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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 [...].

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1718 ROYAL DECREE 75/1990 regulating the use of opiates for the treatment of persons dependent on such substances

The Order of 31 October 1985, regulating the treatment using methadone to break the habit of drug addicts dependent on opiates (Official Gazette No. 269 of 9 November), of the Ministry of Health and Consumer Affairs, regulated such therapeutic treatment, in consideration of the competences assigned to Autonomous Communities by the Spanish Constitution, and under the protection of Law No. 17/1967 of 8 April (Official Gazette No. 11 of 11 April), which in its article 1 authorizes the State to intervene in the prescription, possession, use and consumption of narcotic substances.

The special situation of disorganization and indiscriminate use existing at that time led to the formulation of legislation which was restrictive in some respects.

The appearance of Acquired Immune Deficiency Syndrome, which imposes reconsideration of some of the therapeutic approaches, and four years of application of the aforesaid Law, which have allowed the correction of the former situation, make it advisable to revise some important points regulated by that Law.

The present regulation has the status of a Royal Decree, taking account of the provisions of article 40.5 of the General Law on Health, Law No. 14/1986 of 25 April (Official Gazette No. 102 of 29 April), which establishes as within the competence of the State Administration, without prejudice to the powers of the Autonomous Communities, "the regulation, authorization, registration and approval, as appropriate, of medicaments for human and veterinary use, other health products and articles and products which, when applied to human beings, may be presumed to constitute a risk to human health".

The present regulation is decreed in accordance with the provisions of article 149.1.1 and 16 of the Constitution, since its precepts share the nature of basic rules concerning health or establishing legislation on pharmaceutical products as exclusively the competence of the State.

Thus the present Royal Decree regulates certain administrative matters which are justified by the need to improve the coordination arrangements which have been in operation to combine the activities of the State Administration and the Autonomous Communities in the matters covered by this legislation, these having been the subject, together with the Royal Decree as a whole, of a favourable report by the Interterritorial Council of the National Health System. Notwithstanding, the whole of this should be understood to be without prejudice to the powers of the Autonomous Communities for self-regulation in the exercise of such powers.

By authority, at the proposal of the Minister of Health and Consumer Affairs, in accordance with the Council of State, and following deliberation by the Council of Ministers at its meeting of 19 January 1990,

I DECREE:

CHAPTER ONE

General provisions

Article 1. Object. - The object of the present Law shall be to regulate treatments with the active substances included in the list annexed to the present Royal Decree when they are prescribed for the treatment of dependence on opiates in such cases where the duration of it exceeds twenty-one days.

Article 2. Treatment centres or services. - 1. The treatments to which the present Law refers shall be carried out only by public or private non-profit-making health centres or services, duly accredited for the purpose by the competent authorities of the Health Administration of the Autonomous Community concerned or, when appropriate, the competent authorities of the Ministry of Health and Consumer Affairs.

2. For the purposes established by the present Royal Decree, and provided that it is deemed appropriate, the health authorities of those Autonomous Communities which have functions in this matter or, when appropriate, the Ministry of Health and Consumer Affairs, through its competent authorities, may accredit centres in penal establishments or in other establishments not strictly of a health nature.

Article 3. Prescription, preparation, conservation, dispensation, administration and formulation. - 1. The prescription of the treatments regulated by the present Law shall be carried out by doctors in the accredited centres and services.

2. The medication used for such treatments shall be prepared, when appropriate, conserved, dispensed and administered by the pharmaceutical services of the accredited centres, as provided for in article 2, or, failing that, by the competent authorities of the Ministry of Health and Consumer Affairs or by pharmacies accredited for the purpose.

3. In all cases, the preparation, conservation or dispensation of the medication to which the preceding paragraph refers shall be subject to the legislation on narcotic drugs in force, and shall remain under the control of the Directorate General for Pharmaceutical and Health Products.

4. The medicaments used for such treatments shall be prescribed, formulated, dispensed and administered in an extemporized oral solution whenever possible.

CHAPTER II

Commissions for the accreditation, evaluation and control of centres and services

Article 4. Constitution of the Commissions. - 1. For the implementation of the provisions of the present Royal Decree by the Autonomous Communities, the following shall be taken into account:

(a) In those Autonomous Communities where no accreditation Commission has been established, the competent authorities shall decide its composition and administrative functions, incorporating in each case a member representing both the autonomous drug schemes and the Central Administration.

(b) In those Autonomous Communities in which such Commissions are already established under the Order of 31 October 1985, the competent bodies may amend the composition and regulations of such Commissions to conform with the provisions of the present Royal Decree.

2. The Commissions shall be constituted within not more than two months from the publication of the present Royal Decree.

Article 5. Functions. - The Autonomous Communities shall establish the functions of the Commissions on their administrative territory. These functions shall include the following:

1. Issue of a report concerning applications for accreditation submitted by services or centres to the competent body of the Health Administration.

2. Coordination and evaluation of information on subjects within their competence.

3. Provision to the competent organs of the Health Administration of the Autonomous Community concerned or, if appropriate, the competent authorities of the Ministry of Health and Consumer Affairs, of the information requested by them in a form that always guarantees its confidentiality.

4. Establishment of a register of patients, with arrangements to ensure the right of confidentiality. The minimum information that it should contain is described in article 10.

CHAPTER III

Accreditation of centres or services

Article 6. General criteria for the accreditation of treatment centres or services. - 1. The head of the health centre or service wishing to obtain accreditation to undertake treatment with the active substances to which article 1 of the present Law refers shall submit the application with the required information to the health authorities of the Autonomous Community concerned or, when appropriate, to the competent authorities of the Ministry of Health and Consumer Affairs.

2. The Commissions for accreditation, evaluation and control of centres and services shall issue a report on the application for accreditation made by heads of centres or services. The report issued must be favourable if accreditation is to be granted.

3. Without prejudice to the administrative procedures fixed in each case by the Autonomous Community, and for the purpose of issuing the report mentioned in the foregoing paragraph, the Commissions shall take account of the following criteria:

(a) The attainment of a balance between supply and demand for this type of welfare service in the area concerned.

(b) Priority for the accreditation of public sector centres or services.

(c) Experience in the treatment of drug addicts by the staff of the centre or service.

(d) Consistency between the available resources and the proposed objectives.

Article 7. Period of validity of accreditation. - The authorities of the Autonomous Communities or, when appropriate, the competent authorities of the Ministry of Health and Consumer Affairs, following the report of the Commission, may accredit treatment centres and pharmacies for a period not exceeding two years. Application for renewal of the accreditation must be made before the expiry of the said period.

Article 8. Revocation of accreditation. - The authorities of the Autonomous Communities or, when appropriate, the competent authorities of the Ministry of Health and Consumer Affairs, following the report of the Commission, may revoke the accreditation when there is evidence of non-compliance with the present Law or rules for its implementation, and when grounds of a sanitary or social nature so advise.

CHAPTER IV

Admission for treatment

Article 9. Admission to treatment. - 1. Admission to treatment programmes regulated by this Law, is subject to prior confirmed diagnosis of dependence on opiates and having undergone at least one treatment by another method.

Documents supporting the fulfilment of such requirements may be requested by the Commissions.

2. Without prejudice to the provisions of the foregoing paragraph, persons dependent on opiates who do not meet the required conditions may be included in treatment programmes whenever they have contracted an infection through the human immune deficiency virus or are affected by severe organic pathology.

CHAPTER V

Notification

Article 10. Notification. - The doctor in charge of the centre or service accredited to carry out treatments regulated by the present Royal Decree shall inform the Commission, or when appropriate the competent authorities of the Ministry of Health and Consumer Affairs, quarterly of the number of patients under treatment, indicating also the commencements, interruptions and completions of treatments which have taken place, together with justifications and opiates used. This information is deemed to be the minimum and each Autonomous Accreditation Commission may seek additional information.

SUPPLEMENTARY PROVISION

Centres and services which have been accredited under the Order of 31 October 1985 regulating methadone treatment for addiction shall be considered similarly accredited for treatment with the active substances included in the list annexed to the present Royal Decree, except in those Autonomous Communities where the legislation in force provides otherwise.

REPEALING PROVISION

The following are repealed: Order of the Ministry of Health and Consumer Affairs of 31 October 1985 (Official Gazette No. 269 of 9 November), regulating methadone treatments for addiction in the case of drug addicts dependent on opiates; Resolution of 22 November 1985 (Official Gazette of 27 November) of the Directorate General for Public Health on dosage and criteria for the application of methadone treatments for drug addicts dependent on opiates and any other such provisions of equal or inferior standing which conflict with the present Royal Decree.

FINAL PROVISION

The present Royal Decree shall enter into force on the day following its publication in the Official Gazette.

Given in Madrid on 19 January 1990

JUAN CARLOS R.

The Minister of Health and Consumer Affairs

JULIAN GARCIA VARGAS

ANNEX

List of principal active substances subject to the provisons of the Royal Decree regulating the treatment with opiates of persons dependent on such substances

Buprenorphine
Butorphanol
Codeine
Dextropropoxyphene
Dihydrocodeine
Ethylmorphine
Pholcodine
Methadone
Morphine
Noscapine
Opium extract
Pentazocine
Pethidine
Tilidine

E/NL.1991/43

26174 ORDER of 19 October 1990 to include specified active substances in Schedules I and IV attached to the Single Convention on Narcotic Drugs, 1961

In view of decisions 1 (S-XI) to 6 (S-XI) adopted by the United Nations Commission on Narcotic Drugs which were adopted at its 1035th meeting, held in Vienna on 29 January 1990, and communicated by the Secretary-General of the United Nations on 5 March 1990, in accordance with the reports and recommendations received from the World Health Organization, to include the substances listed below in the Schedules attached to the Single Convention on Narcotic Drugs, 1961 (Official Gazette No. 264 of 4 November 1981):

Taking into account the provisions of paragraphs 3 (subparagraph (iii)) and 5 of article 3 of the aforesaid Single Convention, and by virtue of the powers conferred by chapter I, article 2 of Law No. 17/1967 of April on Narcotic Drugs,

This Ministry has decided to provide as follows:

First. - To include the following substances in Schedules I and IV attached to the Single Convention on Narcotic Drugs, 1961:

Alpha-methylthiofentanyl, formula N-[1-[1-methyl-2-(2-thienyl)ethyl]-4-piperidyl]proprionanilide.

Para-fluorofentanyl, formula 4'-fluoro-N-(1-phenethyl-4-piperidyl)proprionanilide.

Beta-hydroxyfentanyl, formula N-[1-(beta-hydroxyphenethyl)-4-piperidyl]proprionanilide.

Beta-hydroxy-3-methylfentanyl, formula N-[1-(beta-hydroxyphenethyl)-3-methyl-4-piperidyl]proprionanilide.

Thiofentanyl, formula N-[1-[2-(2-thienyl)ethyl]-4-piperidyl]proprionanilide.

3-methylfentanyl, formula N-(3-methyl-1-phenethyl-4-piperidyl)proprionanilide.

Second. - The six above-mentioned substances, together with their salts, esters and ethers whenever the existence of such substances is possible shall not be produced, manufactured, exported or imported, traded in, held or used except in quantities necessary for medical and scientific research, including clinical experiments with the aforesaid narcotic drugs carried out under the supervision and control of the Directorate General for Pharmaceutical and Health Products.

Third. - Establishments which possess or are importers or manufacturers of the aforementioned substances shall, upon entry into force of this Order, declare and surrender them to the Directorate General for Pharmaceutical and Health Products.

Fourth. - The present Order shall enter into force on the day following its publication in the Official Gazette.

Madrid, 19 October 1990.

GARCIA VARGAS

To the Director General for Pharmaceutical and Health Products.

26177 ORDER of 19 October 1990 to include active substances in Schedules I and IV attached to the Convention on Psychotropic Substances, 1971

In view of decisions 7 (S-XI) to 10 (S-XI), adopted by the United Nations Commission on Narcotic Drugs at its 1035th meeting, held in Vienna on 29 January 1990, and communicated by the Secretary-General of the United Nations on 5 March 1990, in accordance with the reports and recommendations received from the World Health Organization, to include the substances mentioned below in the Schedules annexed to the Convention on Psychotropic Substances, done in Vienna on 21 February 1971, Official Gazette No. 218 of 10 September 1976, and Official Gazette No. 246 of 13 October 1976, in which the Schedules of psychotropic substances were published;

Considering the provisions of paragraph 7 of article 2 of the aforesaid Convention ratified by Spain and by virtue of the powers conferred by the final provision of Royal Decree 2829/1977 of 6 October, regulating psychotropic substances and medicinal preparations,

This Ministry has decided to provide as follows:

First. - 1. The inclusion of the following substances in Schedule I of Annex I of Royal Decree 2829/1977 of 6 October:

N-hydroxy MDA or N-OH MDA, formula (±)-N-[alpha-methyl-3,4(methylenedioxy) phenethyl]hydroxylamine.

N-ethyl MDA or MDE, formula (±)-N-ethyl-alpha-methyl-3,4(methylenedioxy)phenethylamine.

4-methylaminorex, formula (±)-cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine.

2. In accordance with the provisions of the above-mentioned article 2 of Royal Decree 2829/1977, the use, manufacture, import, carriage, trade in and possession of such substances, including preparations containing them, is prohibited, including for the purposes of the Law of Contraband.

To that end, within thirty days of the entry into force of the present Order, any establishment or person in possession of such substances or preparations shall deposit them with the Narcotic Drugs Control Service of the Directorate General for Pharmaceutical and Health Products, or with the Administrative Authorities of the Ministry of Health and Consumer Affairs in the various provinces.

Second. - 1. The inclusion of the following substance in Schedule IV of Annex I of Royal Decree 2829/1977 of 6 October:

Midazolam, formula 8-chloro-6-(o-fluorophenyl)-1-methyl-4H-imidazo [1,5-a][1,4]benzodiazepine.

Third. - Within thirty days of the entry into force of the present Order, establishments manufacturing, importing, exporting, distributing or dispensing the substance included in the second provision or preparations thereof shall bring their actions into line with the legal requirements for psychotropic products included in Schedule V of the Annex to Royal Decree 2829/1977, as provided therein and in the Order of 14 January 1981.

Fourth. - Laboratories that are registered as licensed to produce pharmaceutical specialities containing the substance midazolam shall modify their material and equipment for processing these specialities within a period of ninety days.

Fifth. - The manufacture, distribution, prescription and dispensation of these pharmaceutical specialities, as well as the control of the stocks thereof, shall be carried out in conformity with the provisions of Royal Decree 2829/1977 of 6 October.

FINAL PROVISION

The present Order shall enter into force on the day following its publication in the Official Gazette.

Madrid, 19 October 1990.

GARCIA VARGAS

To the Director General for Pharmaceutical and Health Products.