67-7**

Trade and brand names

Descresepet
Fago-paraxin
Fluocinova
Predno-facilus haemota
Tardolyt
Tr 1736

For regulatory information, see page 21

Product name **Astemizole**

C.A.S. number **68844-77-9**

Trade and brand names

Alermizol
Histamanal
Novo-nastizol

For regulatory information, see page 22

Product name **Azapropazone**

C.A.S. number **13539-59-8**

Trade and brand names

Ahr 3018
Apazone
Azapren
Cinnamin
Cinnopropazone
Dolo-prolixan
Pentosol
Prodisan
Prolix
Prolixan
Prolixana
Rheumox
Sinnamin
Tolyprina
Xani

For regulatory information, see page 22

Product name **Azaribine**

C.A.S. number **2169-64-6**

Trade and brand names

Cb 304
Ribo-azauracil
Triazure

For regulatory information, see page 23

Product name Barbital

C.A.S. number 57-44-3

Trade and brand names

Deba
Dormileno
Dormon
Dormonal
Escoderm
Hypnogene
Hypnox
Lidor
Malonal
Sedeval
Uronal
Verinogen
Verodon
Veroletten
Verolitten
Veronal
Veronigen

For regulatory information, see page 25

Product name Bencyclane

C.A.S. number 2179-37-5

Trade and brand names

Angiocician
Angiodel
Bioarterol
Card-fludilat
Dantrium
Desoblit
Dilangio
Dilangio caposium
Dilapres
Fludilat
Fludilat (r)-dti
Fludilat amp 50 mg
Fludilat drag 100 mg
Fludilat dragee
Fludilat retard
Fludilat tropfen
Flussema
Fluxema
Halidor
Iloramina
Ludilat
Ludilat dti
Novo card-fludilat
Tardilat
Tensilence
Vasodarkey

For regulatory information, see page 25

Product name Benorilate

C.A.S. number 5003-48-5

Trade and brand names

Benolat
Benoral
Benorile
Benortan
Benorylate
Benotamol
Bentum
Doline
Duvium
Faw 76
Fenasprate
Quinexin
Salipran
Sinalgin
Spierifex
Triadol
Vetedol
Win 11450
Winolate
Winorlate
Winorylate
Winrolate

For regulatory information, see page 26

Product name Benoxaprofen

C.A.S. number 51234-28-7

Trade and brand names

Benoxapran
Bexopron
Compound 90459
Coxigon
Inflamid
Lilly 3794
Lilly 90459
Lrcl 3794
Opren
Oraflex
Uniprofen
90459 compound

For regulatory information, see page 26

Product name Benzarone

C.A.S. number 1477-19-6

Trade and brand names

Benzarin
Fragivix
Fragivix (r) forte
Vasco
Vasoc
Venagil

For regulatory information, see page 27

Product name Benzyl alcohol

C.A.S. number 100-51-6

Trade and brand names

Actamin c
B-neuron
Benhur
Bigram
Brophylline
Dermaspray
Dex-a-vet
Duphaspasmin
Eclipse
Fertagyl
Hydraplex
Lokalin
Madinex
Omnadren
Orostat
Parkestal
Procadolor
Reflex-spray
Solvidont
Sudocrem
Triofan

For regulatory information, see page 27

Product name Benzylpenicillin sodium (topical preparations)

C.A.S. number 69-57-8

Trade and brand names

Ceilipen
Cidan
Crisocilin-g
Crystapen
Dermosa cusipenicilina
Hormocillin forte
Ilcocillin
Juvanesta
Liademycin
Monocillin
Natricilin
Penibiot
Penilevel
Penimiluy
Peniroger
Saniciline
Servipan
Sodipen
Specilline
Therapen-na
Unicilina

For regulatory information, see page 28

Product name Berberine

C.A.S. number 2086-83-1

Trade and brand names

Berberal
Berbericine
Berberil
Detal
Kenmin-s
Kinosin s
Phelloverin a
Tangenin
Thalsin
Umbellatin
Umbellatine
3 p maid

For regulatory information, see page 29

Product name Bithionol

C.A.S. number 97-18-7

Trade and brand names

Actamer
Anafogene
Bacteriostat cs-1
Bidiphen
Bit
Bithin
Bitin
Cp 3438
Lorothidol
Lorothiodol
Neopellis
Nobacter
Prevenol
Tbp
Vancid
Vancide bl
Xl 7

For regulatory information, see page 31

Product name Boric acid and borates

C.A.S. number 10043-35-3

Trade and brand names

Alpagelle
Anojel
Anugard
Berlicetin
Betadrin
Bexon
Bluboro
Borogal
Cacimag
Caclcifor
Calcamyl-24
Calcibenzamin
Camilca
Chibro
Coneolent
Cutaden
Dissol
Ear-dry

...(Continued)

Product name Boric acid and borates ...(Continued)

Trade and brand names

Evercil
Fermakzem
Flex-care
Glaucadrine
Glucocalcium
Kalopsisi
Kerapos
Kodomo smarin
Lindemil
Macaldex
Neo-smarin dia
Neo-vagipurin
O-biol
Ophtalmin
Pedoz
Phoscanol
Preferal
Proculin
Rhinophenazol
Saddle mate
Swim-ear
Swim-eye
Tensophoril
Timazincum
Tipolin
Unisol
Vetacalin-m

For regulatory information, see page 31

Product name Broxyquinoline (see also halogenated hydroxyquinoline derivatives)

C.A.S. number 521-74-4

Trade and brand names

Aprilin
Auanosept
Brodiar
Bromoxin
Colepur
Colipar
Dibromoksin
Dibromoquin
Dibromoxin
Dibromoxine
Digesept
Dirorno
Dysentrocym
Enosept
Enterokvin
Enterosept
Fenilor
Intestopan
Intestopan-q
Noroquinol
Paramiba
Paramibe
Paramibrodiar
Phenipan
Sandocycline
Sandoin
Starogyn
Susiform ad is vet

For regulatory information, see page 34

Product name Bucetin

C.A.S. number 1083-57-4

Trade and brand names

Beelin
Bonanza
Haitmin
Hoe 15239
New isomidon
Ringl-s

For regulatory information, see page 34

Product name Bufexamac

C.A.S. number 2438-72-4

Trade and brand names

Anderm
Bufemac
Bufexamac-ratiopharm (r) creme
Bufexine
Bufexine ratiopharm(r) f-sable
Calmaderm
Droxan
Droxarol
Droxaryl
Droxaryl zalf 50 mg
Duradermal
Flogicid
Flogocid
Flogocid gel n.n
Flogocid sable
Malipuran
Mofenar
Norfemac
Paraderm
Parafenac
Parafenac (r) milch
Parafenac basishad
Parafenac sable
Parafenac 5% creme
Parafenal
Parfenac
Parfenal
Parfenal creme derm
Viafen
Viafen u est.crema 40 g

For regulatory information, see page 35

Product name Buformin

C.A.S. number 692-13-7

Trade and brand names

Adebit
Andebit
Andelit
Andere
Biforon
Bigunal
Biquinal
Bs-5892
Bufonamin
Bulbonin
Diabrin
Dibetos
Dutformin
Gliporal
Glybigid
Insulamin
Krebon
Panformin
Silubin
Silubin retard
Sindiatil
Tidemol retard
Ziavetine

For regulatory information, see page 35

Product name Bumadizone

C.A.S. number 3583-64-0

Trade and brand names

Bumadizon

For regulatory information, see page 36

Product name Bunamiodyl

C.A.S. number 1233-53-0

Trade and brand names

Bunaiod
Buniodyl
Orabilex
Orabilix

For regulatory information, see page 36

Product name Buprenorphine

C.A.S. number 52485-79-7

Trade and brand names

Buprenex
Buprex
Finibron
Temgesic

For regulatory information, see page 37

Product name Cadralazine

C.A.S. number 64241-34-5

Trade and brand names

Cadraten
Cadraten 21 cpr 20 mg
Cadraten 30 cpr 10 mg
Cadraten 30 cpr 15 mg
Cadratin
Cadrilan

For regulatory information, see page 38

Product name Calamus

C.A.S. number 8015-79-0

Trade and brand names

Acore vrai
Oil of calamus
Sweet flag root

For regulatory information, see page 38

Product name **Camphor**

C.A.S. number **76-22-2**

Trade and brand names

Root bark oil
Spirit of camphor

For regulatory information, see page 38

Product name **Canthaxanthin**

C.A.S. number **514-78-3**

Trade and brand names

Apotrin
Food orange 8
Phenoro

For regulatory information, see page 39

Product name **Cathine**

C.A.S. number **492-39-7**

Trade and brand names

Adiposetten n
Amorphan depot
Dietene
Exponcit
Insacial
Miniscap
Mirapront
Nobese
Phyteia schlankheitsdragees
Reduform
Thinz

For regulatory information, see page 41

Product name **Chloramphenicol**

C.A.S. number **56-75-7**

Trade and brand names

Acne-sol
Acnoxin
Actimac
Actinac
Alficetyn
Alficetyn susp.
Altabactin
Ambofen
Ambrasynth
Amphemycin-prednisonum
Amphenicol
Amphicol
Ampliomicetin
Amseclim
Amseclor
Anacetin
Angimidone
Angiters
Antibiopto
Aquamycetin
Aquapred
Armacol
Arrlicetin
Austracol
Aviatrin
B-cpct
Balkamycin
Bemacol
Bio-exazol
Biocetin
Biofeniol
Biophenicol
Biophtas
Biotocap
Bismophenyl
Bitencyl
C. o fluo-tenicol
C. o hidrocor-clora
Caf
Cafenolo
Caladryl
Calmina
Cam
Campiol
Caosol
Cap
Catilan
Cavumycetina
Ccombinado balsamico
Ccorticol
Cebenicol
Cetina
Chemibal
Chemicetin
Chemicetina
Chemyzin
Chlomin
Chlomycol
Chlora-tabs
Chloramex
Chloramfenicol
Chloramficin
Chloramfilin
Chloramol
Chloramphenicol cinnamate
Chloramphenicol intervetra
Chloramphenicol sodium succinate
Chloramphenicol-pos
Chloramphycin
Chloramplast
Chloramsaar
Chloramson
Chloranfeni-mck
Chloranfeni-opipno
Chloranfeni-otico
Chloranfeni-ungena
Chlorasol
Chloreptic
Chlorical
Chloricol
Chlornitromycin
Chloro-25 vetag
Chloroantibion
Chlorocaps
Chlorocid
Chlorocide
Chlorocidin c
Chlorocidin c tetran
Chlorocortal
Chlorofair
Chloroject l
Chloroject s
Chloromex
Chloromik
Chloromimyxin
Chloromycetin
Chloromycetin kapseals
Chloromycetin palmitate
Chloromycetin sodium succinate
Chloronitrin
Chloroptic
Chloroptic p. oint.
Chlorosol
Chlorostrep
Chlorotin

...(Continued)

Product name # Chloramphenicol ...(Continued)

Trade and brand names

Chlorotyxin
Chlorovules
Chlorsig
Chlotaon
Ciclepen
Cidocetin
Ciplamycetin
Clinafenol
Clofenal
Clofibrase
Clomicin enzym
Cloramex
Cloramfen
Cloramicol
Cloramidina
Cloran
Cloranfeni-opifno
Cloranfeni-otico
Cloranfeni-ungena
Cloranfenicol-mck
Cloransul
Clorbiotina
Clorbis supp.
Clorocyn
Clorofenicina
Cloromicetin
Cloromisan
Cloromoin
Cloromycetin
Cloroptic
Cloroptic farmicetina
Clorosyntex
Colidene
Colimy-c
Comycetin
Cortican
Cortidermale
Cortimisin
Cortiphenicol
Cortison-quemicet
Cortivert
Cortol
Cph
Cutispray no. 4
Cyphenicol
Cysticat
D-chloramphenicol
D-threo-chloramphenicol
Davuron sedante
Dectamicina
Delta optil
Desphen
Detreomycin
Devamycetin
Dexa-biofinicol
Dextromycetin
Doctamicina
Donibin
Duphenicol
Econoclor
Ejificol
Ejificol strept
Ejificol sulfa
Elase chloromycel
Embacetin
Emetren
Enicol
Enteromycetin
Enttocetrin
Erbaplast
Erittronicol
Erteilen
Esterofenil
Estevecicina cloranfenico
Eubetal
Extracicilina
Fago-praxin
Farmicetina
Fastin
Fenicol
Furacol I
Furamecetil alpha magna
Furamecetil magna
Furatrimon
Furokatin
Gammaphenicol
Ginetris
Gino-dectacil
Gliscol
Globenicol
Globveticol
Glorous
Goticas
Gotimycetin
I-caps
Ichthoseptal
Intramycetin
Iruxol
Iruxolum
Isicetina
Ismicetina
Isopto fenicol
Juvamycetin
Kamaver
Kavipe
Kemicetine
Kloramfex
Klorita
Klorocid s
Kloromicin
Labamicol
Labamicol-bismuth
Lennacol
Leuchlon
Leukamycetin
Leukomyan
Leukomycin
Levocycline
Levomanilin
Levomicetina
Levomicin
Levomitsetin
Levomycetin
Levomycetina
Levoninizol
Levopa
Levosin
Levovetin
Lifabiotico
Liquichlor
Lisoprecol
Locomycetine
Lomecetina
Loromisin
Mammphenicol
Mastiphen
Mediamycetin
Medichol
Medicol
Meliplus
Mephenicol powder
Metisept
Micloretin
Micoclorina
Micoclorine
Micodry
Micofilina
Microcetina
Mindaril
Minims
Minims chloramphenicol
Misetin
Muracin
Mycetin
Mycetobis
Mychel
Mychel-s
Mychel-vet
Mycinol
Myclocin
Mycochlorin
Naxogin compositum
Neo-dexoclin
Neobiotic
Neocetin
Niamycetin
Nifuramicin
Nitrocetin
Nitrocol
Norburn
Normimycin v
Nova-phenicol
Novoclorocap
Novomycetin
Oftalent
Oftan
Oleomycetin
Opclor
Ophthaphenicol
Ophthochlor
Opthalon
Optrin
Oralmisetin
Otachron
Otiprin
Otobacid
Otocortison
Otomycin
Otophen
Otopred ear drops
Pantofenicol
Pantovernil
Paraxin
Parcyclin
Pedimycetin
Pentamycetin
Pentocetina
Pertarii
Pimabiciron
Pinimentac
Plastoderma
Prednomycetine
Procusulf
Protercicline
Prurivet
Pulmo vinco
Quemicetina
Quitrase
Quitrase antibiotico
Ranphenicol
Ranstrepcol
Reclor
Redidropsol
Renegen
Reocetin
Reostop
Rheofin
Rivomycin
Rivomycin sulfa
Rolintrex
Romphenil
Roncovita
Ronphenil
Roscomycin
Rovictor

...(Continued)

Product name Chloramphenicol ...(Continued)

Trade and brand names

Samaphenicol
Scanicol
Scanicoline
Scieramycetin
Septicol
Sergo-amigdalar
Serviclofen
Sificetina
Sigmicilina
Sintomicetin
Sintomicetina
Sintomicetine r
Sintomitsin
Sno-phenicol
Snophenicol
Soludectancil
Sopamycetin
Spasmo-paraxin
Spersanicol
Stanomycetin
Strepticine
Streptoglobenicol
Streptophenicol
Subital supp.
Suismycetin
Sulfaglobenicol
Sulfamycetin
Synthomycetin
Synthomycetina
Synthomycetine
Synthophtone
Tardomyocel
Tega-cetin
Tetra-phenicol oculos
Tetrachlorasone
Tetracol
Tetranfen
Tetraphenicol
Tevcocin
Tifomycine
Tiframilk
Tiromycetin
Toramin
Transicetina
Transpulmycin
Tribiotic
Troc
Trophen
Troymycetin
Tusolone
Tycloran
Unimycetin
Uro-gliscal
Uro-gliscal 500
Uroletten-s
Uroplex 4
Ut forte
Uvomycin
V-crayolan
Vagisept
Variolan
Vetical
Vetophenicol
Viceton
Viklorin
Virogin
Vitaklorin
Vsmpozim
Wintetil
Zoppib spray blu

For regulatory information, see page 43

Product name Chlornaphazine

C.A.S. number 494-03-1

Trade and brand names

Aleukon
Chloronaftina
Erysan
Naficlorina
Naphthylamine mustard

For regulatory information, see page 44

Product name Chloroform

C.A.S. number 67-66-3

Trade and brand names

Ametuss
Benafed
Benatuss
Benyphed
Broncho-rivo syrup
Chlor-histine
Co-specto
Codacol
Codimal dm
Cotrol-d
Cyprol expectrant
Dalet
Dectuss
Dristan
Eludril
Endal
Expec-c
Fk-tussex
Guanor
Histalix
Hydril
Kentuss
Linctuss
Mc 3
Muflin
Nagalyn
Notose
Orthos kavident
P-m-z
Panosoma
Penta-zine
Phenacol-dm
Phenatuss
Phlogarol
Promex
R 20
Rexahisine
Tussilene-dm

For regulatory information, see page 45

Product name Chloroquine

C.A.S. number 54-05-7

Trade and brand names

Aralen
Aralen hcl
Aralin (diphosphate)
Artrichin
Artrochin
Avloclor (diphosphate)
Bemaphate
Bipiquin
Chemochin
Chlorochin
Cidanchin
Clorochina

...(Continued)

Product name Chloroquine ...(Continued)

Trade and brand names

Delagil
Dichinalex
Endamal
Erestol
Gontochin
Hiliopar
Imagon
Instana
Intestopan-q
Lagaquin
Letaquine
Malaraquin
Malarex (diphosphate)
Malariron (diphosphate)
Malquin
Mesylith
Miniquine
Nivaquine
Nivaquine b'
Nivembin
Norolon
Pfizerquin
Presocyl
Quinachlor
Quinercyl
Resichin
Resochin (diphosphate)
Resoquine
Reumachlor
Rivoquin
Salestol
Sanoquin
Scaniquine (diphosphate)
Serviquin
Silbesan
Siragon
Tanakan
Tresochin
Trochin

For regulatory information, see page 46

Product name Chlorphentermine

C.A.S. number 461-78-9

Trade and brand names

Apsedon
Avicol
Avipron
Chenracol
Clorfentermina
Desopimon
Effox
Emagrin
Lucofen
Lucofen retard
Lucofen sa
Minilip
Pre-sate
Reamine
Sinfat
Teramine

For regulatory information, see page 47

Product name Cianidanol

C.A.S. number 154-23-4

Trade and brand names

Ausoliver
Catergen
Cirramina
Transepar

For regulatory information, see page 47

Product name Cinchophen

C.A.S. number 132-60-5

Trade and brand names

Aglophenyl
Agotan
Alcophenyl
Alutyl
Artam
Artexin
Atigoa
Atocin
Atofan
Atophan
Cefeno
Cinchophene
Cinconal
Cincosal
Fenofan
Iriphan
Mylofanol
Mylophanol
Phenoquin
Rhematan
Rheumin
Tervalon
Tophol
Traubofan
Vantyl
Viophan

For regulatory information, see page 48

Product name Clemastine

C.A.S. number 15686-51-8

Trade and brand names

Agasten
Alagyl
Aller-ez
Aller-ez plus
Alogynan
Alphamin

...(Continued)

Product name **Clemastine** ...(Continued)

Trade and brand names

Anhistan
Antihist-1
Arrest
Benaznyl
Clemanil
Clemastin fumerate syrup
Corto-tavegil
Dexa-tavegil
Fuluminol
Fumarsutin
Inbestan
Kinotomin
Lacretin
Licasol
Maikohist
Mallermin
Marsthine
Masletine
Piloral
Rhinergal tavegil
Tavegil
Tavegyl
Tavist
Tavist tablets
Tavist 1
Tavist-d
Tavist-syrup
Tavist-1
Telgin-g
Xolamin

For regulatory information, see page 49

Product name **Clioquinol (see also halogenated hydroxyquinoline derivatives)**

C.A.S. number **130-26-7**

Trade and brand names

Alchloquin
Amebio-formo
Amoenol
Anterobe
Aristoform
Bactol
Barquinol
Barquinol hc
Britaderm
Britadex-vioform
Budoform
Carboform
Cifoform
Cleocin
Cliquinol
Cloro-yodo-hidroxi
Clorpine
Combias
Copover
Cortex
Corti-glottyl
Corticreme
Cremo-quin
Dependal
Dermadex
Dermo-quinol
Dermozolan
Dexalocal
Diaban
Dioderm
Dioderm c
Diodotracin
Dioquinol
Diproform
Dizenterol
Domeform
Eczecidin
Emaform
Ente-rivo
Enteral
Enteritan
Entero-valodon
Entero-vioform
Entero-vioformio
Entero-vioformo
Enterokin
Enterosan
Enterosept
Enteroseptol
Enterozol
Enterquinol
Entox
Entrasorb
Entrokin
Entrokinol
Fraquinol
Fusalor-yodocloro
Fyloxxal
Gmd
Guanosept
Haelan-c
Hi-enterol
Iodenterol
Iodo-max
Iodochlorhydroxyquinol
Iodocortindon
Iodoenterol
Isoderm
Khlorlinkotsin
Klinicin
Lecortin
Lederform-d
Lekosept
Lemoderm
Linola
Locorten
Metrijet
Metrityl
Mexafermento
Mexaform
Mexaform
Mycoquin
Nasello
Nefurox
Nioform
Obstecrim
Oralcer
Oxyquin
Percural
Quadriderm
Quin
Quin iii
Quinambicide
Quiniodochlor
Reticus
Rheaform
Rometin
Sebryl
Sedacol
Septo-canulase
Steroderm
Tequinophil
Toptic
Torofor
Unidiarea
Uteroject
Ventribex
Vioform
Vioform bolus
Vioform hydrocortisan
Viosept

For regulatory information, see page 50

Product name **Clofibrate**

C.A.S. number **637-07-0**

Trade and brand names

Amotril
Angiocapsul
Anparton
Antilipid
Apolan
Arterioflexion
Artes
Artevil
Asa/cpib
Ateculon
Aterioplexin
Ateriosan
Ateroayrest
Ateroclar
Aterofront

...(Continued)

Product name Clofibrate ...(Continued)

Trade and brand names

Ateronlen
Aterosol
Atevil
Atheromide
Atheropront
Atroayerst
Atrofort
Atrolen
Atromid
Atromid-s
Atromidin
Atrovis
Ay 61
Azionyl
Biocleran
Bioscleran
Cartagyl
Cinnarizin
Citiflus
Clareden
Claresan
Claripex
Claripex cpib
Cloberab
Cloberat
Clobrat
Clobrate
Clobren
Clobren-5 f
Clof
Clofenit
Clofi-t
Clofibral
Clofibrat
Clofibrate ayerst
Clofibrate compose
Clofibrato ayerst
Clofibrato procaps
Clofibrem
Clofimide
Clofin-icn
Clofini
Clofinit
Clofipront
Clofipront 5000
Clofirem
Clofirin
Col 180
Contra-lipide
Corafen
Cr/085
Dabical
Delipid
Deliva
Dilectus
Doctus
Duplinal
Duraclofibrate
Ellemger
Elpi
Epib
Eramid
Fibramid
Fibrolynt
Geri-70
Geromid
Gerostop
Healthstyle
Hyclorate
Ici 28257nt
Ipolipid
Klofibrat
Klofiran
Kontalipide
Levatram
Levatrom
Liapten
Liparil
Lipaten
Lipavil
Lipavlon
Lipavlon 500
Lipicidon
Lipofacton
Lipomid
Liponorm
Liporan
Liporeduct
Liporil
Liposid
Liprin
Liprinal
Liptrinal
Lobetrin
Lostat
Miscleron
Negalip
Neo-atromid
Nibratal
Nibratol
Nnormet
Nobret
Norinolipol
Normalip
Normet richter
Normolipol
Nosterolin
Novofibrate
Omelip
Persantinat
Provasa
Recade
Recolip
Regelan
Regelan n 500
Sclerovasal
Serolipid
Serotinex
Sestron
Sinteroid
Sklero
Sklero-tablinen
Sklerocip
Sklerolip
Skleromex
Skleromexe
Sklerovasal
Supraoxid
Tepincal
Tepingal
Ticlobran
Vimedel
Vocaline
Xyduril
Yoclo

For regulatory information, see page 52

Product name Cloforex

C.A.S. number 14261-75-7

Trade and brand names

Avicol sl
Avicol-la
Chloferex
D 237
Frenapyl
Lipociden
Oberex
Vidipon
Zeisin

For regulatory information, see page 53

Product name Clomethiazole

C.A.S. number 533-45-9

Trade and brand names

Clomiazin
Distraneurin
Emineurina
Gebriazol
Hemineurin
Heminevrin
Somnevrin

For regulatory information, see page 54

Product name Clozapine

C.A.S. number 5786-21-0

Trade and brand names

Clozaril
Iprox
Leponex

For regulatory information, see page 55

Product name Cobalt (non-radioactive forms)

C.A.S. number 7440-48-4

Trade and brand names

C.i. 77320
Cobalt-59
Impromin
Inter-con
Kometileneamin
Levacide-c
Orkomin
Panacur
Sofracaps
Tasvite
Trelenium

For regulatory information, see page 56

Product name Cyclamates in drugs

C.A.S. number 139-05-9

Trade and brand names

Adocyl
Ampenoline balsamoco
Assugrin
Azucrona
Cyclarin
Glusac super
Ilgon
Sladicin
Sucaryl
Sucrum

For regulatory information, see page 56

Product name Cyproheptadine

C.A.S. number 129-03-3

Trade and brand names

Anarexal
Antegan
Apeplus
Brantina
Brantine
Brontin
Carnigol
Carpantin
Ciplactin
Cipractin
Cipro
Cipro n
Ciprocort
Cypromin
Cyrasarl
Eiproheptadine
Estialim
Ifrasarl
Kontrast u
Naidoretico
Nuran
Nurdelin
Nuttriben
Oractine
Orexigen
Periactin
Periactine
Periactinol
Periactol
Peritol
Pranzo
Reparal carnitina
Siglatan
Sigloton
Sipraktin
Siprodin
Vimicon

For regulatory information, see page 57

Product name Depot medroxyprogesterone acetate (DMPA)

C.A.S. number 71-58-9

Trade and brand names

Amen
Clinovie
Cliovir
Curretab
Depcorlutin
Depo-prodasone
Depo-progevera
Depo-promone
Depo-provera
Deporone
Depo-clinover
Depo-map
Dugen
Farlurin
Farlutal
Farlutale
G-farlutal
Gesinal
Gestapuran
Gestapuron
Hysron
Intex
Luteocrin orale
Luteodione

...(Continued)

Product name Depot medroxyprogesterone acetate (DMPA) ...(Continued)

Trade and brand names

Luteos
Lutoporal
Lutoral
Metigestene
Metigestrona
Nadigest
Nidaxin
Nogest
Onco-provera
Oragest
Perlutest
Perlutex
Petogen
Piermap
Povera
Prodasone
Progestalfa
Progevera
Promone-e
Pronone
Provera
Proverone
Provest
Repromix
Sindomens
Sirprogen
Sodelut
Sodelut "g"
Supprestal
Verafen
Veramix
Veramix plus v

For regulatory information, see page 59

Product name Dexamfetamine

C.A.S. number 51-64-9

Trade and brand names

Adiparthrol
Afatin
Amfe-dyn
Curban
D-amfetasul
Dexadrine
Dexamin
Dexampex
Dexedrine
Dexten
Dextro-profetamine
Mephadexamine-r
Obotan
Proptan
Robese
Simpamina d
Stil-2
Synatan

For regulatory information, see page 60

Product name Dibenzepin hydrochloride

C.A.S. number 315-80-0

Trade and brand names

Ansiopax
Deprex
Ecatrol
Hf 1927
Neodalit
Neodit
Noveril
Victoril

For regulatory information, see page 61

Product name Diclofenac sodium

C.A.S. number 15307-79-6

Trade and brand names

Alfamin
Allvoran
B-voltaren
Blesin
Cgp 9194
Chlorgyl
Ct-diclo
Dichloronic
Dichronic
Diclo-attritin
Diclo-burg
Diclo-phlohont
Diclo-puren
Diclo-recip
Diclo-spondyril
Diclo-wolf
Dolobasan
Doragon
Duravolten
Effekton
Feloran
Fenoflam
Flogogenac
Inflamac
Klast
Kriplex
Monoflam
Myogit
Neriodin
Neuro-effekton
Neuro-voltaren
Neurofenac
Novapirina
Olfen
Parsal
Prophenatin
Rewodina
Rheumavincin-n
Seecoren
Shignol
Silino
Sofarin
Sorelmon
Thicataren
Toryxil
Tsudomin
Valetan
Voltaren
Voltarene
Voltarol

For regulatory information, see page 61

Product name Dicycloverine

C.A.S. number 77-19-0

Trade and brand names

Ametil
Babyspasm
Babyspasmil
Baycyclomine
Benacol
Bentomine
Bentyl
Bentylol
Clomin
Cyclocen
Diarrest
Dicyclomine
Dicycloverin
Diocyl
Dyspas
Eatongel
Esentil
Formulex
Gastrosilane
Icramin
Incron
Isospamex
Lagasediv
Lagaspasm
Lomine
Mamiesan
Merbantal
Merbentyl
Mydocalm
Neoquess
Nomocramp
Notensyl
Or-tyl
Ovol
Panakiron
Prinel
Procyclomin
Protylol
Sawamin
Spactil
Spascol
Spasmoban
Spasmotal
Spastil
Viscerol
Wyovin

For regulatory information, see page 62

Product name Dienestrol

C.A.S. number 84-17-3

Trade and brand names

Agaldog
Crinohermal fem
Cycladiene
D.v.
Dehydrostilboestrol
Dienoestrol
Dienol
Dienstrogen
Dinestrol
Dinol
Dinovex
Dv
Estraguard
Estrodienol
Estroral
Farmacyrol
Follidiene
Follormon
Foragynol
Frein
Gynefollin
Hormofemin
Isodienestrol
Klianyl
Lipamone
Neo-oestrogenine
Oestrasid
Oestrodien
Oestrodiene
Oestrodienol
Oestroral
Oestrovis
Ortho (cream)
Para-dien
Restrol
Retalon
Sexadien
Sexadieno
Synestrol
Synoestrol
Teserene
Willnestrol

For regulatory information, see page 62

Product name Diethylaminoethoxyhexestrol

C.A.S. number 2691-45-4

Trade and brand names

Coralgil
Coralgina
Coralgyl
Trimanyl

For regulatory information, see page 63

Product name Difenoxin

C.A.S. number 28782-42-5

Trade and brand names

Dioctin
Lyspafen
Lyspofen
Lyspofenac
Motofen

For regulatory information, see page 64

Product name **Difurazone**

C.A.S. number **804-36-4**

Trade and brand names

Panzon
Payzone

For regulatory information, see page 65

Product name **Dihydrostreptomycin**

C.A.S. number **128-46-1**

Trade and brand names

Abiocine
Abocillin
Biostrep
Complexobiotico
Dhsm
Diapenin balsamico
Diapenin 3
Diarrestival
Didromycin
Didrothenate
Dihydrocidan sulfato
Dihydrostreptofar
Dihydrostreptom
Diidro-pantostrept
Distreptopab
Dreiciclina balsamica
Dst
Entera-strept
Estreptoluy
Helle-strep-forte
Hp 48
Mastigun
Mixtencillin
Retromyopen
Rocopenstrep
Sanstrepto
Solmycin
Solvo-strept
Streptoduocin
Veticar
Veycil-as
Vibriomycin

For regulatory information, see page 65

Product name **Dihydroxymethylfuratrizine**

C.A.S. number **794-93-4**

Trade and brand names

Furatone
Panfuran s

For regulatory information, see page 66

Product name **Dimazole**

C.A.S. number **95-27-2**

Trade and brand names

Asterol
Atelor
Atelora
Aterola
Kesten
Mycotol

For regulatory information, see page 67

Product name **Diphenoxylate**

C.A.S. number **915-30-0**

Trade and brand names

Diarphem
Diarsed
Diarsed-neomycin
Diatro
Eldox
Logen
Lomanate
Lomax
Lomotil
Lomotil liquid
Lonox
Protector
Reasec
Saleton
Sedistal

For regulatory information, see page 68

Product name Dithiazanine iodide

C.A.S. number 514-73-8

Trade and brand names

Abminthic
Anelmid
Anguifugan
D.i.m.
Dejo
Delvex
Deselmine
Dilombrine
Dithiazine (dye)
Dizan
Dtdc
Eastman 7663
Elmizin
Nekel
Netocyd
Omni-passin
Ossiurene
Partel
Telmicid
Telmid
Telmide

For regulatory information, see page 69

Product name Domperidone(injectable)

C.A.S. number 57808-66-9

Trade and brand names

Euciton
Kw 5338
Moperidona
Motilium
Nauzelin
Neta662
Praxis
R 33812
Tametil
Touristic

For regulatory information, see page 70

Product name Doxepin

C.A.S. number 1668-19-5

Trade and brand names

Adapin
Apo-doxepin
Aponal
Co dox
Deptran
Doksapan
Dolat
Doxal
Doxedyn
Doxepin hcl
Gilex
Novo-doxepin
Novoxapin
Quitaxon
Sinequan
Sinquan
Sinquan concentrate
Sinquane
Tolliluan
Triadapin
Zonalon

For regulatory information, see page 70

Product name Emetine

C.A.S. number 483-18-1

Trade and brand names

Asmorex
Broncho-tetracycline
Dicton-retard
Emedrin
Emetin
Emetina
Emetocamphrol
Optairosol
Pectinfant

For regulatory information, see page 71

Product name Epinephrine

C.A.S. number 51-43-4

Trade and brand names

Adnephrine
Adrefil
Adrehinal
Adren
Adrenal
Adrenalin
Adrenalin chloride
Adrenalin medihal
Adrenalina ace.p.d.
Adrenalina clorhi
Adrenalina delta
Adrenalina fustery
Adrenalina hormona
Adrenalina p davis
Adrenalina wiener
Adrenaline
Adrenamine
Adrin
Bronkaid mistometer
Cetanest
Chelafrin
D epinefrin
D-epifrin
Dento-caine
Depinefrin
Dysne-inhal
E-caprine

...(Continued)

Product name **Epinephrine** ...(Continued)

Trade and brand names

Epiboran ofteno
Epifrin
Epiglaufrin
Epinal
Epinephrine hcl
Epinephrine pediatric
Epineramine
Epipen
Epirenan
Epitrate
Exadrin
Ganda
Glaucadrin
Glaucadrine
Glaucoaicon
Glaucon
Glauconin
Glaucosan
Glaucotahil
Glycirenan
Haemostasin
Hektalin
Hemisine
Hemostatin
Intranefrin
Isopto epinefrina
Kidoline
L-caine
L-epinephrine
Levorenine
Levorenin-adrenaline
Licothionil
Lidoacton
Lyodrin
Lyophrin
Marcaom
Medihaler-epi
Metanephrine
Methylaminoethanolcatechol
Methylarterenol
Mucidrina
Neo-rybarex
Nephridine
Nieraline
Niphridine
Octacaine
Orostat
Paranephrine
Piladren
Primatene mist
P2e1
Renagladin
Renaglandin
Renaglandulin
Renaleptine
Renalina
Renoform
Renostypticin
Renostyptin
Scurenaline
Sedo-asmol
Simplene
Styptirenal
Supracapsulin
Supranephrane
Supranephrine
Supranol
Suprarenaline
Suprarenine
Suprel
Suprexon
Suprexon 5
Surrenine
Sus-phrine
Susphrine
Sympathin i
Takamina
Vaponefrin
Vaponephrine
Vasoconstrictine
Vasoconstrictor
Vasodrine
Vasotonin
Xylestesin a
Xylotox

For regulatory information, see page 72

Product name **Erythromycin estolate**

C.A.S. number **3521-62-8**

Trade and brand names

Apo-erythro-s
Bio-exazol
Biometran
Biomicron
Bristamycin
Chemthromycin
Cimetrin
Cusimicina balsamica
Doboiosol
Dowmicyn
Dreimicina
Duozplin vitaminado
Dynabiotal
E.e.s
E-mycin
E-mycine
Ees-200
Ees-400
Endoeritrina
Erimec
Erirobios
Eriscel
Eritrazol
Eritro-wolf
Eritrobios
Eritrobiotic
Eritrocin
Eritrodes
Eritroger
Eritronicol
Eritropan
Eritrovienite
Ermysin
Eromycin
Ery derm
Ery-tar
Ery-toxinal
Eryc
Erymycin
Erypar
Eryped
Eryt-toxinal
Erythro-prat
Erythrocin
Erythromictine
Erythromid
Erytrarco
Erytro-prot
Erytrodol
Estimina
Estomicina
Ethril
Fesmicina
Ilosone
Ilosone pulvules
Ilosone ready-mix
Ilothycin
Ilotycin
Kesso-mycin
Laucetin
Laurilin
Lauritran
Lauromicina
Lubomycina
Lubomycine
Makrocyklina
Manilina
Marcoeritrex
Marocid
Mistral
Neo-erycinum
Neo-ilolycina
Niux
Novorythro
Pediamycin
Pels
Pfizer-e
Propriocin enfante
Prospiocine
Proterytrin
Pulmomas
Purmycin
Ritromin
Robimycin
Roxochemil
Rp-mycin
Rubibacter
Selvicin
Sk-erythromycin
Stellamicina
Taimoxin
Togerin
Togrien
Tosinova
Tropoxin
Wyamycin
Wyamycin e
Wyamycin s

For regulatory information, see page 73

Product name **Ethanol**

C.A.S. number **64-17-5**

Trade and brand names

Absolute alcohol
Alcool
Avitoin
B-tonin
Banatol
Colfin
Desqyam-x
Efatin
Equithesin
Hizeneck-d
Honkon-n
Kapsitrin
Keralyt
Levovinizol
Mikrozid
Neotizol
Panoxy
Papette
Piadarn
Polislerol
Protectaderm
Sedopsic
Sicol
Sodaphilline
Softa man
Sotracarix
Verucid
Weingeist
Xeracin

For regulatory information, see page 74

Product name **Ethyl nitrite (spirit)**

C.A.S. number **109-95-5**

Trade and brand names

Timazincum

For regulatory information, see page 74

Product name **Ethylestrenol**

C.A.S. number **965-90-2**

Trade and brand names

Dexabolin
Durabolin-o
Duraboral
Ethylnandrol
Fertabolin
Maxibolin
Neodurabolin
Orabolin
Orgabolin
Orgaboral
Vibolin

For regulatory information, see page 75

Product name **Etomidate**

C.A.S. number **33125-97-2**

Trade and brand names

Amidate
Hypnomidat
Hypnomidate
Hypnomidate concentrate
Hypnomidate injection
Nalgol
Radenarcon

For regulatory information, see page 76

Product name **Etretinate**

C.A.S. number **54350-48-0**

Trade and brand names

Tegison
Tigason

For regulatory information, see page 76

Product name Factor IX

Trade and brand names

Proplex
Prothromplex

For regulatory information, see page 77

Product name Factor VIII

Trade and brand names

Factorate
Hemofil
Humafac
Humanate
Hyate:c
Koate
Kryobulin
Profilate

For regulatory information, see page 78

Product name Fenclofenac

C.A.S. number 34645-84-6

Trade and brand names

Flenac
Monosan
Rx 67408nac

For regulatory information, see page 78

Product name Fenetylline

C.A.S. number 3736-08-1

Trade and brand names

Biocapton
Captagon
Captagon cpr nsfp

For regulatory information, see page 78

Product name Feprazone

C.A.S. number 30748-29-9

Trade and brand names

Analud
Bentudor
Brotazona
Cocresol
Da 2370
Danfenona
Feniprenazone
Fepramole
Golaman
Grisona
Impremial
Methrazone
Metrazone
Naloven
Nazona
Nilatin
Prenazon
Rangozona
Represil
Solielin
Tabrien
Vapesin
Zepelin
Zerinol
Zontal
Zoontal

For regulatory information, see page 79

Product name Fipexide

C.A.S. number 34161-24-5

Trade and brand names

Attenil
Attenil 30 conf. 20 mg
Fipexitum
Fipexium
Vigilor
Vigilor 200 mg cpr msfp

For regulatory information, see page 80

Product name Flunitrazepam

C.A.S. number 1622-62-4

Trade and brand names

Darkene
Flumipam
Flunipam
Hipnosedon
Hypnodorm
Hypnosedon
Narcozep
Primun
Riopnol
Rohpinol
Rohpnol
Rohypnol
Roipnol
Valseram

For regulatory information, see page 83

Product name Furazolidone

C.A.S. number 67-45-8

Trade and brand names

B-fsudi
Benilen
Biofur
Carbopuradin
Coryzium
Dapecfuran
Dectolin
Dependal
Diafuron
Dialidene
Diarexin
Diarin
Diclofur
Dorepiston
Dushel
Enteral
Enterar
Enteroxon
Foroxon
Foroxone
Framenterol
Ft 15
Furaberin
Furacol l.
Furacort
Furalatin p.
Furalidan
Furaliqua
Furall
Furazol
Furazon
Furovag
Furox
Furoxal
Furoxane
Furoxon
Furoxona
Furoxona-cp
Furoxone
Furoxone swine mix
Fuvitan
Fuxol
Fuzatyl
Galacid
Gamafur s.
Giardil
Giarlam
Giarlin
Ginvel
Injecur
Intefuran
Kalpec-f
Lacolysat
Mastisept
Medaron
Metrijet
Multi-med 2
Multi-med 3
Multi-med 6
Neforox
Neforox alpha cpto
Neftin
Neftivit
Nefurox
Nf 180
Nicolen
Nicolen r
Nifulidone
Nifulin
Nifuramicin
Nifuran
Optazol
Parkestress forte
Pertaril
Procijec
Puradin
Roptazol
Saleton
Sanibiovit
Sanimix
Sanistress
Scantrimon
Sclaventerol
Sibren
Syralbuna
Tetrafur
Tikofuran
Topazone
Tranatogen-ova
Trichofuron
Tricofuron
Tricoron
Trifurox
Ufa-cfo-400
Uterojekt
Vagifurona
Vetoprim
Viofuragyn
Vsf-medical g 15

For regulatory information, see page 83

Product name Glafenine

C.A.S. number 3820-67-5

Trade and brand names

Adalgur
Disipan
Espasmo-giliganan
Glafezon
Glifadex
Glifan
Glifanan
Glifarelax
Osodent
Privadol

For regulatory information, see page 85

Product name **Glucosamine sulfate**

C.A.S. number **3416-24-8**

Trade and brand names

Adaxil
Antatril
Corti-anartril
Dona compositum
Dona 200-s
Donna 200
Thiocondramine

For regulatory information, see page 86

Product name **Glutethimide**

C.A.S. number **77-21-4**

Trade and brand names

Alfimid
C "5"
Doriden
Doriden-sed
Doridene
Doridine
Dorimid
Elrodorm
Glimid
Gludorm
Noxyron
Rigenox
Sarodormin
Somid
Somvit
Tardyl

For regulatory information, see page 87

Product name **Griseofulvin**

C.A.S. number **126-07-8**

Trade and brand names

B-gf
Delmofulvina
Fulcine
Fulcine-s
Fulcine-125
Fulvicin
Fulvicin u/f
Fulvicina
Fungivin
Gefulvine
Greosin
Gricin
Grifulin
Grifulvin
Grifulvin v
Gris-peg
Grisactin
Grisaltin
Grisefulin
Grisefulvin
Griseo
Griseomed
Griseostatin
Grisovin
Grisovin-fp
Grisovina
Grisowen
Grysio
Lamoryl
Lamoryl-novum
Likuden
Neo-filcin
Norofluvin
Polygris
Sulvina

For regulatory information, see page 87

Product name **Halogenated hydroxyquinoline derivatives**

C.A.S. number **148-24-3**

Trade and brand names

Aci-jel
Cp-cap
Fennosan h 30
Heriat
Hydroxybenoxopyridine
Oxin
Oxine
Oxyquinoline-rhp
Pedivol
Phenopyridine
Preconsol
Quinoped
Quinophenol
Semori
Serohinol
Superol
Tumex

For regulatory information, see page 88

Product name **Halogenated salicylanilides**

Trade and brand names

Alamin
Annul
Bada
Hilomid
Salinidol
Temasept

For regulatory information, see page 89

Product name Heptabarb

C.A.S. number 509-86-4

Trade and brand names

Heptadorm
Medapan
Medomin
Medomina
Medomine

For regulatory information, see page 89

Product name Herpes simplex vaccines

Trade and brand names

Deptavac hvt
Herpevac
Herpevax
Herpevax hvt
Marimune
Medapan
Medomin
Taf test
Tracherine

For regulatory information, see page 90

Product name Hexachlorophene

C.A.S. number 70-30-4

Trade and brand names

Acnestrol (broparestrol)
Acnestrol 3
Aeroseb-hc
Akne pyodron kur
Aknelan
Armohex
Asecool
Bilevon
Bilvon vet
Cidal
Cinthol
Clenisep
Coopaphene
Cotofilm
Cresophene
Delta pimafucort
Derivative
Derl
Derma leaf
Derma 10
Dermadex
Dermalex
Dermohex
Dermolle
Dexolan
Dial toilet soap
Distocid
Dk 2
Dovaso
E-z scrub
Ecto pellicur
Ectofum
Emlab
Exofene
Fisohen
Fitty derm
Flenaphthol
G-11
Gamophen
Gamophen surgical soap
Germibon
Gill soap
Haemovin
Hcp
Heksaden
Hepadist
Hex-o-san
Hexabalm
Hexadespon
Hexal
Hexaph
Hexaphenyl
Hexaphenyl(1&b)
Hexascrub
Hexocreme
Hexosan
Jabon antiseptico
Kalacid
Lf 530
Loftyzon
Mamex
Mantacido
Med liquide san t
Micogamma
Nabac
P 47
Paradentol
Permucal
Phaisohex
Phasca
Phiso-med
Phisohex
Phisohex(winthrop)
Phisoscrub
Phlebodine
Phorac
Phosohex
Pre-op
Predekzem
Pretulon
Proct anex
Prodermopur
Sapo-chlor
Sapoderm
Sebbafon
Sebo-cds
Sebryl
Sergi-cen
Skrub kreme
Solu-heks
Soy-dome
Ster-zac
Ster-zac antibacterial shaving foam
Ster-zac antibacterial soap
Ster-zac dc skin cleanser
Ster-zac powder
Steraskin
Steridermis washing cream
Sumasept
Super sat
Surg salve
Surge vet
Surgi-cen
Surofene
Tersaseptic
Vanseb
Vetalderm
Vulnusol spray
Wesco hex
Wescohex
Westasept
Xerac
Zalpon antibacterial washing cream
99 armour formula

For regulatory information, see page 90

Product name **Hexobarbital**

C.A.S. number **56-29-1**

Trade and brand names

Citodon
Citopan
Cyclonal
Cyclonal sodium
Cyclopan
Dorico
Dorico soluble
Evipal
Evipal sodium
Evipan
Hexanal
Hexanastab
Hexanastab oral
Hexatrol
Hexenal
Methexenyl sodium
Narcosan soluble
Noctivane
Noctivane sodium
Privenal
Sedragesic
Sleepwell
Sodium narcosate
Sombucaps
Sombulex
Somnalert
Stodinox
Tobinal
Toleran

For regulatory information, see page 91

Product name **Hydroquinone**

C.A.S. number **123-31-9A**

Trade and brand names

Aida
Ambi- skin tone
Artra
Black and white
Creme des 3 fleur d'orient
Eldopaque
Eldopaque forte
Eldoquin
Eldoquin forte 4% cream
Epocler
Esoterica
Esoterica facial
Esoterica regular
Esoterica sensitive skin
Esoterica sunscreen
Melanex
Melanex topical sollution
Melpaque hp
Melqui hp
Neostrata aha gel
Neostrata hq
Nuquin hp
Phiaquin
Pigmanorm
Porcelana
Sinquin
Solaquin
Solaquin forte
Solaquin forte sun bleaching
Superfade age spot
Ultraquin
Ultraquin plaine

For regulatory information, see page 92

Product name **Hyoscine methonitrate**

C.A.S. number **6106-46-3**

Trade and brand names

Mescomine
Mesconit
Skopolate
Skopyl
Skopyle
Viscope

For regulatory information, see page 92

Product name **Ibuprofen**

C.A.S. number **15687-27-1**

Trade and brand names

Abbifen
Abu-tab
Abuprohm
Aches-n-pain
Acril
Actifen
Actiprofen
Actren
Addaprin
Advil
Advil cold & sinus
Advil 200 mg
Agisan
Aktren
Aldospray
Algiasdin
Algifor
Algisan
Algofen
Algofer
Altior
Amersol
Anadin ibuprofen
Analgesico
Analgil
Analgyl
Anco
Andran
Anflagen
Antalgil
Antiflam
Antiruggen
Apo-ibuprofen
Apsifen
Arfen
Artofen
Artren
Artril
Artrofen
Bayer select
Bayer select ibuprofen pain reliever
Benflogin
Betagesic
Betaprofen
Brofen 200 mg
Brofen 400 mg
Brufanic
Brufen
Brufert
Brufort
Buborone
Bufedon
Bufigen
Burana

...(Continued)

Product name Ibuprofen ...(Continued)

Trade and brand names

Butylenin
Cesra
Children's advil
Children's motrin
Coadvil
Codafen
Codafen continus
Contraneural
Contrneural
Cope
Cuisialigil
Cunil
Cuprofen
Danilon
Dansida
Dentigoa forte
Dignoflex
Dimetap sinus
Dimidon
Dismenodi n
Dolgirit
Dolgit
Dolo-dolgit
Dolo-neos
Dolo-puren
Dolocyl
Dologesic
Doltibil
Dolven
Donjust-b
Dorival
Dristan sinus
Dura-ibu
Duradyne
Duralbuprofen
Dysdolen
Ebutac
Ecoprofen
Ediluna
Emodin
Epobron
Esprenit
Evasprin
Excedrin ib
Exneural
Femafen
Femapirin
Femidol
Fenalgic
Fenbid
Fenlong
Flubenil
Focus
Genpril
Guildprofen
Halprin
Haltran
Ibenon
Ibol
Ibosure
Ibruthalal
Ibu-attritin
Ibu-cream
Ibu-slo
Ibu-slow
Ibu-tab
Ibucasen
Ibufac
Ibufen tablets
Ibufen-l
Ibufug
Ibugel
Ibugesic
Ibuhexal
Ibular
Ibulav
Ibuleve
Ibulgan
Ibumetin
Ibuphlogont
Ibupirac
Ibuprin
Ibuprocin
Ibuprofen 200
Ibuprohm
Ibusure
Ibutad
Ibutid
Ibutop
Ibuvivimed
Ibux
Imben
Inabrin
Incefal
Inflam
Inoven
Inza
Ipren
Iproben
Irfen
Isdol
Isisfen
Junifen
Kos
Lacondan
Lamidon
Leonal
Librofem
Librofen
Lidifen
Liptan
Lisi-budol
Medipren
Mediprofen
Melfen
Menado ibuprofen usp
Midol
Midol ib
Midol 200 advanced pain formula
Migrafen
Minadol
Mobilat
Moment
Motrin
Motrin ib
Myprodol
Narfen
Neobrofen
Neobrufen
Nerofen
Niapren
Nobfelon
Nobfen
Novaprin
Novogent
Novoprofen
Nu-ibuprofen
Nuprin
Nurofen
Optalidon
Optifen
Opturem
Pacifene
Padudent
Pamprin
Pantrop
Parsal
Paxofen
Pediaprofen
Phor pain
Posodolor
Proflex
Prontalgin
Rafen
Rebugen
Recudik
Relcofen
Rheufen
Rimafen
Rofen
Roidenin
Rufen
Saleto
Saleto-600
Seclodin
Sedaspray
Serviprofen
Sine-aid ib
Solufen
Spedifen
Stadasan
Superior pain medicine
Supreme pain medicine
Supren
Suspren
Tabalon
Tendar
Trauma-dolgit
Ultraprin
Urem
Valprin

For regulatory information, see page 93

Product name Indalpine

C.A.S. number 63758-79-2

Trade and brand names

Lm 5008
Upstene

For regulatory information, see page 94

Product name **Indoprofen**

C.A.S. number **31842-01-0**

Trade and brand names

Bor-ind
Endyne
Fenint
Flogosan
Flosin
Flosine
Flosint
Flosyn
Isindone
K 4277
Miantor
Praxis
Reumofene

For regulatory information, see page 94

Product name **Iodinated casein strophanthin (neo-barine)**

Trade and brand names

Coratose

For regulatory information, see page 95

Product name **Iproniazid**

C.A.S. number **54-92-2**

Trade and brand names

Euphozid
Ipropran
Isotamine
Laniazid
Marsilid
Nydrazid
P-1-n forte
Pms isoniazid
Rifamate
Rimactane
Rimifon
Ro 7-1554
Teebaconin
Triniad
Uniad

For regulatory information, see page 95

Product name **Isaxonine phosphate**

C.A.S. number **4214-72-6**

Trade and brand names

Nerfactor
Verfactor

For regulatory information, see page 96

Product name **Isocarboxazid**

C.A.S. number **59-63-2**

Trade and brand names

Enerzer
Marplan
Marplon
Ro 5-0831/1

For regulatory information, see page 96

Product name **Isoprenaline**

C.A.S. number **7683-59-2**

Trade and brand names

Aerolone
Aerotrol
Afdosa
Aldo asma
Aleudrin
Aleudrina
Aludrin
Anthastmin
Asmadren
Asmalar
Asmastop
Atom-asma
Bellasthman
Dey-dose
Dispos-a-med
Duo-autohaler
Duo-medihaler
Dyspnoesan
Erydin
Euspiran
Frenal composium

...(Continued)

Product name Isoprenaline ...(Continued)

Trade and brand names

Imuprel
Ingelan
Intal compositum
Iprenol
Iso-autohaler
Isomenyl
Isonorin
Isoprel
Isoprel-neomistometer
Isoprop
Isorenin
Isovon
Isuprel
Katwilon n
Lenoprel
Luf-iso
Medihaler-duo
Medihaler-iso
Meterdos-iso
Neo epinine
Nephenalin
Norisodrin aerotol
Norisodrin with calcium idodide
Norosodrine
Novodrin
Older
Orotenol
Prenomiser
Propynalin
Protenol
Saventrine
Sedantosol
Sooner
Suscardia
Vapo-iso
Vapo-n-iso

For regulatory information, see page 96

Product name Isotretinoin

C.A.S. number 4759-48-2

Trade and brand names

Accutane
Accutane roche
Aknefug
Apsor
Isotretinoin
Neovamin a acid
Neovitamin a acid
Ro 4-3780
Roaccutan
Roaccutane
Roacutan

For regulatory information, see page 97

Product name Isoxicam

C.A.S. number 34552-84-6

Trade and brand names

Floxicam
Maxicam
Pacy
Pacyl
Vectren

For regulatory information, see page 98

Product name Kaolin

C.A.S. number 1332-58-7

Trade and brand names

Donnagel
Donnagel pg liquid
Donnagel-mb
Kao-spen
Kaodinnon-narcotic
Kaolin w/pectin
Kapetolin
Kc

For regulatory information, see page 99

Product name Kebuzone

C.A.S. number 853-34-9

Trade and brand names

Benjor
Chebutan
Chepirol
Chetazol
Chetazolidin
Chetil
Chetopir
Chetosol
Copirene
Ejor
Gammachetone
Hichillos
Kenta-s
Kentan
Kentan-s
Kenzon r
Ketanol
Ketazon
Ketazone
Ketobutane-jade
Ketofen
Neo-panalgyl
Neuphenyl
Pecnon
Phloguron
Recheton
Reuchetal
Reumo
Tkb
Vintab
Vintop

For regulatory information, see page 99

Product name **Ketoconazole**

C.A.S. number **65277-42-1**

Trade and brand names

Cerozalol
Cetonax
Fetonal
Fungarest
Fungarol
Fungo-hubber
Ketocidin
Ketoderm
Ketoisdin
Ketonan
Ketoral
Micoral
Micotek
Micoticum
Nizcrem
Nizoral
Nizoral 2% shampoo
Nizoral 20% cream
Nizovules
Nizshampoo
Oromycosal
Oronazol
Panfungol
Rofenid

For regulatory information, see page 100

Product name **Latamoxef**

C.A.S. number **64952-97-2**

Trade and brand names

Festamoxin
Moxacef
Moxalactam
Moxam
Shiomalin
Shiomarin

For regulatory information, see page 102

Product name **Lead oxide and lead salts**

Trade and brand names

Hiroval
Wndomethasone

For regulatory information, see page 102

Product name **Levamfetamine**

C.A.S. number **156-34-3**

Trade and brand names

Amphedrine-m
Cydril

For regulatory information, see page 103

Product name **Loperamide**

C.A.S. number **53179-11-6**

Trade and brand names

Ami-29
Arret
Blox
Brek
Colifelin
Dissenten
Dissenter
Duplibiot
Etcoman
Firtasec
Imodium
Imosec
Lopemid
Lopemin
Loperan
Loperin
Lopermid
Loperyl
Motilix
Orulop
Pf 185
Pricilone
R-18553
Regulane
Seldiar
Suprasec
Taguinol
Telboc
Totrtasec

For regulatory information, see page 105

Product name Lynestrenol

C.A.S. number 52-76-6

Trade and brand names

Anacylin
Anacylin 101
Anacylin 28
Ancylin
Athilyn
Endometril
Exlutena
Exlution
Exluton
Exluton (a)
Exlutona
Fisioquens
Fysioquens
Lindiol 2.5
Lyn-ratiopharm
Lyndeol
Lyndiol
Lyndiol e
Lyndiolett
Lynoenstrenol
Minette
Mini pregnon
Minilyn
Ministat
Neo-lindiol
Neo-lynobol
Nonovulet
Noracyclin
Noracyclin 22
Normophasic
Org 485-50
Orgaluton
Orgametil
Orgametril
Orgametrol
Ovamezzo
Ovoresta
Ovoresta m
Ovosta
Ovostat
Ovostat-micro
Ovostat-28
Physistat
Pregnon
Pregnon-28
Restovar
Yermonil

For regulatory information, see page 106

Product name Mazindol

C.A.S. number 22232-71-9

Trade and brand names

Dasten
Degonon
Fagolipo
Lipese
Magrilan
Mazanor
Mazanor tablets
Mazeldene
Mazinil
Maznor
Sanorex
Tenorac
Terenac
Teronac

For regulatory information, see page 106

Product name Meclozine

C.A.S. number 569-65-3

Trade and brand names

Ancolan
Ancoloxine
Antivert
Bonamina
Bonamine
Bonexyl
Bonine
Calmonal
Chiclida
Cobinamide
Diadril
Dradril
Duremesan
Itinerol
Mecazine
Navicalm
Neo-istafene
Peremesin
Postafen
Postafene
Ravelon
Rovert-m
Ru-vert-m
Sabari
Sea-leg
Supermesin
Suprimal
Taizerl
Ucb 5062
V-cline
Veritab
Vertizine
Vomaxine
Vomisseis

For regulatory information, see page 107

Product name Megestrol acetate

C.A.S. number 3562-63-8

Trade and brand names

Citestrol
Co-ervonum
Combiquens
Femagest
Kombiquens
Megace
Megecat
Megeron
Megestat
Menoquens
Neo-delpregnin
Nia
Niagestin
Niagestine
Novaquin
Novokvens
Novolina
Novoquens
Oracolnal
Ovaban
Ovarid
Pallace
Volidan
Volplan

For regulatory information, see page 107

Product name **Mephenesin**

C.A.S. number **59-47-2**

Trade and brand names

Atensin
Avosyl
Bioglan m/q
Cresoxydiol
Curythan
Daserd
Daserol
Decontractyl
Diloxol
Dioloxol
Geno-sal
Glykresinum
Glyotol
Glyptol
Kencaps
Kinavosyl
Lissephen
Mefentil
Memphenesin
Mepha-gesic
Mepherol
Mephesin
Mephesol
Mephson
Midisalb-m
Myanesin
Myocalm
Myocuran
Myolisysin
Myoxane
Nochyrol
Noctynol
Oranixon
Prolax
Relaxar
Relaxil
Relaxil-g
Renarcol
Rhex
Rhex "hobein"
Rp 3602
Sansdolor
Sinan
Spartoloxyn
Spasmolyn
Stilalgin
Thioxidil
Tolansin
Tolax
Tolcil
Tolhart
Tolosate
Toloxyn
Tolseram
Tolserol
Tolseron
Tolsin
Tolulexin
Tolulox
Tolyspaz
Walconesin

For regulatory information, see page 108

Product name **Meprobamate**

C.A.S. number **57-53-4**

Trade and brand names

Adalgur
Amepromat
Amosene
Anastress
Anatimon
Andaxin
Aneural
Ansietan
Ansiowas
Anzil
Apascil
Apo-meprobamate
Arcoban
Artolon
Atraxin
Ayeramate
Bamo 400
Biobamat
Biobamate
Calmax
Calmiren
Canquil-400
Cap-o-tran
Carb-a-med
Carbaxin
Cirpon
Cirponyl
Clindoorm
Coprobate
Crestanil
Cusitan
Cyrpon
Dapaz
Daritran
Detensitral
Dicandiol
Diron
Dolovisano
Dormabrol
Dormilfo n
Dystoid
Ecuanil
Edental
Epikur
Equanil
Equiner
Equinil
Equqtrqte
Europan
Fas-cile 200
Gadexyl
Gene-bamate
Harmonin
Hartol
Holbamate
Idemin
Indemin
Irs 109 a
Iterco
Juvamidon
Kaologeais
Kesso-bamate
Klort
Koronar
Lan-dol
Larten
Lenicor
Lepetown
Libiolan
M.a.s.
M.p. trantabs
Mar-bate
Margaris
Meditran
Mep-e
Mepantin
Mepavlon
Meposed
Meprate
Mepriam
Meprin
Meprindon
Mepro
Mepro-secergan 400
Meprobadal
Meprobamat
Meproban
Meprobil
Meprobit
Meprocompren
Meprocon cmc
Meprodil
Meprogesic q
Meprol
Meprolin
Mepron
Mepronel
Mepronil
Mepropon
Meprosa
Meproserpina
Meprospan
Meprospan 400
Meprotabs
Meproten
Meprotil
Meproyrin
Meprozine
Meptran
Meriprobate
Mesmar
Metranquil
Micrainin
Microbamat
Midixin
Milspan
Miltaun
Miltown
Miltown s-r
Misedant
Morbam
My-trans
Myo-europan

...(Continued)

Product name Meprobamate ...(Continued)

Trade and brand names

N 8
Neo-nervostal
Neo-tran
Nervonus
Neuramate
Neuro
Neurocalm
Novomato
Novomepro
Nyktogen
Oasil
Oasil procalmadiol
Odsil 10
Panquil
Paxin
Pensive
Pentaneural
Perequil
Pertranquil
Placitate
Pm 2
Pmb 4000
Prequil
Probal
Probasan
Probromato
Procalmidol
Promate
Protran
Psico-retard
Quaname
Quanil
Quietidon
Rastenil
Regium
Relaxin
Reostral
Restenil
Rilax
Robamate
Seda baxacor
Sedanyl
Sedavier
Sedazil
Selene
Selodorm
Serenade
Seril
Setran
Shalvaton
Sintown
Sk-bamate
Sopanil
Sowell
Spantran
Spasmobamat
Stensolo
Stopayne
Tamate
Tcm 200
Tcm 400
Trankilin
Trankvilan
Tranlisant
Tranmep
Tranquil
Tranquilan
Tranquilax
Tranquiline
Trelmar
Tri-reumo-campil
Urbil
Urbilat
Vasocalm
Vio-bamate
Visano cor
Vistabamate
Wescomep
3p bamte

For regulatory information, see page 108

Product name Mercuric derivatives (topical)

Trade and brand names

Mercuro clinico
Mercurocol
Neko

For regulatory information, see page 109

Product name Mesna

C.A.S. number 19767-45-4

Trade and brand names

Ausobrone
Mexnex
Mistabron
Mistabron co
Mistabronco
Mistalon
Mucofluid
Mucolene
Uromitexan
Uronexitan

For regulatory information, see page 109

Product name Metamfetamine

C.A.S. number 537-46-2

Trade and brand names

Amone
Dexophrine
Dexoval
Doxyfed
Doxyn
Drinalfa
Efroxine
Elibese
Euphrodinal
Gardstat
Gerobit
Geronyl
Lemobese
Madrine
Meloda
Metamsustac
Methampex
Methedrinal
Methedrine
Neodrine
Neodrine-triple
Norodin
Obe-slim
Obedrin-la
Obelones
Oxabar
Pervitin
Phedrisox
Philopon
Soxympamine
Syndrox
Tonedron
Uno

For regulatory information, see page 110

Product name # Metamizole sodium

C.A.S. number 68-89-3

Trade and brand names

Abalgine
Acabel compositum
Acefalgin
Acrobal
Acrogesico
Adolkin
Algia-nil
Alginodia
Alginodia compose.
Algisedal
Algobuscopan
Algocalmin
Algoprib
Algopriv
Algopyrin
Algopyriv
Alkozin
Amiglan
Aminocid
Amitralil
Ampi tumisan
An-t
Anadex
Anador
Analcedor
Analgilasa
Analgin
Analginum
Analject
Anarinyl
Anchrina
Andolor
Anespas cpto
Angiter
Ankaljin
Apasmo
Apracur
Arantil
Arpf
Arquidon
Artritex
Ascorbalgine
Ascortin
Aseptobron
Atecilina
Atn-020/2
Aureomicina
Avafortan
Ayoral
Baralgin
Baralgine
Bayer 1387
Bebealjin
Bebigut
Belatropin
Belflex/2
Beneurin
Beserol
Bexopirona
Biogamma2
Biotangin
Bipasmin compuesto
Bitencyl
Bonpyrin
Bort
Bristacilia
Britercina
Bromalgin
Bromalgon
Broncofenil
Broncolysin
Bucarboxal
Buscapina comp.
Buscapina compuesto
Buscapina compuestum
Buscol compositum
Buscopan composto
Buscopan compostum
Buscopina compostum
Butalgine
Butylpan
Byladoce
Calgayan-c
Calmetron
Camizol
Causalon
Cessantyl
Chini-med
Cintaverin compuesto
Citalgan
Clizim
Clofexan
Codalgin
Codasal injetavel
Cofen
Colgenol
Comaril 5000
Conmel
Corilin pediatric
Cortempirol
Cortitracin
Cronopen balsamico
D-pron
Deltricin
Devalgin
Dexa butarin
Di-bal-rone
Dimethedon
Dinopirina
Dioxadol
Dipiron
Dipirona
Dipirone
Diprofarm
Dipyrivo
Dispalgine
Divarin
Divarmin
Do-ba-rone
Dobetin
Dolaren
Dolazon
Dolemicin
Dolispan
Dolispasmo
Dolo adamon
Dolo baralgine
Dolo buscopan
Dolo nerv
Dolo neurobion
Dolo neurobion forte
Dolo pangavit
Dolo raptalgin
Dolo spasuret
Dolo-neurobion
Dolojudolor
Dolopirina
Doloscopin
Dopiral
Dorflex merrell
Dorlisin
Doron
Dorscopena
Dorsedin
Dumalgin
Duralnordin
Dya-tran
Edgartet
Eespanal
Enzipan combinado
Espasther
Espasmir
Espasmo-cibalgina
Espasmoqual
Espasmotex
Espasmoviral
Espyre
Farbinol
Farmolisina
Feverall
Fevonil
Flogolisin
Formatrix
G.r. ulix compuesto
Genservet
Gentil
Geralgine
Gifaril
Glutisal
Greplicina belsa
H 116
H 117
H 118
Indextron
Influbene
Kb-502
Kefren
Kesan
Keypyrone
Killgrip
Kipyrone
Kitax alpha
Kitax n
Konitan
Labymetacincpo
Lactmicina
Lagalgin
Lagalgine
Lamprcsnum
Lapalgine
Larq 731
Lasain
Lauroanginol
Lavaciclina
Levapa
Levismon
Lisador
Lisalgil
Magdor
Magnalsa
Magnemidon
Magnol
Magnopyrol
Mapir
Mecoten
Megal
Meliplus
Melpen
Menalgine
Metapyrin
Methampyrone
Metilon
Mialgan
Minalgin
Minoval
Miocitalgan
Nadalgine
Naftalgin
Naltrium

...(Continued)

Product name Metamizole sodium ...(Continued)

Trade and brand names

Napasone
Naron
Nartate
Natralgin
Natric
Neo-melubrin
Neo-melubrina
Neo-melubrine
Neo-oxipen
Neosal-n
Neosoldina
Neuro-fortamin
Nevralgin
Nevralgina
Nisidina
Nlo conicilina balsamica
Nobelgin
Nolotil
Nolotil composirum
Notermin
Nova-lyseen
Novacid
Novalcina
Novaldin
Novalgetol
Novalgin
Novalgin quinine
Novalgina
Novalgine
Novamidazofen
Novamidazophen
Novamideazophene
Novamina
Novaminophenazone
Novaminsulfon
Novaminsulfon ratiopharm
Novaminsulfone sodium
Novaminsulfonium
Novaminsulfonum
Novazolon dexametasona
Noveltex
Novemida
Novemina
Novil
Oftlamin
Optalgin
Orphalginen
Ortopirona
Oxiquinazine
Pabron gold
Panalvon
Panax
Papnin
Paralgin
Patalgin
Pentrodin
Phanalgin
Pharmalgine
Porbiot
Pplan 2500
Probaphen
Prodol
Prydonnal
Pydirone
Pyralgin
Pyralgine
Pyretin
Pyril
Pyrilgin
Pyriligin
Pyrisan
Pyrojec
Quarelin
Reflex rectal
Relexal compuesto
Repriman
Resquim
Rheuma-spalt
Ridol
Rivodol
Ron-drive
Rumalisine
Rupalgin
Santeprednisan a
Sebon
Sedabel
Sedalmerck
Sedarel
Sedarene
Sedazepane
Segudol
Selpiran
Sertalanalgesico
Severen
Severin
Sinalgex
Sintaverin
Sinvirol
Sistalgin
Spasdolsom
Spaslar
Spasmalgon
Spasmin
Spasmium-comp.
Spasmizol
Spasmodor
Spasmopyralgin
Spasmothil
Sulfonovin
Sulpin
Sulpyrin
Sulpyrine
Supadol
Supergine
Surpyrine
Syntaverin
Tanper
Tapal
Tega-pyrone
Temp
Tempil
Tepal
Termonil
Tetrabal-hosbon
Tetraspasmil
Tiadexol
Tiartan
Toloxin andromaco
Trenteron
Triartan
Trinalgen
Tumisan globulina
Ultragim
Ultragin
Unagen
Unalgen hc
Vetalgin
Viperone
Visceralgine forte

For regulatory information, see page 110

Product name Methapyrilene

C.A.S. number 91-80-5

Trade and brand names

Bio-vitastrept
Brexin
Conac
Dexapirilene
Dormin
Duo-tussin
Duohist
Dylhista
Histadyl
Hitalones
Isopap
Lallamin
Lullamin
M.p.
Methistaline
Methril spansul
Mycl-spray
Norane
Paradormalene
Peral
Placitabs
Pyrathyn
Pyrinistab
Pyrinistol
Rejam
Rest-on
Restryl
Sedanoct
Semikon
Sleepwell
Tenalin
Thenylene
Thionylan
W83
3p pane

For regulatory information, see page 113

Product name Methaqualone

C.A.S. number 72-44-6

Trade and brand names

Aqual
Babix-rectal
Bon-sonnital
Cateudyl
Citexal
Daturmed
Diudorm
Divinoctal
Dormigoa
Dormigoa-schlafmittel
Dormir
Dormisedital
Dormogen
Dormutil
Dorsedin
Duromine m 40
Eatan
Fadormir
Holodorm
Hyminal
Hypocol
Hyptor
Hyptor base
Ipnofil
Isonox
Jurmun
Juvamidon
Maoa
Melsed
Melsedin
Melsedine base
Melsomin
Mepalgic
Mequal
Mequelon
Mequin
Metadorm
Metakvalon
Metaqualon
Methadorm
Methaquaion
Methaqualoneinone
Methased
Methasedil
Metodril
Metodril napa
Metodril 2
Metolquizolone
Mollinox
Motolon
Mozambin
Mtq
Neuro a2
Neurocalm
Nitro-tromacardin
Nobadorm compostium
Nobedorm
Noctilene
Noctulon
Normi-nox
Normorest
Noxybel
Nyktogen
Oblioser
Omnyl
Optimil
Optinoxan
Orthonal
Ortonal
Paldona
Pallidan
Papatral
Parest
Parmilene
Paxidorm
Pexaqualone
Portaderm
Pro dorm
Quaalude
Qz 2
Rebuso
Rectulon
Revonal
Ric 272
Riporest
Rm 526
Rorer 148
Rorer 714
Roulone
Rouqualone
Savedorm
Sedalone
Sedanoct
Sedatyl
Selodorm
Silternum
Sindesvel
Sleepinal
Somberol
Somnafac
Somnex
Somnibel
Somnium
Somnomed
Somnosan
Somnotropon
Sonal
Sopor
Soval
Sovelin
Soverin
Sovinal
Spasmopront
Tiqualone
Toquilone
Toraflon
Torinal
Tr 495
Tualone
Tuazole
Tuazolona
Tuazolone

For regulatory information, see page 114

Product name Methiodal sodium

C.A.S. number 126-31-8

Trade and brand names

Abrodan
Abrodil
Conturex
Diagnorenol
Kontrast
Myelotrast
Neo-sombraven
Radiographol
Segosin
Sergozin
Skiodan sodium
Urombal

For regulatory information, see page 114

Product name Methylphenidate

C.A.S. number 113-45-1

Trade and brand names

Calocain
Cetedrin
Meridil
Ritalin
Ritalin sr
Rubifen
4311 ciba

For regulatory information, see page 115

Product name **Methyprylon**

C.A.S. number **125-64-4**

Trade and brand names

Noludar
Nolurate

For regulatory information, see page 115

Product name **Metofoline**

C.A.S. number **2154-02-1**

Trade and brand names

R 4-1778/1
Versidyne

For regulatory information, see page 115

Product name **Mianserin**

C.A.S. number **24219-97-4**

Trade and brand names

Athymil
Bolvidon
Lantanon
Lerivon
Miansan
Norval
Org gb 94
Tolvin
Tolvon

For regulatory information, see page 116

Product name **Mifepristone**

C.A.S. number **84371-65-3**

Trade and brand names

Mifegyne
Ru-486

For regulatory information, see page 116

Product name **Mofebutazone**

C.A.S. number **2210-63-1**

Trade and brand names

Arcobutine
Arcomonol
Buta lyseen
Butazone
Clinit
Diadin
Fenartril
Jovapyrin
Mobutazone
Mobuzon
Mofasal
Mofesal
Monazan
Monazone
Monobutina
Monobutyl
Monofen
Monomil
Monorheumetten
Monozon
Mozol
Reumatox
Rheuma
Rheuma-cur
Rheumaorctat
Rivodol
Sodepyrine b 1

For regulatory information, see page 117

Product name **Nandrolone decanoate (injectable)**

C.A.S. number **360-70-3**

Trade and brand names

Abolon
Anabolin la 100
Analone-50
Androlone d
Androlone d 100
Androlone d 50
Deca-durabol
Deca-durabolin
Deca-hybolin
Deca-noralone
Decabolin
Durabol

...(Continued)

Product name Nandrolone decanoate (injectable) ...(Continued)

Trade and brand names

Fortabolin
Hybolin-decanoate
Iebolan
Methybol
Methybol-depot
Nandrolone decanoate
Nordecon
Retabolil
Sterobolin
Turinabol-depot

For regulatory information, see page 119

Product name Nandrolone phenylpropionate (injectable)

C.A.S. number 62-90-8

Trade and brand names

Activin
Anabolicus
Anador
Anadur
Androline
Anticatabolin
Bexobolic
Docabolin
Durabol
Durabolin
Energital
Fenobolin
Fts
Hepa-obaton
Hybolin improved
Kompleteron
Nandrobolic
Nandrolin
Nerobil
Nerobolil
Nerobolin
Neutrosteron
Norabol
Noralone
Norandrol
Norandros
Noromon
Norstenol
Nortesto
Npp
Ntpp
Phenobolin
Sintabolin
Strabolene
Superanabolon
Superbolin
Turinabol

For regulatory information, see page 120

Product name Neomycin sulfate

C.A.S. number 1405-10-3

Trade and brand names

Abilene
Akentect
Amcort
Amphocort
Antibitulle
Apokalin
Aurex
Auriod
Baneopol
Barriere-mycin
Bastu-angin
Bedermin 100
Benestermycin
Bio-vitastrept
Biodry
Biofradin
Biofur
Biosol
Biosol-m
Bivacyn
Blastoestimulina
Bykanula
Bykomycin
Canaural
Canoral
Cebemyxine
Cefrocyn
Cg 3224
Cicatrex
Cleniderm
Clorpine
Conderm
Conjuctilone
Cornemin
Cortinen
Damapo
Davimycin
Degramycin
Dermadex
Dermicema
Dermo sonerge
Dermoface
Dermosan
Dermovate-nn
Derobion
Dexaamisolone-n
Dexabiotan
Dexacidin
Dexamist
Dexavetaderm
Dia-ject
Diaban
Diacin
Diarest
Dicortineff
Dienterol
Dimicina
Doreplaston/doser/f
Dorithicin
Dulcicortine
Duphacerate
Dv 201
Emcortina
Emorex k berna
Enbacin
Endomixin
Enteral
Enteromac
Enteropast
Enterosintex
Eustoporin
Extracort
Febrizene
Fissan
Fl 6321 n
Fluonid
Fml-neo-liquifilm
Foille
Forbesotic
Formula 888
Forte
Forticillin
Fradyl
Frakidex
Frakitacine
Gastromycin
Gregoderm
Gustibon
H plus n
Hagrosept
Halicomb
Halog
Heliomycort
Hydro-neo oculos
Hydrocortiderm
I-caps
Idepa
Ido-op
Intradermo caf
Iodenteroneomicina
Itro
Jenomycin
Kanagotas
Kortikiod mepha
Lanbiotic
Larmicin
Latodurin
Linitut

...(Continued)

Product name Neomycin sulfate ...(Continued)

Trade and brand names

Mammanopen
Mastrinal
Medisec neo
Medisec-cloxa
Medri-biotic
Meimyd
Menaderm antiacne
Myacyne
Mycerin
Mycidex
Mycifradin
Myciguent
Mycimist
Mycipo
Mytrex
Naso-neomicin
Nasomixin
Nasydrin
Nefluan
Neimicina roger
Neo decaderm
Neo-analsona
Neo-cantil
Neo-delta-cortef
Neo-hydro
Neo-m
Neo-mantle
Neo-mastitar
Neo-myx
Neo-otosol-hc
Neo-remusin
Neoaristovet
Neobacimyx-h
Neobicin
Neobiotic
Neobrettin
Neobristan
Neocidin
Neocillin
Neoclox
Neocones
Neodecasone
Neofluid
Neointestin
Neolate
Neomac
Neomin
Neomix
Neomycane
Neopenol
Neopt
Neostrep
Neosule
Neosulf
Nifuramicin
Nisocla
Nisoclyn
Nisodyn
Nivemycin
Nodryl
Nokamycin
Noperil
Normoc
Npa
O-biol
Ophthlmycin
Optiprime opthcoat
Optison
Optisone
Oribiotic
Oterna
Oticair
Oto vitna
Oto-flunal
Oto-sinerbe
Otocortison
Otomycin
Panotile
Paralen
Parkeole
Parkesteron
Pervet
Phytacorcin
Pivalone
Polemycin
Poly-pred
Polybactrin-g
Polydexa
Polygynax
Polyspecrin
Porcijec
Prednicidin
Prevotec
Propaderm-n
Pulveodil
Pyocidin hc
Quadrex
Renokab
Rino
Rino vitna
Rinofilax
Rinojet
Rovicine
S-thalmic
Sanibiovit
Sanimix
Sanistress
Secantol
Septa
Septomixine forte
Silderm
Siquent neomycin
Sofan
Spersapolymyxin dispersa
Steros-anal
Stiedex
Sulfix-6
Super masticort
Super mastitare
Synalar polyvalent
Syralbina
Tampovagan
Tariston
Telestyl
Tiframild
Tobispray
Topicon
Topitasico
Tresaderm
Tri-bow
Tri-optics
Tricilone
Troc
Trofodermin
Tweenal
Ubrocelan
Ucb 630
Unidiarea
Uniriod
Uro-beniktol
Uro-nebctin
V-cortanmycetine
V-softa
Varicella-rit
Vetroyl
Vetsovate
Vista-methasone n

For regulatory information, see page 120

Product name Nialamide

C.A.S. number 51-12-7

Trade and brand names

Espril
Nialamid
Niamid
Niamidal
Niamide
Niaquital
Niaquitil
Niazin
Novazid
Nuredal
Nyazin
Psyco-retard
Surgexl

For regulatory information, see page 121

Product name **Nitrefazole**

C.A.S. number **21721-92-6**

Trade and brand names

Altimol
Emd 15700

For regulatory information, see page 121

Product name **Nitrofural**

C.A.S. number **59-87-0**

Trade and brand names

Acmor
Acmor-s
Akutol
Aldomycin
Alfucin
Amifur
Anginofur
Auroid
Babrocid
Bifuran
Burnazone
Chemofuran
Coxistat
Dermobion
Dymazone
Ectofural
Escofuran
Escofuron
Fastin
Fluorobioptal
Fultrexin
Fura
Fura-septin
Fura-vet
Furacilinum
Furacin
Furacin-sol
Furacin-streusol
Furacinas
Furacine
Furacinethin
Furacinetten
Furacoccid
Furacocid
Furacol
Furaderm
Furaldon
Furalone
Furan
Furan-ofteno
Furaplast
Furaseptin
Furaskin
Furazin
Furazina
Furazol w
Furea
Furesan
Furesol
Furosem
Furotalgin
Furovol
Germex
Ginejuvent
I fomula
Ii formula
Kamfomen
Kindrog
Lifuzol
Macmiror
Mammex
Mammiject
Mastidol
Mastofuran
Muldacin
Nefco
Neovagon
Nfs
Nfz mix
Nfz 1
Nifucin
Nifuzon
Nitocetin
Nitro-rea
Nitrocol plus
Nitrozone
Notaba
O-biol
Sanifur
Scandantin
Shield
Sulfamyton-n
Taristop
Tipolin
Tranoxa
Trophen
Tuocurine
Urafadyn
Uroletten
Vabrocid
Vagisept
Viropulver
Yalrocin
Yatrocin
Zoppin spray blu

For regulatory information, see page 122

Product name **Nitroxoline**

C.A.S. number **4008-48-4**

Trade and brand names

Dovenix
Entercol
Enterocol
Isinok
Nibiol
Nicene
Nikinol
Nikopet
Noxibiol
Noxine
Trodax
Uritrol
Urocoli
5-nitrok

For regulatory information, see page 123

Product name **Nomifensine**

C.A.S. number **24526-64-5**

Trade and brand names

Alival
Anametrin
Caribium
Hoe 984
Hostalival
Merital

...(Continued)

Product name **Nomifensine** ...(Continued)

Trade and brand names

Merival
Musettamycin
Neurolene
Nomival
Psicronizer
Psyton

For regulatory information, see page 123

Product name **Norethisterone enantate (injectable)**

C.A.S. number **3836-23-5**

Trade and brand names

Binovum
Brevicon
Brevinor
Conceplan
Doryxas
Gesta plan
Lg 335
Medicon
Menonorm
Menophase
Miconor
Modicon
Neocon
Nor 50
Nor-q-d
Noriday
Norigest
Norimin
Noristerat
Norlutate acetate
Norquentiel
Norquest fe
Novulon
Nur-isterate
Orlestrin
Ortho-novum
Ovcon-50
Ovismen
Ovosiston
Ovysmen
Primolut
Tri-norinyl
Utovlar

For regulatory information, see page 124

Product name **Noscapine**

C.A.S. number **128-62-1**

Trade and brand names

Bequitussin
Bisolvon compositum
Broncha-tulisan eucalyptol
Broncho-tulisan eucalyptol
Brosolin-rectocap
Capval
Codipect
Codyl
Codyl cum expectoras
Coscopin
Coscotab
Degoran
Dettuso
Difimetus
Difimetus compositum
Finipect
Hederix
Lyabex retard
Lyobex
Narcotussin
Nipaxan
Nipaxon
Nitepax
Nosaclin
Noscalin
Noscapal
Noscapect
Noscarex
Noscatuss
Reatos
Rectolmin bronquial
Ribelfan
Spasmofen
Stilco
Teletux
Tucotin
Tuscapin
Tussamine plus
Tussanil n
Tusscalman
Tussicure
Tussisedal
Tussoretard

For regulatory information, see page 124

Product name **Opium in antitussive preparations**

C.A.S. number **8008-60-4**

Trade and brand names

Dia-quel
Escopon
Ka-thal-pec
Pantopon
Pat

For regulatory information, see page 125

Product name **Oxyphenbutazone**

C.A.S. number **129-20-4**

Trade and brand names

Algi-tandril
Anarreumol-b
Artroflog
Artzone
Butaflogin
Butapirone

...(Continued)

Product name Oxyphenbutazone ...(Continued)

Trade and brand names

Butazonic
Buteril
Butilene
Californit
Campozim
Crovaril
Defolgin
Difmedol
Dolo-phlogase
Dolo-tandril
Fibutrox
Flanaril
Floghene
Flogistin
Flogitolo
Flogodin
Flogoril
Gp 40705
Iltazon
Iltoxon
Imbun
Inflamil
Iridil
Isobutil
Kymalzone
Metabolite i
Mindaril
Miyadril
Mysite
Neo-farmadol
Offitril
Oflamin
Optimal
Otone
Oxalid
Oxybutazone
Oxybutol
Oxybuton
Oxyperol
Oxyphenbutone
Oxyphentamin
Phlogase
Phlogistol
Phlogont
Phloguran
Pilabutina
Piraflogin
Rapostan
Realin
Rheumapax
Rumapax
Segudol
Suganril
Tanal
Tandacot
Tandalgesic
Tandearil
Tanderil
Telidal
Tendearil
Teneral
Vefren
Visubutina

For regulatory information, see page 126

Product name Oxyphenisatine acetate

C.A.S. number 115-33-3

Trade and brand names

Acelax
Acetalax
Alophen pills
Ameiax
Api-slender
Belloform
Biivectan
Bisflatan
Boxogetten
Brocatine
Bydolax
Chlofel
Chur-lax
Ciracen
Cirotex
Cirotyl
Contax
Critex
Curolax
Darmoletten
Deililax
Dialose plus
Diasatin
Ditinil
Espotabs
Eulaxin
Evac-u-gen
Evac-u-lax
Ex-lax
Ex-lax pills
Fenisan
Fim-a-mint
Fin-a-mint gum
Fisiolax
Flib 518
Intax
Isaaxan
Isacen
Isaphen
Isaphenyn
Isocrin
Izaman
La 96
Lavema
Laxan-vomoxin
Laxaseptol
Laxem
Laxnormal
Laxo-isatin
Laxocol
Laxocoleva
Laxon
Laxos
Laxyl
Lisagal
Med-laxan
Menabil complex
Muxol
Neo-soldana
Neocervulax
Nourilax
Nurilaksi
Obstilax
Phenlaxine
Phenolax
Potsilo
Promassolax
Promassoletten
Prulet
Prulet liquitab
Prusol
Puragaceen
Purgaceen
Purgophen
Regal
Rivolax
Sanapert
Schokilax
Syndian
Tete-lax
Veripaque

For regulatory information, see page 128

Product name Pargyline

C.A.S. number 555-57-7

Trade and brand names

A 19120
Eudatin
Euditron
Eutonyl
Mo 911
Supirdyl

For regulatory information, see page 130

Product name Pectin

C.A.S. number 9000-69-5

Trade and brand names

Adm
Arhemapectin
Astriharina s
Betaine digestive aid
Bio hubber
Bio hubber fuerte
Biskapect
Chloropect
Collodyne
Dexinca
Diacalm
Diaguard
Diaguard forte
Diareze
Diarrhosan d
Diban
Diban diet complex 1500
Diet-trim
Donnage
Donnagel pg capsule
Donnagel pg liquid
Donnagel-mb
Donnagel-pg
Enterolyte
Estreptokectil
Estreptonetrol
Estreptoral
Estreptosirup
Fiblet
H.e.c
Humagel
Kantrexil
Kaomagma
Kaomagma with pectin
Kaomycin
Kaoneo
Kaopectate
Kaopectate n
Kaopectin
Kaoprompt-h
Kaostaten
Kln
Medipect
Neopec
Norquinol
Noventerol
Orahesive
Parepectolin
Pectigels
Pectolin
Pectrolyte
Peterpect
Pomana a
Salvacolina nn
Sorbitoxin
Streptomagma
Varihesive

For regulatory information, see page 131

Product name Pentobarbital

C.A.S. number 76-74-4

Trade and brand names

Aethaminalum
Barbamyl
Barbityral
Barbopent
Burtylonel
Butylone
Calpental
Chloropent
Contlnal
Di-barbs
Dipental
Distonocalm
Dolomo
Embutal
Ephestmin
Equithesin
Ergobel plus
Ethaminal
Hypnol
Hypnotal
Hyptonal
Isoamytal
Isobarb
Isom rapido
Iturate
Jurmun
Lunadon
Mebubarbital
Mintal
Napental
Narcoren
Natt-lunedon
Nembutal
Neodorm
Nicaphlogyl
Nova-rectal
Novo-pentobarb
Obelones
Or-trin
Pacifan
Palpent
Pembul
Penbar
Penbon
Pental
Pentanca
Pentodorm
Pentodormol
Pentogen
Pentolos
Penton
Pentone
Pentosol
Praecicalm
Prodormol
Quad-sed
Repocal
Rivadorm
S-spac
Sedanox
Sombutol
Somnopentyl
Somnophyt
Somnotol
Sonistan
Sopental
Stopp-15
Yastyl

For regulatory information, see page 132

Product name Phenacetin

C.A.S. number 62-44-2

Trade and brand names

Acetylosal
Achrocidin
Acifein
Acromas
Acropac
Adexogan
Algocratine
Alumidyne
Amypron
Amypylo-n
Anapac
Angifebrine
Anodin
Anti-opt
Antiflu des
Antigripina
Apadine
Apc
Apidin
Apracur
Arcin
Asa compound
Asceine
Ascophen
Ascthimindon
Asfeen
Ban-o-pain
Bexophene
Bromo quinina
Bromo seltzer

...(Continued)

Product name **Phenacetin** ...(Continued)

Trade and brand names

Buff-a-comp
Butal compound
Butorinal
Calmante muri
Capacetyl
Capramin
Caps dr knapp
Capsula dr. knapp
Ceachin
Cefinal
Cequinyl fort
Chloracet
Citra-fort
Citramol
Clistanol
Codempiral
Codopyrin
Codral
Coffan
Coffecodin
Commotional
Compralgyl
Conta-schmerz
Contradouleur
Coricidin
Coricidin f
Coriforte
Coryban-d
Cotradol
Daprisal
Darvocomp-n
Darvon compound
Darvon compuesto 65
Darvon n compuesto
Dasikon
Dasin
Dasin ch
Daturmed
Dbnf
Dentocaps
Dol-stop
Dolafort
Dolene
Dolomo
Dolostop
Doloxene comp forte, capsules
Dolviron
Doregrippin
Doscafis
Doviron
Drinacet
Duerin
Edrisal
Elmigrin
Empiral
Empirin compound
Emprazil
Emprazil-c
Epragen
Estrifen
Fasconal
Femcaps
Fenaçetina
Fenascor
Fenbutal
Fenidina
Fenina
Florinal
Flexalgit
Florital
Fonal
Fortacyl
Fridol
Friocellin
Funapann
Gelonida
Gesic
Gewodin
Gripanidan
Harbureta
Heaven
Helvagit
Hemagene taylor
Hisense-p
Hjorton's powder
Hocophen
Icn 65
Influenza tabs
Isollyl
Isomidon
Kafa
Kalmin
Kapron
Katagrip
Larodon
Legatin
Lekasin
Lidor
Linarol
Malex
Manasul
Mardon
Melabon
Melaforte
Migesic
Migrane-dolviran
Mironal
Monacet
Myolate
Neopyrine
Nevral vit b1 b6
Norgesic
Novacetol
Novosephalgin
Olfano
Omniadol
Pamprin
Papnin
Para-grip
Paramette
Parametten
Paratodol
Pargesic compound
Pasadex
Pedigel
Percobarb
Percodan
Pertonal
Phenacet
Phenacetine powder
Phenacetinum
Phenacitin
Phenacon
Phenalgin
Phenapap
Phenaphen
Phenaphen plus
Phenazetin
Phenazetina
Phenedina
Phenidin
Phenin
Phenodyne
Phenorial
Polypyrine
Poxy
Procomp-65
Prodigestan
Prodolor
Progesic
Protension
Pulmomas
Pyraphen
Pyrroxate
Quadrochin
Quadronal
Rectoral
Refagan
Reformin
Reomin
Repro
Respritin
Rhinazol
Rilan
Rinurel
Rinutan
Robaxisal-ph
Robaxisan-pm
Ron-drive
Rumicine
S antineuralgic
S fc
Sacadol
Sadaspir
Salgydal
Sanalgin
Sanalgine
Sanasthmyl
Saridon
Sedafen
Sedalgin
Sedalmerck
Seranex
Sinac
Sinacin
Sinedal
Sinubid
Sinudan
Sinus
Sinutab
Sinutab ii
Sk 65 compound
Sk 65 compound caps.
Soma
Soma compound
Soma compuesto
Sonalgin
Spacin
Spasmindon
Spasmo-compralgyl
Stellacyl
Super anahist
Supralgin
Synalgos
Synalogos-dc
Synpyrin
T h
Tacol
Teofedrin
Terracydin
Tetrex-apc
Tetrracydin
Thephorin a-c
Tiiomapirina
Tomapiena
Treupel
Tripin
Triplex
Tsefokon
Uga-no
Valcophen
Vandar-65
Vasogesic
Veganine
Vicks action 500

...(Continued)

Product name **Phenacetin** ...(Continued)

Trade and brand names

Viden
Wigraine
Xaril
Zactirin compound-100
292-comprimes
3p bugesic
369, pulvules

For regulatory information, see page 132

Product name **Phenazone**

C.A.S. number **60-80-0**

Trade and brand names

Adexogan
Aerol
Analgesine
Anodynin
Anodynine
Antigestin
Antipyrin
Apirelina
Azophen
Azophene
Bajumol
Calmasmin
Cetussan
Dol-stop
Doleron novum
Dolo-med-much
Fenazone
Furotalgin
Goticas
Iap
Kalopsis
Melaforte
Methozin
Mig-antos
Migranin
Natt-lunedon
Neo-felsol
Neo-hydro
Noric
Novogen
Orecil
Otosan-sulfan
Otothricinol
Palacaine
Parodyne
Pasta antisola
Phenazon
Phenicarbazide
Phenylon
Phenylone
Prophyllen
Pyrazophyl
Remolmed
Salicopil
Sanasthmyl
Sedatin
Sedatine
Shhe 21
Visublefarite

For regulatory information, see page 135

Product name **Phendimetrazine**

C.A.S. number **634-03-7**

Trade and brand names

Adipo ii
Adipost
Adphen
Amphasub
Anorex
Anoxine-t
Antapentan
Arcotrol
Bacarate
Bontril
Di-ap-trol
Dietrol
Elphemet
Fringanor
Hourbese
Hyrex
Limit
Minus
Neo-nilorex
Obe-del
Obepar
Obesan
Obex-la
Obezine
Panrexin-m
Phenazine
Plegline
Prelu-2
Reducto
Reton
S 7
Sedafamen
Sly-li
Sprx 105
Statobex
Statobex-d
Stodex
Symetra
Trimcaps
Trimstat
Trimtabs
Weighttrol
X-trozine

For regulatory information, see page 135

Product name **Phenformin**

C.A.S. number **114-86-3**

Trade and brand names

Adibetin
Antipond
Azucaps
Beta-pebg
Bi-uglucon ud87
Cronoformin
D bretard
Daopar
Db comb.
Db retard
Db-retard
Dbi
De be
Debej
Debeon
Debinyl
Diabis
Diaformin
Dibein
Dibein retard
Dibenide
Dibinyl
Dibiraf
Dibolin

...(Continued)

Product name **Phenformin** ...(Continued)

Trade and brand names

Dibophen
Dibotin
Dibun
Diebin
Diebin retard
Diguabet
Dipar
Dobeom
Feguanide
Fenfoduron
Fenformin
Fenguanide
Fenormin
Gluciferne
Glucopostin
Glukopostin
Glyphen
Insoral
Kataglicina
Lentobetic
Ls 6030
Meltrol
Nci-c01741
Normoglucina
Oraleo
Pbi
Pedg
Phenformine
Phenformix
Prontoformin
Retard
Retardo
Tolbrtaphen
W 32

For regulatory information, see page 136

Product name **Phenicarbazide**

C.A.S. number **103-03-7**

Trade and brand names

Antipyretic dellepsoids d26

For regulatory information, see page 138

Product name **Phenmetrazine**

C.A.S. number **134-49-6**

Trade and brand names

A 66
Anorex
Bromadryl
Emagrin
Gratsidin
Marsin
Neo-zine
Oxazimedrine
Phenmetrazine
Prelazine
Preludin
Probese-p
Psychamine a 66

For regulatory information, see page 138

Product name **Phenobarbital**

C.A.S. number **50-06-6**

Trade and brand names

Aaciasthma
Adocor
Adonal
Agrypnal
Allergasthmin
Alnagon
Amylofene
Anaspaz
Anti-spas
Apb
Aphenylbarbit
Asmo fedrilum
Asthmatussin
Austrominal
Bakersed
Barbellen
Barbenyl
Barberine
Barbilletae
Barbiphenyl
Barbipil
Barbita
Barbivis
Barcole
Barophen
Bay-ase
Bebtoyl
Bediphen
Belergamin
Bellademal s
Belladenal
Bellasectal
Bellastal
Bellergal
Bellergal s
Belllumal
Bergofen
Blu-phen
Bock-ase
Bonexyl
Broncosmin
C 147
Calminal
Ce 10010
Ceepa
Cemealonal
Clemodril
Coffecodin
Commotional
Cor-asthmolyticum
Cortasmyl
Corverum
Dafodil
Damoral
Digi-pulsnorma
Dithene-r
Dolo-eupaco
Donibin
Donna-lix
Donnaplex
Dormiral
Doscalun
Duneryl
Duovent
Eeskabarb span
Elibese
Elmigrin
Ensobarb
Ephedrobarbital-t
Ephestmin
Epidormb
Epilantin
Epsylone
Ergojuvan
Eskabarb

...(Continued)

Product name **Phenobarbital** ...(Continued)

Trade and brand names

Espafren
Extrovent
Fasconal
Fedrilum
Fedrinal
Fenalgin
Fenemal
Fenilcal
Fenosed
Fenosed bitabs
Gardenal
Gardenale
Gardepanyl
Gastrop
Gentarol
Giolate
Glyanphen
Glyuferal
Gourmase
Gratusminal
Hasp
Hyonol
Hypnaletten
Hypnolone
Hysteps
Ila-med
Irs 109a
Kenedes
Koronar
Lagaspasm
Lardet
Legatin
Lepinal
Lepinaletten
Liquital
Lircapil
Lixophen
Lubergal
Lumcalcio
Luminal
Lunadon
Lysadestal
Mazur-a
Md 1020
Mediphen
Meprobit
Mepropon
Metrojen
Mialgone
Migrane-dolviran
Modirit
Myocardon
Neo-nervostat
Neurobarb
Nilspasm
Noptil
Nova-pheno
Novodon
Novospasmin
Nunol
Oxabar
Oxoids
Pavadel
Peba
Pen-nitate
Pencardin
Pentran
Perphyllon
Phen bar
Phen-bel
Phenaemal
Phenemal
Pheno-gesic
Phenobar
Phenobarbyl
Phenogen
Phenonyl
Phental
Phentral cratecil
Phob
Piraminal
Plivalgin
Preminal
Prenoxan
Pribetal
Purphen
Quad-sed
Rau-fridetten
Resirol
Respisane
S 611-3
Salviton
Sanepil
Sapos
Scotatal
Secophen-c
Seda-intestain
Seda-ko
Seda-tablinen
Sedacoral
Sedalgin
Sedapar
Sedo corodil
Sedonal
Sedophen
Sedopsic
Sedragesic
Sevenal
Solofoton
Somonal
Soniphen
Spascol
Spasdel
Spasmalones
Spasmo-compragyl
Spasmo-van
Spasmogentarol
Spasmotal
Spasmoveragin
Spastyl
Spondyneuron
Stental extentabs
Stollerine
Suparnidal
Susano
Syntospon
Tedralan
Teofedrin
Teolaxin
Thefedral
Theodrine
Theotabs
Tridezibarbitur
Triphenatol
Valpin
Vanital
Vantal
Versomnal
Zirkonorm
3p spas

For regulatory information, see page 138

Product name **Phenol**

C.A.S. number **108-95-2**

Trade and brand names

Agre-gola
Apralan
Benamine
Benzenol
Carbolic acid
Cepastat
Chloraseptic
Epivetol
Fenicado
Hydroxybenzene
Izal
Izal germicide
Monophenol
Paoscle
Poscle
Pregine
Protaphane hm insulin
Sarna
Vaopin
3p maid

For regulatory information, see page 139

Product name **Phenolphthalein**

C.A.S. number **77-09-8**

Trade and brand names

Agaffin
Ap-la-day
Bom-bon
Canisan
Certolax
Chocolax
Darmol
Euchessina
Evac-q-tabs
Feen-a-mint
Formosa camphor
Fructines-vichy
Gum camphor
Japan camphor
Kalimalterin
Koprol
Laurel camphor
Laxatabs
Laxatone
Laxin
Laxogen
Laxon
Lilo
Minilax
Musilaks
Novopuren
Peplax
Petro-mul-phen
Phenolax
Prifunal
Prunetta
Purex
Purga
Purganos-daguin
Purgant aleman
Purgen
Purgenum
Purgophen
Purgyl
Purjen sahap
Spulmako-lax
Thalinol
Thalinol mrt
Trilax
Unisvelt

For regulatory information, see page 139

Product name **Phentermine**

C.A.S. number **122-09-8**

Trade and brand names

Adipex
Adipex-p
Aneroxina
Dapex
Duromin
Ex-adipos
Fastin
Ionakraft
Ionamin
Ionamine
Levum
Linyl
Lipopill
Minobese
Mirapront
Netto-longcaps
Obestin 30
Oby-trim
Ona-mast
Panbesy
Panshape
Parmine
Phentermyl
Raucherstop 5 ht
Reducyl
Regulin

For regulatory information, see page 140

Product name **Phenylbutazone**

C.A.S. number **50-33-9**

Trade and brand names

Algesin
Algirreudin
Algoverine
Alindor
Alka-sterazolidin
Alkabutazona
Ambene
Anarthral
Antadol
Anuspiramin
Apo-phenylbutazone
Arteopan
Arthirikin
Artibrin
Artrisin
Artrodesmol extra
Azolid
Benzone
Betazed
Bizolin 20
Bizolin 700
Buta-phen
Butacal
Butacompren
Butacote
Butadilat
Butadin
Butadion
Butadiona
Butadyne
Butafenil
Butagesic
Butagros
Butakvertin
Butalan
Butalgin
Butalgina
Butaluy
Butaparin
Butapirazol
Butarex
Butatril
Butazina
Butazolidin
Butazone
Butidiona
Butinol
Butiwas
Buto beta
Butone
Butoroid
Butoz
Butrex
Buvetzone
Buzon
Carudol
Celestalgon
Celestazone
Chembutazone
Colfezone
Corbuvit
Dartranol
Debutazon
Delta-demoplas
Delta-myogit
Delta-tomanol
Deltawaukobuzon
Demoplas
Dephimixn
Dexa tomanol
Dexa-attritin
Dexa-escopyrin
Dexamed
Dexatrzona
Digibutina
Direstop
Ditrone
Doctofril
Dolosin dexa
Dolpirina
Dona compositum
Ecobutazone
Ectobutazone
Elmedal

...(Continued)

Product name Phenylbutazone ...(Continued)

Trade and brand names

Equi bute
Equipalazone
Eributazone
Escopyrin
Exrheudon
F 650
Fenibutasan
Fenibutina
Fenibutol
Fenotone
Flebosil
Flexazone
Hepabuzon
Ia-but
Intalbut
Intrabutazone
Intrazone
Kadol
Malgesic
Mammyl
Megazone
Mephabutazon
Mepropyrin
Merizone
Mi 540
Naupax
Neo-zoline
Neuro-demoplas
Neuro-elmedal
Novobutazone
Novophenyl
Oluprin
Osadrinim
Panazone
Parzolidon
Pasirheuman
Pbz
Penetradol
Phebuzin
Phenbuff
Phenbutazol
Phenylarthrite
Phenylbetazone
Phenylone
Phenyzone
Phlebolan
Pirabutil
Pirarreumol-b
Praecirheumin
Prebutex
Prednirheumin
Proxyfezone
Proydynam
Pyrbutal
Ranocor
Rectofasa
Reopin
Reumasyl
Reumazin
Reumuzol
Reupolar
Rheopyrin
Rheosolon
Rheumanoln
Rheumaphen
Rheumycalm
Rhumalgan
Robizone-v
Salzone
Schemergen
Servizolidin
Shigrodin
Sigma-elmedal
Spondyril
Spongamed
Stabilat
Tetnor
Tevocodyn
Therazone
Ticinil
Ticinil calico
Todalgil
Trabar
Trabit
Uzone
Waukobuzon
Wescozone
Wofapyrin
Zolapelin
Zolidinium

For regulatory information, see page 141

Product name Phenylpropanolamine

C.A.S. number 14838-15-4

Trade and brand names

A.g.multix
Acutrim
Adistop-f
Am-tuss liq
Amertuss
Amplisiex
Anorexin
Antiadipositum
Aridose
Arm
Bifed-20
Biphetane
Biphetap
Blu-hist
Brocon cr
Bromanate
Bromepaph
Brometapp
Bromophen
Bronco-quintoxil
Cenadex
Chlor-rest
Cinturex
Cletanol
Codimal
Cofpac
Col-decon
Cold cap
Coldecon
Conex-grippe
Contop
Control
Corsym
Coryztime
Cremacoat
D-sinus
Dalca
Day nurse
Decidex
Decomine
Demazine
Deprecstop
Dexatrim
Dimetane
E-son
E-tapp 3
Efed ii
Eficol
Endal
Endecon
Endex
Espornade spansule
Exyphen
Factus
Fornagest
Fugoa n
Gardax
Ginsopan
Headway
Histabid
Histade
Histatapp
Hsp 540
Ipercron
Kol-tac
Kontexin
Koryza
Leder
Lipo-sinahist
Lunerin
Mardram
Minus-x
Monatuss
Monydrin
Mucolyt-expecto
Mucorama
Nasomixin
Nd-hist
Nectatussin
Neosoldana
Nexaam
Nobese
Nornatane
Obestat
Ornacol
Ornatos
Ornex
Pabron nose
Panacorn
Panadyl
Parhist
Partapp
Partuss
Permatrim
Phenapap
Pholcolix
Pholcolix spansule
Pneumidex
Polcimut
Probocon
Profenade
Propadrine

...(Continued)

Product name **Phenylpropanolamine** ...(Continued)

Trade and brand names

Propagest
Reduzin
Rhindecon
Rhinergal
Rhinervert
Rhinicept
Rhinidrin
Rhinocap
Rinexin
Rinomar
Rinotussal
Rinurel lictus
Rinurel tablets
Rotabromophen
Ru-tuss
Rupton
Rynatapp
Rynex
Ryza-gesic
Sacietyl
Scotuss
Secron
Sinac
Sinacin
Sinu-lets
Sinubid
Sinudan
Sinus
Sinutab cough l
Spandecon
Srda
Sto-caps
Sulfa-probocon
Symptrol
Syrtussar
Taviset
Tepanil
Tinaroc
Totolin
Tri-congestic
Tricon
Triogesic elixir
Triominic
Triotussic
Tritane
Turbispan
Tussilene-dm
V cold
Veltap
Vernate
Vistaminic
Voxin-pg
W 58
W 66
X 112 antiadipo
Zerinol

For regulatory information, see page 143

Product name **Phthalylsulfathiazole**

C.A.S. number **85-73-4**

Trade and brand names

Afi-ftalyl
Canidis-anti-diarr
Carbidiar
Carbotalin
Colicitina
Coliclase
Cortinen
Crematalil
Cremothalidine
Diaban
Diacolin
Diarrestival
Dienterol
Direver
Disenterol
Ef-micin
Enteramida
Entero-hermes
Entero-red
Entero-sulfina
Entero-toxan
Enterocalme
Enterosteril
Entexidina
Esteraplidin mag
Eugeniteed
Fitazil
Ftalil-esteve
Ftalil-septol
Ftalil-tiazol
Ftalysept
Ilentazol
Ingalipt
Inrestibla strepto
Intestiazol
Iodentero-neomicina
Logical
Massotalil
Neo-sulfazon
Novosulfina
Phtalazol
Phtazol
Porcijec
Septiftalil
Sulfacetil
Sulfathalidine
Sulftalyl
Syptan
Syralbina
Taleudron
Talidine
Talisulfazol
Taloudron
Tamil
Thalazole
Thalinil
Thalistanin
Thalistatyl
Thiazole
Trisulvet
Ultratiazol
Vetoryl

For regulatory information, see page 144

Product name **Pipamazine**

C.A.S. number **84-04-8**

Trade and brand names

Mornidine
Nausidol
Normetine

For regulatory information, see page 145

Product name **Pipenzolate**

C.A.S. number **13473-38-6**

Trade and brand names

Dropenzil
Pedroacal
Pipenzolate mb san

...(Continued)

Product name **Pipenzolate** ...(Continued)

Trade and brand names

Piper
Piptal
Piptal pediatrico
Piptal pediatrique
Piptalin

For regulatory information, see page 145

Product name **Piperazine**

C.A.S. number **110-85-0**

Trade and brand names

Adelmintex
Adipalis
Adipalit
Adiprazine
Adiver
Ancaris thenium
Ancazine
Antelmina
Antepar
Antepar (b-w)
Anterobius
Anthalazine
Anthelmina
Anticucs
Antiren
Antivermine
Antoban
Arduvermin
Arpezine
Asca-trol no.3
Ascalix
Ascarinex
Ascarivet
Asepar
Askaripar
Averamexan
B-piperazine
Bel-zine
Bioxurin
Brirel
Bryrel
Candizine
Ciperazin
Citrazine
Coopane
Dak
Demovermil
Diatesurico
Dicevermin
Dietelmin
Digesan
Dilaurazine
Dispermin
Diurazina
Divermex
Dowzene
Dyrex
Ecosan
Endorid
Entacyl
Entazin
Equizole-a
Eraverm
Escovermin
Esteropipate
Etaphylline (acetyllinate)
Exelmin
Exopin
Gentiazina
Glycopiparsol
Heksapar
Helmacid
Helmezin
Helmicide
Helmifren
Helmipar
Helmirazine (adipate)
Helmirazine (citrate)
Helmitin
Helmizin
Herb royal round worm treatment
Hexanthelin
Ismiverm
Janes liquid permifu
Jarabe neox
Jetsan supp. (adipate)
Justalmin
Kennel-maid
Kihomato
Kontipar
Lamboxil
Lom
Lombricida tropico
Lombrifher
Lombrikal
Lombrimade
Lumbrical
Mapiprin
Maskito
Multifuge
Multifuj
Mydriaticum
Nea-vermiol
Nemadital
Nemafugan
Nemasin
Nematocton
Nematorazine
Neo-ifusa
Neox
Nometan
Noxiurotan
Ogen
Okuside
Optiverm
Oxiril syrup (hydrate)
Oxiuran (hydrate)
Oxiurasin
Oxiustip
Oxiustip elix
Oxivermin
Oxizin
Oxucid
Oxurasin
Oxuril
Oxypaat
Oxypip
Oxyzin
P.c. (citrate)
Padrax
Par-tega
Paravermin
Parazine
Pariamate
Parid
Perin
Piaverm
Piavermit
Pin-tega
Pincet
Pincide
Pinozan
Pinrou
Pinsirup
Pip-a-ray
Pipadox
Pipan
Pipenin
Piper-jodina
Piperacid
Piperamicin
Piperascat
Piperaskat
Piperasol
Piperate
Piperaverm
Piperazate
Piperazinal
Piperazine (adipate)
Pipercrean
Piperex
Piperiod
Piperital od
Piperitol
Piperol fort
Piperone
Piperoverm
Pipertox
Piperver
Piperzinal
Pipeverm
Pipezol
Pipizan
Pipizan citrate
Pipracid
Piprazid
Piprazyl
Pipricide
Piptelate
Piverma
Polo-verm
Polyquil
Pripsen
Provtovermil
Pulvex
Razinol
Rhomex
Rondelim
Rondoxyl
Safersan
Santoban
Siropar
Supraverm
Ta-verm
Taenifigin
Tasnon

...(Continued)

Product name **Piperazine** ...(Continued)

Trade and brand names

Teniver
Thelmin
Thenatol
Tivazine
Toxocan
Uricida
Uridina
Uroclear (hexamine)
Urodan (phosphate)
Urosolvina
Uvilon syrup (hydrate)
Vanpar (hydrate)
Veripar
Vermago
Vermazine
Vermenter
Vermicompren
Vermidol
Vermifug
Vermilass
Vermipan
Vermiphsarmette
Vermiquimpe
Vermiquimyc
Vermisit
Vermisol
Vermitox
Vermofrik
Verocid
Veroxil
Wairmex
Worm-away
Wurmex
Wurmirazin
Wurmsirup siegfried

For regulatory information, see page 145

Product name **Pipradrol**

C.A.S. number **467-60-7**

Trade and brand names

Gerodryl
Leptidrol
Meratonic
Meratran
Metadin
Piridrol
Stimolag fortis

For regulatory information, see page 146

Product name **Pituitary-chorionic gonadotropin (injectable)**

Trade and brand names

A.p.l.
Antuitrin
Choragon
Choriantin
Choritropin
Chorulon
Dap-test
Ekluton
Endocorion
Entromone
Ferti-cept
Follutein
Fractolon
Gonabion
Gonadex
Gonadoplex
Gonafollin
Gonagestrol
Gonault
Gravimun
Grom hgh
Hcg
Hcg standard tablets
Lh 5000
Luteovet
Neogonadil
Nymfalon
Praelutin forate
Pregine
Pregnesin
Profasi hp
Puberogen
Riogon
Sensi-t
Suigonan

For regulatory information, see page 147

Product name **Podophyllum resin**

Trade and brand names

Biliboldo
Bon korets
Condilomin
Dermacytostat
Podofilm
Salicylin-p

For regulatory information, see page 147

Product name **Polyoxyethylated castor oil**

Trade and brand names

Cremophor el
Cremophor rh40
Cremophor rh60

For regulatory information, see page 148

Product name **Polyvidone**

C.A.S. number **9003-39-8**

Trade and brand names

Acu-dyne
Adapettes
Adsorbobase
Agent at 717
Albigen a
Aldacol q
Amiorel eritro
Amyderm s
Andrestrac 2-10
Anexa
At 717
B 7509
Betadine
Betaisod
Bolinan
Bridine
Clinidine
Crospovidone
Disphex
Efo-dine
Final step
Frepp
Frepp/sepp
Ga-pvp-101
Ganex p 804
Gyno-bidex
Hemodesis
Hemodez
Iodopiron
Isodine
Isoline
Isoplasma
Jodoplex
K 115
K 15
K 25
K 30
K 60
K 90
Kollidon
Kollidon ce 50/50
Kollidon k 25
Kollidon k 30
Kollidon 12pf
Kollidon 17
Kollidon 25
Kollidon 30
Kollidon 90
Luviskol
Luviskol k 17
Luviskol k 25
Luviskol k 30
Luviskol k 90
Luvisteol
Medicort
Molycu
Mundidon
Neojodin
Oftan flurekain
Peragal st
Periston
Periston-n
Pevidine
Peviston
Plasdone
Plasmadone
Plasmosan
Podiodine
Poly-karaya
Polyclar at
Polyclar h
Polyclar l
Polyplasdone xl
Polyvidone-escupient
Polyvidonum
Polyvinyl pyrrolidone
Povadyne
Povidone k 29-32
Protagent
Proviodine
Pvp 0
Pvp 40
Pvp 50
Pvp-k 15
Pvp-k 25
Pvp-k 3
Pvp-k 30
Pvp-k 60
Pvp-k 90
Pvp-macrose
Pvp-macrox
Pvpp
Rocmuth
Sd 13
Sepp
Soft-care
Subtosan
Tears plus
Traumasept
Ultradine
Venostasin retard
Vetedine
Vini
Vinisil
Yodiplexin

For regulatory information, see page 149

Product name **Potassium canrenoate**

C.A.S. number **2181-04-6**

Trade and brand names

Aldactone
Aldactone-diurapid
Aldadiene potassium
Kadiur
Kanrenol
Lasiren
Osiren
Osirenol
Osyrol
Osyrol-lasix
Phanurane
Sincomen
Sincomen pro injectione
Soldactone
Soludactone
Speroctan-m
Venactone

For regulatory information, see page 150

Product name **Potassium nitrate**

C.A.S. number **7757-79-1**

Trade and brand names

Cholal modifico
Cholal simple
Collo-bo
Dewitt's pills for backache and joint pains
Viridite
Viridite k

For regulatory information, see page 150

Product name **Practolol**

C.A.S. number **6673-35-4**

Trade and brand names

A 25
Cardiol
Cordialina
Dalzic
Eraldin
Eraldina
Eramid
Praktol
Pralon
Teranol

For regulatory information, see page 151

Product name **Prasterone**

C.A.S. number **53-43-0**

Trade and brand names

Astenile
Cetavister
Climatost
Dastonil
Deandros
Dha-s (prasterone)
Diandron
Diandrone
Gynodian
Longevital 5000
Maxepa
Mentalormon
Mylis
Neurocotex
Psicosterone
Ro 66827
Sh 833
Ultrapla
17-chetovis
17-hormoforin

For regulatory information, see page 152

Product name **Progabide**

C.A.S. number **62666-20-0**

Trade and brand names

Gabaphore
Gabren
Halogabide
Sl 76 002

For regulatory information, see page 153

Product name **Propafenone**

C.A.S. number **54063-53-5**

Trade and brand names

Arythmol
Nofenan
Nofenon
Nomorytmin
Normotrytmin
Normotrytmin (r) 10 mg
Prolekofen
Retmonorm
Ryhmonorma
Rythmole
Rytmonorm

For regulatory information, see page 153

Product name **Propofol**

C.A.S. number **2078-54-8**

Trade and brand names

Diprivan
Disoprivan
Rapinovet

For regulatory information, see page 154

Product name **Propylhexedrine**

C.A.S. number **3595-11-7**

Trade and brand names

Benzedrex
Chp-depot
Cyclexedrine

...(Continued)

Product name **Propylhexedrine** ...(Continued)

Trade and brand names

Dristan
Eggobesin
Eventin
Obesin

For regulatory information, see page 154

Product name **Propyphenazone**

C.A.S. number 479-92-5

Trade and brand names

Amipylo-n
Azur
Balpiren
Budirol
Caffalgina
Camoplex
Cantacin
Cerebrol
Cibalgina
Commotional
Daturmed
Degripol
Dentocaps a
Dim-antos
Dolibral
Dolibrax
Dolo-mineuron
Dolo-phlogase
Dysmalgin
Ejcopyrin
Epizon
Escomen
Estesina
Eufibron
Europan
Fd 8
Febral
Finigripp
Grippocaps
Heaven
Infantex
Influvit
Isopronazon
Kavapyret
Kuronde
Larodon
Lysadestat
Mamaslu
Milneuron
Myo-europan
Neuramin
Neuridal
Neuro-spondryl
New isomidon
Nodiras
Noric
Otobacid
Pfeil
Reomin
Retamex
Rheumanol
Rhinivict
Sanalgin-p
Saridon neu
Sedospin
Servalgin
Sonotryl
Spalt
Spongamed
Stona
Synpyrin
Vivcet
Wauco-sin
Wecontrin
539 grippe-dragees

For regulatory information, see page 155

Product name **Pyritinol**

C.A.S. number 1098-97-1

Trade and brand names

Biocefalin
Biontabol
Bonifwn
Bonol
Cefalogen
Cerebrotrofina
Cervitalin
Danaden
Divalvon-d
Enbol
Encefabol
Encefort
Encephabol
Encerebron
Enerbol
Geribolina
Gerontabol comp.
Juniormen
Leonar
Life
Logos
Neuroxin
Piriditol
Piririomin
Piritinol
Piritiomin
Plenumil
Sawaxin
Scintidin
Tibased
Tomevit
Tonobrein
Tonomentis

For regulatory information, see page 155

Product name **Santonin**

C.A.S. number 481-06-1

Trade and brand names

Digesan
Semenen

For regulatory information, see page 157

Product name Silver acetate

C.A.S. number 563-63-3

Trade and brand names

Smokerette
Tabmint

For regulatory information, see page 158

Product name Sodium dibunate

C.A.S. number 14992-59-2

Trade and brand names

Antussan
Balmini
Becantal
Becantex
Bechisan
Bexedyl dibunaat
Bexedyl dibunaat expectasans
Cito-guakalin
Expect-blacken-pastillen n
Makatussin
Pastillas koki
Sedobex
Super koki

For regulatory information, see page 159

Product name Somatropin (pituitary-derived)

C.A.S. number 12629-01-5

Trade and brand names

Antuitrin growth
Antuitrin-t
Asellacrin
Cb 311
Corpormon
Crescormon
Grorm
Hgh
Human growth hormon
Leutrophin
Nanormin
Nanormon
Phynatol
Phyol
Phyoneon
Protopin
Protropin
Rx 099916
Somacton
Somatonorm
Somatormone
Somatrofin
Somatropin
Sth
22krl

For regulatory information, see page 159

Product name Spironolactone

C.A.S. number 52-01-7

Trade and brand names

Acelat
Airolactone
Aldace
Aldactide 25
Aldactone
Aldactone-a
Aldazida
Aldonorm
Aldopur
Aldospirone
Aldozone
Alexan
Almatol
Alpamed
Altex
Altexide
Aporasnon
Aquareduct
Carditan
Crk 635
Ct-spiro
Deverol
Diatensec
Digi-aldopur
Dilakton
Dira
Duraspiron
Euteberol
Hokulaton
Hokuraton
Hydrospiron
Idrolatton
Lacalmin
Lacdene
Lasilacton
Lasitone
Loractone
Mf 218d
Nefurofan
Noidouble
Osiren
Osyrol
Osyrol-lasix
Penantin
Pirolcaton
Plarenil
Practon 50
Raudazida
Risicordin
Rolactone
Sagisal
Sali-spiroctan
Saluretin
Sas 1060
Sc 9420
Servilactone
Sincomen
Spiresis
Spiretic
Spiridazide
Spiridon
Spirix
Spiro comp
Spiro-f
Spiro-tablinen
Spiroctan
Spirodigital
Spirolang
Spiron
Spironomocompren
Spironone
Spironothiazide
Spiropal
Spiroprop
Spirostada
Spirotone
Spiro50-d
Suprapuren

...(Continued)

Product name Spironolactone ...(Continued)

Trade and brand names

Suracton
Synureticum
Tensoflex
Uractone
Urusonin
Verospiron
Xenalone

For regulatory information, see page 160

Product name Streptomycin

C.A.S. number 57-92-1

Trade and brand names

Antidiarrhoicum
Bio hubber
Bio hubber fuerte
Bio hubbersimple
Cidan est
Darostrep
Derbitan antibiotico
Diastat
Direver
Estrepromade
Estrepromicina
Estrepto e
Estrepto level
Estrepto ph
Estrepto wolner
Estreptomicina normon
Gamafin
Injectin
Neodistreptotab
Neodualtrepto
Novo-strep
Novostrep
Servistrep
Solustrep
Solvo-strep-s
Solvo-strepi-s
Strep-diva
Strepolin
Streptan
Streptaquaine
Strepto-fatal
Streptocal
Streptomycin
Streptosol 25
Streptothenat
Stretobretin
Strycin
Sul-mycin ii

For regulatory information, see page 161

Product name Sulfadicramide

C.A.S. number 115-68-4

Trade and brand names

Ingamid
Ingamid ophtal
Irgamid

For regulatory information, see page 162

Product name Sulfadimidine

C.A.S. number 57-68-1

Trade and brand names

Crermomethazine
Deladine
Dimezathine
Dimidin
Hava-span
Intradin
Neotrizine
Rigesol
Rivodin
S-dimidine
Spanbolet
Sulka-s
Sulphamezathine
Sulphfmezatine
Superseptyl
Sustain iii
Tersulpha
Trisulfaminie

For regulatory information, see page 163

Product name Sulfaguanidine

C.A.S. number 57-67-0

Trade and brand names

Aseptil-guanidina
Aterian
Coliseptale
Devaguanil
Diacta
Dirkan
Emerin
Ente-rivo simplex
Ganidan
Granidan
Guamide
Guanicil
Guanidan
Guanowept
Guasept
Inorgan
Intestovet
Ordenol
Orgaguanidon
Percural
Resulfon
Ruocil
S-guanidan
Sgd
Shigatox
Suganyl
Sulfacarbon

...(Continued)

Product name Sulfaguanidine ...(Continued)

Trade and brand names

Sulfaglobenicol
Sulfentidine
Sulfogua
Sulgin
Tetrawest
Trisulvet

For regulatory information, see page 163

Product name Sulfamerazine sodium

C.A.S. number 127-58-2

Trade and brand names

Bio hubber simple
Cremo-merazine
Debnal m
Mebacid
Neotrizine
Peccocode
Septosil
Spanbolet ii
Tersulpha
Trisulfaminic
Trisulpha

For regulatory information, see page 164

Product name Sulfamethizole

C.A.S. number 144-82-1

Trade and brand names

Amer-azo
Ayerlucil
Azocline
Famet
Lu
Lucatyl
Lucosil
Methazol
Methisul
Microsul
Micturol ampicilina seda
Nicene
Orozl
Procijec
Proklar-m
Renasul
Rp 2145
Rufol
S-methizole
Salimol
Spasmo-harnosal
Starisil
Suladyne
Sulfa gram
Sulfametin
Sulfapyelon
Sulfstat
Sulfurine
Tetracid
Thidicur
Thiosulfil
Tiosulfan
Ultrasul
Uratrac
Uro-beniktol
Uro-nebactin
Urocydal
Urodiaton
Urolex
Urolucosil
Uropeutic
Urotrex
Utrasul
Vk 53
3p methazol

For regulatory information, see page 165

Product name Sulfamethoxypyridazine

C.A.S. number 80-35-3

Trade and brand names

Amidin
Angimidone
Aseptilex
Asey-sulfa
Bimalong
Bio-cron
Bio-exazol
Bio-pectodil
Biocorn
Davosin
Davosin suspension
Deltavagin
Depovernil
Desulfon
Donibin
Durasul
Durasul jarabe
Durox
Dynabiotal
Elix
Eusulfa
Exazol
Farinffnicol
Fercasulf
Hesse-sulfon
Ketiak
Kiron
Kynex
Kynex acetyl
Lederkyn
Lentac
Lentosulfa
Linder
Logisul jarabe
Longamid
Longisul
Metamit
Metazina
Microcid
Midicel
Midikel
Minikel
Myasul
Mylosul
Novosulfin
Opinsul
Paramid supra
Petrisul
Pirasulfon
Quinoseptyl
Ralenta
Retasulfin
Roncovita
Rotardon
S.d.m.
Septotryl
Sergo-amigdalar
Smop
Spofadazine
Sulamin
Sulfa spirig
Sulfabon
Sulfadazina
Sulfadepot
Sulfadin
Sulfadurazin

...(Continued)

Product name Sulfamethoxypyridazine ...(Continued)

Trade and brand names

Sulfaintensa
Sulfakeyn
Sulfalex
Sulfametopyridazin
Sulfamizina
Sulfamyd
Sulfapyrazin
Sulfatar
Sulfdurazin
Sulfo-rit
Sulfocidan
Sulfonamid
Sulforetent
Sultirene
Unisulfa
Unisulfa dulcis
Uroplex
Velaten
Vinces
Volocid
Vtg 44

For regulatory information, see page 165

Product name Sulfanilamide

C.A.S. number 63-74-1

Trade and brand names

Acetonal vaginal
Amidrin
Astreptine
Avc
Avc cream suppositoty
Avc/dienestrol
Avril
Azol
Azol polvo
Azol pomada
Buco pental
Buco regis
Chemiovis
Daromid
Defonamid
Dorsec
Exoseptoplix
Expseptoplix
Faderma
Fricton
Gagaril sulfamida
Gynaedron
Instilin
Jacosulfon
Medeyol
Mentol sedans sulfamidad
Nasopomada
Odamida
Oestro-gyneadron
Otocaina
Otonasal
Otorrilan
Ovuthricinol
Oxidermiol
Paraseptol
Pental
Pental forte
Pentalmicina
Polvo sulfamida leti
Polvo sulfamida orrvan
Polvos wilfe
Pomada heridas
Pomada wilfe
Prontablin
Pulvi bacteramide
Pyodental
Pyodron
Quimpeamida
Rhinamide
Rino glucol sulf
Septoplix
Streptamin
Sulfacromo
Sulfonamid spuman
Sulfonamide-spuman-style
Sulfonanilamid
Sulfosellan-salbe
Ung. vemleigh
Vagitrol

For regulatory information, see page 166

Product name Sulfathiazole

C.A.S. number 72-14-0

Trade and brand names

Argazol
Azoseptale
Bucosol
Chemosept
Cibazol
Coryza
Crionil
Csp 500
Csp-250
Eleudron
Femakzem
Flumamine
Gyne-sulf
Ingalipt
Neosutrin
Percural
Prothiazol
Septozol
Streptacillin
Sulfa-orzon
Sulfamul
Sulfazol
Sulfhatose
Sulfopyrol
Sulfour
Sulfzol
Sulnac
Sulzol
Thiadyl
Thiazamid
Thiuramide
Tiadyl
Trimeto
Trysul
Tylasul
Ufa 902-duo
Vetoprim mi
Wintrazol

For regulatory information, see page 166

Product name Sulfisomidine

C.A.S. number 515-64-0

Trade and brand names

Aristamid
Elkosin
Gynedron
Isosulf
Oestro-gynedron
Poly-gynedron
Sulfamethine
Tricho-gynedron

For regulatory information, see page 167

Product name **Suloctidil**

C.A.S. number **54767-75-8**

Trade and brand names

Bemperil
Cerebro
Circleton
Cp 556s
Dulasi
Duloctil
Euvasal
Farectil
Fluversin
Fluvisco
Hemoantin
Iangene
Ibisul
Loctidon
Locton
Metactiv
Octamet
Polivasal
Sudil
Sulc
Sulocton
Sulodene
Suloktil
Sutidil
Tamid
Vascudil

For regulatory information, see page 168

Product name **Sultopride**

C.A.S. number **53583-79-2**

Trade and brand names

Banotil
Barnetil
Barnotil
Topral

For regulatory information, see page 168

Product name **Suprofen**

C.A.S. number **40828-46-4**

Trade and brand names

Algiamida
Algiasdi
Bordol
Maldocil
Masterfen
Supranol
Suprol

For regulatory information, see page 169

Product name **Suxibuzone**

C.A.S. number **27470-51-5**

Trade and brand names

Calibene
Danilon
Flamilon
Flogos
Solurol

For regulatory information, see page 169

Product name **Tartrazine**

C.A.S. number **1934-21-0**

Trade and brand names

A.f. yellow no.4
Acid leather yellow t
Acid yellow t
Acid yellow 23
Acilan yellow
Acilan yellow gg
Airedale yellow t
Aizen tartrazine
Amacid yellow t
Amacid yellow t-ex
Atul tatrazine
Ayellow t
B 3014
Biovital
C.i. acid yellow 23
C.i. food yellow 4
C.i. 19140
Calcocid yellow mcg
Calcocid yellow xx
Cancert tartrazine
Certecol tartrazol yellow s
Cilefa yellow t
Curon
D and c yellow no. 5
Dolkwal tartrazine
Dye yellow lake
E 102
E 102 (dye)
Edicol supra tartrazine n
Egg yellow a
Erio tartrazine
Erio yellow t supra
Eurocert tartrazine
Fast yellow 5g
Fd and c yellow no. 5
Fenazo yellow t 4
Food dye yellow 4
Food yellow no. 4
Food yellow 4
Galinid
Hd tartrazine
Hd tartrazine supra

...(Continued)

Product name Tartrazine ...(Continued)

Trade and brand names

Hexacert yellow no 5
Hexacol tartrazine
Hişpacid fast yellow t
Hydrazine yellow
Hydroxine yellow l
Japan yellow no. 4
Jaun tartrique
Kako tartrazine
Kayaku food colour yellow no. 4
Kayaku tartrazine
Kca foodcol tartrazine pf
Kca tartrazine pf
Kiton yellow t
L yellow z 1020
Lake yellow
Lemon yellow a
Lemon yellow a geigy
Maple tartrazol yellow
Mitsui tartrazine
Naphtocard yelow o
Neklacid yellow t
Oxanal yellow t
San ei tartrazine
Sugai tartrazine
Tartar yellow fs
Tartar yellow n
Tartar yellow pf
Tartar yellow s
Tartran yellow
Tartraphenine
Tartrayellow
Tartrazin
Tartrazine a export
Tartrazine b
Tartrazine b.p.c.
Tartrazine c
Tartrazine extra pure a
Tartrazine fq
Tartrazine g
Tartrazine lake
Tartrazine lake yellow n
Tartrazine m
Tartrazine mcgl
Tartrazine n
Tartrazine ns
Tartrazine o
Tartrazine o specially pure
Tartrazine t
Tartrazine xx
Tartrazine xx especially pure
Tartrazine xxx
Tartrazine yellow
Tartrazol bpc
Tartrazol yellow
Tartrine yellow o
Unitertracid yellow te
Usacert yellow no 5
Vondacid tartrazine
Wood yellow
Xylene fast yellow gt
Yellow lake 69
1 yellow
1409 yellow

For regulatory information, see page 170

Product name Temafloxacin

C.A.S. number 108319-06-8

Trade and brand names

Omniflox
Teflox
Temac

For regulatory information, see page 170

Product name Terodiline

C.A.S. number 15793-40-5

Trade and brand names

Bicor
Mictrol
Micturin
Mitrol
Miucurin
Terolin

For regulatory information, see page 171

Product name Testosterone propionate (injectable)

C.A.S. number 57-85-2

Trade and brand names

Agovirin
Andro heart injecta
Androfort
Androlan in oils
Androtest
Androteston
Anertan
Aquaviron
Bio-testiculina
Cortrifosal
Durateston v
Enarmon
Enarmon-oil
Encilcort
Galanrent
Gondrone
Hermo m
Homandren
Homosterone
Hormoteston
Jeifer-old
Malogen
Malogen in oil
Malotrone
Masenate
Mertestate
Micro-sterandryl
Napionate
Nasdol
Neo-hombreol
Okasa-mascul
Omnadren
Orchiol
Orchisterone-p
Orchistin
Oreton
Oreton-f
Pantesin
Perandern
Percutacrine androgenique
Pertesis
Primotest
Primotestone
Propiokan
Recthormone
Recthormone testosterone
Solvotest
Sterotest
Sutanone
Synandrol
Syneron
Synovex-h
Telipex
Teslen
Tesrina
Testaform
Testanderogen

...(Continued)

Product name Testosterone propionate (injectable) ...(Continued)

Trade and brand names

Testenat
Testex
Testigrmon
Testilen
Testirene
Testo-retard
Testobase
Testodet
Testodrin
Testogen
Testoici
Testoidral
Testolets
Testonate
Testonique
Testopin
Testopinate
Testopropon
Testoral
Testormol
Testosid
Testoviron
Testoviron (ampule)
Testoviron-depot-50/-100
Testoviron-10/-25/-50
Testovis
Testoxyl
Testrex
Testron
Tostrina
Triomone
Uniteston
Vantostol-p
Viromon
Virormone
Virosterone

For regulatory information, see page 172

Product name Tetracycline (paediatric)

C.A.S. number 60-54-8

Trade and brand names

Achromycin
Achromycin v
Achromycin y
Apo-tetra
Cyclopar
Decycline
Double-t
Gt-250
Hosta-500
Medicycline
Muracine
Mysteclin-f
Neo-tetrine
Nor-tet
Novotetra
Panmycin
Retet
Robitet
Sk-tetracycline
Steclin
Sumycin
Tepcycline
Teropicycline
Tetra-c
Tetrabotic
Tetracaps
Tetracyn
Tetralan
Tetram
Tetrex
Tetrpsol
Wintracin

For regulatory information, see page 172

Product name Thalidomide

C.A.S. number 50-35-1

Trade and brand names

Algosediv
Asidon
Bonbrain
Contergan
Distaval
E-217
Glupan
Glutanon
Hippuzon
Imidan
Isomin
Kevadon
Nerufatin
Neurosedyn
Pangul
Pantosedive
Pro-ban
Quetimid
Sanodormin
Sedalis
Sedoval
Shinaito
Shinnibrol
Sleepan
Slipro
Softenil
Softenon
Talimol
Tlargan
Yodomin

For regulatory information, see page 174

Product name Thenalidine

C.A.S. number 86-12-4

Trade and brand names

Sanbosten
Sandosten
Sandostene

For regulatory information, see page 175

Product name **Ticlopidine**

C.A.S. number **55142-85-3**

Trade and brand names

Anagregal
Aplaquette
Caudaline
Derivatives
Klodin
Opteron
Panaldine
Pcr 5332
Tcp
Ticlid
Ticlidan
Ticlodix
Ticlodone
Ticlopedine
Ticlosan
Tiklid
Tilcid
4-c-32
53-32-c

For regulatory information, see page 175

Product name **Tienilic acid**

C.A.S. number **40180-04-9**

Trade and brand names

Anp 3624
Diflurex
Fr 3068
Selacryn
Selcryn
Skf-62698
Ticrex
Ticrynafen
Ticrynapen

For regulatory information, see page 176

Product name **Tocainide**

C.A.S. number **41708-72-9**

Trade and brand names

Apx
Citocard
Taquidil
Tonocard
Toquidil
Xylotocan

For regulatory information, see page 177

Product name **Tranylcypromine**

C.A.S. number **155-09-9**

Trade and brand names

Cuait
Estelapar
Jatrosom
Oculocidon
Parnate
Parnate tylciprine
Parnetene
Parstelazin
Parstelin
Stelapar
Transamin
Transaminase
Transaminase sgo
Transaminase sgp
Transamine
Tylciprine

For regulatory information, see page 177

Product name **Trazodone**

C.A.S. number **19794-93-5**

Trade and brand names

Beneficat
Bimaran
Desyrel
Devidone
Manegan
Molipaxin
Pragmazone
Taxagon
Thittico
Thombran
Thromban
Tombran
Tramensan
Trittico

For regulatory information, see page 178

Product name **Tretinoin**

C.A.S. number **302-79-4**

Trade and brand names

Aberel
Aberela
Acid a vit
Acnavit
Acnavyse
Airoderm
Airol
Aknebon
Aknefug
Aknoten
Anition
Antibio-aberel
Cordes vas
Dermairol
Dermoclar
Derugin
Effederm
Epi-aberel
Eudyna
Locacid
Menaderm antiacne
Pigmanorm
Retin-a
Ro 1-5488
R0 22-6595
Sebo-psor
Stie vaa
Tretin m
Vas dexa
Verra-med
Vitacid a

For regulatory information, see page 178

Product name **Triacetyldiphenolisatin**

C.A.S. number **18869-73-3**

Trade and brand names

Schlakforte

For regulatory information, see page 179

Product name **Triazolam**

C.A.S. number **28911-01-5**

Trade and brand names

Halcion
Novidorm
Novodorm
Nuctane
Songar

For regulatory information, see page 179

Product name **Trimipramine**

C.A.S. number **739-71-9**

Trade and brand names

Apo-trimip
Herphonal
No-tripramine
Novo-tripramine
Rhotrimine
Rhotromine
Sapilant
Stangyl
Surmantil
Surmontil
Tydamine

For regulatory information, see page 181

Product name **Trolamine**

C.A.S. number **102-71-6**

Trade and brand names

Sabril
Sabrilex

For regulatory information, see page 182

Product name **Vigabatrin**

C.A.S. number **60643-86-9**

Trade and brand names

Sabril
Sobril
Sobril tab 25 mg

For regulatory information, see page 183

Product name **Vinbarbital**

C.A.S. number **125-42-8**

Trade and brand names

Butenemal
Delvinal
Delvinal sodium
Diminal
Suppoptanox
Vinbarbiton

For regulatory information, see page 184

Product name **Xenazoic acid**

C.A.S. number **1174-11-4**

Trade and brand names

Cv 58903
Xenalmine
Xenovis

For regulatory information, see page 185

Product name **Zimeldine**

C.A.S. number **56775-88-3**

Trade and brand names

Normid
Normud
Zelmid
Zelmidine

For regulatory information, see page 185

Product name **Zipeprol**

C.A.S. number **34758-83-3**

Trade and brand names

Antituxil-z
Bronx
Cerm-3024
Citizeta
Mirsol
Ogyline
Respilene
Respirase
Respirex
Santus
Talasa
Zitoxil

For regulatory information, see page 186

Product name **Zomepirac**

C.A.S. number **33369-31-2**

Trade and brand names

Calinador
Calmador
Dolgenal
Dolwas
Mcn 2783
Mcn 2783-21-98
Miranil
Zomax
Zomaxin
Zopirac

For regulatory information, see page 186

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CONSOLIDATED LIST OF PRODUCTS WHOSE CONSUMPTION AND/OR SALE HAVE BEEN BANNED, WITHDRAWN, SEVERELY RESTRICTED OR NOT APPROVED BY GOVERNMENTS

Sixth Issue

Pharmaceuticals

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3184Cd PDF

CONSOLIDATED LIST OF PRODUCTS WHOSE CONSUMPTION AND/OR SALE HAVE BEEN BANNED, WITHDRAWN, SEVERELY RESTRICTED OR NOT APPROVED BY GOVERNMENTS

Sixth Issue

Pharmaceuticals

ANNEXES

ANNEX I

GENERAL ASSEMBLY RESOLUTION 37/137

Protection against products harmful to health and the environment

The General Assembly,

Aware of the damage to health and the environment that the continued production and export of products that have been banned and/or permanently withdrawn on grounds of human health and safety from domestic markets is causing in the importing countries,

Aware that some products, although they present a certain usefulness in specific cases and/or under certain conditions, have been severely restricted in their consumption and/or sale owing to their toxic effects on health and the environment,

Aware of the harm to health being caused in importing countries by the export of pharmaceutical products ultimately intended also for consumption and/or sale in the home market of the exporting country, but which have not yet been approved there,

Considering that many developing countries lack the necessary information and expertise to keep up with developments in this field,

Considering the need for countries that have been exporting the above-mentioned products to make available the necessary information and assistance to enable the importing countries to protect themselves adequately,

Cognizant of the fact that almost all of these products are at present manufactured and exported from a limited number of countries,

Taking into account that the primary responsibility for consumer protection rests with each State,

Recalling its resolution 36/166 of 16 December 1981 and the report on transnational corporations in the pharmaceutical industry of developing countries, [1] and acting in pursuance of Economic and Social Council resolution 1981/62 of 23 July 1981,

Bearing in mind in this context the work of the Food and Agriculture Organization of the United Nations, the World Health Organization, the International Labour Organisation, the United Nations Environment Programme, the General Agreement on Tariffs and Trade, the United Nations Centre on Transnational Corporations and other relevant intergovernmental organizations,

1. **Agrees** that products that have been banned from domestic consumption and/or sale because they have been judged to endanger health and the environment should be sold abroad by companies, corporations or individuals only when a request for such products is received from an importing country or when the consumption of such products is officially permitted in the importing country;

2. **Agrees** that all countries that have severely restricted or have not approved the domestic consumption and/or sale of specific products, in particular pharmaceuticals and pesticides, should make available full information on these products with a view to safeguarding the health and environment of the importing country, including clear labelling in a language acceptable to the importing country;

3. **Requests** the Secretary-General to continue to ensure the provision of the necessary information and assistance by the United Nations system in order to strengthen the national capacities of developing countries to protect themselves from the consumption and/or sale of banned, withdrawn, severely restricted or, in the case of pharmaceuticals, non-approved products;

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[1] **E/C.10/85**

4. Requests the Secretary-General, based upon the work already being done within the Food and Agriculture Organization of the United Nations, the World Health Organization, the International Labour Organisation, the United Nations Environment Programme, the General Agreement on Tariffs and Trade, the United Nations Centre on Transnational Corporations and other relevant intergovernmental organizations, to the maximum extent possible within existing resources, to prepare and regularly update a consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or, in the case of pharmaceuticals, not approved by Governments, and to make this list available as early as possible and, in any case, not later than December 1983;

5. Agrees that the consolidated list referred to in paragraph 4 above should be easy to read and understand and should contain both generic/chemical and brand names in alphabetical order, as well as the names of all manufacturers and a short reference to the grounds and decisions taken by Governments that have led to the banning, withdrawal or severe restriction of such products;

6. Decides, on the basis of the above-agreed criteria, to keep under review the format of the consolidated list with a view to its possible improvements;

7. Requests Governments and the relevant organs, organizations and bodies of the United Nations system to provide all the information and assistance necessary for the prompt and effective fulfilment of the task entrusted to the Secretary-General.

109th plenary meeting
17 December 1982

GENERAL ASSEMBLY RESOLUTION 38/149

Protection against products harmful to health and the environment

The General Assembly,

Recalling its resolutions 36/166 of 16 December 1981 and 37/137 of 17 December 1982,

Bearing in mind the oral report presented by the Secretariat with regard to progress made in the implementation of resolution 37/137 [1]

1. Takes note of the report of the Secretary-General on the exchange of information on banned hazardous chemicals and unsafe pharmaceutical products, [2] and of the work being carried out by the United Nations system of organizations;

2. Notes with satisfaction that the work carried out in consultation with organizations of the United Nations system on the consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or, in the case of pharmaceuticals, not approved by Governments, is in the process of being completed;

3. Requests the Secretary-General to make available the consolidated list, as established on the basis of information supplied up to now in accordance with the objectives of General Assembly resolution 37/137, and to bring it up-to-date on a regular basis;

4. Urges the relevant organs, organizations and bodies of the United Nations system, particularly the Food and Agriculture Organization of the United Nations, the World Health Organization, the International Labour Organisation, the United Nations Environment Programme, the General Agreement on Tariffs and Trade and the United Nations Centre on Transnational Corporations and other intergovernmental organizations, to continue to co-operate fully in providing information for the consolidated list and for its updated versions;

5. Appreciates the co-operation extended by Governments and urges all Governments, in particular those that have not yet done so, to provide the necessary information for inclusion in the consolidated list and its updated versions, as well as comments and views that they deem relevant;

6. Urges non-governmental organizations to extend co-operation to the Secretary-General regarding the preparation of the consolidated list, particularly in the identification of potential sources of information among national Governments and in obtaining governmental information on relevant regulatory actions;

7. Requests the Secretary-General, for purposes of review by the General Assembly at its thirty-ninth session, to submit a report on the implementation of Assembly resolution 37/137, including the consolidated list, taking into account the latest information and comments collected for possible improvement of the list, as envisaged in paragraph 6 of resolution 37/137;

8. Requests the Secretary-General to submit to the General Assembly at its thirty-ninth session, through the Economic and Social Council, a report on the exchange of information on banned hazardous chemicals and unsafe pharmaceutical products identifying elements for possible further work in this area in regard to the needs and capabilities of developing countries to monitor and control those substances in the light of the relevant observations in the report of the Secretary-General; [3]

9. Requests the Secretary-General and the organs, organizations and other competent bodies of the United Nations system to continue to provide, within available resources, the necessary technical assistance to the developing countries, at their request, for the establishment or strengthening of national systems for better use by those countries of the information provided with regard to banned hazardous chemicals and unsafe products, as well as for an adequate monitoring of the importation of those products.

102nd plenary meeting
19 December 1983

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[1] See **A/C.2/38/SR.27**

[2] See **A/38/190-E/1983/67**

[3] See **A/38/190-E/1983/67**

GENERAL ASSEMBLY RESOLUTION 39/229

Protection against products harmful to health and the environment

The General Assembly,

Reaffirming its resolutions 37/137 of 17 December 1982 and 38/149 of 19 December 1983,

Taking note with satisfaction of the report of the Secretary-General on products harmful to health and the environment, [1]

Bearing in mind the report of the Secretary-General on the exchange of information on banned hazardous chemicals and unsafe pharmaceutical products, [2] and welcoming the effort being made in various international forums with regard to the exchange of information on such products,

1. Expresses its appreciation to the Secretary-General and commends him for the distribution of the first issue of the consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or, in the case of pharmaceuticals, not approved by Governments;

2. Reiterates its appreciation for the co-operation extended by Governments in the preparation of the consolidated list, and urges all Governments that have not yet done so to provide the necessary information for inclusion in the updated versions of the list;

3. Notes with satisfaction the co-operation provided by the appropriate organs, organizations and bodies of the United Nations system and other intergovernmental organizations in the issuance of the list and urges them, particularly the Food and Agriculture Organization of the United Nations, the World Health Organization, the International Labour Organization, the United Nations Environment Programme, the General Agreement on Tariffs and Trade and the United Nations Centre on Transnational Corporations, to continue to co-operate fully in the preparation of the updated versions of the list;

4. Expresses its appreciation for the co-operation provided by non-governmental organizations in this regard, and urges them to continue to extend co-operation to the Secretary-General in the preparation of the consolidated list, particularly in the identification of potential sources of information among national Governments and in obtaining governmental information on relevant regulatory actions;

5. Decides that:

(a) An updated consolidated list should be issued annually and that the data should be made available to Governments and other users in such a form as to permit direct computer access to it;

(b) In order to keep costs to a minimum, the consolidated list should be published and made available in all the official languages of the United Nations in sets of alternating languages each year, with no more than three languages per year and with the same frequency for each language;

(c) The format of the consolidated list should be kept under continuing review with a view to its improvement, in accordance with General Assembly resolution 37/137, in co-operation with the relevant organs, organizations and bodies of the United Nations system, taking into account the complementary nature of the list, the experiences obtained and the views expressed by Governments on this matter, and that the next review should be submitted by the Secretary-General to the General Assembly at its forty-first session;

(d) The review of the consolidated list should cover particularly the advantages and disadvantages of introducing to the list such information as the legal, public health and commercial context of the regulatory actions, as well as complementary information on safe uses of the products;

6. Urges importing countries, bearing in mind the extensive legal, public health and safety information already provided to the United Nations Centre on Transnational Corporations, the United Nations Environment Programme, the International Labour Organisation, the Food and Agriculture Organization of the United Nations, the World Health Organization and the General Agreement on Tariffs and Trade, to avail themselves of the information provision facilities of those organizations, which include, in some cases, direct computer access;

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[1] See **A/39/452**

[2] See **A/39/290-E/1984/120**

7. Requests the Secretary-General, with the assistance of the appropriate specialized agencies, to submit to the General Assembly at its forty-first session a report on a review of the various information exchange schemes now in operation within the United Nations system;

8. Requests the Secretary-General and the competent organs, organizations and bodies of the United Nations system to continue to provide the necessary technical assistance to the developing countries, at their request, for the establishment or strengthening of national systems for managing hazardous chemicals and pharmaceutical products, as well as for an adequate monitoring of the importation, manufacture and use of those products;

9. Also requests the Secretary-General, through the Economic and Social Council, to inform the General Assembly at its forty-first session and every three years thereafter about the implementation of resolutions 37/137 and 38/149 and of the present resolution;

10. Further requests the Secretary-General to take the necessary measures for the implementation of the present resolution.

104th plenary meeting
18 December 1984

Traffic in and disposal, control and transboundary movements of toxic and dangerous products and wastes

The General Assembly,

Recalling its resolutions 37/137 of 17 December 1982, 38/149 of 19 December 1983 and 39/229 of 18 December 1984, as well as its decision 41/450 of 8 December 1986,

Recalling also its resolution 42/183 of 11 December 1987 on traffic in toxic and dangerous products and wastes,

Recalling further its resolution 43/212 of 20 December 1988, entitled "Responsibility of States for the protection of the environment: prevention of the illegal international traffic in, and the dumping and resulting accumulation of, toxic and dangerous products and wastes affecting the developing countries in particular",

Recalling Economic and Social Council resolutions 1988/70 and 1988/71 of 28 July 1988 and taking note of Council resolution 1989/104 of 27 July 1989,

Taking note of the report of the Secretary-General on products harmful to health and the environment [1] and Economic and Social Council decision 1989/177 of 27 July 1989,

Taking note also of decisions 15/28 and 15/30 of 25 May 1989 of the Governing Council of the United Nations Environment Programme, [2]

Welcoming the report of the Secretary-General on illegal traffic in toxic and dangerous products and wastes, [3]

Taking note of the conclusion of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, [4]

Inviting all States to consider signing the Basel Convention without prejudice to the final positions to be taken by regional intergovernmental organizations in this regard,

Mindful of the growing threat to the environment and to human health and safety posed by the improper management and the increased generation, complexity and transboundary movement of hazardous wastes,

Convinced that illegal traffic in toxic and dangerous products and wastes poses a severe threat to the environment and to human health and safety,

Also convinced that these problems cannot be resolved without adequate co-operation among members of the international community,

Deeply concerned by the fact that cases of illegal transboundary movement and dumping of dangerous products and wastes particularly harmful for the environment and human health continue to occur, affecting, in particular, developing countries,

Convinced of the need to assist all countries, particularly developing countries, in obtaining all appropriate information concerning toxic and dangerous products and wastes and in reinforcing their capacity to detect and halt any illegal attempt to introduce toxic and dangerous products and wastes into the territory of any State in contravention of national legislation and relevant international legal instruments, as well as traffic not carried out in compliance with internationally accepted guidelines and principles in this field,

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[1] **A/44/276-E/1989/78**

[2] **A/C.2/44/7, annex**

[3] **A/44/362 and Corr.1**

[4] See **UNEP/IG.80/3**

I

TRAFFIC IN TOXIC AND DANGEROUS PRODUCTS AND WASTES

1. Requests each regional commission, within existing resources, to contribute to the prevention of the illegal traffic in toxic and dangerous products and wastes by monitoring and making regional assessments of this illegal traffic and its environmental and health implications, on a continuing basis, in each region, and, in this context, in co-operation with and relying upon expert support and advice from the United Nations Environment Programme and other relevant bodies of the United Nations, including the International Register of Potentially Toxic Chemicals, and ***Ad Hoc*** Working Group of Experts on Prior Informed Consent and Other Modalities to Supplement the London Guidelines for the Exchange of Information on Chemicals in International Trade, and the Interim Secretariat of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, without prejudice to the final position to be taken by regional intergovernmental organizations on the Convention, and to report to the Economic and Social Council at its second regular session starting in 1990;

2. Also requests the regional commissions to interact among themselves and co-operate with the United Nations Environment Programme, with a view to maintaining efficient and co-ordinated monitoring and assessment of the illegal traffic in toxic and dangerous products and wastes;

3. Requests the Economic and Social Council to submit recommendations to the General Assembly on the findings and conclusions of the regional commissions, in their consideration of environmental issues;

4. Calls upon all countries to co-operate with their respective regional commissions with the aim of preventing the illegal traffic in toxic and dangerous products and wastes;

II

PROTECTION AGAINST PRODUCTS HARMFUL TO HEALTH AND THE ENVIRONMENT

1. Expresses its appreciation to the Secretary-General for his report on products harmful to health and the environment, which contains a review of the Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or Not Approved by Governments;

2. Notes with appreciation the co-operative relationship established between the United Nations, the World Health Organization and the United Nations Environment Programme International Register of Potentially Toxic Chemicals for the preparation of the Consolidated List;

3. Notes , in this context, the need to utilize also the work being done by the Working Group on Export of Domestically Prohibited Goods and Other Hazardous Substances established by the General Agreement on Tariffs and Trade and those activities which are currently under way within the framework of the United Nations Environment Programme and the Food and Agriculture Organization of the United Nations in connection with implementation of prior informed consent schemes for chemicals and pesticides in international trade and which implement the system of information exchange envisaged by the developers of the Consolidated List, as well as the work being done under international agreements and conventions in related areas;

4. Expresses its appreciation for the growing co-operation by Governments in the preparation of the Consolidated List, and urges all Governments that have not yet done so to provide the necessary information for inclusion in updated versions of the Consolidated List;

5. Requests the Secretary-General to ensure, within existing resources, publication of the Consolidated List in English, French and Spanish, in accordance with demand, bearing in mind its resolution 39/229;

6. Also requests the Secretary-General to undertake a special effort to ensure effective and wider dissemination of the Consolidated List in all appropriate circles;

7. Further requests the Secretary-General, in this context, to consider ways and means of ensuring more effective involvement of non-governmental organizations in promoting the dissemination and utilization of the Consolidated List;

8. Requests the Secretary-General, in the context of the preparation of his next scheduled report on the question:

(a) To make specific suggestions on ways and means of providing technical co-operation, including through appropriate United Nations organizations, to countries, in particular developing countries, to create and strengthen their capacity to utilize the Consolidated List;

(b) To study all the pending issues, such as sustainable alternatives to banned and severely restricted products and unregistered pesticides, with a focus on improving the usefulness of the Consolidated List;

III

CONTROL OF TRANSBOUNDARY MOVEMENTS OF HAZARDOUS WASTES AND THEIR DISPOSAL

1. Recognizes the necessity of developing rules of international law, as early as practicable, on liability and compensation for damage resulting from the transboundary movement and disposal of hazardous wastes;

2. Requests the Executive Director of the United Nations Environment Programme, in accordance with the resolutions adopted at the Conference of Plenipotentiaries on the Global Convention on the Control of Transboundary Movements of Hazardous Wastes, held at Basel, Switzerland, from 20 to 22 March 1989, to establish, on the basis of equitable geographical representation and in consultation with Governments, an ***ad hoc*** working group of legal and technical experts to develop, as early as practicable, elements that might be included in a protocol on liability and compensation for damage resulting from the transboundary movement and disposal of hazardous wastes and to report to the preparatory committee of the United Nations conference on environment and development and to the Governing Council of the United Nations Environment Programme, in accordance with its mandate in this regard;

3. Invites the Executive Director of the United Nations Environment Programme and the Secretary-General of the International Maritime Organization, in consultation, as appropriate, with other relevant international organizations, to review the existing rules, regulations and practices with respect to the disposal of hazardous wastes at sea, in order to harmonize the provisions of the relevant conventions as adopted in this regard;

4. Requests the Secretary-General, in co-operation with the Executive Director of the United Nations Environment Programme, to report to the General Assembly at its forty-sixth session, through the Economic and Social Council, on the progress achieved in the implementation of the provisions of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal and of the present resolution.

85th plenary meeting
22 December 1989

ANNEX II

Criteria for the inclusion of pharmaceutical and chemical products in the Consolidated List

A. Pharmaceutical products [1]

a) "Banned product"

A product that has been withdrawn from use and/or sale nationally in one or more countries by order of the competent national authority, having regard to its safety in relation to its intended use.

b) "Voluntary product"

A product that has been withdrawn from use and/or sale nationally in one or more countries by voluntary action of the manufacturer, having regard to its safety in relation to its intended use.

c) "Severely restricted"

A product containing:

(a) A substance that is controlled more rigorously than is provided for under the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances or that is subjected to analagous control at the national level before it has been considered for international scheduling,

(b) A substance that may be incorporated in pharmaceutical dosage forms only within the specific limits determined by statute;

(c) A substance that is approved by a competent national authority and is subsequently subjected to restrictions that exclude its use in a substantial proportion of the potential target population of patients having regard to its safety. A substance which from the outset has been severely restricted in its indications having regard to the known balance of safety and efficacy is excluded.

d) "Non-approved"

A product that has been formally submitted for registration by a manufacturer to a national competent authority and which has been rejected on grounds of safety.

B. Chemical products

a) "Banned"

A product that has been prohibited for all uses nationally in one or more countries by final government regulatory action because of health or environmental reasons.

b) "Withdrawn"

A product formerly in commerce that has been withdrawn for all uses nationally in one or more countries by final voluntary action of the manufacturer because of health or environmental reasons.

c) "Severely restricted"

A product for which virtually all uses have been prohibited nationally in one or more countries by final government regulatory action because of health or environmental reasons, but for which certain specific uses remain authorized.

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[1] **Products which are in illicit trade only would not be considered.**

ANNEX III

LISTING OF REFERENCES CITED IN PART I

AARNO
MINISTRY OF HEALTH
LAGOS, NIGERIA

AUDEC
REPORT OF THE AUSTRALIAN DRUG EVALUATION COMMITTEE
COMMONWEALTH DEPARTMENT OF HEALTH
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AUSTGA
THERAPEUTIC GOODS ADMINISTRATION, DEPARTMENT OF COMMUNITY SERVICES AND HEALTH
WODEN, AUSTRALIA

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BELGPI
GENERAL PHARMACEUTICAL INSPECTORATE
MINISTRY OF PUBLIC HEALTH AND ENVIRONMENT
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BELMD
MINISTERIAL DECREE
MINISTERE DE LA SANTE PUBLIQUE ET DE L'ENVIRONNEMENT
BRUSSELS,
BELGIUM

BFOLP
"FOLIA PHARMACOTHERAPEUTICA"
CENTRE BELGE D'INFORMATION
PHARMACOTHERAPEUTIQUE
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BGDCO
"THE DRUGS (CONTROL) ORDINANCE 1982,
ORDINANCE NO. VIII"
GOVERMENT OF THE PEOPLE'S REPUBLIC
OF BANGLADESH
OFFICE OF THE DIRECTOR
HEALTH MANPOWER DEVELOPMENT
105/106 MOTIJHEEL COMMERCIAL AREA
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BGHBL
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PHARMACEUTICAL DIVISION
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BMCHL
"BOLETIN INFORMATIVO SOBRE MEDICAMENTOS"
DEPARTAMENTO CONTROL NACIONAL
INSTITUTO SALUD PUBLICA DE CHILE
MINISTERIO DE SALUD
MARATHON 100, SANTIAGO
CHILE

BMJOAE
BRITISH MEDICAL JOURNAL
BRITISH MEDICAL ASSOCIATION
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BNIPH
BULLETIN OF THE NATIONAL INSTITUTE OF PHARMACY 1984
NATIONAL INSTITUTE OF PHARMACY
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DIARIO OFICIAL MINISTERIO DA SAUDE
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OFFICE OF THE FEDERAL REGISTER NATIONAL ARCHIVES AND RECORDS SERVICE
US GOVERNMENT PRINTING OFFICE
GENERAL SERVICES ADMINISTRATION
WASHINGTON, DC 20402, USA

CHBCM
BULLETIN MENSUEL
ORGANISATION INTERCANTONALE DE CONTROLE DES MEDICAMENTS
BERNE
SWITZERLAND

CHEAZ
SCHWEIZER APOTHEKER ZEITUNG
SWITZWERLAND

CHLMS
MINISTERIO DE SALUD
SANTIAGO, CHILE

CHLRS
INSTITUTE OF PUBLIC HEALTH
AVDA MARATHON 1000
SANTIAGO, CASILLA 48
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COECI
COUNCIL OF EUROPE
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CPMPDP
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COMMISSION OF THE EUROPEAN COMMUNITIES
LUXEMBOURG

CPMPPO
COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS
COMMISSION OF THE EUROPEAN COMMUNITIES
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CPMPPS
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DDRZT
ZENTRALE THERAPIE EMPFEHLUNG DIABETES, ADD.
BERLIN
GDR

DENBH
DANISH NATIONAL BOARD OF HEALTH
COPENHAGEN, DENMARK

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EGYPTION TECHNICAL COMMITTEE FOR DRUG CONTROL
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EGYDI
EGYPTION PHARMACOPOEIAL INFORMATION CENTRE
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ESPINS
INFORMACION TERAPEUTICA DE LA SEGURIDAD SOCIAL
INSTITUTO NACIONAL DE LA SALUD
MADRID
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INFORMACION DE LA TERAPEUTICA DEL SISTEMA NACIONAL DE SALUD
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PROGRAMA SELECTIVO DE REVISION DE MEDICAMENTOS
MINISTERIO DE SANIDAD Y CONSUMO
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MALAYSIA

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DRUG CONTROL AUTHORITY
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MALAYSIA

MYSPR
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SGPMA
THE MEDICINES ACT (CHAPTER 176)
THE MEDICINES (LABELLING OF ASPIRIN PRODUCTS) REGULATIONS 1987
VOL.MH.(HQ) 36:26/1 VOL.3, AG/SL/31/84 PT.
SINGAPORE NATIONAL PRINTERS LTD (GOVERNMENT PRINTERS)
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UNCPS
UNITED NATIONS TREATY SERIES (VOLUME 1019)
UNITED NATIONS SECRETARIAT
NEW YORK, NY. 10017, USA

UNSND
SINGLE CONVENTION ON NARCOTIC DRUGS 1961
(UNITED NATIONS TREATY SERIES VOL. 520, E/CONF.34/22)
AS AMENDED BY THE 1972 PROTOCOL (E/CONF.63/7-8, E.77.XI.3)
UNITED NATIONS
NEW YORK, NY 10017, USA

WHODI
WORLD HEALTH ORGANIZATION
1211 GENEVA 27, SWITZERLAND

WHTAC1
THE USE OF ESSENTIAL DRUGS
2ND REPORT OF THE WHO EXPERT COMMITTEE
TECHNICAL REPORT SERIES, 722, 1985
WORLD HEALTH ORGANIZATION
1211 GENEVA 27, SWITZERLAND

WHTAC2
TWENTY-SECOND EXPERT COMMITTEE ON DRUG DEPENDENCE
TECHNICAL REPORT SERIES, 729, 1985
WORLD HEALTH ORGANIZATION
1211 GENEVA 27, SWITZERLAND

WHTAC3
TWENTY-THIRD REPORT OF JOINT FAO/WHO EXPERT
COMMITTEE ON FOOD ADDITIVES
WHO TECHNICAL REPORT SERIES
WORLD HEALTH ORGANIZATION
1211 GENEVA 27, SWITZERLAND

WHTAC4
THE USE OF ESSENTIAL DRUGS
4TH REPORT OF THE WHO EXPERT COMMITTEE
TECHNICAL REPORT SERIES
WORLD HEALTH ORGANIZATION
1211 GENEVA 27, SWITZERLAND

WIMAM
WICHTIGE MITTEILUNG UBER ARZNEIMITTEL 1984
(IMPORTANT DRUG INFORMATION)
BUNDESMINISTERIUM FUR GESUNDHEIT
UND UMWELTSCHUTZ
GRUPPE PHARMAZIE
LANDSTRASSE HAUPTSTRASSE 55-57
1030 WIEN, AUSTRIA

ZMBSI
STATUTORY INSTRUMENT
MINISTRY OF HEALTH
LUSAKA, ZAMBIA

ZWDCC
NEWS BULLETIN
DRUGS CONTROL COUNCIL
HARARE, ZIMBABWE

ZWESI
STATUTORY INSTRUMENT
MINISTRY OF HEALTH
HARARE, ZIMBABWE

ANNEX IV

QUESTIONNAIRE

Dear Reader,

Both the Economic and Social Council and the General Assembly of the United Nations have expressed interest in ascertaining the use which is being made of the Consolidated List. They have also requested that the Secretariat keep the format of the List under continuing review. This questionnaire has been prepared with a view to obtaining this information which will be reported to the Economic and Social Council and the General Assembly; comments regarding the format of the Consolidated List will be taken into account for future editions of the List.

Please mail the questionnaire as early as possible to: United Nations Secretariat, DPCSP, Room No. S-2977E, New York, New York 10017, U.S.A.

Name and address of Ministry/Organization/Institution/Company:

_____

_____

_____

_____

A) In what capacity do you use the Consolidated List?

Government:

☐ Regulator ☐ Customs enforcement ☐ Policy maker

Other:

☐ Academic ☐ Media

☐ International Organization ☐ NGO/Public Intersecretariat Group

☐ Manufacturer ☐ Other: _____

B) For which category of products have you used the list?

☐ Agricultural chemicals ☐ Industrial chemicals

☐ Consumer products ☐ Pharmaceuticals

C) i. Has the information in the list prompted any action on your part?

☐ Yes ☐ No

If "yes" please describe the nature of this action either in general terms or in relation to specific products.

_____

_____

_____

_____

_____

ii. What is the nature of this action? (Information on the following points is particularly requested from national regulatory authorities)

- ☐ Review of licensing provisions for pharmaceutical products.
- ☐ Review of licensing provisions for chemical products.
- ☐ Review of regulations for already regulated products.
- ☐ Review of enforcement of laws and regulations.
- ☐ Regulation of previously unregulated products.
- ☐ Meeting with manufacturers/distributors.
- ☐ Other actions (please describe them).

_____

_____

_____

_____

_____

D) Are you aware of any additional products or restrictive regulatory actions that should be included in the list?

☐ Yes ☐ No

If "yes" please specify or kindly attach copy of regulation.

_____

_____

_____

_____

_____

E) Are you aware of any additional trade and manufacturer data that should be included in the list?

☐ Yes ☐ No

If "yes" please specify.

_____

_____

_____

_____

_____

F) Do you find the following items of information useful?

	Yes	No
Product category listing	☐	☐
CAS numbers	☐	☐
Synonyms	☐	☐
Date of decision	☐	☐
Citation of national regulations/decisions	☐	☐
Trade names/manufacturer information	☐	☐
WHO comment	☐	☐
Bibliographic references	☐	☐

G) Which other sources you use to obtain information on banned and severely restricted products?

H) Would you be interested in and have the facilities to use 'on-line' access to the information in the United Nations' Consolidated List?

☐ Yes ☐ No

I) Do you have any other comments?

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