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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 psycho- tropic 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 [...].

MINISTRY OF HEALTH AND CONSUMER AFFAIRS ORDER, OF 25 APRIL 1994, ON SPECIAL PHARMACEUTICAL PREPARATIONS, REGULATING PRESCRIPTIONS AND SPECIAL REQUIREMENTS FOR THE PRESCRIPTION AND DISPENSING OF NARCOTIC DRUGS FOR HUMAN USE

[Editor's note: Revokes Order of 6 February 1962 (RCL 1962, 367 and NDL 12425, note). The forms contained in annexes I to III have not been reproduced because their supply is subject to official authorization.]

Regarding official standard prescription form for narcotic drugs stipulated in the Royal Decree of 8 July 1930 (RCL 1930, 1026 and NDL 12420), adopting the provisional regulations on the restriction of narcotic drugs, it is necessary, in the first place, to amend the form itself in conformity with the provisions of Royal Decree No. 1910, of 26 September 1984 (RCL 1984, 2527 and ApNDL 4926) and, secondly, to update the measures designed to ensure security, prevent falsification and promote the rational use of such substances, while also improving the scope for their prescription and dispensing in accordance with the therapeutic advances achieved in this area of health care, at the same time as providing for effective control mechanisms corresponding to the current structure of the National Health System.

At the same time, the treatment procedures intended for persons dependent on opiates were established by Royal Decree 75, of 19 January 1990[1] (RCL 1990, 120), regulating such treatment in duly accredited health-care centres or services.

The new standard form which has been designed for the official prescription of narcotic drugs will be distributed free of charge to medical practitioners through the National Health System and the Professional Medical Association.

This standard form will be used to collect the requisite information so that it can serve as a basic control mechanism, thus obviating the need for any other special safeguard document of the kind that the so-called "overdose booklet", which it replaces, was becoming, since the processing of the information in accordance with the provisions of the present Order makes it possible to detect the first repeat prescription and consequently to avoid multiple treatment of a single patient by more than one physician, or other similar departures from established procedure. In addition, it extends the scope for prescription both with regard to the quantity of medication prescribable and the duration of the treatment for which it is intended.

All these factors make the new prescription form an effective tool both for the purposes of prescription and in the interests of ensuring control of narcotic drugs and meeting the requirements of security and a common system of identification so essential in this type of medicament which, in terms of health care, represents a clear improvement in line with present-day needs, especially from the point of view of making for more rational use of these medicaments in the case of patients undergoing lengthy treatment involving relief from pain.

The present Order, pursuant to the provisions of article 2, paragraphs 1 and 2, of Law No. 25, of 20 December 1990 (RCL 1990, 2643), concerning Medicines, and in conformity with the provisions of article 149.1.16 of the Constitution (RCL 1978, 2836 and ApNDL 2875) has, on the one hand, the status of a basic health standard in that it establishes requirements which need to be of general application since they relate to public health and the health system and, on the other, the status of legislation concerning pharmaceutical products in that they lay down special requirements for the prescription and dispensing of narcotic drugs.

Accordingly, in conformity with the provisions of articles 31(2) and 85(4) of Law No. 25, of 20 December 1990, concerning Medicines and of articles 3(1) and 4(1)(b) of Royal Decree No. 1910, of 26 September 1984, concerning Medical Prescription, and with the consent of the Council of State,

I HEREBY DECREE:

Article 1. General provisions and scope of application

1. The prescription and dispensing of medicines containing narcotic substances included in Schedule I of the Single Convention on Narcotic Drugs, 1961 (*Official State Gazette* of 22 April 1966) (RCL 1966, 733 and NDL 12431) and subsequent amendments shall be effected in all cases, both within the framework of public health care and within that of private medical practice, using official prescriptions subject to the provisions of this Order.

2. The official narcotics prescription is the document necessary for prescribing and dispensing medicines for human use containing narcotic substances included in Schedule I of the aforesaid Single Convention on Narcotic Drugs, 1961.

[1] E/NL.1991/42.

3. Prescription and dispensing of medicines containing such narcotic substances for hospital patients shall be governed by the provisions of article 92 of the Medicines Act and other provisions established in pursuance or application thereof, the controls applicable to this category of substances being maintained.

Article 2. Conditions applying to the official narcotics prescription

1. Official narcotics prescriptions shall be prepared using materials which prevent or impede their falsification, with a single numbering system and format for the whole State territory, in accordance with the provisions of articles 2 and 3 and with the technical specifications contained in annex IV of the present Order.

2. The aforesaid prescriptions shall be issued in numbered counterfoil books, each containing 30 prescriptions bearing the same number and each consisting of the main part of the prescription and a note setting out instructions for the patient; the two sheets shall bear the same number.

The counterfoil book shall further include:

A voucher for receipt of the counterfoil book;

The number of the counterfoil book and the numbering of each prescription;

A prescription control sheet.

3. Printing, preparation and distribution of the official narcotics prescription counterfoil books shall be the responsibility of the health services within the National Health System, in conformity with the provisions of articles 18(11), 44(2) and 45 of the General Health Act (RCL 1986, 1316), or of the respective competent organ of the relevant Autonomous Community.

The Professional Medical Association shall be furnished free of charge with the necessary counterfoil books for their distribution, free of charge and with sufficient safeguards of security, to the practitioners who are members of the Association for the purposes of private treatment and care.

4. The official narcotics prescription, as a document valid for the entire national territory which guarantees the dispensing of narcotic drugs against medical prescription, shall be produced in the official State language of Spanish at least, without prejudice to the official languages of each Autonomous Community, in conformity with the provisions of article 85(1) of the Medicines Act.

Article 3. Standard prescription form

1. The prescription form shall cover all the information specified by article 7(2), (3) and (4) of Royal Decree No. 1910, of 26 September 1984, concerning Medical Prescription, the quantity of prescribed packages being recorded in writing.

2. In addition to the information specified in the preceding paragraph, the following special information shall be stated in the prescription:

The telephone number of the physician or medical centre;

The number of the national identity document of the patient or, if applicable, of his parent or guardian. In the case of foreign citizens, the number of the equivalent identity document shall be given;

The stamp of the professional association, if applicable, or of the health authority through which the counterfoil book was distributed;

An estimate of whether the prescription is likely to be single or repeated, to be provided by marking the appropriate box.

3. The official standard prescription forms for narcotic drugs, the counterfoil book receipt voucher and the prescription control form shall be as set out in annex I (a) (b) (c) and (d) of this Order.

Article 4. Validity of prescription

1. For prescriptions to be valid for the purposes of dispensing by pharmacy establishments, they shall:

Be prescribed using the official standard form, duly certified by the health authority which printed the counterfoil books and by the association or authority which distributed those books;

State all the mandatory data;

Be free of corrections or erasures;

Be presented for dispensing of the relevant drugs before a period of ten days has elapsed after the date of issue of the prescription by the physician.

2. The official narcotics prescription form shall be valid for the entire national territory.

Article 5. Instruction sheet

The instruction sheet, to be easily detachable from and independent of the prescription, shall be provided by the physician as an attachment to the official prescription to the patient, who shall in no circumstances be required to produce it.

Article 6. Conditions governing prescription

1. Each official narcotics prescription shall be used for the prescription of one medicine only.

2. Only medicines completely ready for direct administration to the patient may be prescribed.

3. The prescription as formulated may cover, as a maximum, the precise quantity of the prescribed medicine sufficient for 30 days' treatment and may not exceed a total of four packages.

4. The medical practitioner shall note the number of dose units required for daily treatment and the number of days covered by the prescription. He shall accordingly record in writing the total number of packages prescribed.

5. Once the prescription has been filled, the medical practitioner shall sign and date the instruction sheet and the official prescription, filling in the corresponding entry in his prescription control sheet.

Article 7. Conditions governing dispensing

1. For the purposes of dispensing in the context of private health care, the official narcotics prescription shall be presented at the pharmacy establishment.

2. If dispensing is effected in connection with pharmaceutical drugs supply under the National Health System, it shall be necessary to present and hand over to the pharmacy establishment the official narcotics prescription accompanied by the respective official prescription of the health authority, which shall fulfil the requirements specified in its special regulations.

3. The pharmacist shall check that the prescription meets the established conditions and requirements. If the pharmacist has any doubts as to its validity, he shall carry out the necessary checks prior to dispensing the drug in question. In any case, he shall note on the reverse side of the prescription the number of the national identity document, or equivalent document in the case of a foreign citizen, of the person collecting the medicine from the pharmacy establishment.

The pharmacist shall sign, seal and date the prescription after dispensing the prescribed drug, keeping it in his possession, invalidated for further dispensing. A record of each such procedure shall be made in the narcotics prescription and accounting books.

No erasures or corrections shall be admissible in prescriptions. The pharmacist shall attach to the National Health System prescription the stamps from the dispensed packages and shall then carry out the invoicing of the prescription in the normal manner.

Article 8. Control and processing of official narcotics prescriptions

1. On receipt of the counterfoil book of official narcotics prescriptions, the medical practitioner shall sign the receipt voucher, which shall remain in the possession of the association or authority which issued it. Each association or authority shall send all such vouchers signed each quarter to the pharmaceutical services of the respective Autonomous Community.

On receipt of a new counterfoil book, the medical practitioner shall submit the duly completed prescription control sheet from the used counterfoil book, such sheet being forwarded by the association or authority to the pharmaceutical services of the respective Autonomous Community.

Further, any medical practitioner who ceases his professional activity in a particular association and/or authority shall return to the latter any counterfoil books which he may have had in his use.

2. During the months of January, April, July and October each year, the pharmacy establishments shall submit to the respective Autonomous Community the official prescriptions of narcotic drugs dispensed during the previous quarter.

In addition, during the first 15 calendar days of each six-month period, they shall submit returns regarding the movements of narcotic drugs recorded during the preceding six months, providing the data requested in the printed form, which is set out in annex II(a) and (b) of this Order.

3. Once the prescriptions referred to in paragraph 2 above have been received, the pharmaceutical services of the Autonomous Communities shall proceed to apply their own audit and control programmes, as well as those agreed with the Ministry of Health and Consumer Affairs.

4. Within the calendar month following receipt of the six-monthly returns of narcotic drug movements prepared by the pharmacy establishments, the health authorities of the Autonomous Communities shall submit to the Ministry of Health and Consumer Affairs the information available on stocks and consumption of narcotics in their area of territorial competence, providing the requisite detailed data expressed in the terms necessary for the exercise of its functions.

Article 9. Coordination and control

The State health authorities and those of the Autonomous Communities shall act in coordination and collaboration in order to safeguard security, ensure adequate control, and carry out the printing, production and distribution of the official narcotics prescription counterfoil books, as well as to implement programmes and fulfil control and audit requirements under the relevant international agreements.

Article 10. Confidential status

Personal data contained in the official narcotics prescriptions control and processing system and the auditing programmes shall have the status of classified information to be made available to the parties concerned and, if need be, to the judicial authorities. The use of such data for the purposes of health care or in the interests of public health shall be confined to those purposes, those who use such information being required to respect its personal and private nature, in accordance with article 10 of the General Health Act No. 14, of 25 April 1986, Law No. 25, of 20 December 1990, on Medicines, and its corresponding provisions, as well as the provisions of Law No. 5, of 29 October 1992 (RCL 1992, 2347), concerning regulation of the computerized processing of data of a personal nature.

ADDITIONAL PROVISIONS

First.–1. Deliveries of narcotic drugs to hospitals, clinics, health centres or residential centres without a pharmaceutical service shall be effected by the legally authorized body to which responsibility has been assigned for the supply of the stocks of medicines established in such institutions.

2. The requests referred to in the preceding paragraph shall be made using the special forms set out in annex III.

Second.–On the completion of outpatient treatment, any surplus medicine shall be returned to the pharmaceutical services of the respective Autonomous Community, it being permissible for such procedure to be carried out by the persons or institutions entrusted with the patient's care.

Third.–The present Order shall have the status of basic law under the provisions of article 149.1.16 of the Constitution and articles 2(2) and 85(4) of Law No. 25, of 20 December 1990, concerning Medicines. Articles 1(1), 6 and 7 shall be deemed to have the status of legislation on pharmaceutical products in accordance with articles 2(1) and 31(2) of Law No. 25, of 20 December 1990, on Medicines.

REVOKING PROVISION

The Order of 6 February 1962 (RCL 1962, 367 and NDL 12425, note), establishing provisions on the obtaining and dispensing of narcotic drugs by pharmacists, and any provisions of equal or lower status which are contrary to the provisions of the present Order, are hereby revoked.

FINAL PROVISION

The present Order shall enter into force sixty days following the date of its publication in the *Official State Gazette*, prescriptions modified in accordance with the provisions of this Order being allowed to coexist with those current at the time of its publication until 31 December 1994.

ANNEX IV

Technical specifications

Official narcotics prescription counterfoil books shall be produced in accordance with the following specifications:

(a) The cover printed in two inks, on coated paper with a weight of 150 grams/square metre;

(b) The counterfoil receipt voucher printed in one ink on white offset paper with a weight of 90 grams;

(c) 30 prescriptions, on self-copying paper, each consisting of an original (main part of the prescription) and a copy (instruction note to the patient); the original on white paper and the copy on green paper; printed in one ink;

(d) Prescription control sheet, in offset paper with a weight of 90 grams, printed in one ink;

(e) Size of prescription: 22 by 12 centimetres.

The counterfoil books shall be bound by means of gluing on the left-hand margin in order to make the prescriptions more easily detachable.

The prescriptions shall be numbered correlatively by means of printing and the counterfoil books shall bear a perforated number in the bottom right-hand corner.

The Ministry of Health and Consumer Affairs shall notify the Autonomous Communities issuing narcotics prescription counterfoil books of the requisite numbering sequence, which shall apply to the entire territory of the State.

The narcotics prescription counterfoil books issued by the Autonomous Communities shall be modified in accordance with the form given in annex I, without prejudice to differences of language and means of identification established in such books.