



UNITED NATIONS

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SPANISH AND ENGLISH ONLY
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 7 FEBRUARY 2000 INCORPORATING CERTAIN ACTIVE SUBSTANCES INTO SCHEDULE I ANNEXED TO THE SINGLE CONVENTION ON NARCOTIC DRUGS OF 1961

**Translator's note:* This document has been translated from the text transmitted to the Secretariat.

**ORDER OF 7 FEBRUARY 2000 INCORPORATING CERTAIN ACTIVE
SUBSTANCES INTO SCHEDULE I ANNEXED TO THE SINGLE
CONVENTION ON NARCOTIC DRUGS OF 1961**

During its 42nd session, at its 1163rd meeting, held on 16 March 1999, the United Nations Commission on Narcotic Drugs adopted decision 42/1, which was communicated to our country by the Secretary-General of the United Nations on 31 May 1999. By that decision, it was agreed that the substances remifentanil and dihydroetorphine should be included in Schedule I annexed to the Single Convention on Narcotic Drugs of 1961.

The narcotic substance remifentanil has already been registered as a medicine in Spain, and since that time the provisions of Schedule I of the Single Convention on Narcotic Drugs of 1961 have been applied to it. Dihydroetorphine, however, has not up to now existed as a registered proprietary medicine in our country.

Accordingly, and pursuant to the provisions of paragraphs 3 (iii) and 7 of article 3 of the Single Convention on Narcotic Drugs of 1961, and in application of the powers conferred in chapter I, article 21, of Law No. 17/1967 on Narcotic Substances, of 8 April 1967, I hereby order that:

1. The following substances be included in Schedule I annexed to the Single Convention on Narcotic Drugs of 1961:

Remifentanil, with the formula 1-(2-methoxycarbonyl-ethyl)-4-(phenylpropionylamino)-piperidine-4-carboxylic acid methyl ester;

Dihydroetorphine, with the formula 7,8-dihydro-7 α -[1-(*R*)-hydroxy-1-methylbutyl]-6,14-*endo*-ethano-tetrahydro-oripavine.

2. The following applies to both substances and also to the salts, esters, ethers and isomers which can be formed from them:

(a) On the entry into force of this Order, manufacturers and importers shall declare the stocks of those products in their possession to the Spanish Medicines Agency (AEM);

(b) Estimates of the manufacture, import or export of those products shall be subject to the prior authorization of AEM;

(c) The possession, marketing and distribution of the above substances and/or preparations shall comply with the regulations in force for narcotic substances in Schedule I annexed to the Single Convention of 1961;

(d) Laboratories which possess proprietary medicines containing any of the above active substances, and also pharmaceutical distribution warehouses, pharmacological establishments and hospital pharmacy services, shall declare their stocks of those medicines and substances, as appropriate, to the Narcotics Division of AEM at the time when they make an inventory of those stocks in the manner established by law;

(e) Currently marketed proprietary medicines which contain the above substances shall, on the entry into force of this Order, be distributed, prescribed, dispensed and controlled subject to the regulations for the preparations and products in Schedule I;

(f) Proprietary medicine laboratories shall bring the materials used by them in making preparations which contain the above substances into line with the provisions on narcotic substances within 30 days.

3. This Order shall enter into force on the day following its publication in the Official State Gazette.