UNITED NATIONS

E/NL.1957/129
16 June 1958
ENGLISH
Original: SPANISH

LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF THE CONVENTION OF 13 JULY 1931 FOR LIMITING THE MANUFACTURE AND REGULATING THE DISTRIBUTION OF NARCOTIC DRUGS, AS AMENDED BY THE PROTOCOL OF 11 DECEMBER 1946

CHILE

Communicated by the Government of Chile

NOTE BY THE SECRETARY-GENERAL -- In accordance with Article 21 of the Convention of 13 July 1931 for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs, as amended by the Protocol of 11 December 1946, the Secretary-General has the honour to communicate the following legislative text.

NARCOTIC DRUG REGULATIONS

ORDER NO. 454, DATED 26 APRIL 1957, MADE BY THE MINISTRY OF PUBLIC HEALTH AND SOCIAL WELFARE

(Published in "Diario Oficial" No. 23791 of 10 July 1957)

HAVING CONSIDERED memorandum No. 591, dated 15 April 1957, of the Office of the Superintendent of Social Security; memorandum No. 5287, dated 4 March 1957, of the National Health Service; the provisions of Book IV, title I, of the Health Code and article 272 of the said Code; and the powers vested in me by article 72, paragraph 2, of the National Constitution, I hereby make the following

O R D E R

1. This Ministry's Orders No. 198 of 31 March 1936 and No. 1027 of 18 October 1954[1] are hereby repealed.

2. The following Narcotic Drug Regulations are approved:

SECTION I

Article 1. It shall be unlawful to produce, import, sell or distribute narcotic drugs other than those intended for the purpose of satisfying the medical and scientific needs of the country.

Article 2. The expression "narcotic drug" means:

(a) raw opium, medicinal opium and opium in galenical preparations;

(b) coca leaf;

(c) Indian hemp [cannabis],[2] its resin and galenical preparations;

(d) morphine and its salts, including those prepared directly from raw or medicinal opium which contain more than 20 per cent morphine;

(e) diacetylmorphine (heroin) and other esters and salts of morphine;

(f) dihydrohydroxycodeinone (oxycodone)[3] and its salts (eucodal); dihydrocodeinone (hydrocodone) and its salts (dicodid); dihydromorphinone (hydromorphone) and its salts (dilaudid); acetyldihydrocodeinone [thebacon] and its salts (acedicone); dihydromorphine and its esters; and the salts and ethers of any of these substances, and the esters thereof;

1/ Note by the Secretariat: E/NL.1955/47.

2/ Note by the Secretariat: The words in square brackets have been inserted by the Secretariat.

3/ Note by the Secretariat: Proposed or recommended international non-proprietary names of drugs are underlined.

(g) benzylmorphine and other ethers of morphine, and the salts thereof;

(h) methyldihydromorphinone /7-methyldihydromorphinone/ (metopon) and its salts;

(i) morphine-N-oxide (genomorphine) and its salts; l-3-hydroxy-N-methylmorphinan and its salts (dromoran) /levorphanol/ and morphine-N-oxy derivates; and morphine derivatives of pentavalent nitrogen;

(j) thebaine and its salts;

(k) methylmorphine (codeine); ethylmorphine (dionine) and its salts;

(l) cocaine and its salts, including preparations of coca leaf containing more than 0.1 per cent cocaine and crude cocaine;

(m) ecgonine and its esters and salts;

(n) 1-methyl-4-phenylpiperidine-4-carboxylic acid ethyl ester (pethidine) and its salts (dolantal and demerol);

(n') 4-(3-hydroxyphenyl)-1-methyl-4-piperidyl ethyl ketone or 1-methyl-4-metahydroxyphenyl-4-propionyl-piperidine (ketobemidone) and its salts;

(o) 4,4-diphenyl-6-dimethylaminoheptanone-3 or 6-dimethylamino-4;4-diphenyl 3-heptanone (methadone) and its salts (amidone, sin-algin);

(p) 4,4-diphenyl-6-morpholinoheptanone-3 or 6-morpholino 4; 4-diphenyl 3-heptanone (phenadoxone) and its salts (heptalgin);

(q) dihydrocodeine and its salts (paracodine);

(r) acetyldihydrocodeine and its salts;

(s) all pharmaceutical preparations (tablets, in granulated form, powders, pills, granules, injections, solutions, suppositories etc.) consisting of one or more of the substances enumerated above and an inert or other non-medicinal excipient or vehicle;

(t) all pharmaceutical preparations consisting of one or more medicinal substances which contain more than 5 grammes per thousand of dihydrocodeinone /hydrocodone/, 1 gramme per thousand of cocaine and 2 grammes per thousand of morphine or of any other narcotic drug mentioned in paragraphs (b), (f), (g), (h), (i), (j), (m), (n) and (p).

Article 3. The definitions contained in the International Conventions signed in 1925 and 1931 and in the Protocol of 1948 shall be adopted in respect of the substances mentioned in paragraphs (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (p), (q) and (r) of the foregoing article.

The expression "pure drug" means the anhydrous base; the equivalents shall be those laid down by the Permanent Central Opium Board.

Article 4. The Director-General of the National Health Service may, by an order to that effect, add any new drug or preparation of similar therapeutic action to those enumerated in article 2 of these Regulations.

Any such order shall be published in the "Diario Oficial".

Article 5. The manufacture, import and sale of heroin /diacetylmorphine/, of its salts and of preparations containing it, of ketobemidone (1-methyl-4-metahydroxyphenyl-4-proprionyl-piperidine) /4-(3-hydroxyphenyl)-1-methyl-4-piperidyl ethyl ketone/, of its salts and preparations, and of Indian hemp (cannabis sativa), of its resin and all its preparations, are prohibited.

Opium for smoking shall not be included in opium for quasi-medical purposes or in opium intended for medical or scientific use.

The import and distribution of coca leaf for chewing are prohibited.

Article 6. Thebaine, codeine, dionine /ethylmorphine/ and the salts thereof shall be subject only to the provisions concerning import, production and transit laid down in these Regulations. Importers who deliver these substances to the establishments mentioned in article 11 shall, however, comply with the provisions governing the supply of narcotic drugs to such establishments.

SECTION II

Article 7. The production of narcotic drugs shall not be lawful unless carried on in lawfully established pharmacies, laboratories, druggists' shops with a laboratory annex and plants manufacturing medicinal products.

The following provisions of this section shall affect only the extraction and manufacture of narcotic drugs, in the pure state, the compounding of pharmaceutical preparations with narcotic drugs being governed by the provisions of section V.

Article 8. The owner of any of the establishments mentioned in the previous article who proposes to obtain raw opium or crude cocaine or to manufacture by any means whatsoever one or more of the narcotic alkaloids of opium or coca or derivatives of such alkaloids shall not carry on such operations except with the express authorization of the Director-General of Health, who shall, on the application of the parties concerned, specify, before 1 June of each year, the quantity of each narcotic Drug to be extracted or manufactured.

Article 9. Any person or firm authorized to extract or manufacture one or more of the products mentioned in the previous article shall keep at the disposal of the health authorities a daily register in which shall be entered: (a) the quantity and source of narcotic raw materials entering the establishment; (b) the quantity of narcotic drugs manufactured with such raw material and the quantity sent out, with particulars of the name and address of the consignee; and (c) the respective daily balances.

Article 10. The persons mentioned in article 9 shall report the undermentioned particulars to the Directorate-General of the National Health Service within the first sixty days of each year, by a communication to be delivered by hand or by registered post: (a) the total quantity of narcotic raw materials brought into the establishment and the balance in hand on the day on which the particulars are reported, and (b) the total quantity of each narcotic drug extracted or manufactured during the same period and the balance in hand on the day on which the particulars are reported.

SECTION III

IMPORTS

Article 11. The right to import narcotic drugs shall be reserved, subject to the limitation hereinafter specified, to druggists, pharmacies, laboratories and agencies for pharmaceutical products, on condition that they hold certificates issued by the Director-General of the National Health Service authorizing them to acquire the said drugs, and on condition, furthermore, that they can produce a permit issued by the said Director-General, relating to the particular case, authorizing them to withdraw the drugs from the Customs.

The importation of narcotic drugs shall be authorized as specified hereunder:

(a) class I druggists and pharmacies shall be authorized to import any narcotic drugs, in the pure state or in the form of any pharmaceutical preparation;

(b) class II druggists shall be authorised to import any narcotic pharmaceutical preparation, but not the drug in the pure state;

(c) laboratories shall be authorised to import the narcotic drugs which they require for the manufacture of their products; and

(d) agencies for pharmaceutical products shall be authorised to import, in the original packing, the narcotic drugs manufactured by the firms they represent.

Article 12. Subject to the consideration that the importation of narcotic drugs is to serve the purpose exclusively of satisfying the medical and scientific needs of the country, the Director-General of the National Health Service shall specify the quantity of narcotic drugs which each importer may import during any one year, and for this purpose the parties concerned shall submit, in the month of November preceding the year in question, applications stating the quantities they wish to import. In reaching his decision, the Director-General shall take into account the national production and also the qualifications, commercial repute and past history of the applicant.

Article 13. Any certificate issued which authorizes the acquisition of narcotic drugs abroad shall be valid for a period of four months from the date of issue, and the importation into the country must take place in any case, within a maximum period of six months from the aforesaid date.

If for any reason whatsoever the narcotic drugs acquired are not withdrawn from the Customs within the maximum period laid down in the foregoing paragraph, the parties concerned may, within thirty days of the expiry of the said period, apply to the Director-General of the National Health Service for special permission to import the same, such permission not to be granted except for good and sufficient reasons, and in the absence of such reasons the said Director-General shall order the seizure of the narcotic drugs.

Article 14. It shall not be lawful to import narcotic drugs except through the following Customs posts: Arica, Iquique, Antofagasta, Valparaiso, Talcahuano, Magallanes, Los Andes, and the postal and air Customs of Santiago.

The Director-General of the National Health Service may, if special circumstances so require, designate other Customs posts for such imports.

Article 15. For the purposes of import control, the quantity or quantities of narcotic drugs specified in the permit authorizing their withdrawal from the Customs shall (except in the cases referred to in the next paragraph) be deemed to be the quantity or quantities received by the importer.

If for any reason whatsoever the importer does not receive the narcotic drugs in the quantities authorized, he shall within three days inform the health authorities to that effect and shall produce the necessary evidence to show why he should not be held responsible for the loss or partial loss. In addition, the Directorate-General of the National Health Service may demand any further particulars or explanations which are necessary for the purposes of the investigation.

If the importer does not comply with the terms of the foregoing paragraph, he shall be punishable as a clandestine dealer in narcotic drugs.

Article 16. In the druggists' shops, pharmacies and similar establishments which possess narcotic drugs, the said drugs shall be kept in cabinets or rooms under lock and key.

It shall not be lawful without the permission of the Directorate-General of the National Health Service to keep in a private residence any quantity of narcotic drugs which forms part of the stocks of the establishments mentioned in the foregoing paragraph.

SECTION IV

ACQUISITION OF NARCOTIC DRUGS WITHIN THE COUNTRY

Article 17. The establishments mentioned in article 11 may supply each other with narcotic drugs, subject to the limitations specified in that provision.

DELIVERY OF NARCOTIC DRUGS AND USE IN COMPOUNDING OF PRESCRIPTIONS AND OTHER PHARMACEUTICAL PREPARATIONS

Article 18. It shall not be lawful for any such establishment as aforesaid to deliver narcotic drugs to another except on a request signed by the pharmaceutical chemist in charge and with the prior permission of the National Health Service. Such permission shall be given in triplicate, one copy remaining in possession of the Service and one in the possession of each of the parties concerned.

The person making the request shall acknowledge receipt of the narcotic drug by a receipt which shall, vis à vis the health authorities, constitute proof of delivery.

Article 19. Pharmacies shall not deliver narcotic drugs except on a medical prescription signed by one of the qualified persons mentioned in article 21.

Such narcotic drugs may be prescribed only in the form of proprietary pharmaceutical preparations registered with the National Health Service, in the form of official or magistral prescriptions and in the maximum concentrations established by the Director-General of the aforementioned Service.

Injectable solutions of narcotic drugs may be issued only in ampoules of not more than 2cc. They may not be issued in vials or in vial-ampoules.

Narcotic drugs shall not be prescribed in the pure state, this provision being subject to an exception in the case of cocaine which is required by a dentist for personal administration in the course of his profession, in conformity with the provisions of article 21 (f).

Article 20. Duly authorized private clinics, maternity nursing homes and policlinics without a pharmacy may not obtain narcotic drugs from any source other than druggists, pharmacies or agencies for medical products, for which purpose an order given by the regional head of the National Health Service on the application of the medical director of the establishment in question shall be necessary.

Article 21. Prescriptions in which one or more narcotic drugs are prescribed shall, provided that they fulfil both the general and the special requirements of this Order, be issued only on the following conditions:

(a) They shall specify, in all cases, the full name and address of the medical practitioner, his signature and his number in the college register, and, in addition, the place and date of issue.

Prescriptions shall be valid for dispensing in pharmacies from the date of issue for a maximum of ten days, and thereafter shall be invalid.

(b) On each form shall be recorded the quantity of narcotic drugs prescribed for the particular patient in a period of not more than ten days previously. The practitioner shall also clearly show in figures and in writing the total dosage to be dispensed in the pharmacy and also each single dose or the intervals of its administration.

(c) If the dosage prescribed is greater than the maximum single or daily dosage indicated in the National Pharmacopoeia or established by the Director-General of the National Health Service, the practitioner shall indicate this particular by duplicate signature and state the name and address of the patient. In such cases, the pharmacist shall satisfy himself as

to the identity of the person accepting delivery of the drug by requiring particulars of the name and the production of the identity card of the said person and require him to endorse the prescription form.

(d) Narcotic drugs may be prescribed only by registered medical practitioners, on the official narcotic drug prescription form, which will be prepared and distributed by the National Health Service at the official price. Pharmacies must have such forms available for emergency cases, in which the prescription shall be made out in duplicate and the original sent to the regional chief of the National Health Service within a period of forty-eight hours.

(e) In cases of extreme urgency, the medical practitioner may prescribe injectable morphine without using the official prescription form, in a quantity not exceeding the maximum single dose (0.02 grammes). Pharmacists are authorized to dispense such prescriptions, provided that the same particulars are given therein as in the official prescription form, and they must satisfy themselves as to the identity of the person accepting delivery of the drug.

(f) Registered dentists may obtain powdered cocaine for professional use, on the order of the regional chief of the National Health Service.

(g) Registered veterinary surgeons who are owners or directors of veterinary hospitals may obtain narcotic drugs on the order of the respective regional chief of the National Health Service.

Article 22. In the case of prescriptions for narcotic drugs to be dispensed in pharmacies, establishments or medical services belonging to State institutions or bodies the provisions concerning official forms laid down in article 21 (d) shall not apply.

Article 23. Each prescription for narcotic drugs, other than the substances mentioned in article 6, shall be dispensed once only and for the total dosage prescribed. It shall not be repeated, even if so ordered by the practitioner making the prescription.

Article 24. A stamped copy of every prescription for narcotic drugs shall be delivered and the original shall be filed in serial order according to its date. The receipts mentioned in the second paragraph of article 18 shall be filed in like manner by the supplier.

Article 25. Each druggist's shop, pharmacy, laboratory and, in general, each establishment authorized to deliver narcotic drugs or use them in the compounding of prescriptions, galenical preparations or proprietary medicaments shall keep a narcotic drugs register in conformity with article 22 (b) of the Regulation concerning Pharmacies, Druggists' Shops and Similar Establishments. In the said register a suitable number of pages shall be used for entries giving particulars of incoming supplies, use, outgoing supplies and balances in respect of each of the substances and preparations mentioned in article 2 and the additional substances specified under article 4 of these Regulations.

Article 26. The entries mentioned in the previous article shall be made on the day on which the operation or transaction to which they relate occurs, and on the appropriate page the following particulars shall be noted:

(1) Incoming supplies: date of receipt, quantity and name and address of the establishment from which the supplies are received;

(2) Delivery to other establishments: date of dispatch, quantity, and name and address of the establishment to which the narcotic drug is supplied;

(3) Delivery on prescription or order:

(a) Date dispensed;

(b) Quantity of narcotic drugs issued or used in the prescription;

(c) Corresponding number of prescription or order in prescription register;

(d) Name, address and registration number of prescribing doctor, dentist or veterinary surgeon;

(e) Balance of drugs and preparations;

(4) Use in compounding of galenical and proprietary preparations: date of compounding, quantity used and name of preparation in which narcotic drug has been used. The manufactured substance must be entered among incoming supplies on the corresponding page if the preparation comes within the terms of articles 2 and 4.

Article 27. Independent laboratories of pharmacies which manufacture pharmaceutical preparations not included among narcotic drugs proper but containing one or more of such drugs shall also enter the quantities manufactured and the outgoing supplies of such drugs in the manner laid down in article 26 (1), (2) and (4) of these Regulations.

Pharmacies which manufacture in their laboratories the preparations mentioned in the previous paragraph shall also enter the quantities manufactured.

The Director-General of the National Health Service may, if circumstances so require, direct that the name and address of the person to whom the preparation is delivered shall be recorded by the pharmacy.

Article 28. Dentists shall enter in a special register particulars of the way in which they have utilized cocaine obtained by them under article 21 (f) of these Regulations.

Veterinary surgeons and directors of veterinary hospitals shall record in a similar register the prescriptions containing narcotic drugs dispensed to them for use in the treatment of animals and in each case the quantities used, the species of animal on which used and the name and address of the owner of the animal shall be noted.

The medical directors of private clinics, maternity nursing homes and policlinics shall enter in a special register, paged and stamped by the National Health Service, the quantities of narcotic drugs acquired by them in conformity with article 20, with particulars of the utilization of the said drugs, the quantities administered to patients, the names and addresses of the patients, and the date of administration. The said register shall be kept up to date and may be inspected by the health authorities.

Article 29. Any establishment which delivers narcotic drugs to another shall submit to the competent regional chief of the National Health Service within the first fortnight of each month, by hand or by registered letter, detailed lists of the narcotic drugs it has dispatched during the previous month.

The lists mentioned in this article shall in turn be forwarded by the regional chiefs to the Directorate-General in the second fortnight of the month in which they were received.

Pharmacies shall likewise report to the regional chief of the National Health Service particulars of the issue of narcotic drugs in dosages greater than the single or daily maximum mentioned in article 21 (c). These particulars must be reported monthly.

Article 30. For the purposes of the calculation of the consumption of narcotic drugs in the country and of the number of permits required for their annual production and import, pharmaceutical establishments shall, within the first fortnight of each year, report to the regional chief of the National Health Service, by hand or by registered letter, the balance of their stocks of such substances on 31 December of the previous year.

The regional chief shall in his turn forthwith report the statistical data received to the Directorate-General of the National Health Service, with particulars of the names of the establishments which have not complied with this provision.

Article 31. It shall not be permissible to export narcotic drugs except such as are produced in the country in excess of the medical and scientific needs of its population, and except such as are, for some unforeseen reason, regarded as unnecessary for the purpose of satisfying the said needs.

Article 32. The export of narcotic drugs shall not be lawful except in so far as effected by pharmacies, druggists shops, laboratories and firms manufacturing medicinal products with the express permission (licence) of the Directorate-General of Health. For the purpose of any such export, the exporter shall first be required to produce evidence to show that the consignee has been authorized by the competent authorities of the importing country to acquire the product in question.

It shall not be lawful to export narcotic drugs except through the Customs posts mentioned in the first paragraph of article 14 of these Regulations, and, in each case the exporter shall be required to produce the appropriate licence granted by the Director-General of Health.

The Customs authority shall record the dispatch of the narcotic drugs to destinations abroad and shall communicate this fact to the Directorate-General of the National Health Service.

An export licence shall cease to be valid if not used within a period of six months.

Article 33. Narcotic drugs in transit through the territory of the Republic must not enter the country except at the Customs posts mentioned in article 14, and evidence shall be produced to the Customs authority concerned showing that the export of the drugs in question was authorized by the country of origin.

The Customs Department shall in each case report to the Directorate-General of Health particulars concerning the arrival and subsequent onward shipment of all narcotic drugs passing through the national territory in transit and shall likewise report any substitution or diminution in quantity which may, for any reason whatsoever, have occurred in transit.

Article 34. In no case shall the Customs authorities of the Republic be competent to authorize the import of narcotic drugs which are in transit to another country.

SECTION VII

SPECIAL PROVISIONS

Article 35. The owner and manager of any agency for pharmaceutical products, laboratory or firm manufacturing medicinal products shall be subject to the responsibilities which article 35, paragraph 2, and article 71 of the Regulations governing pharmacies, Druggists' shops and similar Establishments impose upon the owner and manager of any pharmacy and druggists' shop in the matter of the control of incoming and outgoing movements of narcotic drugs.

The owner or person in charge of the establishment, together with the pharmaceutical chemist who takes over the management shall, when the latter assumes his functions, verify the balances of narcotic drugs and enter in the register of narcotic drugs under their respective signatures the correctness of such balances or any discrepancies noted.

The owner or persons in charge of the establishment, together with the pharmaceutical chemist who is surrendering the management shall, when the latter ceases to perform his functions, verify in the manner prescribed in the previous paragraph the balances of narcotic drugs and enter in the register of such narcotic drugs under their respective signatures the correctness of those balances or any discrepancies noted.

Article 36. Educational institutions at the university level may import, in conformity with the rules laid down in these Regulations, the narcotic drugs which they require for scientific purposes, and may also acquire such drugs within the country, with the permission in each case of the Director-General of Health. In all cases they shall keep a register in which

they shall enter particulars of the drugs acquired and of their utilization. The Director-General of Health may, in addition, in cases where he is satisfied that it is proper to do so, permit scientific or industrial research workers to acquire in the country narcotic drugs for the carrying out of specific experiments, the said research workers being required to account to the Director-General for the use of such narcotic drugs.

Article 37. Any contravention of the provisions of these Regulations shall be punishable under Book IV, title VI, of the Health Code.

For the purposes of the application of articles 313 and 314 of the Penal Code, the narcotic drugs mentioned in article 2 of these Regulations shall be deemed to be products "harmful to health" within the meaning of the said provisions of the Penal Code.

Article 38. The Director of the National Health Service shall require the modification or exclusion of the narcotic drug content of proprietary medicines in any case in which sufficient evidence of its therapeutic action is not produced.

Applications for the registration of proprietary medicines containing narcotic drugs shall first be investigated by the Permanent Narcotic Drugs Committee of the National Health Service and then transmitted to the Proprietary Medicines Committee; the Director-General shall give the final ruling on the acceptance or rejection of such applications.

Article 39. Without prejudice to the provisions of these Regulations, the Director-General of the National Health Service shall have power to issue, by departmental order, special instructions governing the acquisition and dispensing of narcotic drugs in National Health establishments and in others with delegated functions.

TRANSITIONAL ARTICLES

Sole Article. This Order shall come into force thirty days after its publication in the "Diario Oficial."

Approved for publication etc.

C. Ibañez C. - Roberto Muñoz Urrutia -