UNITED NATIONS

E/NL.1977/54-56
17 April 1979
ENGLISH ONLY

LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF
THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

MALTA

Communicated by the Government of Malta

NOTE BY THE SECRETARY GENERAL – 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.

INDEX

E/NL.1977/54

L.N. 31 of 1976

MEDICAL AND KINDRED PROFESSIONS ORDINANCE

(CAP. 51)

Drugs (Control) Regulations, 1976

IN exercise of the powers conferred by section 35A of the Medical and Kindred Professions Ordinance, the Minister of Health, on the advice of the Council of Health, has made the following regulations:

Citation and commencement.

1. These regulations may be cited as the Drugs (Control) Regulations, 1976, and shall come into force on the 7th day of March, 1976 with the exception of regulation 9 which shall come into force on the 27th day of March, 1976.

Interpretation.

2. In these regulations, unless the context otherwise requires,

"register" means a bound book with consecutively numbered pages, but does not include any form of loose leaf register or card index;

"restricted drug" means any one of such drugs or chemical substances as are listed in the First Schedule to these regulations;

"specified drug" means any one of such drugs or chemical substances as are specified in the Second Schedule to these regulations;

"Superintendent" means the Superintendent of Public Health.

Importation, etc., of restricted drugs to be specially authorized.

3. (1) No person may import, manufacture, export, purchase, sell, use or be in possession of any restricted drug without a special authorization in writing by the Superintendent.

(2) The Superintendent shall not grant a special authorization to use any restricted drug except in special cases for scientific or very limited medical purposes inside medical or scientific establishments under Government control or specifically approved by the Superintendent, who shall have the power to impose in any authorization any conditions and requirements he may deem fit to impose with a view to safeguard against abuse.

(3) The Superintendent may at any time, without giving any reason whatsoever, withdraw any authorization granted by him under paragraph (1) of this regulation.

(4) Any person who has been authorized in accordance with paragraph (1) of this regulation shall keep such registers as shall be necessary in accordance with the Third Schedule to these regulations in relation to the manufacture, acquisition and/or disposal of restricted drugs, in which registers there shall be entered the details relative to such drugs. Each entry shall be signed, by the person authorized under paragraph (1), within twenty-four hours of any transaction or process, and any such register shall be preserved and kept available for inspection by the Superintendent or his representative for at least two years after the date of the last entry recorded therein.

(5) Any entry in the register shall be made in ink or other indelible material and shall be entered on the same day in which the transaction, administration or process is effected, or, when this is not possible, on the next following day.

(6) Any register used or in use with regard to one particular premises shall not be used also with regard to any other premises or for any purpose other than of this regulation.

(7) No entry in the register referred to in the last preceding paragraphs of this regulation shall be cancelled, obliterated or altered or shall be entered with some untrue particulars:

Provided that if any mistake is committed in any entry, such mistake shall be corrected by means of a note in the margin or at the foot of the page, which note shall contain the correction required and the date of the note.

(8) No person may dispose of any restricted drug except to persons specially authorized to possess or use such drugs.

Transactions regarding specified drugs to be registered.

4. (1) Any person who is licensed or authorized to manufacture, import, sell, supply, distribute, or administer any specified drug, whether in the line of his trade or profession or as a medicament on the presentation of a prescription, shall keep such registers as shall be necessary to show any transaction regarding the manufacture, importation, purchase, sale, supply, distribution or administration of any such drug.

(2) Any specified drug manufactured, imported, exported, purchased, sold, supplied, distributed or administered shall be entered in the register in the form shown with such variations as circumstances may require, and containing such particulars as are shown, in the Third Schedule to these regulations and as are applicable to the case.

(3) Any entry in the register shall be made in ink or other indelible material and shall be entered on the same day in which the transaction, administration or process is effected, or, when this is not possible, on the next following day.

(4) Any register used or in use with regard to one particular premises shall not be used also with regard to any other premises or for any purpose other than of this regulation.

(5) No entry in the register referred to in the preceding paragraphs of this regulation shall be cancelled, obliterated or altered or shall be entered with some untrue particulars:

Provided that if any mistake is committed in any entry, such mistake shall be corrected by means of a note in the margin or at the foot of the page, which note shall contain the correction required and the date of the note.

(6) No medical practitioner, dental surgeon, dentist or veterinary surgeon shall be required to keep any such register in respect of any specified drug obtained by him from a dispensary or from any person duly authorized to deal in drugs.

(7) No person may export any specified drug without the prior authorization from the Superintendent.

(8) In the case of importation or exportation of specified drugs, the Superintendent shall have the power to direct the procedure to be followed and the details to be submitted in the relative application, and may also, before issuing an export authorization, require that the authorization of the importing country be obtained.

Possession of specified drugs.

5. (1) No person, unless duly authorized, may have in his possession any specified drug.

(2) For the purpose of this regulation, a person shall be deemed to be duly authorized if his name is entered in the Medical Register, in the Register of Dental Surgeons, or in the Veterinary Surgeons' Register, or if he is a managing apothecary, or is in possession of a licence issued by the Superintendent under section 74 of the Medical and Kindred Professions Ordinance, or has obtained such drug in virtue of a medical prescription, or otherwise in accordance with the provisions of these regulations:

Provided that, in respect of a person authorized in virtue of a medical prescription, such prescription shall not be deemed to be valid if, at the time of the receipt of the prescription, such person was under the treatment of another medical practitioner and had been receiving such specified drugs in virtue of a prescription from this other medical practitioner and had not informed the prescriber of this fact.

Safe keeping of restricted and specified drugs.

6. Any person authorized to be in possession of specified drugs in accordance with the provisions of regulation 5 of these regulations and any person specially authorized in respect of restricted drugs, as the case may be, shall, when such drugs are not in use, keep same under lock and key and it shall be the duty of any such person to take all steps necessary to ensure security and to prevent theft or other diversification of stock:

Provided that nothing in this regulation shall apply to any person who is in possession of specified drugs in virtue of a medical prescription.

Form and contents of prescription.

7. (1) No prescription for any specified drug shall be released unless it be in writing in ink or other indelible material, dated and signed in full by the person giving it and unless it contains the name and address of the prescriber and the name and address of the person for whose use such drug is intended, and the total amount of specified drug to be supplied, as well as the period of validity of the prescription.

(2) No apothecary shall accept as valid any prescription for the supply of specified drugs unless it conforms to the provisions of paragraph (1) of this regulation.

Validity of prescription.

8. Unless otherwise directed on the prescription, no specified drug shall be supplied more than once on the same prescription;

Provided that if the prescription is intended to be made use of on more than one occasion, there shall be indicated on the prescription the interval of time between one use and another:

Provided further that no prescription for the supply of any specified drug may be directed to be made use of on more than three occasions.

Specimen signature of prescription.

9. (1) Saving the other provisions of these regulations, no medical practitioner, dental surgeon, dentist or veterinary surgeon shall prescribe any specified or restricted drug unless the Superintendent is in possession of his specimen signature.

(2) The Superintendent may, for the purpose of the control of drugs, circulate to all managing apothecaries a copy of any such specimen signature in his possession.

Dispensing of prescription.

10. (1) The person dispensing a prescription for a specified drug shall mark thereon in ink or other indelible material the date of dispensing as well as his signature and the place of dispensing.

(2) Any such prescription shall, after it has been dispensed (whether in part or in full), be kept by the person dispensing it.

Delivery of specified drugs to licensed or authorized persons.

11. (1) Saving the provisions of the following paragraphs of this regulation, no person shall deliver any specified drug to any other person unless against the presentation of a duly signed receipt therefor.

(2) No person shall deliver any specified drug to any other person who is not a managing apothecary or who is not otherwise lawfully authorised to be in possession of such drug, unless such other person produces a written authorization in that behalf duly signed by the managing apothecary or by the person otherwise lawfully authorized to be in possession of such drug, and unless the person delivering the said drug is satisfied that the authorization is genuine.

(3) Nothing in the preceding paragraphs of this regulation shall be deemed to refer to the supply of any specified drug against the presentation of a medical prescription in accordance with the provisions of these regulations or to the administration of any such drug by or under the supervision of a medical practitioner, dental surgeon, dentist or veterinary surgeon.

Preservation of prescriptions, registers, records, and other documents.

12. Any dispensed prescription, register, record, invoice or other document relating to the manufacture, importation, purchase, sale, supply, distribution, or other disposal of specified drugs shall be kept at the premises to which they refer and shall be preserved for a period of not less than two years from the date of the prescription, record, invoice or other document, or from the date of the last entry in the register, as the case may be, and during such time they shall be open to inspection by the Superintendent or his representative.

Information by manufacturer and by importer.

13. (1) Any person who manufactures or imports any drug or any pharmaceutical preparation shall, within eight days of any such manufacture or importation, give notice thereof to the Superintendent giving details as to the contents and relative strengths of such drug or pharmaceutical preparation:

Provided that when a person has complied once with the provisions of this paragraph in respect of a particular drug or pharmaceutical preparation, he shall not be bound to comply therewith in respect of any other manufacture or importation of the same drug or pharmaceutical preparation having the same trade name and made up of the same contents and strength.

(2) The Superintendent may at any time request the manufacturer or importer of any drug or pharmaceutical preparation, as the case may be, to give such information as the Superintendent may require in respect of such drug or pharmaceutical preparation and the said manufacturer or importer, as the case may be, shall comply with such request within fifteen days.

(3) The Superintendent may:

(a) prohibit the importation of any drug unless such drug is accompanied by

(i) a certificate, acceptable to the Superintendent, from the competent Government authority in the country of origin, stating that the drug has been manufactured by a firm duly authorized to produce such drug for sale in the same country, and that the quality control facilities at the firm are satisfactory, and

(ii) a certificate, acceptable to the Superintendent, stating that the drug complies with the standard referred to in the British Pharmacopea or in the British Pharmaceutical Codex or with other standards acceptable to the Superintendent, or, where no such standard exists in respect of such drug, a certificate, similarly acceptable, of analysis of such drug;

(b) suspend or prohibit the distribution, supply, sale or keeping or offering for sale, of any drug already imported, until the certificates referred to in items (i) and (ii) of sub-paragraph (a) of this paragraph are produced:

Provided that no such suspension or prohibition shall take effect before the expiry of one month from the date of the demand of such certificates by the said Superintendent.

(4) For the purpose of this regulation, "drug" includes any medicinal preparation for internal or external use, whether or not listed or specified in the First or Second Schedule to these regulations.

Notification by prescriber and managing apothecary in the case of certain drugs.

14. (1) It shall be the duty of any medical practitioner who delivers a prescription for any preparation consisting of or containing any amphetamine or its derivatives, to inform the Superintendent within twenty-four hours of his prescribing such a preparation. Such notification is to include the name, address and the age of the person for whom the preparation is intended, the quantity and form in which the preparation is prescribed, the daily dose recommended, as well as the date of prescription.

(2) It shall be the duty of any managing apothecary dispensing a prescription as is referred to in paragraph (1) of this regulation to inform the Superintendent within twenty-four hours of such dispensing, setting out the details referred to in the said paragraph (1), as well as the date of dispensing.

(3) All notifications made in compliance with paragraphs (1) and (2) of this regulation shall be in a sealed envelope marked "Confidential".

(4) No veterinary surgeon, dental surgeon or dentist may prescribe any preparation as is referred to in paragraph (1) of this regulation.

(5) It shall be the duty of any medical practitioner prescribing any preparation as is referred to in the said paragraph (1) to ascertain beforehand the identity of the person to whom he is prescribing such preparation.

Warning and cautions on label, etc.

15. (1) The Superintendent may require all manufacturers, importers, exporters, and all other persons who trade or otherwise deal in any restricted drug or any specified drug, to include such cautions or other warnings on the label where practicable, or in the accompanying leaflet of retail packages of such drugs, as are in his opinion necessary for the safety of the persons using such drugs.

(2) It shall not be lawful for any person to advertise in any way to the general public any restricted drug or any specified drug.

Exemptions.

16. (1) These regulations, with the exception of regulation 13, shall not apply, in respect to any specified drug, to any drug when it forms part of, or is incorporated in, a preparation ready for use and which requires no further compounding, unless such drug is a main or the only active ingredient of the preparation.

(2) These regulations, with the exception of regulation 13, shall likewise not apply in the case of a preparation containing a specified drug, compounded in such a way that it presents no risk, or only a negligible risk, of abuse, and the substance cannot be recovered by readily applicable means in a quantity liable to abuse, so that the preparation does not give rise to a public health or social problem.

Revocation and saving.

17. (1) The Drugs (Control) Regulations, 1967, are hereby revoked without prejudice to any liability incurred and to any proceedings taken or to be taken thereunder.

(2) Any dispensed prescription, register, record, invoice or other document which, on the coming into force of these regulations, are preserved under regulation 9 of the regulations hereby revoked shall continue to be preserved and to be open for inspection as if the said regulations were not revoked.

FIRST SCHEDULE

(Regulation 2)

International or other non-proprietary name or other trivial name	Chemical name
DET	N, N - diethyltryptamine
DMPH	3-(1, 2-dimethylheptyl)-1-hydroxy-7, 8, 9, 10-tetrahydro-6, 6, 9-trimethyl-6H-dibenzo [b, d] pyran
DMT	N, N-dimethyltryptamine
(+) LYSERGIDE,1/ LSD, LSD-25	
MESCALINE, MESCAL BUTTON, PEYOTE, PEYOTL ...	3, 4, 5-trimethoxyphenethylamine
PARAHEXYL	3-hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6, 6, 9-trimethyl-6H-dibenzo [b, d] pyran
PSILOCINE, PSILOTSIN	3-(2-dimethylaminoethyl)-4-hydroxyin-dole
PSILOCYBINE	

1/ Note by the Secretariat: International non-proprietary names are underlined.

International or other non-proprietary name or other trivial name	Chemical name
STP, DOM	2-amino-1-(2, 5-dimethoxy-4-methyl) phenylpropane
TETRAHYDROCANNABINOLS ALL ISOMERS	1-hydroxy-3-pentyl-6a, 7, 10, 10a-tetrahydro-6, 6, 9-trimethyl-6-H-dibenzo [b, d] pyran

And any derivatives, salts, or esters of the above.

SECOND SCHEDULE

(Regulation 2)

AMFEPRAMONE; DIETHYLPROPION	
AMOBARBITAL	
AMPHETAMINE	
BARBITAL	
CHLORAL HYDRATE	2, 2, 2-trichloroethane-1, 1-diol
CHLORDIAZEPOXIDE	7-chloro-2-methylamino-5-phenyl-3H-1, 4-benzo-diazepine 4-oxide hydro-chloride
CHLORPHENTERMINE	
CYCLOBARBITAL	
DEXAMPHETAMINE	
DIAZEPAM and other compounds containing the chemical structure of DIHYRDO-1:4 BENZODIAZEPINE substituted to any degree	
ETHCHLORVYNOL	
ETHINAMATE	
FENCAMFAMIN	
FENFLURAMINE	
GLUTETHIMIDE	
MEPHENTERMINE	
MEPROBAMATE	
METHAMPHETAMINE	
METHAQUALONE	
METHYLPHENIDATE	
METHYLPHENOBARBITAL	
METHYPRYLON	
PARALDEHYDE	acetaldehyde trimer
PENTOBARBITAL	
PHENTERMINE	
PIPRADROL	
PHENCYCLIDINE	
PHENMETRAZINE	
PHENOBARBITAL	
SECOBARBITAL	
SPA	(—)-1-dimethylamine -1, 2, diphenylethane

And any salts or esters of the above.

(Regulation 3 and 4)

THIRD SCHEDULE

FORM OF REGISTERS

I (a) Restricted Drugs, imported, purchased, or otherwise obtained

Name of substance imported, purchased or otherwise obtained	Date on which supply is received	Name of person or firm from whom obtained	Address of person or firm whom obtained	Amount obtained	Form in which obtained	Purpose of use	Date of Authorization from S.P.H.	Signature of Authorized Person

(b) Restricted Drugs sold, supplied, administered or otherwise used

Name of substance	Date	Name of person or firm to whom sold, supplied or administered or purpose of use whichever applicable	Address of person to whom sold, supplied or administered or premises where used whichever applicable	Amount sold or used	Form	Prescription No. or authorization from S.P.H.	Quantity remaining in stock	Signature of Authorized Person

II (a) Specified Drugs imported, purchased or otherwise obtained

Name of substance imported, purchased or otherwise obtained	Date on which supply is received	Name of person or firm from whom obtained	Address of person or firm whom obtained	Amount obtained	Form in which obtained

(b) Specified Drugs exported, sold, supplied or administered

Name of substance exported, sold, supplied or administered	Date on which exported, sold, supplied or administered	Name of person or firm to whom exported, sold, supplied or administered	Address of person or firm to whom exported, sold, supplied or administered	Amount exported, sold, supplied or administered	Form in which exported, sold, supplied or administered	When sale is on prescription prescription number

III (a) Manufacture of Restricted Drugs

Name of substance manufactured	Date of manufacture	Amount manufactured	Form	Signature of Authorized Person	Date of authorization

(b) Manufacture of Specified Drugs

Name of substance manufactured	Date of manufacture	Amount manufactured	Form	Signature of person responsible

E/NL.1977/55

L.N. 123 of 1976

MEDICAL AND KINDRED PROFESSIONS ORDINANCE

(CAP. 51)

Drugs (Control) (Amendment) Regulations, 1976

IN exercise of the powers conferred by section 35A of the Medical and Kindred Professions Ordinance, the Minister of Health, on the advice of the Council of Health, has made the following regulations:

Citation and commencement.

1. (1) These regulations may be cited as the Drugs (Control) (Amendment) Regulations, 1976, and shall be read and construed as one with the Drugs (Control) Regulations, 1976,2/ hereinafter referred to as "the principal regulations".

(2) These regulations shall come into force on the 20th September, 1976.

Amends regulation 14 of the principal regulations.

2. Regulation 14 of the principal regulations shall be amended as follows:

(a) for the words "any amphetamine or its derivatives" in paragraph (1) thereof there shall be substituted the words "any amphetamine, its salts or esters, or any isomer of amphetamine or salt or ester of such isomer"; and

(b) immediately after paragraph (5) thereof there shall be added the following new paragraphs:

"(6) No medical practitioner may issue a prescription for any preparation as is referred to in paragraph (1) of this regulation unless:

(a) the preparation is for the treatment of narcolepsy or of a hyperkenetic brain damaged child; or

(b) he has the prior authorization in writing of the Superintendent.

(7) The Superintendent may, before granting any authorization as is referred to in sub-paragraph (b) of paragraph (6) of this regulation, request from the medical practitioner such information as the Superintendent may require, including whether, according to the opinion of the medical practitioner, the patient is suffering from drug dependancy.".

Amends Second Schedule to the principal regulations.

3. The Second Schedule to the principal regulations shall be amended as follows:

..... 3/

E/NL.1977/56

L.N. 153 of 1976

MEDICAL AND KINDRED PROFESSIONS ORDINANCE

(CAP. 51)

Drugs (Control) (Amendment) (No. 2) Regulations, 1976

IN exercise of the powers conferred by section 35A of the Medical and Kindred Professions Ordinance, the Minister of Health and Environment, on the advice of the Council of Health, has made the following regulations:

Citation and commencement.

1. (1) These regulations may be cited as the Drugs (Control) (Amendment) (No. 2) Regulations, 1976, and shall be read and construed as one with the Drugs (Control) Regulations, 1976,2/ hereinafter referred to as "the principal regulations".

2/ Note by the Secretariat: E/NL.1977/54

3/ Note by the Secretariat: These amendments have already been incorporated in the publication E/NL.1977/54.

(2) These regulations shall come into force on the 4th day of January, 1977.

2. Immediately after paragraph (8) of regulation 4 of the principal regulations there shall be added the following new paragraph: Amends regulation 4 of the principal regulations.

"(9) The Superintendent may prohibit, or otherwise restrict, the importation of any specified drug if he so considers it necessary in the public interest.".

3. For regulation 14 of the principal regulations there shall be substituted the following: Substitutes regulation 14 of the principal regulations.

"Authorization to prescribe certain drugs.

14. (1) No medical practitioner may issue a prescription for any preparation consisting of or containing amphetamine, or any isomer of amphetamine, or methaqualone, methylphenidate, or phenmetrazine, or any salts or esters of any of such drugs, unless he has the prior authorization in writing by the Superintendent.

(2) The Superintendent may, before granting any authorization as is referred to in paragraph (1) of this regulation, request from the medical practitioner such information as the Superintendent may require, including whether according to the opinion of the medical practitioner the patient is suffering from drug dependency, and may also submit such patient to such further medical investigations and for such respective medical purposes, as he may deem necessary.

(3) It shall be the duty of any medical practitioner prescribing any preparation as is referred to in the said paragraph (1) to ascertain beforehand the identity of the person to whom he is prescribing such preparation.

(4) It shall be the duty of any medical practitioner who delivers a prescription as is referred to in paragraph (1) of this regulation to inform accordingly the Superintendent within twenty-four hours of his prescribing such a preparation, giving the details as set out in the Fourth Schedule to these regulations.

(5) It shall be the duty of any apothecary dispensing a a prescription as is referred to in paragraph (1) of this regulation to inform the Superintendent accordingly within twenty-four hours of his dispensing such a preparation, giving the details as set out in the Fifth Schedule to these regulations.

(6) All notifications made in compliance with paragraphs (4) and (5) of this regulation shall be marked "Confidential".

(7) No veterinary surgeon, dental surgeon or dentist may prescribe any preparation as is referred to in paragraph (1) of this regulation".

4. Immediately after the Third Schedule to the principal regulations there shall be added the following new Schedules: Adds new Schedules to the principal regulations.

"FOURTH SCHEDULE

Regulation 14(4)

CONFIDENTIAL

(Return in terms of Regulation 14 - Prescriptions for amphetamine and its isomers, methaqualone, methylphenidate and phenmetrazine, and their respective salts or esters)

IMPORTANT - Prescription for these preparations can only be issued after written approval is obtained from the Superintendent of Public Health for each prescription.

NAME AND ADDRESS OF PATIENT ....

....

.....

AGE .....

NAME OF PREPARATION AND STRENGTH .....
.....

QUANTITY PRESCRIBED .....

DAILY DOSE .....

DATE OF PRESCRIPTION .....

DATE AND REF. NO. OF APPROVAL BY SUPERINTENDENT OF PUBLIC HEALTH .....

SIGNATURE OF MEDICAL PRACTITIONER

NAME (Block Letters) .....

ADDRESS .....
.....
.....

FIFTH SCHEDULE

Regulation 14 (5)

CONFIDENTIAL

(Return in terms of Regulation 14 - Prescriptions for amphetamine and its isomers, methaqualone, methylphenidate and phenmetrazine, and their respective salts or esters)

NAME AND ADDRESS OF PATIENT .....
.....
.....

NAME OF PREPARATION AND STRENGTH .....
.....

QUANTITY PRESCRIBED .....

DATE OF PRESCRIPTION .....

NAME OF PRESCRIBER .....

SIGNATURE OF APOTHECARY .....

NAME (Block Letters) .....

ADDRESS (Of Pharmacy) .....
....."