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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

ROMANIA

Communicated by the Government of the People's Republic of Romania

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 texts.

DECREE NO. 227

OF THE PRESIDIUM ON THE REGULATION OF THE USE OF NARCOTIC DRUGS

The Presidium of the Grand National Assembly of the People's Republic of Romania.

In pursuance of Article 44 (2) and Article 45 of the Constitution of the People's Republic of Romania;

Having regard to Decision of the Council of Ministers, No. 958 of 7 September 1950;

Hereby enacts the following :

Decree No. 227 on the Regulation of the Use of Narcotic Drugs

Article 1

The following products and substances shall be subject to the narcotic drugs regulations established by the present Decree:

(a) opium, coca leaves and hashish [cannabis] 1/ and their preparations in any form and their active elements and derivatives;

(b) all natural or synthetic substances having similar effects;

(c) proprietary preparations containing these substances;

(d) officinal and magistral preparations containing these substances;

(e) synthetic preparations and products having similar effects and consequences, which exist at present or which may be developed in future.

The annexed list, which forms an integral part of this Decree, enumerates all the products, substances and proprietary preparations which are subject to the narcotic drugs regulations. The list may be supplemented or amended by decision of the Ministry of Health.

1/ Note by the Secretariat: The word in square brackets has been inserted by the Secretariat.

Article 2

The substances referred to in article 1 may be manufactured, imported, stored, sold or held, and plants containing the said substances may be grown for industrial purposes only by State undertakings and public health economic units, with the authorisation of the Ministry of Health.

Article 3

Pharmacies may use the products and substances referred to in article 1 in accordance with the official pharmacopoeia of the People's Republic of Romania.

The requirements to be satisfied by substances not described in the pharmacopoeia shall be established by the Institute of Pharmaceutical Research.

Article 4

The undertakings and public health economic units referred to in article 2 may distribute the products and substances referred to in article 1 only through pharmaceutical units.

Article 5

Pharmaceutical units may dispense the products and substances referred to in article 1 only on the prescription of a medical or veterinary practitioner duly licensed to practise.

In prescribing narcotic drugs, medical practitioners shall use a form bearing the stamp of the Health Section of a District People's Council or of the People's Council of a town assimilated to a district.

Article 6

Medical prescriptions referring to the products and substances mentioned in article 1 shall indicate the doses and quantities, which must be stated in both figures and words.

Such prescriptions shall not be repeated. They shall be kept by the pharmacy as vouchers for one year and shall not be destroyed until they have been duly checked.

Article 7

Medical practitioners and dentists duly licensed by the Ministry of Health to practise medicine or dentistry and veterinary practitioners may obtain the narcotic products or substances necessary for the practice of their profession, in accordance with articles 5 and 6 of the present Decree, subject to conditions to be established by the Ministry of Health. The said products and substances shall be obtained from a single pharmacy situated near the place of practice, which shall be determined in each case by the Health Section of the competent People's Council.

Article 8

The undertakings and units referred to in article 2 shall submit to the Pharmacies and Medicaments Department of the Ministry of Health in January each year a statement showing the incomings, outgoings and balances of stocks of the products and substances referred to in article 1, for the preceding year.

Article 9

Any infraction of the foregoing provisions shall be punished in conformity with article 382 of the Penal Code.

Article 10

Infractions covered by the present Decree shall be established and investigated by the authorities of the Militie (gendarmerie) and of the Office of the Public Prosecutor.

It shall be the duty of the Ministry of Health and of the Health Sections of People's Councils and agencies of the Ministry of Finance at frontier points, ports and airports to report any infractions to the local branch of the Militie or Office of the Public Prosecutor and, as specialised technical agencies, to assist in the preparation of the official report on the establishment and investigation of the facts.

Article 11

In criminal proceedings instituted for infractions covered by the present Decree, the Ministry of Health and the Health Section of the People's Council within whose district the competent People's Court is situated shall be joined in the action as civil parties by the legal office of the respective People's Council, which shall give notice thereof to the Ministry of Health and the Health Section of the People's Council in whose area the infraction was committed.

Article 12

The Ministry of Health shall determine, by way of decisions and orders, the cases in which pharmacists may dispense certain preparations containing the substances referred to in article 1, the quantities of the said substances which may be held by medical practitioners and dentists, the obligations incumbent upon the undertakings and units mentioned in article 2 and the rules for the application of the present Decree.

Article 13

The Act to combat the abuse of narcotic drugs, of 25 April 1928, the Regulations for the State monopoly of narcotic drugs, of 24 July 1933, and all provisions inconsistent with the present Decree are hereby abrogated.

Done in Bucharest on 7 September 1950

C.I. Parhon

Dr. V. Mirza
Minister of Health

Marin Florea Ionescu

Stelian Nitulescu
Minister of Justice

List annexed to the Decree on the Regulation of the use of Narcotic Drugs.

Raw opium
Medicinal opium
Opium in all forms containing 0.2% morphine
Morphine and its salts
Diacetylmorphine (Heroin) and its salts
Coca Leaves
Crude Cocaine
Cocaine and its salts
Cannabis Indica
Cannabis Indica in the form of galenic preparations (extracts and tinctures)
Resin of Cannabis Indica (Hashish)
Laudanum
Dihydrohydroxycodeinone /Oxycodone/ 2/ (Eucodal) in all forms
Dihydrocodeinone /Hydrocodone/ (Dicodide) in all forms
Acetyldihydrocodeinone /Thebacon/ (Acedicon)

2/ Note by the Secretariat: The words in square brackets have been inserted by the Secretariat. Proposed or recommended international non-proprietary names of drugs are underlined.

7-methyldihydromorphinone (Metopon)
1-methyl-4-phenylpiperidine-4-carboxylic acid ethyl ester (Dolantine, also known as Dolosal, Demerol, S.140, D.140, Pethidine, Dolantol) in all forms
Benzedrine - phenylisopropylamine: sulphate, known as Ortedrinae, Amphetamine, Orforin, Phenedrine; phosphate, known as Actemine or Aktedol
Phenylisopropylmethylamine or Methyl Amphetamine, known as Methedrine, Pervitine or Estimulex
Totoponal-Methyldihydromorphine
Valbine - Dihydrooxycodeinone hydrochloride and a barbiturate /Oxycodone hydrochloride/
Borocaine in tablets
Dilauden in vials
Dilauden-atropine in vials
Dilauden-Scopolamine in vials
Pentazol D. solution
Scopomorphine in vials
Dilaudid in all forms /Hydromorphone/
Acetylcodone or Acetyldihydrocodeine hydrochloride
Methadone or Amidone

E/NL.1957/37

DECISION No. 116086/1950

Establishing Rules for the Application of Decree No. 227 of 7 September 1950 3/ on the Regulation of the use of Narcotic Drugs

The Minister of Health, having regard to article 12 of Decree No. 227 of 7 September 1950 on the regulation of the use of narcotic drugs, DECIDES as follows:

Article 1

Only the Ministry of Health, acting through the Pharmacies and Medicaments Department shall be authorized to issue to State undertakings and economic and public health units licences to import, cultivate, manufacture, store, hold and sell narcotic products and substances.

All licences issued before the publication of the present decision are hereby cancelled.

All the said undertakings and economic and public health units must apply for new licences within thirty days from the date of publication of the present Decision, with the exception of pharmacies of all categories, since they do not need a licence.

The holder of such a licence shall, on the cessation of his activity relating to narcotics, return the licence to the Ministry of Public Health, Pharmacies and Medicaments Department, within 30 days.

Article 2

Undertakings and economic and public health units may use as finished narcotic products and substances only those which satisfy the conditions set out in the Pharmacopoeia of the People's Republic of Romania now in effect.

The conditions which must be satisfied by products and substances not listed in the Pharmacopoeia of the People's Republic of Romania in effect shall be communicated by the Institute of Pharmaceutical Research by publication in the Bulletin of the Ministry of Health.

Article 3

Authorized stores and producing units shall accept narcotic drugs only after analysis by an official laboratory.

3/ Note by the Secretariat: E/NL.1957/36.

Stores shall issue narcotic drugs to pharmaceutical units in packing bearing a guarantee label showing the name of the store, the number and date of the analysis certificate and the name of the laboratory which performed the analysis.

Article 4

Narcotic drugs shall be kept as follows:

(a) Stores and factories shall set aside a special room or at least part of a room so arranged that stocks of narcotic drugs can be kept under lock and seal and quantities intended for current use under lock only.

(b) Pharmaceutical units of all categories shall keep the said drugs in special closed cabinets or drawers, marked with the skull and crossbones and the word "Venena". The cabinets in the store rooms of pharmaceutical units which keep reserve stocks of such medicaments shall be sealed after each addition to or withdrawal from the stocks.

(c) In medical and dental surgeries of all categories narcotic drugs shall be kept under lock and key.

In all the aforementioned units narcotic drugs shall be arranged in the respective cabinets in accordance with the instructions contained in Circular No. 30747 of 17 March 1950, published in Bulletin of the Ministry of Health No. 16 of 1 April 1950.

Article 5

One person in each factory, store and pharmaceutical unit shall be made responsible for storing, handling and keeping the records of narcotic drugs.

Narcotics shall be handled with the greatest care, by using utensils intended solely for this purpose and kept separately.

These utensils shall be washed separately from other recipients.

Article 6

In factories and stores recipients of metal, glass, crockery, terracotta, or bakelite shall be used as containers for narcotics in quantities exceeding 10 gr. with the exception of hydroscopic drugs, for which special packing shall be provided.

Quantities of less than 10 gr. may also be packed in sacks lined with waxed paper without folds.

Each package shall be provided with -

(a) a guarantee label bearing the name of the factory or store, the number and date of the analysis certificate and the name of the laboratory which performed the analysis.

(b) a label showing the name of the product, the quantity, the word "poison" and the skull and crossbones.

This label shall be signed by the packer.

Article 7

For each consignment of narcotic drugs from a factory or store the responsible person or his authorized agent shall exercise personal supervision to ensure that the packing conforms with the regulations and to check the documents accompanying the consignment, and shall sign a copy of the invoice kept by the store.

Pharmaceutical units shall issue narcotic drugs only on the basis of a medical prescription exhibiting the name and address of the medical practitioner, the name, diagnosis and address of the patient, and the stamp affixed by the Health Section of the local People's Council.

The Health Sections of the local People's Councils shall maintain records of prescriptions approved in accordance with the instructions issued in Circular No. 70135 of 13 June 1950 published in Bulletin of the Ministry of Health No. 28 of 13 July.

This rule shall not however apply to the issue of narcotic drugs for patients in hospitals, in which case the said drugs shall be issued by the hospital pharmacy on the basis of the medical prescriptions register.

The administration of narcotic drugs to patients in hospitals shall be carried out under the direct supervision and responsibility of the medical practitioner.

All medical prescriptions containing narcotic drugs shall be written legibly in ink.

The quantity shall be stated in figures and words. The medical practitioner shall also state on the prescription the directions for use and the date.

Pharmacists shall sign all medical prescriptions containing narcotic drugs which they prepare.

Pharmaceutical units shall not issue on a single prescription a quantity of narcotic drugs exceeding the maximum doses for three days even if the medical practitioner adds the notation "sic-volo".

If the patient is unable to pay for the prescribed dose the pharmacy may dispense the prescription in instalments, noting on the prescription the quantities delivered and the respective dates.

Pharmacies may issue without a prescription only -

- Pulvis Doveri 3 gr
- T-ra Anticholerina 10 gr

In such cases the quantity, the date and the name and address of the patient shall be recorded in the prescription transcription ledger.

Article 8

Factories, stores and pharmacies of all categories shall keep records of the consumption of narcotic drugs in a standard ledger, in which all the operations effected shall be entered daily. Until such time as the standard ledger for narcotic drugs records is available, all the units aforementioned shall keep a record book in accordance with Circular No. 70137 of 13 June 1950 published in Bulletin of the Ministry of Health No. 26 of 19 June 1950.

Orders and invoices for narcotic drugs shall be made out separately from other orders and invoices.

All documents relating to incomings and outgoings of narcotic drugs shall be kept by the person responsible for narcotic drugs and in a manner ensuring complete security.

Prescriptions for narcotic drugs shall be kept at the pharmacy as vouchers until they have been checked by the special agent of the Ministry of Health.

State and private pharmacies serving the public shall underline in coloured pencil the narcotic drugs entered in the prescription transcription ledger.

Copies of prescriptions held by pharmacies shall be issued at the request of the patient.

Article 9

The surpluses or deficiencies found in stocks of narcotic drugs shall be noted in a statement prepared in triplicate; this statement shall be signed by the staff of the unit, and shall include an explanation of the discrepancies.

One copy shall be forwarded to the Ministry of Health, Pharmacies and Medicaments Department, one shall be forwarded to the superior administrative body and one shall be kept for recording and conservation in the archives of the unit.

Article 10

Medical and veterinary practitioners may keep in their offices a maximum of ten phials of narcotic drugs, as follows:

- not more than five phials containing 0.02 g of morphine and five phials of other narcotic drugs.
- stomatologists and dentists may possess cocaine in phials or in solution containing a total of not more than 0.25 g.

An exception is made in the case of ear, nose and throat specialists, who may keep up to 2.5 g of cocaine in substance.

Medical and veterinary practitioners and dentists who procure medicaments containing narcotic drugs for their surgeries shall keep an account of the consumption thereof in a record book approved by the Health Section of the People's Council, in which the quantity, the name and address of the patient and the date on which the narcotic drug was administered shall be recorded.

Article 11

The control of the manufacture, importation, storage, possession, sale and use in any form of narcotic drugs shall be effected by the Ministry of Health through agencies designated for that purpose.

Dr. Mîrza Vasile
Minister of Health

E/NL.1957/38

THE COUNCIL OF MINISTERS OF THE PEOPLE'S REPUBLIC OF ROMANIA

DECISION No. 1178/1954

Concerning the Communication of Certain Data on the Importation, Use and Distribution of Narcotic Drugs

The Council of Ministers of the People's Republic of Romania

DECIDES:

Article 1

The Ministries, institutions, organizations and economic undertakings of the State, public and co-operative organizations and People's Councils which use or distribute the narcotic drugs mentioned in the annexed list, which forms an integral part of the present Decision, shall communicate to the Pharmaceutical Directorate-General of the Ministry of Health each year returns of incomings and consumption of the said narcotic drugs.

The returns for each year shall be submitted not later than 31 January of the following year.

Article 2

The Ministry of Foreign Trade shall report to the Ministry of Health, Pharmaceutical Directorate-General, all quantities of the products referred to in article 1 which are imported or exported, together with a copy of an itemized list of the said products, not later than ten days after the date of importation or exportation.

Article 3

The Ministry of Health shall be the only authorized importer of the products listed in the Annex and shall distribute them to users in the country.

Article 4

For the purpose of the application of international conventions on narcotic drugs the establishment is hereby approved, as from 1 July 1954, of a Narcotic Drugs Section under the Ministry of Health, Pharmaceutical Directorate-General, within the manning table and the salaries and wages budget of the Ministry of Health for 1954.

Article 5

Within thirty days from the date of the present Decision, the Ministry of Foreign Trade, the Ministry of Foreign Affairs and the Ministry of Health shall issue joint instructions for its application.

No. 1178/16 July 1954

LIST OF NARCOTIC SUBSTANCES AND PRODUCTS

1. Raw opium;

2. Medicinal opium;

3. Coca leaves;

4. Indian hemp [Cannabis] [4/] in the form of galenical preparations (extracts and tinctures);

5. Resin of Indian hemp (hashish) [Cannabis];

6. Morphine and its salts;

7. Diacetylmorphine (Diamorphine, Eclorion, Heroin) and other esters (ether salts) of morphine and their salts;

8. Crude cocaine;

9. Cocaine and its salts;

10. Dihydrohydroxycodeinone (Oxycodone) and its salts (Boncodal, Cardanon, Dinarcon, Eucodal, Hydrolaudine, Narcobasina, Nucodan, Ocytonargenol, Oxicon, Percodan, Pronarcin, Scophedal, Tebodal);

11. Dihydrocodeinone (Hydrocodone, Dicodide) and its salts (Codinovo, Diconone, Hycodan, Hydrocodin, Multacodin, Nyodid, Orthoxicol, Padrina, Ydrocod);

12. Dihydromorphinone (Hydromorphone) and its salts (Dilaudide, Dimorphid, Laudacon, Novolaudon);

13. Acetyldihydrocodeinone or acetyldemethylodihydrothebaine [Thebacon] and its salts (Acedicon, Novocodon);

14. Dihydromorphine and its salts (Paramorfan);

15. Dihydrodesoxymorphine (Desomorphine) and its salts (Permonid, Scopermid);

16. 7-methyldihydromorphinone (Metopon) and its salts;

17. Esters and salts of each of the seven preceding substances and of their esters;

18. Morphine-N-oxide (Genomorphine), also the morphine-N-oxide derivatives, and the other pentavalent nitrogen morphine derivatives;

19. Ecgonine and its salts as well as esters of ecgonine and their salts;

20. Thebaine and its salts;

21. Benzylmorphine and its salts (Peronine);

22. Methylmorphine (Codeine) and its salts;

23. Ethylmorphine and its salts (Dionine);

24. β-4-morpholinylethylmorphine) (Pholcodine) and its salts (Homocodeine, Hybernyl);

25. N-allylnormorphine (Nalorphine, Nalline);

4/ Note by the Secretariat: The words in square brackets have been inserted by the Secretariat. Proposed or recommended international non-proprietary names of drugs are underlined.

26. 1-methyl-4-phenylpiperidine-4-carboxylic acid ethyl ester (Pethidine, Demerol, Dolantal, Dolisan, Isonipecaine) and its salts (Antiduol, Biphenal, Centralgin, Dispadol, Dodonal, Dolantin, Dolantol, Dolaren, Dolarin, Dolatol, Dolental, Dolinal, Dolisina, Dolopethin, Dolosal, Dolsin, Dolvanol, Eudolat, Felidin, Gratidina, Meperidine, Mephedine, Pantalgine, Piridosal, Precedyl, Sauteralgyl, Suppolosal);

27. 4-(3-hydroxyphenyl)-1-methyl-4-piperidyl ethyl ketone or 1-methyl-4-metahydroxyphenyl-4-propionyl-piperidine (Ketobemidone) and its salts (Cliradon, Ketogan);

28. 1-methyl-4-(3-hydroxyphenyl)-piperidine-4-carboxylic acid ethyl ester or 1-methyl-4-metahydroxyphenylpiperidine-4-carboxylic acid ethyl ester (Hydroxypethidine, Bemidone) and its salts;

29. α-1,3-dimethyl-4-phenyl-4-propionoxypiperidine (Alphaprodine, Nisintil) and its salts (Nisentil);

30. β-1,3-dimethyl-4-phenyl-4-propionoxypiperidine (Betaprodine) and its salts;

31. 4,4-diphenyl-6-dimethylaminoheptanone-3 or 6-dimethylamino-4,4-diphenyl-3-heptanone) (Methadone, Amidone, Amidosan, Depridol, Diaminon, Dianone, Dolafin, Dolamid, Dolcsona, Dolophine, Dorexol, Heptadol, Heptanal, Hoechst 10820, Ketalgin, Mepecton, Miadone, Moheptan, Polamidon, Sin-algin, Symoron, Turanone) and its salts (Adanon, Algidon, Algolysin, Butalgin, Heptadon, Levadone, Mecodin, Mephenon, Physeptone, Physopeptone);

32. 4,4-diphenyl-5-methyl-6-dimethylaminohexanone-3 or 6-dimethylamino-5-methyl-4,4-diphenyl-3-hexanone (Isomethadone, Isoamidone) and its salts;

33. 6-dimethylamino-4,4-diphenyl-3-heptanol or 4,4-diphenyl-6-dimethylamino-heptanol-3 (Dimepheptanol, Methadol) and its salts;

34. 6-dimethylamino-4,4-diphenyl-3-acetoxyheptane or 4,4-diphenyl-6-dimethylamino-3-acetoxyheptane (Acetylmethadol, Methadyl acetate) and its salts;

35. 4,4-diphenyl-6-morpholinoheptanone-3 or 6-morpholino-4,4-diphenyl-3-heptanone) (Phenadoxone, Hepagin) and its salts (Heptalgin, Heptalin, Heptazone);

36. β-1-methyl-3-ethyl-4-phenyl-4-propionoxypiperidine (Betameprodine) and its salts;

37. DL-3-hydroxy-N-methylmorphinan (Racemorphan) and its salts (Cetarin, Methorphinan);
L,3-hydroxy-N-methylmorphinan (Levorphanol, Levo-Dromoran) and its salts (Dromoran);

38. DL-3-methoxy-N-methylmorphinan (Racemethorphan) and its salts;
L,3-methoxy-N-methylmorphinan (Levomethorphan) and its salts;

39. Dihydrocodeine, (Codhydrine, Paracodin) and its salts (Novocodina);

40. Acetyldihydrocodeine and its salts (Acetylcodone);

41. Galenical products and proprietary medicines containing the drugs mentioned in this list with the exception of those prepared directly from raw or medicinal opium and containing less than 0.2% morphine, as well as those prepared directly from coca leaves and containing less than 0.1% cocaine.