ST/ESA/ 322

**Department of Economic and Social Affairs**

# Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or not Approved by Governments

## *Fourteenth Issue*

***(New data only)***

***(January 2005 – October 2008)***

## *Pharmaceuticals*

**United Nations – New York, 2009**

## DESA

The Department of Economic and Social Affairs of the United Nations Secretariat is a vital interface between global policies in the economic, social and environmental spheres and national action. The Department works in three main interlinked areas: (i) it compiles, generates and analyses a wide range of economic, social and environmental data and information on which Member States of the United Nations draw to review common problems and to take stock of policy options; (ii) it facilitates the negotiations of Member States in many intergovernmental bodies on joint courses of action to address ongoing or emerging global challenges; and (iii) it advises interested Governments on the ways and means of translating policy frameworks developed in United Nations conferences and summits into programmes at the country level and, through technical assistance, helps build national capacities.

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# INTRODUCTION

As before, the next, fourteenth issue of the *Consolidated List of Products whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or not Approved by Governments*, is published in a "short version", for limited distribution in printed form, and as usual, it will contain only new data. The updated fourteenth issue of the *Consolidated List*, containing new as well as historical data on pharmaceuticals, is now available on the internet at the DESA website www.un.org/esa/coordination under publications.

The short version is continued to be printed for the benefit of the *List* users, particularly for those in the developing countries, who may not have easy access to the Internet or for those who would like to continue to receive the publication in the printed version for reasons of their own. In this regard, it should be understood that to obtain complete coverage, the present issue could only be used in conjunction with the previously printed even numbered issues, focused as well on pharmaceuticals data.

According to an agreed rotation schedule, the yearly focus of the *Consolidated List* alternates between pharmaceuticals (even numbered issues) and chemicals (odd numbered issues). The seventh issue of the *List*, containing chemicals data, was the last issue to be published in the printed version only. The eighth issue of the *List*, containing data on pharmaceuticals, became the first issue to be printed as well as posted on the United Nations Economic and Social Council (ECOSOC) website in September 2003, in accordance with the General Assembly and ECOSOC resolutions (see annex I). More specifically the General Assembly resolution 39/229 called for the *List* data to be made available to Governments and other users in such a form as to permit direct computer access to it, and ECOSOC resolution 2001/33, requested the Secretary-General to look at the possibility of online dissemination of the *List* data.

Accordingly, beginning with the ninth, updated issues of the *List* are posted regularly on the above mentioned website. In order to provide complete and up to date coverage of both pharmaceuticals and chemicals, two most recent issues are maintained on the web site. It is hoped that this new procedure will help the *List* to reach a much wider audience in a shorter period of time, as mandated in previously mentioned and other General Assembly and ECOSOC resolutions.

The fourteenth issue of the *List* contains data received by WHO from national authorities on new regulatory decisions and from voluntary withdrawals of products by manufacturers on grounds of safety. It may also include other drug-related information issued by WHO through WHO Rapid Alerts, WHO Pharmaceuticals Newsletter and the journal WHO Drug Information.

This printed version contains information received from 24 countries, six of them (China, Cameroon, Kenya, Serbia, Timor-Leste and Ukraine) reporting for the very first time on pharmaceuticals. It includes data on 66 new products, together with updated and/or new information on 22 existing products. No new data was collected on commercial information regarding available proprietary trade/brand names of new pharmaceutical products included in this issue.

# ALPHABETICAL LISTING OF PRODUCTS

## Product name — Page

# ALPHABETICAL LISTING OF PRODUCTS

## LIST OF CODES USED FOR COUNTRIES, TERRITORIES AND AREAS

| | |
|---|---|
| **@EC** | European Union |
| **@WD** | World |
| **ARE** | United Arab Emirates |
| **ARG** | Argentina |
| **ARM** | Armenia |
| **AUS** | Australia |
| **AUT** | Austria |
| **BDS** | Brunei Darussalam |
| **BEL** | Belgium |
| **BGD** | Bangladesh |
| **BGR** | Bulgaria |
| **BHR** | Bahrain |
| **BLZ** | Belize |
| **BRA** | Brazil |
| **BRB** | Barbados |
| **CAN** | Canada |
| **CHE** | Switzerland |
| **CHL** | Chile |
| **CHN** | China |
| **CMR** | Cameroon |
| **COE** | Council of Europe |
| **COG** | Congo |
| **COL** | Colombia |
| **CRI** | Costa Rica |
| **CUB** | Cuba |
| **CYP** | Cyprus |
| **DEU** | Germany |
| **DNK** | Denmark |
| **DOM** | Dominican Republic |
| **EGY** | Egypt |
| **EME** | European Agency |
| **ESP** | Spain |
| **ETH** | Ethiopia |
| **FIN** | Finland |
| **FRA** | France |
| **GBR** | United Kingdom |
| **GHA** | Ghana |
| **GRC** | Greece |
| **HKG** | Hong Kong |
| **HND** | Honduras |
| **HUN** | Hungary |
| **IDN** | Indonesia |
| **IND** | India |
| **IRL** | Ireland |
| **IRN** | Iran |
| **IRQ** | Iraq |
| **ISL** | Iceland |
| **ISR** | Israel |
| **ITA** | Italy |
| **JAM** | Jamaica |
| **JOR** | Jordan |
| **JPN** | Japan |
| **KEN** | Kenya |
| **KOR** | Republic of Korea |
| **KWT** | Kuwait |
| **LBN** | Lebanon |
| **LIY** | Libyan Arab Jamahiriya |
| **LKA** | Sri Lanka |
| **LTH** | Lithuania |
| **MAR** | Morocco |
| **MEX** | Mexico |
| **MUS** | Mauritius |
| **MYS** | Malaysia |
| **NGA** | Nigeria |
| **NLD** | Netherlands |
| **NOR** | Norway |
| **NPL** | Nepal |
| **NZL** | New Zealand |
| **OMN** | Oman |
| **PAK** | Pakistan |
| **PAN** | Panama |
| **PER** | Peru |
| **PHL** | Philippines |
| **PRT** | Portugal |
| **ROM** | Romania |
| **RWA** | Rwanda |
| **SAU** | Saudi Arabia |
| **SDN** | Sudan |
| **SGP** | Singapore |
| **SLV** | Slovak Republic |
| **SRB** | Serbia |
| **SUN** | Union of Soviet Socialist Republics |
| **SUR** | Suriname |
| **SWE** | Sweden |
| **SYR** | Syria |
| **TCD** | Chad |
| **THA** | Thailand |
| **TLS** | Temor-Leste |
| **TUN** | Tunisia |
| **TUR** | Turkey |
| **UKR** | Ukraine |
| **URT** | United Republic of Tanzania |
| **USA** | United States |
| **VEN** | Venezuela |
| **VTN** | Viet Nam |
| **YEM** | Yemen |
| **ZAF** | South Africa |
| **ZMB** | Zambia |
| **ZWE** | Zimbabwe |

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

***Fourteenth Issue***

***PART I***

***REGULATORY INFORMATION***

# *MONOCOMPONENTS PRODUCTS*

**Product Name** **Acetylsalicylic acid (paediatric)**

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

**Scientific and common names, and synonyms**

2-ACETOXYBENZOIC ACID

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| SRB | May 2005 | Due to risk of Reye's syndrome, all registered products containing acetylsalicylic acid are contraindicated in children under the age of 12 years and in women during lactation.<br>(Reference: (SRBNPC) Communication, , , Mar 2005) |

**Product Name** **Alefacept**

**C.A.S. number** **222535-22-0**

**Scientific and common names, and synonyms**

AMEVIVE

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| USA | Nov 2005 | This recombinant human fusion protein is contraindicated in patients with HIV infection because it reduces CD4+ T lymphocyte counts which in turn can increase disease complications or accelerate disease progress in these patients.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.5, , 2005)<br>(Reference: (USASI) Safety information, , , 09 Nov 2005) |

**Product Name** **Amlodipine**

**C.A.S. number** **88150-42-9**

**Scientific and common names, and synonyms**

3-ETHYL 5-METHYL 2-(2-AMINOETHOXYMETHYL)-4-(2-CHLOROPHENYL)-1 4-DIHYDRO-6-METHYLPYRIDINE-3,5-DICARBOXYLATE MONOBENZENESULPHONATE

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| SRB | Aug 2006 | All registered original and generic amlodipine containing products are contraindicated in patients with any of the following conditions: cardiogenic shock, clinically significant aortic stenosis, unstable angina pectoris (excluding Prinzmetal's angina), as well as during lactation.<br>(Reference: (SRBNPC) Communication, , , July 2006) |

**Product Name** **Aprotinin**

**C.A.S. number** **9087-70-1**

**Scientific and common names, and synonyms**

TRASYLOL

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| @WD | 2008 | The manufacturer (Bayer Inc.) has been advised to suspend the marketing of this product |

**Product Name** **Aprotinin**

**C.A.S. number** **9087-70-1**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| | | because the risks from this medicine are greater than the benefits.<br>(Reference: (USFDAN) FDA News, , , 14 May 2008)<br>(Reference: (EMEAPR) EMEA Press Release, , , 21 Nov 2007) |

**Product Name** **Astemizole**

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

**Scientific and common names, and synonyms**

ASTOL

ASTEZOL

1 -(4-FLUOROBENZYL)BENZIMIDAZOL-2-YI[1 -(4-METHOXYPHENETHYL)-4-PIPERIDYL] AMINE

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **CHL** | **24 Nov 2004** | The import, distribution and sale of products containing astemizol have been banned due to cardiotoxic effects of these products.<br>(Reference: (CHLIPH) Resolucion no., 10228, , 24 Nov 2004) |

**Product Name** **Buflomedil**

**C.A.S. number** **55837-25-7**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **FRA** | **2006** | The French Regulatory Agency (AFSSAPS) has decided to withdraw buflomedil 300 mg tablets from the market and to strengthen the summary of product characteristics (SPC) for buflomedil 150 mg. The Agency undertook a benefit-harm evaluation of buflomedil (used chiefly to treat peripheral vascular disease), following the results of two enquiries about cardiovascular and neurological toxicity in accidental or voluntary buflomedil overdoses. The Agency says that neurological and serious cardiac adverse events occurred within 15-90 minutes in cases of suicide with buflomedil and, because of a narrow therapeutic index, the clinical manifestations of buflmedil overdose are serious. The majority of voluntary overdose cases occurred with 300 mg dose of buflomedil. The Agency has decided to recall batches of buflomedil 300 mg tablets from the market, and to include the following information in the SPC for buflomedil 150 mg: - indicated for improvement of symptoms of peripheral occlusive arterial disorders or Raynaud's disease only; - contraindicated in patients with severe renal failure (creatinine clearance < 30 mL/min); - dose adaptation in patients with moderate renal failure (creatinine clearance between 30 and 90 mL/min) and low body weight (< 50 kg); - control of creatinine clearance before and during treatment; and - information about low therapeutic range of buflomedil.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.1, , 2007) |

**Product Name** **Cabergoline**

**C.A.S. number** **81409-90-7**

**Scientific and common names, and synonyms**

CABASER

DOSTINEX

**Legislative or regulation action**

**Product Name** **Cabergoline**

**C.A.S. number** **81409-90-7**

**Scientific and common names, and synonyms**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| JPN | 19 Apr 2007 | The Ministry of Health, Labour and Welfare, Tokyo has instructed the company to update the package insert to contraindicate the use of this product in patients with valvular heart diseases, etc.<br>(Reference: (JPNPSI) PMDS Information, No.237, , ) |

**Product Name** **Carbamazepine**

**C.A.S. number** **298-46-4**

**Scientific and common names, and synonyms**

TAGRETOL

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| USA | Dec 2007 | The US FDA has modified the label to include a warning about the increase of risk of Stevens-Johnson Syndrome and toxic epidermal necrolysis with this product in patients who are positive for the HLA-B*1502 allele. The allele occurs exclusively in patients with Asian ancestry. Screening for this allele should be performed in the patients and treatment with carbamazephine should not be started in those testing positive for the allele.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.1, , 2008)<br>(Reference: (USFDAA) FDA Alert, , , 12 Dec 2007) |

**Product Name** **Ceftriaxone**

**C.A.S. number** **73384-59-5**

**Scientific and common names, and synonyms**

ROCEPHIN

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| USA | Jun 2007 | The US FDA advises that hyperbilirubinaemic neonates, especially those who are premature, should not receive ceftriaxone. This action is based on reports of death of neonates worldwide associated with calcius-ceftriaxone precipitates in the lungs and kidneys of these infants.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.4, , 2007)<br>(Reference: (USADHR) "Dear Health-care Professional " letter, , , June 2007) |

**Product Name** **Cinacalcet**

**C.A.S. number** **226256-56-0**

**Scientific and common names, and synonyms**

SENSIPAR

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|

**Legislative or regulation action**

**Product Name** **Cinacalcet**

**C.A.S. number** **226256-56-0**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **CAN** | **Jun 2007** | Cinacalcet (Sensipar) is no longer indicated in the treatment of secondary hyperparathyroidism in chronic Kidney disease (CKD) patients who are not receiving dialysis. The use is now restricted for the treatment of secondary hyperparathyroidism in patients with CKD who are receiving dialysis. This restriction follows study results involving cinacalcet recipients with secondary hyperparathyroidism and CKD which showed that cinacalcept recipients not receiving dialysis were more likely to develop serum calcium levels below the lower limit of the normal range (8.4 mg/dL) compared with those receiving dialysis.<br>(Reference: (CANAMG) "Dear Health-care professional" letter, , , 09 June 2007) |

**Product Name** **Cisapride**

**C.A.S. number** **810968-60-4**

**Scientific and common names, and synonyms**

CIS-4-AMINO-5-CHLORO-N-(1-[3-(4-FLUOROPHENOXY)PROPYL]-3-METHOXY-4- PIPERIDYL)-2-METHOXYBENZAMIDE MONOHYDRATE; CISAPRIDUM

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **SRB** | **Aug 2005** | Cisapride injections have been withdrawn due to concerns about life-threatening cardiac arrhythmias. This measure follows actions previously taken worldwide. The use of cisapride tablets has been restricted to treatment of acute and severe exacerbations of chronic idiopathic or diabetic gastroparesis in adults who are refractory to other therapy. Administration in hospital environment accompanied with cardiologic monitoring is required.<br>(Reference: (SRBNPC) Communication, , , May 2005) |

**Product Name** **Clobutinol**

**C.A.S. number** **14860-49-2**

**Scientific and common names, and synonyms**

SILOMAT

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **ARG** | **04 Sep 2007** | All products containing clobutinol have been withdrawn.<br>(Reference: (ARGNPC) Communication, , , 04 Sep 2007) |

**Product Name** **Codeine**

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

**Scientific and common names, and synonyms**

METHYLMORPHINE

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **SWE** | **Dec 2006** | The Swedish Medical Products Agency (MPA) has warned that, breastfeeding mothers |

**Product Name** **Codeine**

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

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| | | receiving codeine should use the lowest dose possible and monitor their infant for signs of overdose such as breathing difficulties, difficulty in breastfeeding, drowsiness or listlessness, flaccidity and small pupils; should any of these signs be noted, medical care should immediately be sought. This warning has been issued because in rare cases, codeine in normal doses given to breastfeeding mothers can lead to dangerously high amounts of morphine being delivered to the infant. Codeine is converted to morphine in the body. In rare cases in nursing mothers who are ultra-rapid metabolizers of codeine, a very high dose of morphine could get delivered to the child through the mother's milk, with serious adverse results.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.2, , 2007)<br>(Reference: (SWEMPA) Alert, , , Dec 2006) |

**Product Name** **Desmopressin nasal spray**

**C.A.S. number** **16679-58-6**

**Scientific and common names, and synonyms**

DESMOSPRAY

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **GBR** | **Apr 2007** | Desmopressin nasal spray products are no longer indicated in Primary Noctural Enuresis (PNE) (bedwetting). This measure was implemented by the UK Medicines and Healthcare products Regulatory Agency (MHRA) because of the nasal formulations were associated with a majority of the adverse drug reactions occurring in PNE patients while the oral formulations had a more favourable risk-benefit profile. Rare, serious adverse reactions associated with nasal desmopressin included hyponatraemia, seizures and water intoxication. (Nasal desmopressin still approved in cranial diabetes insipidus and multiple sclerosis-related nocturia).<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.3, , 2007)<br>(Reference: (GBRLHP) Letter to health-care providers, , , 18 Apr 2007) |

**Product Name** **Dolasetron**

**C.A.S. number** **115956-12-2**

**Scientific and common names, and synonyms**

ANZEMET

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **CAN** | **Jun 2006** | This product is contraindicated in patients below 18 years of age. In addition the product is not to be used to manage postoperative nausea and vomiting. These actions follow reports of myocardial infarction, sustained arrhythmias, and one fatal cardiac arrest associated with the use of dolasetron (Anzemet) in children and adolescents, and because there is an unfavourable risk/benefit ratio for postoperative use of the drug in patients aged > =18 years.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.4, , 2006)<br>(Reference: (CANAWR) Advisories, Warnings and Recalls, , , 23 June 2006) |

**Product Name** **Ephedrine**

**Legislative or regulation action**

**C.A.S. number** **299-42-3**

**Scientific and common names, and synonyms**

EPHEDRINUM

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| TLS | 2005 | To be removed from market. Not safe for use in asthma.<br>(Reference: (TLSFR) SEMWE Farmacia Report, , , 06 Apr 2005) |

**Product Name** **Ergometrine**

**C.A.S. number** **60-97-7**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| TLS | 2005 | Tablets to be removed from the market because tablets are unstable in tropical countries under high temperature and humidity. Only the injection will be available.<br>(Reference: (TLSFR) SEMWE Farmacia Report, , , 06 Apr 2005) |

**Product Name** **Gatifloxacin**

**C.A.S. number** **160738-57-8**

**Scientific and common names, and synonyms**

1 -CYCLOPROPYL-6-FLUORO-8-METHOXY-7-(3-METHYL PIPERAZIN-1-YL)-4-OXO-QUINOLINE-3-CARBOXYLIC ACID

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| BRA | Mar 2006 | Severely restricted use due to risks of hypo-and hyperglycaemic events.<br>(Reference: (BRAHSA) Communication, , , 05 Sep 2007) |
| MYS | May 2006 | Products containing gatifloxacin will not be registered since they are contraindicated in diabetic patients and due to cases of serious hypo-and hyperglycaemia that have been reported worldwide in patients receiving gatifloxacin.<br>(Reference: (MYSNPC) Communication, , , 2007) |

**Product Name** **Glucosamine**

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

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| MYS | Dec 2005 | To include the statement "Derived from seafood" for products containing glucosamine and chitin. But this statement does not apply to products where the source is clearly from seafood.<br>(Reference: (MYSNPC) Communication, , , 2007) |

**Product Name** **Hydromorphone hydrochloride**

**C.A.S. number** **71-68-1**

**Scientific and common names, and synonyms**

PALLADONE

**Legislative or regulation action**

**Product Name** **Hydromorphone hydrochloride**

**C.A.S. number** **71-68-1**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **CHE** | **2005** | Withdrawn due to potential to cause life threatening respiratory depression.<br>(Reference: (CHEMED) Communication, , , 2007) |
| **USA** | **Jul 2005** | The US FDA has recommended suspending the sales and marketing of hydromorphone hydrochloride (Palladone) controlled-release capsules in the USA, as co-ingestion of the drug with alcohol may cause severe adverse effects, such as depressed breathing, coma and even death.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.3, , 2005)<br>(Reference: (USFDAN) FDA News, , , 13 July 2005) |

**Product Name** **Interferon-gamma-1b**

**C.A.S. number** **98059-61-1**

**Scientific and common names, and synonyms**

ACTIMMUNE

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **USA** | **Mar 2007** | The U.S. FDA states that interferon-gamma-1b (IFN-γ-1b) (Actimmune) is not approved for the treatment of idiopathic pulmonary fibrosis, IPF. An interim analysis of the international study of survival outcome in IPF of IFN-γ-1b showed that IFN-γ-1b recipients did not benefit from the drug. Compared with 12.7% deaths in the placebo group, 14.5% of patients died in the IFN-γ-1b group.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.2, , 2007)<br>(Reference: (USAPHA) Public Health Advisory, , , 09 Mar 2007) |

**Product Name** **Isotretinoin**

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

**Scientific and common names, and synonyms**

ACCUTANE

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **USA** | **Aug 2005** | The U.S. FDA has approved a strengthened isotretinoin (Accutane and generics) risk management programme (iPLEDGE) in an effort to prevent use of the drug during pregnancy. Prescribers, pharmacies, wholesalers and patients, who agree to accept specific responsibilities, will be required to register in iPLEDGE before receiving authorization to prescribe, dispense, distribute or obtain isotretinoin. The responsibilities are designed to reduce the risk of exposure to isotretinoin during pregnancy since exposure to isotretinoin during pregnancy may significantly increase the risk of congenital disorders. From 1 November 2005, only iPLEDGE-registered wholesalers will be able to obtain isotretinoin from the manufacturers and only iPLEDGE-registered pharmacies will be able to receive isotretinoin from registered wholesalers. From 31 December 2005, pharmacies will be required to receive iPLEDGE authorization before dispensing an isotretinoin prescription, and only prescriptions from registered prescribers for registered patients will be accepted.<br>(Reference: (USAPHA) Public Health Advisory, , , 12 Aug 2005)<br>(Reference: (FDAPR) Press Release, , , 12 Aug 2005) |

**Product Name** **Isotretinoin**

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

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| CHL | 30 Dec 2005 | Indication limited to oral or topical use, and only in the treatment of severe acne that does not respond to other treatments; not to be used during pregnancy and during lactation. The package insert should warn about the teratogenic potential and suicidal ideation associated with this product.<br>(Reference: (CHLIPH) Resolucion no., 12359, , 30 Dec 2005) |

**Product Name** **Ketamine**

**C.A.S. number** **6740-88-1**

**Scientific and common names, and synonyms**

KETAMINI HYDROCHLOIDUM

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| GBR | Jan 2006 | As of 1 January 2006, ketamine has become a controlled drug, under the Misuse of drugs Act. It is now a Class C drug, in Schedule 4 part 1, which puts it in the same category as a majority of the benzodiazepines such as diazepam. This step has been taken because of its increasing misuse.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.1, , 2006) |

**Product Name** **Ketoconazole**

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

**Scientific and common names, and synonyms**

NIZORAL

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| GBR | Mar 2008 | Several therapeutic indications were removed due to the risk of serious hepatotoxicity. The Medicines and Healthcare products Regulatory Agency (MHRA) advises that oral ketoconazole should only be used for malassezia folliculitis, dermatophytosis and chronic candidosis, which cannot be treated topically. Ketoconazole should only be used in patients with infections resistant to fluconazole, terbinafine or itraconazole, or in patients who are intolerant to these drugs.<br>(Reference: (GBRDSU) Drug Safety Update, 1(8), , 02 Mar 2008) |

**Product Name** **Lamotrigine**

**C.A.S. number** **84057-84-1**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| SRB | Mar 2007 | Due to risk of cleft lip and/or palate in neonates associated with mother's use of lamotrigine during first trimester of pregnancy. If therapy with lamotrigine is necessary during pregnancy, if the lowest possible dose should be used. This measure refers to all registered original and generic products containing lamotrigine.<br>(Reference: (SRBNPC) Communication, , , Oct 2006) |

**Product Name** **L-arginine (l-arginine)**

**C.A.S. number** **74-79-3**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **CAN** | **May 2006** | Use contraindicated in patients who have previously had a heart attack (1) since a recent study published in the Journal of the American Medical Association in January 2006 suggests that l-arginine may not help improve heart and circulatory function following a first heart attack and may be associated with an increased risk of death when used after a heart attack (2). All l-arginine products are now required to carry a warning on their label reflecting this recent scientific information.<br>(Reference: (JAMA) Journal of American Medical Association, 295:, 58-64, 2006)<br>(Reference: (CANAHC) Advisory, , , 16 May 2006) |
| **MYS** | **Sep 2006** | The following warning must be included on labels and package inserts of oral health supplement products containing l-arginine: "Arginine is not recommended for patients following a heart attack". This recommendation follows similar measures taken in Canada.<br>(Reference: (MYSNPC) Communication, , , 2007) |

**Product Name** **Lidocaine**

**C.A.S. number** **137-58-6**

**Scientific and common names, and synonyms**

LIGNOCAINE

2-(DIETHYLAMINO)-N-(2,6-DIMETHYLPHENYL) ACETAMIDE

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **SRB** | **Dec 2005** | Not to be used in children under the age of 12 years due to risk of lidocaine overdosage with nervous and cardiovascular system toxicity. This measure refers to all registered original and generic lidocaine containing products intended for local administration.<br>(Reference: (SRBNPC) Communication, , , Oct 2005) |

**Product Name** **Lindane**

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

**Scientific and common names, and synonyms**

GAMEX

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **SRB** | **Aug 2006** | The use of all products containing lindane has been restricted to treatments only when response to other pediculocides and scabicides is inadequate, contraindicated in neonates and infants. Precaution is required for use in children with low body weight or in children predisposed to convulsions. Application in thin layer on dry and intact skin using protective gloves is recommended. Medical advice is required for repeated administration. New findings of neurological side effects led to these measures.<br>(Reference: (SRBNPC) Communication, , , June 2006) |

**Product Name** **Lumiracoxib**

**C.A.S. number** **220991-20-8**

**Scientific and common names, and synonyms**

PREXIGE

**Legislative or regulation action**

**Product Name** **Lumiracoxib**

**C.A.S. number** **220991-20-8**

**Scientific and common names, and synonyms**

{2-[(2-CHLORO-6-FLUOROPHENYL)AMINO]-5-METHYLPHENYL}ACETIC ACID

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **NZL** | **2007** | Withdrawn from the New Zealand market due to the risk of liver damage associated with prolonged use of low-dose lumiracoxib.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.1, , 2008) |
| **AUS** | **Aug 2007** | Australia's Therapeutic Goods Administration (TGA) cancelled the registration of lumiracoxib due to reports of serious liver adverse effects associated with the use of the drug.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.5, , 2007)<br>(Reference: (AUSMS) Media Statement, , , 11 Aug 2007) |
| **TUR** | **15 Aug 2007** | Turkey has withdrawn the marketing authorization for 100 mg lumiracoxib tablets due to a case of serious liver adverse effects reported in Australia.<br>(Reference: (TUFAM) Communication, , , )<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.5, , 2007) |
| **CAN** | **Oct 2007** | Health Canada has requested that Novartis stop the sale of lumiracoxib in Canada. This action follows Health Canada's review of all safety and efficacy data for lumiracoxib and it's conclusion that the risk of serious hepatotoxicity associated with the use of lumiracoxib cannot be safely and effectively managed.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.5, , 2007) |
| **EME** | **13 Dec 2007** | Following the suspension of lumiracoxib licences in the UK (19 November 2007), and similar action in some other countries, because of concerns over liver side effects, EMEA has recommended the withdrawal of lumiracoxib across all Member States.<br>(Reference: (EMEAPR) EMEA Press Release, , , 13 Dec 2007) |

**Product Name** **Meloxicam**

**C.A.S. number** **71125-38-7**

**Scientific and common names, and synonyms**

MELOX

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **SRB** | **Feb 2006** | Use of meloxicam is contraindicated in patients with gastrointestinal bleeding, recent cerebrovascular bleeding or other bleeding disorders, and in patients with severe uncontrolled heart failure. Warning has been issued regarding risk of masking symptoms of infectious disease by use of meloxicam, as well as interaction with angiotesin Ii receptor antagonists and Angiotensin Converting Enzyme (ACE) inhibitors leading to acute renal failure.<br>(Reference: (SRBNPC) Communication, , , Oct 2005) |

**Product Name** **Meprobamate**

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

**Scientific and common names, and synonyms**

EQUANIL

**Legislative or regulative action**

**Legislative or regulation action**

**Product Name** **Meprobamate**

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

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **GBR** | **Feb 2008** | The MHRA is advising health-care professional that treatment with meprobamate should not be initiated due to risks of dependence, withdrawal, abuse and other unpleasant adverse effects.<br>(Reference: (GBRDSU) Drug Safety Update, 1(7), , 05 Feb 2008) |

**Product Name** **Metamizole sodium**

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

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **NGA** | **2005** | In view of recorded cases of adverse reactions, the National Agency for Food and Drug Administration & Control (NAFDAC) has warned against the use of all brands of dipyrone drugs (Novalgin, Analgin, Optalgin, Drunalgin, Dr. Meyers Novalmin, Akarin, etc.). With effect from 1 September 205, the Agency will not allow the manufacture and importation of these drugs in any dosage form (injections, tablets and syrups) into the country. Also, with effect from 1st January 2006, the sale and use of all brands of matamizole drugs are banned.<br>(Reference: (NAFDAC) Communication, , , 04 Dec 2007)<br>(Reference: (NGAPCC) Communication, , , 27 July 2007) |
| **TLS** | **2005** | To be removed due to reports of agranulocytosis.<br>(Reference: (TLSFR) SEMWE Farmacia Report, , , 06 Apr 2005) |
| **SRB** | **May 2005** | The labels of all registered products containing metamizole are required to include the boxed warning: "The use is not recommended in children and adolescents under the age of 18 years." The use of products containing metamizole has been restricted to short-term treatment of severe post-traumatic and post-surgical pains where other non-opioid analgesics show ineffectiveness. These measures are based on postmarketing reports of agranulocytosis (including one case with fatal outcome) associated with the use of metamizole, regulatory measures taken worldwide, and relevant medical literature.<br>(Reference: (SRBNPC) Communication, , , Mar 2005) |
| **FRA** | **18 Jul 2006** | Dipyone/metamizole/noramidopyrin containing products are no longer marketed due to negative benefit/risk evaluation.<br>(Reference: (AFSSAP) Communication, , , 03 Aug 2006) |

**Product Name** **Metoclopramide (paediatric)**

**C.A.S. number** **364-62-5**

**Scientific and common names, and synonyms**

PRIMPERAN

REGLAN

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **NLD** | **Feb 2007** | Following an increase in the number of registered cases of extrapyramidal symptoms in children receiving metoclopramide, the Medicines Evaluation Board (MEB) in the Netherlands has restricted the use of metoclopramide in this population. The Board says metoclopramide should be used only in the treatment of severe nausea and vomiting of known origin, and only if treatment with other products is ineffective or is not possible.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.2, , 2007) |

**Legislative or regulation action**

**Product Name** **Natalizumab**

**C.A.S. number** **189261-10-7**

**Scientific and common names, and synonyms**

TYSABRI

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **USA** | **Jul 2006** | The US FDA has reintroduced natalizumab as monotherapy for patients with relapsing forms of multiple sclerosis (MS) under a restricted distribution/risk management plan. Previously the companies concerned had voluntarily suspended natalizumbad (Tysabri) from the US market due to reports of progressive multifocal leukoencephalopathy (PML). Natalizumab (Tysabri) will not be available only through a special restricted distribution and risk management program called the Tysabri Outreach: Unified Commitment to Health (TOUCH) Prescribing Program. The TOUCH Program was developed to ensure the proper use of natalizumab (Tysabri) and to evaluate the PML incidence. PML risk factors and other serious opportunistic infections associated with the drug.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.4, , 2006) |

**Product Name** **Nevirapine**

**C.A.S. number** **129618-40-2**

**Scientific and common names, and synonyms**

VIRAMUNE

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **MYS** | **Mar 2005** | Restriction of indication for product containing nevirapine due to risk of serious liver toxicity in patients with high CD4+ cell counts. The indication is restricted as follows: - Indications and Usage section of the product label now recommends against starting nevirapine treatment in women with CD4+ cell counts greater than 250 cells/mm3 unless benefits clearly outweigh risks.<br>(Reference: (MYSNPC) Communication, , , 2007) |
| **BRA** | **Jun 2007** | Withdrawn by manufacturer.<br>(Reference: (BRAHSA) Communication, , , 05 Sep 2007) |

**Product Name** **Nimesulide**

**C.A.S. number** **51803-78-2**

**Scientific and common names, and synonyms**

AULIN

MESINE

MESULID

NIMULID

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **CHL** | **24 Nov 2004** | Products containing more than 100 mg of nimesulide (active principle) may not be used in paediatric population. According to the Dirección del Instituto de Salud Pública, there is sufficient scientific evidence to support the safety of a dose of > 100 mg nimesulide in this population.<br>(Reference: (CHLIPH) Resolucion no., 10228, , 24 Nov 2004) |

**Product Name** **Nimesulide**

**C.A.S. number** **51803-78-2**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **NGA** | **2005** | Nimesulide containing products banned due to adverse health effects.<br>(Reference: (NAFDAC) Communication, , , 08 Nov 2007)<br>(Reference: (NGRPCC) , , , 27 July 2007) |
| **SRB** | **Nov 2005** | The use of all registered products containing nimesulide for systemic administration has been restricted to treatment of acute pain, symptomatic treatment of osteoarthritis and primary dysmenorrhea, and contraindicated in children under the age of 12 years, in patients with active peptic ulcer, hepatic disease or serious renal impairment, as well as in hypersensitive patients. Concomitant use with potential hepatotoxic drugs, other non-steroidal anti-inflammatory drugs (NSAID) and alcohol are not recommended. These measures are based on findings of increased risk of hepatotoxicity and nephrotoxicity with nimesulide.<br>(Reference: (SRBNPC) Communication, , , Oct 2007) |
| **IRL** | **May 2007** | The Irish Medicines Board (IMB) has announced the suspension of the marketing and sale of nimesulide-containing medicinal products for oral use available in Ireland. The suspended products include Aulin (100 mg tablets and granules), Mesulid (100 mg tablets and granules) and Mesine (100 mg tablets). The IMB decision was based on new information from a National Liver Transplant Unit that six patients required liver transplant following treatment with nimesulide. The IMB has received 53 liver-related adverse reaction reports with nimesulide since the product was first approved for use in Ireland in 1995.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.3, , 2007)<br>(Reference: (WHOIES) Alert, No. 113, , 23 May 2007)<br>(Reference: (IRLMB) Press Release, , , 15 May 2007) |
| **UKR** | **Jul 2007** | Use of nimesulide-containing medicinal products in children under 12 years of age is banned.<br>(Reference: (UKRNPC) Information, , , 2007) |
| **GHA** | **Aug 2007** | The National Regulatory Agency (NRA) suspended the marketing authorization for nimesulide-containing products; a 'Dear Health-care Professional' letter was also issued based on the WHO Drug Alert No. 113 that highlighted the decision in the Republic of Ireland to withdraw these products from the Irish market.<br>(Reference: (GHAFDB) Communication, , , 01 Dec 2008) |
| **EME** | **21 Sep 2007** | In order to minimize the risk of liver injury, he Committee for Medicinal Products for Human Use (CHMP) has recommended that treatment with nimesulide should be restricted to a maximum of 15 days and that consequently all packs of nimesulide containing more than 30 doses (tablets or sachets) should be removed from the market.<br>(Reference: (EMEAPR) EMEA Press Release, , , 21 Sep 2007) |

**Product Name** **Nitrofural**

**C.A.S. number** **59-87-0**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **ARM** | **2006** | Scientific Centre of Drug and Medical Technology Expertise Ministry of Health (SCDMTE MoH) has withdrawn the use of nitrofurazone tablets. Nitrofurazone was approved only for external application, for the topical treatment of various skin conditions following findings of 'in vitro' mutagenicity and carcinogenicity, the use of topical preparations containing nitrofurazone was restricted in several countries.<br>(Reference: (ARMDRA) Communication, , , 2007) |

**Product Name** **Nitrofural**

**C.A.S. number** **59-87-0**

**Bibliographical references**

IARC MONOGRAPH, 50, 195, 1990
WHO FOOD ADD., 31, 125, 1993

**Product Name** **Parecoxib**

**C.A.S. number** **202409-33-4**

**Scientific and common names, and synonyms**

DYNASTAT

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **CHL** | **17 Dec 2004** | Because of severe risk of adverse reactions, use not recommended in pain related to coronary bypass surgery.<br>(Reference: (CHLPCC) Communication, , , 2007) |
| **MYS** | **Aug 2005** | Following a review of the appeal submitted by Pfizer (M), the Malaysian Regulatory Authorization has decided to reinstate the registration for intravenous (IV) parecoxib (Inj Dynastat) but with the following conditions: - Indication: Restricted to the management of postoperative pain in the immediate postoperative setting only. - Use limited to two days only with a maximum dose of 80 mg.<br>(Reference: (MYSNPC) Communication, , , 2007) |

**Product Name** **Pemoline**

**C.A.S. number** **2152-34-3**

**Scientific and common names, and synonyms**

CYLERT

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **USA** | **Oct 2005** | Withdrawn due to risk of liver toxicity. The US FDA has concluded that the overall risk of liver toxicity from pemoline (Cylert) outweighs the benefits of this drug indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). US FDA is aware of 13 reports of liver failure resulting in liver transplant or death associated with pemoline use. The manufacturer (Abbott) of the proprietary version (Cylert) of the product discontinued its sales in May 2005. Subsequently, manufacturers of the generic versions also stopped sales and marketing of all generic pemoline products.<br>(Reference: (USFDAA) FDA Alert, , , Oct 2005) |

**Product Name** **Pergolide**

**C.A.S. number** **66104-22-1**

**Scientific and common names, and synonyms**

PERMAX

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **USA** | **Mar 2007** | Removed from the market due to the risk of serious damage to the heart valves of patients treated with these products. The US FDA notes that new studies confirm old data associating pergolide with increased chance of regurgitation (back-flow of blood) of the mitral, tricuspid and aortic valves of the heart. The Agency advises that the products |

**Product Name** **Pergolide**

**C.A.S. number** **66104-22-1**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| | | being removed include two generic versions of pergolide manufactured by Par and Teca and a proprietary version (Permax) manufactured by Valeant Pharmaceuticals.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.2, , 2007) |
| **JPN** | **Apr 2007** | Contraindicated in patients with valvular disease. Package insert updated.<br>(Reference: (JPNPSI) PMDS Information, No.237, , ) |
| **CAN** | **30 Aug 2007** | Sales of pergolide products (Permax) have ceased in Canada as of 30 August 2007 because of further evidence of valvulopathy associated with its use.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.5, , 2007) |

**Product Name** **Phenylpropanolamine**

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

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **CMR** | **2000** | All phenylpropanolamine (PPA)-containing products are banned and no longer marketed.<br>(Reference: (CMRPCC) Communication, , , 24 July 2007) |
| **NGA** | **2004** | All preparations containing PPA are banned.<br>(Reference: (NAFDAC) Communication, , , 13 Sep 2007) |
| **PRT** | **2005** | The Portuguese regulatory body, Infarmed, has suspended cold and flu products containing the decongestant PPA, while it reviews PPA'S risk/benefit profile following worldwide concerns of cerebral haemorrhage and other adverse reactions.<br>(Reference: (PRTBFV) Boletim de Farmaco Vigilancia, 9(2), , 2005) |
| **TLS** | **2005** | PPA products to be gradually removed from the market due to risk of haemorrhagic stroke.<br>(Reference: (TLSFR) SEMWE Farmacia Report, , , 06 Apr 2005) |

**Product Name** **Piroxicam**

**C.A.S. number** **36322-90-4**

**Scientific and common names, and synonyms**

BREXIDOL

FELDENE

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **EME** | **Jun 2007** | The EMEA has recommended restrictions on the use of piroxicam-containing medicinal products because of the risk of gastrointestinal side effects and serious skin reactions. The Agency advises that piroxicam should no longer be used for short-term painful and inflammatory conditions, can be prescribed to relieve the symptoms of osteoarthritis, rheumadoid arthritis and ankylosing spondylitis, but should not be used as a first-line treatment for these disorders. Treatment should be reviewed after 14 days.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.4, , 2007)<br>(Reference: (EMEAPR) EMEA Press Release, , , 25 June 2007) |
| **SRB** | **Jul 2007** | Not indicated for acute pain and inflammatory conditions. The use has been restricted to second-line therapy for symptomatic treatment of osteoarthritis, rheumatoid arthritis, |

**Product Name** **Piroxicam**

**C.A.S. number** **36322-90-4**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| | | ankylosing spondylitis. Lowest effective dose (up to 20 mg daily) and use for shortest time period as possible are recommended. Contraindicated in patients considered to be at high risk of side effects, as well as in patients who already take NSAID or anticoagulant therapy.<br>(Reference: (SRBNPC) Communication, , , June 2007) |

**Product Name** **Promethazine**

**C.A.S. number** **60-87-7**

**Scientific and common names, and synonyms**

AVOMINE

PHENERGAN

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **SRB** | **May 2005** | The new contraindication and box warning are required to be labelled: "Not to be used in children under the age of two years." Caution is required for use in children over two years of age; the lowest effective dose should be administered, and combination with drugs associated with depression of respiratory function should be avoided. These measures are based on new findings of risk of fatal respiratory depression and apnea in paediatric population.<br>(Reference: (SRBNPC) Communication, , , Mar 2005) |
| **MYS** | **May 2006** | The following warning statement should be included in the package inserts of all products containing promethazine hydrochloride: - "It (brand or generic versions) should not be used in paediatric patients less than two years of age because of the potential for fatal respiratory depression".<br>(Reference: (MYSNPC) Communication, , , 2007) |

**Product Name** **Pseudoephedrine**

**C.A.S. number** **90-82-4**

**Scientific and common names, and synonyms**

(+)-(1 S,2S)-2-METHYLAMINO-1-PHENYLPROPAN-1–OL;

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **SRB** | **Sep 2006** | All registered oral products containing pseudoephedrine which do not provide reliable dosing in children aged 2-6 years are contraindicated in children under the age of six years. All registered oral products containing pseudoephedrine which provide reliable dosing in children aged 2-6 years are contraindicated in children under the age of two years. Dosage was revised: 15 mg. 3 times daily in children aged 2-6 years; 30 mg, 3 times daily in children aged 6-12 years, 60 mg, 3 times daily in children aged 12-18 years. Administration restricted up to 5 days. Risk of pseudoephedrine related toxicity due to overdose led to these measures.<br>(Reference: (SRBNPC) Communication, , , Mar 2006) |

**Product Name** **Quinine**

**Legislative or regulation action**

**C.A.S. number** **130-95-0**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **NZL** | **2007** | Medsafe (medicines and Mecical Devices Safety Authority) under advice from the Medicines Adverse Reactions Committee (MARC) in New Zealand has ruled that quinine should no longer be used in treating nocturnal leg cramps. According to MARC, there is no evidence of efficacy of quinine for leg cramps; however, there is sufficient evidence of harm due to unpredictable and potentially life threatening thrombocytopenia due to quinine.<br>(Reference: (NZLPU) Prescriber Update, 28(1), , Nov 2007) |

**Product Name** **Rimonabant**

**C.A.S. number** **168273-06-1**

**Scientific and common names, and synonyms**

ACOMPLIA

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **EME** | **2008** | The EMEA has suspended the marketing authorization for rimonabant (Acomplia) based on evidence that suggest serious psychiatric side effects associated with this product use.<br>(Reference: (WHOIES) Alert, No. 119, , 25 Oct 2008)<br>(Reference: (EMEAPR) EMEA Press Release, , , 23 Oct 2008) |

**Product Name** **Rofecoxib**

**C.A.S. number** **162011-90-7**

**Scientific and common names, and synonyms**

COXXIL

VIOXX

4-[P-(METHYLSULFONYL)PHENYL]-3-PHENYL-2(5H)-FURANONE

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **CHL** | **17 Jan 2005** | Marketing authorization of products containing rofecoxib has been suspended due to adverse cardiovascular events associated with the drug in a clinical trial.<br>(Reference: (CHLIPH) Resolucion no., 168, , 17 Jan 2005) |

**Product Name** **Rosiglitazone**

**C.A.S. number** **122320-73-4**

**Scientific and common names, and synonyms**

AVANDIA

(±)-5-{P-[2-(METHYL-2-PYRIDYLAMINO)ETHOXY]BENZYL}-2 ,4-THIAZOLIDINEDIONE

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **AUS** | **2007** | The Adverse Drug Reactions Advisory Committee (ADRAC) is warning that rosiglitazone and its combinations are contraindicated in the New York Heart Association (NYHA) heart failure Grades 3 and 4 and are only to be used with caution in Grades 1 and 2. A boxed warning states: “The use of rosiglitazone (AVANDIA/AVANDAMET) is not |

**Product Name** **Rosiglitazone**

**C.A.S. number** **122320-73-4**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| | | recommended in patients with known ischaemic heart disease, particularly in those taking nitrates. AVANDIA/AVANDAMET has been shown to be associated with an increased risk of myocardial ischaemia (angina, infarction) in pooled short-term clinical studies, particularly in those who needed several antidiabetic drugs or nitrates.<br>(Reference: (AUSADR) Australian Adverse Drug Reactions Bulletin, 26(6), , 2007) |
| **CAN** | **2007** | Due to reasons of cardiac safety, rosiglitzaone (AVANDIA®) is no longer approved as monotherapy for type 2 diabetes, except when metformin use is contraindicated or not tolerated; rosiglitazone is no longer approved for use in combination with a sulfonylurea, except when metformin is contraindicated or not tolerated; treatment with all rosiglitazone products is now contraindicated in patients with any stage of heart failure (i.e., NYHA Class I, II, III or IV); rosiglitazone is not indicated for use with insulin since this combination is associated with an increased risk of heart failure. Rosiglitazone is not indicated for triple therapy (i.e., therapy with rosiglitazone in combination with both metformin and a sulfonylurea). Increases in congestive heart failure and other fluid retention-related events have been reported in patients receiving rosiglitazone as part of triple therapy.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.4, , 2007) |
| **EME** | **Jan 2008** | The EMEA has recommended updating the product information for rosiglitazone-containing antidiabetic medicines with the following: - a new warning that the use of rosiglitazone in patients with ischaemic heart disease and/or peripheral arterial disease is not recommended; - a new contraindication stating that rosiglitazone must not be used in patients with an acute coronary syndrome, such as angina or some types of myocardial infarction.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.1, , 2008)<br>(Reference: (EMEAPR) EMEA Press Release, , , 24 Jan 2008) |

**Product Name** **Sargramostim**

**C.A.S. number** **123774-72-1**

**Scientific and common names, and synonyms**

LEUKINE

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **USA** | **Jan 2008** | The liquid formulation of sargramostim has been withdrawn due to an increase in adverse reaction reports since the liquid formulation was changed to include edetate disodium EDTA).<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.1, , 2008)<br>(Reference: (BHCP) "Dear Health-care professional" letter, , , 23 Jan 2008) |

**Product Name** **Sulfanilamide**

**C.A.S. number** **63-74-1**

**Scientific and common names, and synonyms**

STREPTOCIDUM

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|

**Legislative or regulation action**

**Product Name** **Sulfanilamide**

**C.A.S. number** **63-74-1**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **ARM** | **2006** | The Scientific Centre of Drug and Medical Technology Expertise, Ministry of Health (SCDMTE MoH) has decided not to approve the marketing of sulfaniamide because of increasing bacterial resistance and due to the availability of other antibiotics.<br>(Reference: (ARMDRA) Communication, , , 2007) |

**Product Name** **Technetium (99mTc) fanolesomab**

**C.A.S. number** **2009-0-001**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **USA** | **Dec 2005** | Voluntary suspension by manufacturer due to serious safety concerns. Technetium (99m Tc) fanolesomab (NeutroSpec) is indicated for radiologic imaging patients with unclear signs and symptoms of appendicitis who are five years of age and older. There were reports of two deaths and 15 additional life-threatening adverse events in patients receiving technetium (99m Tc) fanolesomab (NeutroSpec). These events occurred within minutes of administration of Technetium (99m Tc) fanolesomab (NeutroSpec) and included shortness of breath, low blood pressure, and cardiopulmonary arrest. A review of all postmarketing reports showed an additional 46 patients who experienced adverse events that were similar but less severe.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.1, , 2006)<br>(Reference: (USAPHA) Public Health Advisory, , , 19 Dec 2005) |

**Product Name** **Tegaserod**

**C.A.S. number** **145158-71-0**

**Scientific and common names, and synonyms**

ZELNORM

ZELMAC

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **JOR** | **2007** | Marketing of Tegaserod have been suspended.<br>(Reference: (JORPCC) Communication to WHO, , , 03 Apr 2007) |
| **BRA** | **Apr 2007** | Severely restricted use, change in package insert information (of ZelmacR) restricting its use for "women with diagnosis of irritable bowel syndrome, up to 55 years-old, without known cardiovascular illnesses or risk factors for them".<br>(Reference: (BRAHSA) Communication, , , 05 Sep 2007) |
| **AUS** | **04 Apr 2007** | Recalled from the market because a recent retrospective analysis of pooled clinical trial data showed that the incidence of cardiovascular ischaemic events in patients taking tegaserod was higher than in those taking placebo.<br>(Reference: (AUSPR) Product Recall, , , 2007) |
| **CHE** | **Jun 2007** | The Swiss Institute of Therapeutic Products, Swissmedic has declined to extend the marketing authorization for tegaserod (Zelmac) in Switzerland after a new analysis of clinical data showed that tegaserod had an increased risk of cardiovascular disorders compared with placebo.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.4, , 2007)<br>(Reference: (CHEJSM) Journal Swissmedic, , p342, June 2007) |

**Product Name** **Tegaserod**

**C.A.S. number** **145158-71-0**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **CHN** | **Jun 2007** | The production, sale and use of tegaserod (Zelnorm) have been suspended by the Chinese State Food and Drug Administration (SFDA) because the drug has been associated with an increased risk of strokes and heart attacks.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.4, , 2007) |
| **ARG** | **15 Jun 2007** | Suspended due to reports of adverse cardiovascular events<br>(Reference: (ARGFDM) Communication from ANMAT, , , 01 June 2007) |
| **USA** | **Jul 2007** | The United States Food and Drug Administration (US FDA) has permitted the restricted use of tegaserod (Zelnorm) as an investigational new drug for the treatment of irritable bowel syndrome with constipation, and chronic idiopathic constipation. The use of tegaserod (Zelnorm) for such treatment is restricted to women aged < 55 years whose physicians decide that treatment with tegaserod is medically necessary. The US FDA had previously suspended the sales and marketing of tegaserod following a safety analysis that demonstrated an increased risk of myocardial infarction, stroke and unstable angina associated with tegaserod, compared with placebo.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.4, , 2007)<br>(Reference: (USFDAN) FDA News, , , 27 July 2007) |

**Product Name** **Telithromycin**

**C.A.S. number** **173838-31-8**

**Scientific and common names, and synonyms**

KETEK

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **USA** | **Feb 2007** | The US FDA has removed two of the three previously approved indications for telithromycin - acute bacterial sinusitis and acute bacterial exacerbations of chronic bronchitis. The Agency determined that the balance of benefits and risks no longer supported approval of telithromycin (Ketek) in the two indications. The antibacterial will remain on the market for the treatment of community-acquired pneumonia of mild-to-moderate severity. Additional changes include a boxed warning that telithromycin is contraindicated in patients with myasthenia gravis and a strengthened warning section regarding specific drug-related adverse events including visual disturbances and loss of consciousness.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.2, , 2007)<br>(Reference: (FDAPR) Press Release, , , 12 Feb 2007) |
| **EME** | **Mar 2007** | The EMEA has recommended restrictions on the use of telithromycin (Ketek) in three of its four approved indications: for the treatment of bronchitis, sinusitis, and tonsillitis/ pharyngitis; telithromycin should only be used for infections caused by bacterial strains that are suspected or proved to be resistant to or cannot be treated with macrolide or beta-lactam antibiotics. The Agency has recommended no restrictions for the remaining indication, the treatment of community-acquired pneumonia. The Agency has also recommended the contraindication of the use of telithromycin in patients with myasthenia gravis and strengthened warnings on transient loss of consciousness and effects on vision. These recommendations are based on the conclusions of a comprehensive review that the Agency has been carrying out since January 2006, following reports of severe liver injuries in patients taking telithromycin.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.2, , 2007)<br>(Reference: (EMEAPR) EMEA Press Release, , , 30 Mar 2007) |

**Product Name** **Terfenadine**

**C.A.S. number** **50679-08-8**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **SRB** | **May 2005** | Products containing terfenadine should not be used in patients who are concomitantly treated with CYP 3A4 inhibitors, proarrhythmic drugs, drugs that prolong QT interval, and with drugs that lead to electrolyte imbalance: serious cardiotoxic effects have been reported when terfenadine-containing products have been used in conjunction with these types of drugs.<br>(Reference: (SRBNPC) Communication, , , Mar 2005) |

**Product Name** **Thioridazine**

**C.A.S. number** **50-52-2**

**Scientific and common names, and synonyms**

MELLERIL

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **UKR** | **Feb 2005** | Maximum daily dose limited to 300 mg/day.<br>(Reference: (UKRNPC) Information, , , 2007) |
| **MYS** | **Jun 2005** | Following the voluntary cancellation of registration for Melleril R by Novartis due to adverse cardiovascular events and poor benefit risk profile, a risk-benefit analysis of other generic products containing thioridazine was conducted. Based on this review, the Malaysian Regulatory Agency took the decision to disallow the continued use of thioridazine in Malaysia and the registration of these products was cancelled.<br>(Reference: (MYSADR) MADR Newsletter, , , Aug 2005) |
| **CHL** | **09 Jun 2005** | Indication restricted for use as second line treatment in schizophrenia that does not respond adequately to other antipsychotics. And the package inserts are required to include warnings of adverse cardiac events (e.g. QT prolongation) associated with the use of this medicine; contraindication in children below 18 years of age and in patients who are at risk for adverse cardiac events (history of arrhythmias etc).<br>(Reference: (CHLIPH) Resolucion no., 4689, , 09 June 2005) |
| **KOR** | **Jul 2005** | Withdrawn due to safety concern about QT-prolongation.<br>(Reference: (KRFDA) Communication, , , 06 Apr 2006) |
| **TUR** | **Jul 2005** | Marketing of Thioridazine have been suspended.<br>(Reference: (TUFAM) Communication, , , 07 Apr 2006) |
| **CAN** | **30 Sep 2005** | As of 30 September 2005, the sales of all thioridazine products have been discontinued in Canada, due to the lack of convincing benefit/harm information that support the continued safe use of the drug as an antipsychotic. Thioridazine will be available through the Special Access Programme in Canada for patients who cannot be adequately managed on alternative therapies.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.4, , 2005) |

**Product Name** **Tizanidine**

**C.A.S. number** **51322-75-9**

**Scientific and common names, and synonyms**

5-CHLORO-N-(2-IMIDAZOLIN-2-YI)-2,1,3-BENZOTHIADIAZOL-4-YLAMINE HYDROCHLORIDE

**Legislative or regulative action**

**Legislative or regulation action**

**Product Name** **Tizanidine**

**C.A.S. number** **51322-75-9**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **SRB** | **Jan 2006** | Concomitant use of tizanidine with fluvoxamine or ciprofloxacin is contraindicated due to clinically significant interaction resulting in hypotension, somnolence, dizziness, decrease of psychomotor abilities. Concomitant use of tizanidine with antiarrhythmics (amiodarone, mexiletine, and propafenone), fluoroquinolones (enoxacin, perfloxacin and norfloxacin), oral contraceptives and ticlopidine is not recommended.<br>(Reference: (SRBNPC) Communication, , , Dec 2005) |

**Product Name** **Trimethobenzamide**

**C.A.S. number** **138-56-7**

**Scientific and common names, and synonyms**

TEBAMIDE

TIGAN

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **USA** | **Apr 2007** | The US FDA has announced that suppository products of trimethobenzamide are not approved to treat nausea and vomiting in adults or children because there is no evidence of their effectiveness. The Agency has asked the responsible companies to stop manufacturing and distributing these products which are marketed under names (Tigan, Tebamide, T-Gen, Trimazide and Trimethobenz). This current action includes only the suppository forms and does not affect several oral capsules and injectable products containing trimethobenzamide that have been approved by the US FDA. Any company wishing to market a product containing trimethobenzamide in suppository form must now obtain an approved new drug application prior to marketing.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.3, , 2007)<br>(Reference: (USFDAN) FDA News, , , 06 Apr 2007) |

**Product Name** **Valdecoxib**

**C.A.S. number** **181695-72-7**

**Scientific and common names, and synonyms**

BEXTRA

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **CHL** | **17 Dec 2004** | Because of severe risk of adverse reactions, use not recommended in pain related to coronary bypass surgery.<br>(Reference: (CHLPCC) Communication, , , 2007) |
| **CHE** | **2005** | Provisional suspension (while awaiting additional information) due to reports of skin hypersensitivity reactions, myocardial infarction and cardiovascular risks.<br>(Reference: (CHEMED) Communication, , , 2007) |
| **CAN** | **Apr 2005** | Sale suspended while awaiting evidence to establish the safety of this drug under the conditions of use for which it is recommended; and while awaiting risk benefit analysis from the manufacturer, indicating the unique therapeutic advantage.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.3, , 2005)<br>(Reference: (CANAHC) Advisory, , , 07 Apr 2005) |
| **USA** | **Apr 2005** | The US FDA asked Pfizer to withdraw valdecoxib (Bextra) from the market because of: - lack of adequate data on the cardiovascular safety of long-term use of valdecoxib |

**Product Name** **Valdecoxib**

**C.A.S. number** **181695-72-7**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| | | (Bextra), along with the increased risk of adverse cardiovascular events in short-term coronary artery bypass surgery (CABG) trials; - reports of serious and potentially life-threatening skin reactions, including deaths, in patients using valdecoxib and, - lack of any demonstrated advantages for valdecoxib compared with other NSAIDs.<br>(Reference: (USAPHA) Public Health Advisory, , , 07 Apr 2005) |
| **EME** | **Mar 2008** | Having reviewed the Cox-2 inhibitors safety data, the EMEA issued a decision for suspension of the marketing authorization of valdecoxib in October 2005.<br>(Reference: (EMEAPS) Public statement, , , 27 Mar 2008) |

**Product Name** **Venlafaxine**

**C.A.S. number** **93413-69-5**

**Scientific and common names, and synonyms**

EFFEXOR

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **GBR** | **May 2006** | The MHRA has introduced a smaller pack size to minimize the risk of overdose with the product. This is in addition to previous regulatory measures when concerns about potential cardiotoxicity and toxicity in overdose with venlafaxine led to the drug being restricted to specialist initiation and contraindicated in patients with heart disease.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.4, , 2006)<br>(Reference: (MHRAPR) Press Release, , , 31 May 2006) |

**Product Name** **Veralipride**

**C.A.S. number** **66644-81-3**

**Scientific and common names, and synonyms**

AGREAL

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **EME** | **Jul 2007** | The EMEA has recommended the withdrawal of the marketing authorization for medicinal products containing veralipride. The EMEA's Committee for Medicinal Products for Human Use (CHMP) concluded that the risks of veralipride (psychiatric and movement disorders) in the treatment of hot flushes associated with menopause in women are greater than its benefits and therefore recommended that the medicine should be taken off the market.<br>(Reference: (EMEAPR) EMEA Press Release, , , 23 July 2007) |
| **BRA** | **Aug 2007** | Withdrawn with reference to EMEA's decision.<br>(Reference: (ANVISA) Communication and Alerts, , , 05 Sep 2007) |

**Product Name** **Ximelagatran**

**C.A.S. number** **192939-46-1**

**Scientific and common names, and synonyms**

EXANTA

**Legislative or regulation action**

**Product Name** **Ximelagatran**

**C.A.S. number** **192939-46-1**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **CHE** | **2006** | Withdrawn due to hepatotoxicity.<br>(Reference: (CHEMED) Communication, , , 2007) |
| **GBR** | **Feb 2006** | Withdrawal of product from the market due to association with serious liver injury in patients in a trial (EXTEND trial) examining the use of the product in extended venous thromboembolism (VTE) prophylasis in orthopaedic surgery.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.2, , 2006) |
| **BRA** | **14 Feb 2006** | Withdrawn due to evidence of hepatic risk.<br>(Reference: (ANVISA) Communication and Alerts, , , 05 Sep 2007) |

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

***Fourteenth Issue***

***PART I***

***REGULATORY INFORMATION***

# *COMBINATION AND GROUP PRODUCTS*

**Product Name** **ACE inhibitors and Angiotensin II receptor antagonists**

**C.A.S. number** **2009-1-101**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| MYS | Oct 2006 | The following statement must be included on labels and package inserts of all products containing ACE inhibitors including the combination under the "Warning" and "Use for Pregnancy" sections: - "Increased risk of birth defects, foetal and neonatal morbidity and death when used throughout pregnancy".<br>(Reference: (MYSNPC) Communication, , , 2007) |
| GBR | Dec 2007 | The MHRA has advised that ACE inhibitors and angiotensin II receptor antagonists should not be used at any stage of pregnancy due to the risk of congenital anomalies.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.1, , 2008)<br>(Reference: (GBRDSU) Drug Safety Update, 1(5), , 09 Dec 2007) |

**Product Name** **Alendronic acid and other bisphosphonates**

**C.A.S. number** **66376-36-1**

**Scientific and common names, and synonyms**

AMINOHYDROXYBUTYLIDENE DIPHOSPHONIC ACID

4-AMINO-1-HYDROXYBUTANE-1,1 -DIYLBIS(PHOSPHONIC ACID)

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| SRB | Dec 2006 | Due to risk of jaw osteonecrosis, precaution is required, especially in cancer patients treated with cortisosteroids and chemotherapy, as well as in patients with tooth extraction or local infection. Dental examination and preventive measures before including bisphosphonates in therapy are recommended in patients with additional risk factors. This measure refers to all registered oral and parenteral products containing bisphosphonates, including generic alendronate.<br>(Reference: (SRBNPC) Communication, , , Oct 2006) |

**Product Name** **Alimemazine - Paracetamol teething mixture**

**C.A.S. number** **2009-1-001**

**Scientific and common names, and synonyms**

NEUTROSPEC

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| GBR | Feb 2005 | The MHRA issued a warning that a teething mixture containing alimemazine tartrate and paracetamol is contraindicated in children under the age of two years due to risk of adverse effects with the product in this population.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.2, , 2005) |

**Product Name** **Antidepressants**

**C.A.S. number** **2009-1-103**

**Legislative or regulative action**

**Legislative or regulation action**

**Product Name** **Antidepressants**

**C.A.S. number** **2009-1-103**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **CHL** | **05 Jan 2005** | Health-care professionals and patients have been informed that suicidal thoughts and aggressive behaviour have been observed in children receiving antidepressant treatment for major depression, obsessive compulsive disorder or other mood disorders. The labels for these products are required to note the above adverse events and that this population needs to be monitored closely during antidepressant treatment for signs of suicidal thoughts and that they may not be used in children below the age of 18 years.<br>(Reference: (CHLIPH) Resolucion no., 380, , 05 Jan 2005) |
| **SRB** | **Aug 2005** | Special warning has been issued concerning suicidal behaviours and aggression in children and adolescents under the age of 18 years using antidepressives. This measure refers to all registered original and generic products containing selective serotonin reuptake inhibitors (SSRI) (paroxetine, citalopram, sertraline, escitalopram) and some other antidepressants (mianserin, mirtazapine, venlafaxine).<br>(Reference: (SRBNPC) Communication, , , June 2005) |

**Product Name** **Antiretroviral agents**

**C.A.S. number** **2009-1-104**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **CAN** | **2005** | To avoid virologic failure and emergence of resistance, the co-administration of didanosine and tenofovir should be undertaken with caution; patients who are receiving both drugs should be monitored carefully for continued efficacy and for adverse events (AEs); and didanosine should be discontinued in patients who develop AEs associated with the drug.<br>(Reference: (BMSGS) "Dear Health-care Professional " letter, , , 09 June 2005) |

**Product Name** **Atazanavir-Ritonavir**

**C.A.S. number** **2009-1-002**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **EME** | **21 Dec 2004** | Physicians have been warned against the co-administration of atazanavir (Reyataz) combined with ritonavir (RTV) and 40 mg omeprazole, or any other proton pump inhibitor based on the evidence that this type of co-administered statin could reduce the atazanavir exposure levels in these patients.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.1, , 2005)<br>(Reference: (EMEAPS) Public statement, , , 21 Dec 2004) |

**Product Name** **Attention-Deficit/Hyperactivity Disorder (ADHD) drugs**

**C.A.S. number** **2009-1-102**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **CAN** | **May 2006** | Health professionals have been advised that ADHD drugs should be started at the lowest dose and increased slowly, and should not be given to patients with a symptomatic heart disorder, advanced arteriosclerosis, hyperthyroidism, moderate to severe hypertension, or structural cardiac abnormalities; further cardiovascular (CV) system evaluation may be |

**Product Name** **Attention-Deficit/Hyperactivity Disorder (ADHD) drugs**

**C.A.S. number** **2009-1-102**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| | | considered before starting ADHD drugs in patients with relevant risk factors, and patients who require long-term ADHD drugs should undergo periodic CV status evaluation. This applies to the following drugs and all products containing these drugs: methylphenidate (e.g. Ritalin) and methylphenidate extended release (Ritalin SR), dexmethylphenidate (Attenade), dexamfetamine (Dexedrine), atomoxetine (Strattera).<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.4, , 2006)<br>(Reference: (CANAWR) Advisories, Warnings and Recalls, , , 26 May 2006) |

**Product Name** **Betamethasone and other potent corticosteroids for topical use**

**C.A.S. number** **2009-1-105**

**Scientific and common names, and synonyms**

9ALPHA-FLUORO-16BETA-METHYLPREDNISOLONE

9ALPHA-FLUORO-11BETA,17ALPHA,2 1 -TRIHYDROXY-16BETA-METHYLPREGNA-1 ,4-DIENE-3,20- DIONE

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **SRB** | **Jul 2007** | Not indicated in children under the age of one year, and should not be used for longer than seven days without physician's monitoring. Contraindicated in treatment of acne rosacea, perioral dermatitis, perianal/genital pruritus, plaque psoriasis and tuberculosis of skin, primary bacterial and virus skin infections, mycosis, as well as in hypersensitive patients. Children's growth and development can be affected by chronic use of corticosteroid; therefore precaution is required for use in children under the age of two years. Administration on face is not recommended; if it is needed, careful use for up to five days is required. In case of irritation or hypersensitivity reactions, discontinuation of therapy is required. These measures refer to all registered topical products containing potent corticosteroids (betamethasone, flucinolone acetonide, diflucortolone, and desoximethasone).<br>(Reference: (SRBNPC) Communication, , , June 2007) |

**Product Name** **Black Cohosh (Cimicifugae racemosae)-containing products**

**C.A.S. number** **2009-1-106**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **MYS** | **Jul 2006** | All Black Cohosh containing products should carry the following precautionary statement: - stop taking this product if signs and symptoms suggestive of liver injury develop such as tiredness, loss of appetite, yellowing of the skin and eyes or severe upper stomach pain with nausea and vomiting or dark urine, and consult your doctor immediately. - Patients using herbal medicinal products should tell their doctor about it.<br>(Reference: (MYSNPC) Communication, , , 2007) |

**Product Name** **Chelidonium extract**

**C.A.S. number** **2009-1-107**

**Legislative or regulative action**

**Legislative or regulation action**

**Product Name** **Chelidonium extract**

**C.A.S. number** **2009-1-107**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **CHE** | **2007** | Extracts containing more than 0.3 mg product of total alkaloid have been withdrawn due to hepatotoxicity with a total daily alkaloid ingestion > 0.3 mg.<br>(Reference: (CHEMED) Communication, , , 2007) |

**Product Name** **Chlorproguanil and Dapsone**

**C.A.S. number** **2009-1-003**

**Scientific and common names, and synonyms**

LAPDAP

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **KEN** | **Feb 2008** | GlaxoSmithKline has recalled LapDap TM, an anti-malarial product containing chlorproguanil and dapsone, based on the fact that significant reductions of haemoglobin levels have been observed in patients with glucose-6-phosphate dehydrogenase deficiency.<br>(Reference: (WHOIES) Alert, No. 117, , 04 Mar 2008)<br>(Reference: (WHORTC) Report of a Technical Consultation, , , 2005)<br>(Reference: (GSKMMV) Press Release, , , 29 Feb 2008) |

**Product Name** **Clobutinol-containing cough preparations**

**C.A.S. number** **2009-1-108**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **EME** | **Oct 2007** | The EMEA has recommended withdrawing the marketing authorization for cough medicines containing clobutinol. This recommendation is based on the Agency's review of the safety of clobutinol and its conclusion that the use of clobutinol is linked to a clear risk of QT prolongation, the benefits of medicines containing clobutinol therefore no longer outweigh their risks. Boehringer Ingelheim laboratories (manufacturer of clobutinol-containing products) have announced their decision to voluntarily withdraw the product (Siomat) from the global markets.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.5, , 2007)<br>(Reference: (EMEAPR) EMEA Press Release, , , 18 Oct 2007) |

**Product Name** **Cyclo-oxygenase-2 (COX-2) Inhibitors**

**C.A.S. number** **2009-1-109**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **NZL** | **Feb 2005** | COX-2 inhibitors will be available only under very strict restrictions in the New Zealand market. These products should be contraindicated in patients with previous MI or stroke and perioperatively for cardiac or vascular surgery, and perioperatively for major surgery in patients at high cardiovascular (CV) risk; COX-2 inhibitors should not be used if alternatives exist, and, if used, the lowest effective dose should be used for the shortest possible duration; patients should be reviewed after two weeks, with treatment discontinued if there is no benefit, then reviewed every three months. This decision was |

**Product Name** **Cyclo-oxygenase-2 (COX-2) Inhibitors**

**C.A.S. number** **2009-1-109**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| | | based on the recommendations of Medicine Adverse Reaction Committee (MARC) on the benefits and risks of COX-2 inhibitors.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.3, , 2005)<br>(Reference: (NZLLDP) Alert/letter to doctors and pharmacists, , , 29 Apr 2005)<br>(Reference: (NZLMRM) Media release, , , 29 Apr 2005) |
| **MYS** | **Jun 2005** | The following statement has been included in the package inserts of products containing COX-2 Inhibitors: - COX-2 inhibitors be used as second line therapy. - Contraindicated in patients with the risk of ischaemic heart disease and stroke. - Prescribed with care in patients predisposed to the risk of hypertension, hyperlipidaemia, heart disease, peripheral arterial disease and in smokers. - The lowest effective dose for the shortest possible duration should be used.<br>(Reference: (MYSDRA) Communication, , , 2005) |
| **CHL** | **08 Jun 2005** | The package insert for this class of drugs is required to indicate that these products are contraindicated in patients with ischaemic heart disease (present or past) or cardiac insufficiency; that they should not be used in the immediate postoperative period following by-pass surgery; and to use with caution in patients with cardiovascular risks such as hypertension, hyperlipidemia, diabetes, etc. These measures have been recommended because of adverse cardiovascular events that have been reported with COX-2 inhibitors.<br>(Reference: (CHLIPH) Resolucion no., 4575, , 08 June 2005) |

**Product Name** **Cyproterone acetate and ethinylestradiol**

**C.A.S. number** **2009-1-004**

**Scientific and common names, and synonyms**

DIANE-35

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **CAN** | **May 2005** | Health Canada has advised that ethinylestradio/cyproterone (Diane-35) should not be used alone for contraception in women. These restrictions are based on evidence that women who use ethinylestradio/cyproterone (Diane-35) appear to have a higher risk of blood clots than women who used combination oral contraceptives (Diane-35 is used in the treatment of acne). Health Canada advises that the product should be stopped 3-4 months after the complete resolution of the signs of acne.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.3, , 2005) |

**Product Name** **Dextropropoxyphene-paracetamol**

**C.A.S. number** **2009-1-005**

**Scientific and common names, and synonyms**

CAPADEX

PARADEX

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **NZL** | **2006** | The following restrictions in use have been recommended for this combination product, following reports of deaths associated with intentional and accidental overdose: - |

**Product Name** **Dextropropoxyphene-paracetamol**

**C.A.S. number** **2009-1-005**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| | | narrowing of the indication to the relief of chronic pain of moderate severity; - restriction to second-line therapy for patients who have not tolerated, or have inadequately responded to therapeutic doses of alternative analgesics; - restriction of the recommended dose to two tablets up to every four hours, with a maximum daily dose of eight tablets (equivalent to paracetamol 2.6); - reducing the dose in the elderly and in patients with renal or hepatic impairment. Prescribers are advised to avoid the concurrent use of these products with alcohol or with other paracetamol-containing products, and to warrant caution while prescribing them in patients receiving anxiolytics or antidepressants.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.6, , 2006)<br>(Reference: (NZLPU) Prescriber Update, 27(2), 21, 2006) |

**Product Name** **Drug-eluting stents**

**C.A.S. number** **2009-1-110**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **SWE** | **Feb 2007** | The Swedish Medical Products Agency (MPA), conjunction with the National Board of Health and Welfare and the Swedish Society of Cardiology, has recommended utmost restraint in the use of drug-eluting stents. The recommendation was based on the results of clinical studies, including the Swedish Coronary and Angioplasty Registry (SCAAR) study that showed increased risk of thrombosis associated with the use of drug-eluting stents. According to the MPA, drug-eluting stents must only be used in patients for whom no other treatment alternative exists or in patients who are at greatly increased risk of restenosis and for whom the effect of restenosis is expected to be severe.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.2, , 2007)<br>(Reference: (SWEMPA) Alert, , , 13 Feb 2007) |

**Product Name** **Ephedrine and pseudoephedrine containing OTC products**

**C.A.S. number** **2009-1-111**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **GBR** | **Oct 2007** | OTC nasal decongestant products that contain pseudoephedrine and ephedrine are to be placed under tighter control in the UK due to the increasing concern that pseudoephedrine and ephedrine in these products can be extracted and used in the illegal manufacture of methylamfetamine (crystal meth). Large packs of pseudoephedrine and ephedrine are to be replaced by smaller packs of 720 mg (the equivalent of 12 tablets or capsules of 60 mg or 24 tablets or capsules of 30 mg) and a sale limit of one pack per customer will apply.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.5, , 2007)<br>(Reference: (MHRAPR) Press Release, , , 29 Aug 2007) |

**Product Name** **Estradiol-testosterone injection**

**C.A.S. number** **2009-1-006**

**Legislative or regulative action**

**Legislative or regulation action**

**Product Name** **Estradiol-testosterone injection**

**C.A.S. number** **2009-1-006**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **CAN** | **2005** | Discontinued as a hormone replacement therapy due to potential adverse effects such as endometrial hyperplasia or carcinoma, hirsuitism, aggression and virilisation in women.<br>(Reference: (WHOPNL) WHO Pharmaceuticals Newsletter, No.1, , 2006)<br>(Reference: (CANAWR) Advisories, Warnings and Recalls, , , 23 Nov 2005) |

**Product Name** **Ingalipt (Combination aerosol)**

**C.A.S. number** **2009-1-007**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **ARM** | **2005** | Scientific Centre of Drug and Medical Technology Expertise Ministry of Health (SCDMTE MoH) did not approve the marketing of Ingalipt (complex for local treatment of inflammation/infection of oral-throat localization) because combination of two sulfonamides in one medicine was estimated as irrational.<br>(Reference: (ARMDRA) Communication, , , 2007) |

**Product Name** **Metamizole, pitofenone and fenpiverinium**

**C.A.S. number** **2009-1-008**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **SRB** | **May 2005** | The labels are required to include the boxed warning: "The use is not recommended in children and adolescents under the age of 18 years." The use has been restricted to short-term treatment of severe pains caused by smooth muscles' spasm where other therapy shows ineffectiveness. These measures refer to all registered combination products containing metamizole and a spasmolytic drug.<br>(Reference: (SRBNPC) Communication, , , Mar 2005) |

**Product Name** **Nasal/oropharyngeal antibiotics**

**C.A.S. number** **2009-1-112**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **FRA** | **30 Sep 2005** | The French medicines regulatory agency (AFSSAP), has ordered that preparations of the antibiotics bacitracin, fusafungine, gramicidin or tyrothricin, which are locally administered (nasally or by oropharynx route) should be withdrawn from the market due to a lack of therapeutic efficacy. The Agency is of the opinion that such a move would also prevent the emergence of strains of antibiotic-resistant bacteria. These measures are consistent with AFSSAP' recently completed review of locally administered antibiotics as part of a national and European action programme to promote the proper use of antibiotics.<br>(Reference: (AFSSAP) Communication, , , 19 July 2005) |

**Product Name** **Non steroidal anti-inflammatory agents (NSAIDs)**

**C.A.S. number** **2009-1-113**

**Legislative or regulative action**

**Legislative or regulation action**

**Product Name** **Non steroidal anti-inflammatory agents (NSAIDs)**

**C.A.S. number** **2009-1-113**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| CHL | 09 Jun 2005 | Product insert to indicate that these agents are contraindicated in patients who are hypersensitive to one of the other NSAIDs, patients suffering from asthma, rhinitis, urticaria, angioedema, bronchospasm, and anaphylactic reactions to acetyl salicylic acid preparations. The warning section should refer to adverse gastrointentinal effects, potential for adverse cardiac and hepatic effects with nimesulide, sulindac, diclofenac and naproxen; and to use NSAID with caution in patients with renal problems.<br>(Reference: (CHLIPH) Resolucion no., 4687, , 09 June 2005) |

**Product Name** **Products contaning Ginseng**

**C.A.S. number** **2009-1-114**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| MYS | Jun 2005 | Labelling requirement for traditional medicines containing ginseng has been changed from "Continuous use exceeding three months not advisable" to "Safety on long-term use has not been established".<br>(Reference: (MYSDRA) Communication, , , 2005) |

**Product Name** **Propolis and Royal Jelly Products**

**C.A.S. number** **2009-1-115**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| MYS | Jul 2005 | Royal Jelly - For traditional medicines containing Royal Jelly, the product label must carry the following statements: - Royal Jelly may cause severe allergic reactions including fatal anaphylactic reactions in susceptible individuals. - Asthma and allergy sufferers may be at a greater risk. This is due to the fact that Royal Jelly has been identified as a possible cause of contact dermatitis, bronchospasm, anaphylaxis, asthma, urticaria and rhinitis. Propolis - For traditional medicines for topical use containing Propolis, the product label must carry the following statement: - Propolis may cause allergic skin reactions.<br>(Reference: (MYSDRA) Communication, , , 2005) |

**Product Name** **Risperidone and other atypical antipsychotics**

**C.A.S. number** **2009-1-116**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| SRB | Apr 2006 | Additional warning has been issued against the use of these products in elderly patients with dementia due to high incidence of cerebrovascular adverse reactions. This measure refers to all registered original and generic products containing risperidone and to other registered atypical antipsychotics (olanzapine and ziprasidone). Precaution required for the combined use of risperidone and furosemide due to interaction of unknown mechanism leading to increased mortality. For use of products containing risperidone or olanzapine, monitoring of patients is recommended due to risk of hyperglycasmia or diabetes exacerbation.<br>(Reference: (SRBNPC) Communication, , , Dec 2005) |

**Product Name** **Thiazolidinedione antidiabetics**

**C.A.S. number** **2009-1-117**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **USA** | **2007** | The US FDA, based on a review of postmarketing adverse events reports, has requested the addition of a boxed warning on the label about the risk of heart failure for all thiazolidinedione class of antidiabetic drugs. This class includes rosiglitazone (Avandia) pioglitazone (Actos), rosiglitazone and glimepiride (Avandaryl), among others. The warning also states that these drugs should not be used by people with serious or severe heart failure. US FDA's review of the postmarketing adverse events reports found cases of significant weight gain, and oedema, both of which are warning signs of heart failure; some reports were associated with poor treatment outcomes, including death, when treatment was continued.<br>(Reference: (USFDAN) FDA News, , , 14 Aug 2007) |

**Product Name** **Triaminic vapour patch**

**C.A.S. number** **2009-1-009**

**Legislative or regulative action**

| Country | Effective Date | Description of action taken<br>Grounds for decision |
|---|---|---|
| **CAN** | **May 2006** | Health Canada issued a warning that it is recalling Triaminic Vapour Patch, a product that contains camphor, eucalyptus oil and menthol, bacause of a risk of ingestion by children with serious adverse outcome.<br>(Reference: (CANAWR) Advisories, Warnings and Recalls, , , 30 May 2006) |
| **USA** | **Jun 2006** | A nationwide voluntary recall of all Triaminic Vapor Patch products has been conducted in the USA by Novartis Consumer Health.<br>(Reference: (USAPHA) Public Health Advisory, , , 20 June 2006) |

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

*Fourteenth Issue*

*PART II*

*COMMERCIAL INFORMATION*

# TRADE NAMES

(New data on trade names was not collected for this issue)

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

***Fourteenth Issue***

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**(TRADE NAMES WERE NOT COLLECTED FOR NEW PRODUCTS INCLUDED IN THIS ISSUE )**

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

*Fourteenth Issue*

# ANNEXES

# Annex I

## Relevant resolutions of the General Assembly And the Economic and Social Council

### 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

[1] E/C.10/85.

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;

**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 fulfillment 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[2]

**1. Takes note** of the report of the Secretary-General on the exchange of information on banned hazardous chemicals and unsafe pharmaceutical products,[3] 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;

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[2] Official Records of the General Assembly, Thirty-eighth Session, Second Committee, 27th meeting, paras. 1-7.

[3] A/38/190-E/1983/67.

**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;

**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

# 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,[4]

**Bearing in mind** the report of the Secretary-General on the exchange of information on banned hazardous chemicals and unsafe pharmaceutical products,[5] 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;

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[4] A/39/452.

[5] A/39/290-E/1984/120.

(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;

**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

# General Assembly resolution 44/226

## 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[6] 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,[7]

**Welcoming** the report of the Secretary-General on illegal traffic in toxic and dangerous products and wastes,[8]

**Taking note** of the conclusion of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal,[9]

**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,

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[6] A/44/276-E/1989/78.

[7] See Official Records of the General Assembly, Forty-fourth Session, Supplement No. 25 (A/44/25), annex I.

[8] A/44/362 and Corr.1.

[9] See UNEP/IG.80/3.

**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,

## 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

# Economic and Social Council resolution 1998/41

## Protection against products harmful to health and the environment

**The Economic and Social Council,**

**Recalling** General Assembly resolutions 37/137 of 17 December 1982, 38/149 of 19 December 1983, 39/229 of 18 December 1984 and 44/226 of 22 December 1989, as well as Assembly decisions 47/439 of 22 December 1992 and 50/431 of 20 December 1995,

**Taking note** of the report of the Secretary-General on products harmful to health and the environment,[10] 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,

**Noting with satisfaction** the continued close collaboration between the United Nations, the Food and Agriculture Organization of the United Nations, the World Health Organization and the United Nations Environment Programme in the preparation of the Consolidated List,

**Taking note** of the successful conclusion of the negotiations to develop a legally binding instrument for the application of the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade (Rotterdam Convention),

**1. Welcomes** the report of the Secretary-General on products harmful to health and the environment and notes the progress being achieved in increasing the number of countries that participate in the preparation of the Consolidated List of Products Whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or not Approved by Governments;

**2. Expresses** its appreciation for the cooperation extended by Governments in the preparation of the Consolidated List and urges all Governments, in particular those that have not yet done so, to provide the necessary information to relevant organizations for inclusion in future issues of the Consolidated List;

**3. Requests** the Secretary-General to continue to prepare the Consolidated List focusing on chemicals and pharmaceutical products in alternate years, with the same frequency for each official language in publishing the Consolidated List as was envisioned in General Assembly resolutions 39/229 and 44/226;

**4. Also requests** the Secretary-General to continue to provide the necessary technical assistance to developing countries, at their request, for the establishment and/or strengthening of national capacity for managing hazardous chemicals and pharmaceutical products;

**5. Urges** the adoption of the agreed text of the Rotterdam Convention at the diplomatic conference to be held in Rotterdam, the Netherlands, on 10 and 11 September 1998 and calls for a speedy ratification by the signatories of the Convention, aimed at its early entry into force;

**6. Emphasizes** the need to continue to utilize the work being undertaken by relevant organizations of the United Nations system and other

[10] A/53/156-E/1998/78.

intergovernmental organizations in this area, as well as that being carried out under international agreements and conventions in related areas in updating the Consolidated List;

**7. Requests** the Secretary-General to continue to report every three years, in accordance with General Assembly resolution 39/229, on the implementation of the present resolution and of previous Assembly resolutions on the same subject.

46th plenary meeting
30 July 1998

# Economic and Social Council resolution 2001/33

## Protection against products harmful to health and the environment

**The Economic and Social Council,**

**Recalling** General Assembly resolutions 37/137 of 17 December 1982, 38/149 of 19 December 1983, 39/229 of 18 December 1984 and 44/226 of 22 December1989, General Assembly decisions 47/439 of 22 December 1992 and 50/431 of 20December 1995, and Council resolution 1998/41 of 30 July 1998,

**Having considered** the report of the Secretary-General on products harmful to health and the environment, [11] 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, [12]

**Taking note** of the fact that an increasing number of countries participate in the preparation of the Consolidated List,

**Noting** *with satisfaction* the continued close collaboration between the United Nations, the Food and Agriculture Organization of the United Nations, the World Health Organization, the United Nations Environment Programme and the World Trade Organization in the preparation and dissemination of the Consolidated List,

**1. Expresses its appreciation** for the cooperation extended by Governments in the preparation of the Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or Not Approved by Governments,[13] and urges all Governments, in particular those that have not yet done so, to provide the necessary information to relevant organizations for inclusion in future issues of the Consolidated List;

**2. Requests** the Secretary-General to prepare each of the two issuances of the Consolidated List, pharmaceuticals and chemicals, in all official languages – the English version in the already established format, and the versions in the other languages as a text file. In this connection, the Consolidated List should continue to include previously collected data, while at the same time making distinct entries for those products covered in the interim prior informed consent procedure, in line with the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, and should consequently keep updating the information contained therein, in accordance with relevant action being taken by the Convention;

**3. Invites** multilateral and bilateral agencies to continue to strengthen and coordinate their activities for improving the capacity-building of developing countries, particularly least developed countries, including innovative methodologies for earmarking, assessing

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[11] A/56/115-E/2001/92.

[12] For previous issues of the Consolidated List, see United Nations publications, Sales Nos. E.84.IV.8, E.87.IV.a, E.91.IV.4, E.94.IV.3 and E.97.IV.2.

[13] UNEP/FAO/PIC/CONF/5, annex III.

and monitoring technical assistance in the area of the sound management of hazardous chemicals and dangerous pharmaceutical products;

**4. Emphasizes** the need to continue to utilize the work being undertaken by relevant organizations of the United Nations system and other intergovernmental organizations in this area, as well as that being carried out under international agreements and conventions in related areas in updating the Consolidated List;

**5. Requests** the Secretary-General to continue to report every three years, in accordance with General Assembly resolution 39/229, on the implementation of the present resolution and of previous Assembly resolutions on the same subject;

**6. Requests** the Secretary-General, within existing resources, to continue to disseminate the list as widely as possible and to look at the possibility of using online dissemination in collaboration with the World Trade Organization, the Food and Agriculture Organization of the United Nations, the World Health Organization and the United Nations Environment Programme.

*43rd plenary meeting*
*26 July 2001*

# Economic and Social Council resolution 2004/55

## Protection against products harmful to health and the environment

**The Economic and Social Council,**

***Recalling*** General Assembly resolutions 37/137 of 17 December 1982, 38/149 of 19 December 1983, 39/229 of 18 December 1984 and 44/226 of 22 December 1989, Assembly decisions 47/439 of 22 December 1992 and 50/431 of 20 December 1995, and Economic and Social Council resolutions 1998/41 of 30 July 1998 and 2001/33 of 26 July 2001,

***Having considered*** the report of the Secretary-General on products harmful to health and the environment,[14] which contains a review[15] of the Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or Not Approved by Governments,[16]

***Taking note*** of the fact that an increasing number of countries participate in the preparation of the Consolidated List,

***Noting with satisfaction*** the continued close collaboration among the United Nations, the Food and Agriculture Organization of the United Nations, the World Health Organization and the United Nations Environment Programme in the preparation and dissemination of the Consolidated List,

***Taking note*** of commitments made and targets established regarding environmentally sound management of chemicals in the Plan of Implementation of the World Summit on Sustainable Development ("Johannesburg Plan of Implementation"),[17] adopted by the Summit on 4 September 2002,

***Noting*** the coming into force, in early 2004, of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade[18] and the Stockholm Convention on Persistent Organic Pollutants,[19]

1. ***Takes note*** of the report of the Secretary-General on products harmful to health and the environment and notes the online availability[20] of the Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or Not Approved by Governments;

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[14] A/59/81-E/2004/63.

[15] Ibid., sect. II.

[16] United Nations publications, Sales Nos. E.03.IV.9 and E.04.IV.2. For previous issues of the Consolidated List, see United Nations publications, Sales Nos. E.84.IV.8, E.87.IV.1, E.91.IV.4, E.94.IV.3, E.97.IV.2, E.02.IV.3 and E.03.IV.3.

[17] *Report of the World Summit on Sustainable Development, Johannesburg, South Africa, 26 August - 4 September 2002* (United Nations publication, Sales No. E.03.II.A.1 and corrigendum), chap. I, resolution 1, annex. 5 Text available from http://www.pic.int/en/ViewPage.asp?id=104 (accessed 22 July 2004).

[18] Text available from http://www.pic.int/en/ViewPage.asp?id=104 (accessed 22 July 2004).

[19] Text available from http://www.pops.int/. (accessed 22 July 2004).

[20] Available from www.un.org/esa/coordination/ecosoc/Path:Publications (accessed 22 July 2004).

2. ***Expresses its appreciation*** for the cooperation extended by Governments in the preparation of the Consolidated List, and urges all Governments, in particular those that have not yet done so, to provide the necessary information to relevant organizations for inclusion in future issues of the Consolidated List;

3. ***Requests*** the Secretary-General to continue to update the electronic version of the Consolidated List, alternating between chemicals and pharmaceuticals every year, while printing only new data to complement previously printed issues for the benefit of those, particularly in developing countries, who may not have easy access to the electronic version;

4. ***Urges*** all Governments to participate fully in the process of developing a strategic approach to international chemicals management by 2005, in order to achieve the 2020 target of the World Summit on Sustainable Development, as set out in paragraph 23 of the Plan of Implementation of the World Summit on Sustainable Development ("Johannesburg Plan of Implementation"), pursuant to which chemicals would be used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment, using transparent science-based risk assessment procedures and science-based risk management procedures, taking into account the precautionary approach, as set out in principle 15 of the Rio Declaration on Environment and Development,[21] and support developing countries in strengthening their capacity for the sound management of chemicals and hazardous wastes by providing technical and financial assistance, and calls for a more coordinated use of existing international instruments in this field, taking into account the work undertaken by the United Nations system in this regard;

5. ***Encourages*** countries to implement the new Globally Harmonized System of Classification and Labeling of Chemicals[22] as agreed in paragraph 23 (c) of the Johannesburg Plan of Implementation as soon as possible, with a view to having the system fully operational by 2008;

6. ***Urges*** all Governments that have not yet done so to consider ratifying the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade and the Stockholm Convention on Persistent Organic Pollutants and to fully implement them;

7. ***Invites*** multilateral and bilateral agencies to continue to strengthen and coordinate their activities for improving the capacity-building of developing countries, particularly least developed countries, as well as countries with economies in transition, inter alia, through technical assistance in the area of the sound management of hazardous chemicals and dangerous pharmaceutical products;

8. ***Emphasizes*** the need to continue to utilize the work being undertaken by relevant organizations of the United Nations system and other intergovernmental organizations in this area, as well as that being carried out under international agreements and conventions in related areas, in updating the Consolidated List;

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[21] *Report of the United Nations Conference on Environment and Development, Rio de Janeiro, 3-14 June 1992*, vol. I, *Resolutions Adopted by the Conference* (United Nations publication, Sales No. E.93.I.8 and corrigendum), resolution 1, annex I.

[22] United Nations publication, Sales No. E.03.II.E.25.

9. ***Requests*** the Secretary-General to continue to report every three years, in accordance with General Assembly resolution 39/229 of 18 December 1984, on the implementation of the present resolution, taking into account previous Assembly resolutions on the same subject, as appropriate.

*50th plenary meeting*
*23 July 2004*

## Economic and Social Council decision 2007/264

### Products harmful to health and the environment

At its 47th meeting, on 27 July 2007, the Economic and Social Council took note of the report of the Secretary -General on products harmful to health and the environment[23] and requested the Secretary -General, in consultation with Member States and relevant intergovernmental entities, to evaluate the continued usefulness for the Member States of the Consolidated List of Products Whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or Not Approved by Governments and to report to the Council at its substantive session of 2008.

[23] A/62/78- E/2007/62.

# Economic and Social Council resolution 2008/13

## Protection against products harmful to health and the environment

**The Economic and Social Council,**

***Recalling*** its decision 2007/264 of 27 July 2007, in which the Economic and Social Council requested the Secretary-General, in consultation with Member States and relevant intergovernmental entities, to evaluate the continued usefulness for the Member States of the Consolidated List of Products Whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or Not Approved by Governments and to report to the Council at its substantive session of 2008, and taking note of the report of the Secretary-General on products harmful to health and the environment,[24]

1. ***Invites*** the United Nations Environment Programme to continue updating the chemicals volume of the Consolidated List of Products Whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or Not Approved by Governments and to report to the Economic and Social Council at its substantive session in 2010;

2. ***Invites*** the World Health Organization to continue updating the pharmaceuticals volume of the Consolidated List and to report to the Economic and Social Council at its substantive session in 2010.

*41st plenary meeting*
*23 July 2008*

[24] A/63/76-E/2008/54.

# Annex II

## Criteria for the inclusion of pharmaceutical and chemical products in the Consolidated List

### A. Pharmaceutical products[a]

**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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[a] Products, which are in illicit trade only, would not be considered.

# Annex III

## List of references cited in the regulatory text

| | |
|---|---|
| AFSSAP | AGENCE FRANÇAISE DE SÉCURITÉ SANITAIRE DES PRODUITS DE SANTÉ (AFSSAPS)<br>93285 SAINT DENIS CEDEX, FRANCE<br>www.recherche.sante.gouv.fr |
| ANVISA | PHARMACOVIGILANCE OFFICE<br>NATIONAL HEALTH SURVEILLANCE AGENCY (ANVISA)<br>BRASILIA, BRAZIL<br>www.anvisa.gov.br |
| ARGFDM | ADMINISTRACIÓN NACIONAL DE MEDICAMENTOS, ALIMENTOS Y TECNOLOGÍA MÉDICA (ANMAT)<br>BUENOS AIRES – ARGENTINA<br>www.anmat.gov.ar |
| ARGNPC | NATIONAL PHARMACOVIGILANCE CENTRE<br>ARGENTINA |
| ARMDRA | ARMENIAM DRUG REGULATORY AUTHORITY<br>ARMENIA |
| AUSMS | THERAPEUTICS GOODS ADMINISTRATION<br>AUSTRALIA<br>www.tga.gov.au |
| AUSPR | THERAPEUTICS GOODS ADMINISTRATION<br>AUSTRALIA<br>www.tga.gov.au |
| BHCP | BAYER HEALTHCARE PHARMACEUTICALS<br>www.fda.gov |
| BMSGS | BRISTOL MYERS SQUIBB AND GILEAD SCIENCES<br>CANADA<br>www.hc-sc.gc.ca |
| BRAHSA | PHARMACOVIGILANCE OFFICE<br>NATIONAL HEALTH SURVEILLANCE AGENCY (ANVISA)<br>BRASILIA, BRAZIL<br>www.anvisa.gov.br |
| CANAHC | HEALTH CANADA<br>www.hc-sc.g.ca |
| CANAMG | AMGEN CANADA INC.<br>www.hc-sc.gc.ca |
| CANAWR | HEALTH CANADA<br>www.hc-sc.g.ca |

# List of references cited in the regulatory text

| | |
|---|---|
| CHEJSM | JOURNAL SWISSMEDIC<br>www.swissmedic.ch |
| CHEMED | SWISS AGENCY FOR THERAPEUTIC PRODUCTS (SWISSMEDIC)<br>BERN, SWITZERLAND<br>www.swissmedic.ch |
| CHLIPH | INSTITUTE OF PUBLIC HEALTH<br>CHILE<br>www.ispch.cl |
| CHLPCC | NATIONAL DRUG INFORMATION AND PHARMACOVIGILANCE CENTRE (CENIMEF)<br>INSTITUTE OF PUBLIC HEALTH<br>SANTIAGO, CHILE<br>www.ispch.cl |
| CMRPCC | NATIONAL PHARMACOVIGILANCE CENTRE<br>CAMEROON |
| FDAPR | U.S. FOOD AND DRUG ADMINISTRATION<br>www.fda.gov |
| GBRDSU | MEDICINES AND HEALTHCARE REGULATORY AGENCY<br>LONDON, UNITED KINGDOM<br>www.mhra.gov.uk |
| GBRLHP | MEDICINES AND HEALTHCARE REGULATORY AGENCY (MHRA)<br>LONDON, UNITED KINGDOM<br>www.mhra.gov.uk |
| GHAFDB | FOOD AND DRUGS BOARD<br>GHANA |
| GSKMMV | GLAXOSMITHKLINE AND MEDICINES FOR MALARIA VENTURE<br>LONDON, UNITED KINGDOM; GENEVA, SWITZERLAND |
| IRLMB | IRISH MEDICINES BOARD<br>www.imb.ie |
| JAMA | JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION<br>(SCHULMAN SP ET AL. L-ARGININE THERAPY IN ACUTE MYOCARDIAL INFRACTION)<br>www.jama.ama-assn.org |
| JORPCC | FOOD AND DRUG ADMINISTRATION<br>AMMAN, JORDAN |
| JPNPSI | PHARMACEUTICALS AND MEDICAL DEVICES SAFETY INFORMATION<br>TOKYO, JAPAN |
| KRFDA | FOOD AND DRUG ADMINISTRATION<br>SEOUL, REPUBLIC OF KOREA |

# List of references cited in the regulatory text


MHRAPR MEDICINES AND HEALTHCARE REGULATORY AGENCY (MHRA)
LONDON, UNITED KINGDOM
www.mhra.gov.uk

MYSADR ADVERSE DRUG REACTIONS NEWSLETTER
DRUG CONTROL AUTHORITY
MINISTRY OF HEALTH, MALAYSIA

MYSDRA DRUG REGULATORY AGENCY
MINISTRY OF HEALTH, MALAYSIA

MYSNPC NATIONAL PHARMACOVIGILANCE CENTRE
MINISTRY OF HEALTH, MALAYSIA

NAFDAC NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)
www.nafdacnigeria.net

NGAPCC NATIONAL PHARMACOVIGILANCE CENTRE
NIGERIA

NZLLDP NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
www.medsafe.govt.nz

NZLMRM NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
www.medsafe.govt.nz

NZLPU NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
www.medsafe.govt.nz

PRTBFV BOLETIM DE FARMACOVIGILÂNCIA
INSTITUTO NACIONAL DA FARMÁCIA E DO MEDICAMENTO
MINISTÉRIO DA SAÚDE, PORTUGAL

SRBNPC NATIONAL PHARMACOVIGILANCE CENTRE
BELGRADE, SERBIA

SWEMPA SWEDISH MEDICAL PRODUCTS AGENCY
www.lakemedelsverket.se

TLSFR SEMWE FARMACIA REPORT
DEMOCRATIC REPUBLIC OF TIMOR-LESTE

TUFAM TURKISH PHARMACOVIGILANCE CENTRE (TUFA)
MINISTRY OF HEALTH
REPUBLIC OF TURKEY

UKRNPC NATIONAL PHARMACOVIGILANCE CENTRE
UKRAINE

USADHR ROCHE LABORATORIES INC.
www.fda.gov

USAPHA U.S. FOOD AND DRUG ADMINISTRATION
www.fda.gov

# List of references cited in the regulatory text


USASI U.S. FOOD AND DRUG ADMINISTRATION
www.fda.gov

USFDAA U.S. FOOD AND DRUG ADMINISTRATION
www.fda.gov

USFDAN U.S. FOOD AND DRUG ADMINISTRATION
www.fda.gov

WHOIES INFORMATION EXCHANGE SYSTEM
WORLD HEALTH ORGANIZATION
www.who.int/medicines

WHOPNL PHARMACEUTICALS NEWSLETTER
WORLD HEALTH ORGANIZATION
www.who.int/medicines/publications/newsletter

WHORTC REVIEW OF THE SAFETY OF CHLORPROGUANIL-DAPSON……. ……FALCIPARUM MALARIA IN AFRICA
WORLD HEALTH ORGANIZATION
www.who.int/malaria/docs/LapDap.pdf

# 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. The present 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 List will be taken into account in the preparation of future editions.

Please mail the questionnaire as soon as possible to: United Nations Secretariat, DESA/DESC/EICB, One United Nations Plaza, Room DC1-1438, New York, NY 10017, United States of America.

**Name and address of ministry/organization/institution/company/university**:

_____

_____

_____

_____

**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

**C. 1. Has the information provided 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.

_____

_____

**2. What is the nature of this action?** (Information on the following points is particularly requested from national regulatory authorities)

___ 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)

_____

_____

_____

_____

_____

***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 attach a copy of any such regulation.

_____

_____

_____

_____

_____

***E. Are you aware of any additional trade and manufacturing 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 do you use to obtain information on banned and severely restricted products?**

_____

_____

_____

_____

***H.*** ***Would you be interested in and have the facilities to obtain on-line access to the List?***

**____ Yes** **____ No**

***I.*** ***What are your suggestions regarding the use of the List?***

_____

_____

_____

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***J.*** ***What are your suggestions regarding the preparation of the List?***

_____

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_____

***K.*** ***Do you have any other comments?***

_____

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_____