

**MINISTERIAL DECREE No. 12/2004
Of October 6th**

CLASSIFICATION OF MEDICINES

Decree-Law No. 12/2004, of June 16, approved the legal regime of pharmaceutical activities, providing in article 15 for the approval by the Minister of Health Ministerial Diploma of the regime of classification of medicines as well as the respective lists.

Thus:

The Government, by the Minister of Health, orders, under the provisions of article 15 of Decree-Law No. 12/2004, of 16 June, to publish the following legal diploma:

Article 1

Medicines shall be classified into over-the-counter medicines and medicines subject to prescription by health professionals.

Article 2

Over-the-counter medicines are those listed in Annex I to the present statute, both those included in List A, which can be sold in any retail commercial establishment, in accordance with subparagraph a) of paragraph 1 of article 8 of Decree-Law no. 12/2004, of 16 June, and those included in List B, which can only be sold in pharmacies or in duly licensed private health units, in accordance with subparagraph b) of paragraph 1 of article 8 of the said Article.

Article 3

All the remaining medicines are subject to prescription by health professionals, which may only be sold in duly licensed pharmacies or private health units, in accordance with the conditions set out in subparagraph b) of paragraph 1 of article 8 of Decree-Law No. 12/2004, of 16th June.

Article 4

Among the medicines subject to medical prescription, the narcotic and psychotropic medicines listed in Annex II are subject to special control, which can only be prescribed by doctors and are subject to the special international and national norms, namely the control provided for in number 4 of Annex I of Ministerial Diploma No. 5/2004, of 14 July.

Article 3

The present legal diploma enters into force on September 17th, 2004.

The Minister of Health

Rui Maria de Araújo

Díli, 15 de setembro de 2004.

ANNEX 1

OVER-THE-COUNTER DRUGS

List A

Over-the-Counter Medicinal Products in Commercial Retail Stores

- Paracetamol
- Acetylsalicylic Acid
- Calamine Lotion
- Povidone slurry in preparation for external topical use
- Chlorhexidine and/or cetrimide in preparation for external topical use
- Dimethylpolysiloxane/dimethylpolysiloxane
- Dimethicone/simethicone
- Antacids, e.g. aluminum hydroxide, polyol, trisilicate/magnesium hydroxide
- Antiseptic mouthwash in preparation for external topical use
- Vitamins and minerals, including preparations with ferrous salts and folic acid
- Antidandruff shampoos (with zinc pyrithione, selenium) in preparation for external topical use
- Condoms with or without spermicide

List B

Over-the-counter medicines in pharmacies (does not cover injectable formulas)

ANALGESICS

Ibuprofen

TOPICAL USE MEDICINES

Analgesic creams:

- Containing camphor, menthol, eucaplast oil, methyl salicylate, pine oil, provided they do not contain steroidal anti-inflammatory drugs
- Topical anesthetic preparations for external use
- Topical preparations for hemorrhoids, containing anesthetics, astringents or anti-inflammatories

Anti-inflammatory or anti-allergic creams:

- Creams or ointments containing not more than 0.5% hydrocortisone
- Antihistamines in preparations for external topical use

Antiseptics and anti-infectives:

- Dermatological preparations, non-anogenital, containing e.g. salicylic acid, trichloroacetic acid, silver nitrate, glutaraldehyde, podophilic resin, lactic acid
- Gentian violet solution or powder
- Potassium permanganate
- Idoxuridine for skin (not eye) treatment

Topical antifungal preparations:

- Preparations for external topical use, containing amphotericin B
- Creams or ointments for external use containing benzoic acid or salicylic acid
- Preparations for external topical use with clotrimazole
- Preparations for external topical use with miconazole
- Preparations for external topical use with nystatin
- Preparations for external topical use with terbinafine
- Preparations for External Topical Use with Clioquinol
- Preparations for external topical use with undecylenic acid?

Antisarna preparations:

- Benzyl benzoate lotion
- External topical preparation with permethrin - External topical preparation with lindane

Ophthalmic preparations for topical use:

- Eye decongestants and antihistamines, non-steroidal, for external use

Nasal preparations for topical use:

- Decongestants and antihistamines, nonsteroidal, for external use

Otologic preparations for topical use:

- Wax removing preparations, for external use

Preparations for topical treatment of acne:

- Preparations for external use, e.g. sulfur, resorcin, benzyl peroxide, provided they do not contain antibiotics, retinoids, azelaic acid or triclosan

Other topical preparations:

- Urea for external use
- Tar for external use
- Heparin or heparinoid for external use.

GASTROINTESTINAL MEDICATIONS

- Activated charcoal
- Laxatives, e.g. bisacodyl, lactulose, sene, sorbitol, magnesium sulfate, ispaghula bark
- Ranitidine (not cimetidine or other similar H₂ antagonist)
- Kaolin
- Pectin
- Mint oil
- Moisturizing salts

Anthelmintics:

- Pyrantel
- Piperazine
- Mebendazole

Dietary supplements:

- Digestive enzymes

MEDICINES FOR RESPIRATORY SYSTEM

- Non-steroidal antihistamines
- Cough and cold preparations, provided they do not contain triprolidine, narcotics, ephedrine, phenylpropanolamine, nacetylcysteine, carbocysteine, phenylephrine, noscapine.
- Preparations with dextromethorphan and chlorpheniramine are only allowed in combination with other products, but not alone.
- Bronexine and ambroxol. - Pseudoephedrine.

OTHERS

- Imported medicinal plants.
- Urinary antacids, e.g. sodium bicarbonate.

ANNEX 11

Drugs Subject to Special Control

(including salts, esters, ethers, isomers, extracts and chemical derivatives)

NARCOTICS

- Acertofin
- Acetylmethadol
- Alfentanil
- Allylprodine
- Alphacetylmethadol
- Alfameprodine
- Alfamethadol
- Alfaprodine
- Anileridine
- Benzetadine
- Beta-acetylmethadol
- Betametadol Betaprodine
- Benxitramide
- Dioxaphetyl butyrate Cannabis
- Clonitazene
- Coca (folha)
- Cocaine
- Codeine
- Codoxin
- Papaya palm condensate
- Desomorphine
- Dextromoramide
- Diampromide

- Diethylthiambutene
- Diphenophine
- Dihydrocodeine
- Dihydrocodeinone
- Dihydroetorphine
- Dihydromorphine ,
- Dihydromorphinone
- Dimenoxadol
- Dimetheptenol
- Dimethylthiambutene
- Diaphenoxylate
- Dipipanone
- Drotebanol
- Ecgonine
- Ethylmethylthiambutene
- Etorphine
- Ethoxeridine
- Phenadoxone
- Phenampromide
- Phenazocine
- Phenomorphan
- Phenoperidine
- Fentanyl
- Furetidine
- Heroin (diacetylmorphine)
- Hydrocodone
- Jidromorphenol
- Hydromorphone
- Hydroxypetidine
- Isomethadone
- Ketobemidone Levomethorphan
- Levomoramide
- Levofenacilmorphan
- Levorphanol
- Methazocine
- Methadone
- Methyl-desorphine
- Methyl-dihydromorphine
- Methopon

- Morpheridine
- Morphine
- Myrophin
- Nicomorphine
- Noracimetadol
- Noracimetadol
- Normorphine
- Norpipanone
- Opium
- Oxycodone
- Oxymorphone
- Pethidine
- Pyiritramide
- Proheptazine
- Properidine
- Racemethorphan
- Racemoramide
- Racemorphan
- Remifentanil
- Sufentanil
- *Tabecão*
- Thebaine
- Tilidine
- Trimeperidine

The following are not considered narcotics:

- a) Codeine, Dihydrocodeine, Ethylmorphine, Nicodicodine, Norcodeine and Folcodine when combined with one or more ingredients and containing not more than 100 milligrams of the substance per dose unit and with a concentration of not more than 2.5% in indivisible preparations.
 - b) Dextropropoxyphene for oral use containing not more than 135 milligrams per dosage unit or with a concentration.
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