

**E/NL.**1998/45 23 June 1998

SPANISH AND ENGLISH ONLY ENGLISH ORIGINAL: SPANISH

# LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

In accordance with the relevant articles of the international treaties on narcotic drugs and psychotropic substances, the Secretary-General has the honour to communicate the following legislative texts.

#### **SPAIN**

## Communicated by the Government of Spain

#### NOTE BY THE SECRETARIAT

- (a) Some editing of texts may be done by the Secretariat in the interest of clarity. In this connection, words in square brackets [] have been added or changed by the Secretariat.
- (b) Only passages directly relevant to the control of narcotic drugs or psychotropic substances have been reproduced in this document. Non-relevant parts of laws and regulations have been deleted by the Secretariat; such deletions are indicated by [...].

ORDER OF 27 DECEMBER 1995 INCLUDING CERTAIN ACTIVE PRINCIPLES IN ANNEX I OF ROYAL DECREE No. 2829 OF 6 OCTOBER 1977, REGULATING PSYCHOTROPIC SUBSTANCES AND PREPARATIONS

#### MINISTRY OF HEALTH AND CONSUMER AFFAIRS

1865 ORDER of 27 December 1995 including certain active principles in annex I of Royal Decree 2829 of 6 October 1977, regulating psychotropic substances and preparations.

At its thirty-eighth session the United Nations Commission on Narcotic Drugs adopted a number of decisions: Decision 1 (XXXVIII), 2 (XXXVIII), 3 (XXXVIII) and 4 (XXXVIII). It was decided to include therein certain substances in the schedules annexed to the Convention on Psychotropic Substances concluded at Vienna on 21 February 1971 (Boletin Oficial del Estado, No. 218, dated 10 September 1976).

Therefore, according to the provisions of article 2, section 7 of the Convention as ratified by Spain, and in exercise of the powers conferred by the Final Provision of Royal Decree 2829 of 6 October 1977, regulating medicinal psychotropic substances and preparations, annex I of the Royal Decree in question shall be amended to include the relevant substances.

<sup>1</sup>E/NL.1978/59.

V.98-54971 (E) (a:\1998\nar.2)

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ONE: Include in annex I, list I of Royal Decree No. 2829/1977 the substances etriptamine [3-(2-aminobutyl)indole] and metacatinone [2-(methylamino)-1-phenylpropane-1-one] and the esteroisomeric variants of both.

TWO: Include in annex I, list II of Royal Decree No. 2829/1977 the substance zipeprol [alpha(alpha-methoxy-benzyl)4-betamethoxyphenetil)-1-pipera-zinaethanol] and its esteroisomeric variants.

THREE: Include in annex I, list IV of Royal Decree No. 2829/1977 the substances aminorex (2-amino-5-phenyl-2-oxazoline), brotizolam [2-bromo-4-(ortho-chlorophenyl)-9-methyl-6H-thieno {3,2-f}-triazole {4,5-a} {1,4} diazepine] and mesocarbo [imine of 3-(alpha-methylphenethyl)-N-(phenylcarbamoil) sydnone] and its esterochemical variants.

FOUR: Transfer from annex I, list IV to annex I, list III of Royal Decree No. 2829/1977 the substance flunitrazepam [5-orthofluorophenyl)-1,3 dihydro-1-methyl-7-nitro-2H-1,4 benzodiazepine-2-one].

FIVE: The two substances included in the first provision of this Order, etriptamine and metcatinone, together with the salts, esters or ethers which can be derived therefrom, may not be objects of production, manufacture, export or import, trade, possession or use, with the exception of the quantities necessary for medical and scientific research, including clinical experiments involving these substances and performed under the supervision and control of the Directorate-General of Pharmacy and Health Products.

Upon the entry into force of this Order, the possessors or importers or manufacturers of the above substances shall proceed to declare and deliver them to the Directorate-General of Pharmacy and Health Products.

SIX: With regard to the substances contained in provisions Two, Three and Four, zipeprol, aminorex, brotizolam and mesocarbo, parties concerned as manufacturers, importers, exporters, distributors or dispensers thereof shall, as from the date of entry into force of this Order, bring their activities into conformity with the legal requirements for the psychotropic products included in annex I, lists II, III and IV of Royal Decree No. 2829/1977, as laid down therein and in the Order of 14 January 1981.

## Temporary provision

Laboratories possessing authorization to register pharmaceutical specialities containing substances included in provisions Two and Three of this Order shall adapt the relevant make-up material within a maximum of ninety days.

First final provision

The Directorate-General of Pharmacy and Health Products shall be authorized to adopt whatever measures may be necessary for the implementation of this Order.

## Second final provision

This Order shall enter into force on the day following its publication in the Boletin Oficial del Estado.

Madrid, 27 December 1995.

AMADOR MILLAN

The Director-General for Pharmacy and Health Products.