

SUBSIDIARY LEGISLATION 31.18**DRUGS (CONTROL) REGULATIONS**

2nd August, 1985

LEGAL NOTICE 22 of 1985, as amended by Legal Notices 65 of 1986, 26 of 1987, 70 of 1988, 34 and 103 of 1989, 173 of 1994, 78 of 1998 and 183 of 1999.

- 1.** The title of these Regulations is Drugs (Control) Regulations. Title.
- 2.** In these Regulations, unless the context otherwise requires - Interpretation.
- "identity card" means a valid identity card issued in accordance with the provisions of the Identity Card Act, and of any regulations made thereunder; Cap. 258.
- "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;
- "register" means a bound book with consecutively numbered pages, but does not include any form of loose leaf register or card index;
- "Superintendent" means the Superintendent of Public Health.
- 3.** (1) No person may import, manufacture, export, purchase, sell, use or be in possession of any restricted drug without a special authorisation in writing by the Superintendent. Importation, etc., of restricted drugs to be specially authorised.
- (2) The Superintendent shall not grant a special authorisation 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 authorisation 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 authorisation granted by him under sub-regulation (1) of this regulation.
- (4) Any person who has been authorised in accordance with sub-regulation (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 authorised under sub-regulation (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 sub-regulations 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 authorised to possess or use such drugs.

Transactions
regarding specified
drugs to be
registered.

4. (1) Any person who is licensed or authorised 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) (i) No person shall import, stock or sell any specified drug by wholesale unless he holds a specific licence for the purpose from the Superintendent.

(ii) No licence for the purposes of the foregoing paragraph shall be issued unless the drug or drugs in respect of which it is issued are under the direct responsibility of an apothecary.

(3) 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.

(4) 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.

(5) 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.

(6) No entry in the register referred to in the preceding sub-regulations 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.

(7) No person may export any specified drug without the prior authorisation 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 authorisation, require that the authorisation of the importing country be obtained.

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

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

Possession of specified drugs.

(2) For the purpose of this regulation, a person shall be deemed to be duly authorised 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 article 89 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:

Cap. 31.

Provided that, in respect of a person authorised 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.

6. Any person authorised to be in possession of specified drugs in accordance with the provisions of regulation 5 of these regulations and any person specially authorised 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:

Safe keeping of restricted and specified drugs.

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

7. (1) Every prescription for a specified drug shall be written in ink or in other indelible material on the form set out in the Seventh Schedule to these Regulations.

Use and contents of prescription.

(2) It shall be the duty of a medical practitioner issuing a prescription for a specified drug to fill in a clear and legible hand Part A of the form set out in the Seventh Schedule, and to supply all the details and give all the information in the appropriate space as therein required; the medical practitioner shall further add his

signature in full and the date when the prescription was issued:

Cap. 31.

Provided that in the case of a medical practitioner authorised under article 5 of the Medical and Kindred Professions Ordinance to practise the medical profession but who is not yet registered with the Medical Council, such practitioner shall insert the number given to him by the Superintendent instead of the Medical Council registration number on the said prescription.

(3) Subject to the provisions of sub-regulation (11) of this regulation, no medical practitioner shall issue a prescription for a specified drug unless the prescription complies with the provisions of this regulation and such drug is required for the purpose of medical treatment:

Provided that a medical practitioner may, subject to the other provisions of these Regulations, issue a prescription for professional use for an amount not in excess of ten phials for injection or of twenty tablets or capsules.

(4) Every medical practitioner who obtains a specified drug for professional use as provided in the proviso to sub-regulation (3) of this regulation shall keep in accordance with, and without prejudice to, the provisions of regulation 4 of these Regulations, a record in an appropriate register of the name and surname (if applicable), the age and address of the patient to whom the drug has been administered and the date of administration.

(5) No medical practitioner shall issue a prescription for a specified drug to any person unless such person is well known to him or unless the medical practitioner has ascertained the identity of such person through his identity card.

(6) No medical practitioner shall issue a prescription for a specified drug to any person unless the said medical practitioner has taken reasonably sufficient steps to ascertain that such person is not, at the time of issuing the prescription, receiving treatment from another medical practitioner in respect of addiction to any specified drug or otherwise, and that such person has not been supplied with any such drug on a prescription issued by that other medical practitioner.

Cap. 101.

(7) A medical practitioner shall use a separate form in respect of every drug prescribed by him under this regulation and no drug other than a specified drug or a drug falling under the Dangerous Drugs Ordinance, may be prescribed on those forms.

(8) A medical practitioner shall, in prescribing a specified drug, use only prescription forms from the booklet of forms in serial number, issued to him by the Superintendent upon a request made on the form set out in the Eighth Schedule to these Regulations and it shall be the duty of every medical practitioner, whether for the purpose of his private practice or for carrying out his duties in an official capacity as a result of his employment with Government, with a view to meeting the needs of his patients, to make any request for such prescription booklets on the said form; such request form shall be correctly filled in all respects and signed by the practitioner, and shall be either handed in by such practitioner personally to the chief pharmacist at the Government

Medical Stores at Gwardamangia or sent by post to the Superintendent of Public Health at the Department of Health in Valletta; and when sent by post the envelope may be marked "Public Health Notifications" for the purpose of exemption from postage.

(9) It shall be the duty of a medical practitioner to report in writing forthwith to the Superintendent any case of theft or loss of such booklet and it shall not be lawful for a medical practitioner to use any prescription form from any booklet of forms issued to another medical practitioner.

(10) For the purpose of this regulation, unless the context otherwise requires, the expression "medical practitioner" includes a dental surgeon, a dentist and a veterinary surgeon.

(11) The provisions of sub-regulations (1), (2), (7) and, in so far as applicable, sub-regulations (8) and (9) of this regulation shall not apply to the prescription of specified drugs for administration to ward patients in government hospitals, which prescription shall be controlled by the hospital internal rules.

8. (1) No person other than an apothecary shall dispense a prescription for a specified drug.

Dispensing of prescriptions.

(2) No apothecary shall dispense a prescription for a specified drug unless -

- (a) he is acquainted with the signature of the person by whom it purports to have been issued, he has no reason to suppose that it is not genuine and he has taken reasonable steps to satisfy himself that it is genuine; and
- (b) the prescription complies with the provisions of regulation 7 of these regulations.

(3) No specified drug shall be supplied more than once on the same prescription.

(4) An apothecary dispensing a prescription for a specified drug shall fill in a clear and legible hand, in ink or other indelible material, Part C of the form set out in the Seventh Schedule to these Regulations, and supply all the details and give all the information as therein required; the apothecary shall further add his signature in full and the date, and shall, after dispensing the prescription, retain it.

(5) For the purpose of sub-regulation (4) of this regulation, it shall be the duty of an apothecary dispensing a prescription for a specified drug to request the identity card of the person in respect of whom the prescription has been issued and it shall be the duty of the person who intends to acquire a specified drug, whether for himself or on behalf of the person to whom the drugs have been prescribed, to present the said identity card as well as his own identity card together with the prescription:

Provided that the provisions of this sub-regulation and the relative part of the provisions of sub-regulation (4) of this regulation shall not apply in respect of a person who has not yet

been issued with an identity card.

(6) It shall be the duty of every managing apothecary of a licensed dispensary to send to the Superintendent in a sealed envelope on the first day of every month all the prescriptions for specified drugs dispensed from that dispensary during the preceding month; that envelope shall be addressed "Superintendent of Public Health, Department of Health, Valletta" and may be marked "Public Health Notifications" for the purpose of exemption from postage.

Control card.
Added by:
L.N. 65 of 1986.
Amended by:
L.N. 34 of 1989.

9.(1) (a) No medical practitioner may prescribe any specified drug to any person unless such person is in possession of a control card, as per Ninth Schedule to these Regulations, issued for the purpose by the Superintendent of Public Health;

(b) in prescribing any specified drug to any person, the prescriber shall enter in a clear, indelible and legible manner all the details set out in columns 1 to 4 of the control card, and shall then return the card to such person together with the prescription:

Provided that a medical practitioner may, in making the application on behalf of a person on the request form as set out in the Tenth Schedule to these Regulations, also issue a prescription for a supply of a specified drug to such person and may attach the prescription to such request form:

Provided further that such prescription shall only become valid when the provisions of the proviso to sub-regulation (2) of this regulation have been complied with.

(2) The Superintendent shall issue such control card to the person concerned on receipt of a request, from a medical practitioner to this effect, made on the form as set out in the Tenth Schedule to these Regulations:

Provided that in the case of a prescription for a supply of a specified drug as provided for in the provisos to sub-regulation (1) of this regulation, the Superintendent shall enter the details of the relative prescription in columns 1 to 4 of the control card.

(3) No control card shall be valid in excess of a period of one year from the date on which it is issued, unless it is renewed by the Superintendent following a request by a medical practitioner to this effect, on the form set out in the Tenth Schedule to these Regulations.

(4) No apothecary shall dispense any specified drug to any person who is not in possession of a control card as set out in sub-regulation (1) of this regulation.

(5) On dispensing a specified drug the apothecary shall, in addition to other duties laid down by these regulations or by any law, enter in a clear, indelible and legible manner all the details set out in columns 5 to 8 on the card, and shall then return the card to the person presenting the prescription.

(6) (a) It shall be lawful for a medical practitioner to prescribe

in urgent cases a drug to a patient who is not in possession of a control card, provided that:

- (i) the prescription is labelled "URGENT";
- (ii) the amount prescribed does not exceed seven days' supply;
- (iii) it complies with other requirements of these regulations; and
- (iv) the prescriber notifies the Superintendent within forty-eight hours of issuing such prescription, giving full particulars of the patient, the name, form, dose and amount of drug prescribed, and the reason for the urgency.

(b) It shall be lawful for an apothecary to dispense such a prescription complying with sub-paragraphs (i), (ii) and (iii) of paragraph (a) of this sub-regulation.

(7) The provisions of this regulation shall not apply to the prescription of specified drugs by a medical practitioner employed in a government hospital, for administration to ward patients at that time under his care in such hospital, which prescription shall be controlled by hospital internal rules.

(8) Any request or notification in terms of this regulation may be made in person or sent by post in a sealed envelope addressed to the Superintendent of Public Health, Department of Health, Valletta, and marked "Public Health Notification - Confidential" for the purpose of exemption from postage.

(9) For the purpose of this regulation, the expression "medical practitioner" includes a dental surgeon and a dentist.

(10) The Superintendent may withdraw the control card of a person who is suspected to be abusing a drug prescribed to him, or who is in any other way abusing the control card system.

(11) The Superintendent may include on the control card such guidelines as he may deem necessary regarding the prescription of specified drugs.

10. (1) 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.

Specimen
signature of
prescription.

(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.

11. (1) No person shall deliver any specified drug to any other person except against the presentation of a duly signed receipt therefor.

Delivery of
specified drugs to
licensed or
authorised persons.

(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 authorisation in that behalf, duly signed by the managing apothecary or by the person otherwise

lawfully authorised to be in possession of such drug, and unless the person delivering the said drug is satisfied that the authorisation is genuine.

(3) Nothing in the preceding sub-regulations 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.

(4) For the purpose of this regulation, "deliver" includes any act or omission whereby a person allows or suffers any other person, not being a person authorised to be in possession of specified drugs under these Regulations, to take possession of any such drug.

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

12. Saving the provisions of sub-regulation (6) of regulation 8 of these Regulations, any dispensed prescription, register, 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.

Notification by prescriber and managing apothecary in the case of certain drugs.
*Amended by:
L.N. 70 of 1988.*

13. (1) No medical practitioner may issue a prescription for any preparation consisting of or containing amphetamine, or any isomer of amphetamine, cathine, fenetylline, flunitrazepam, mecloqualone, methaqualone, methylphenidate, or phenmetrazine, or any salts or esters of any such drugs, or for any preparation consisting of secobarbital or amobarbital or of a combination of secobarbital and amobarbital, in either case in tablet or capsule form, or in sachet or cachet, or of any salts or esters thereof in such presentation, unless he has the prior authorisation in writing by the Superintendent.

(2) The Superintendent may, before granting any authorisation as is referred to in sub-regulation (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.

(3) When a request for such authorisation is made, the Superintendent shall submit such request to a panel of medical specialists who shall advise the Superintendent as to whether such request is to be authorised or not.

(4) Before making their recommendations it shall be the duty of the panel to see whether such prescribing is indicated and the panel shall also, where indicated, make such recommendations as may be necessary with a view to weaning of patient from such drug.

(5) The Superintendent may, if he considers it is in the interest

of the patient, authorise the prescription of such drug until the report of the panel is received.

(6) It shall be the duty of any medical practitioner who delivers a prescription as is referred to in sub-regulation (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.

(7) It shall be the duty of any apothecary dispensing a prescription as is referred to in sub-regulation (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.

(8) All notifications made in compliance with sub-regulations (6) and (7) of this regulation shall be marked "Confidential".

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

(10) If the President of the Republic has reason to suspect that a medical practitioner, or a dental surgeon or dentist, is supplying or prescribing any specified drug to or for either himself or any other person other than, or more than, is properly required for medical or dental treatment of himself or that other person, as the case may be, or that a veterinary surgeon is supplying or prescribing any specified drug in respect of an animal under his care other than, or more than, is properly required for the treatment of such animal, as the case may be, the President may refer the matter to the Medical Council, and, if the Council so recommends, the President may prohibit the said medical practitioner, dental surgeon or dentist, or veterinary surgeon, from supplying, prescribing, procuring or possessing such drug, for such period as the President may deem fit, and it shall then be unlawful for that medical practitioner, dental surgeon or dentist, or veterinary surgeon to supply, prescribe, procure or possess any such drug during such period:

Provided that the said President may, at any time, modify or withdraw any such prohibition.

(11) Notice of any prohibition, modification or withdrawal of any prohibition as is referred to in sub-regulation (10) of this regulation shall be given in writing to the person affected thereby.

(12) It shall be lawful for the Superintendent to circulate to -

- (a) all medical practitioners the name, and other details as are shown in the Sixth Schedule to these Regulations, of any person in respect of whom any preparation as is referred to in sub-regulation (1) of this regulation has been prescribed; and
- (b) all medical practitioners, dental surgeons and dentists the name, and other details as are shown in the Sixth Schedule to these Regulations, of any person in respect of whom any specified drug has been prescribed or dispensed.

Warning and
cautions on label,
etc.

14. (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.

Information by
manufacturer and
by importer.
Added by:
L.N. 173 of 1993.

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

Provided that when a person has complied once with the provisions of this sub-regulation in respect of a particular drug or pharmaceutical preparation, he shall not be bound to comply herewith 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 dosage form.

(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 authorised 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 Pharmacopoeia 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 subparagraphs (i) and (ii) of paragraph (a) of this sub-regulation 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) The Superintendent may withdraw or cause to be withdrawn from the market any drug or pharmaceutical preparation if, because of adverse reactions or of other information relating to ill effects, manufacturing practices or other technical or scientific information, such withdrawal is in his opinion indicated in the interest of the health of patients.

(5) For the purposes 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.

16. (1) These Regulations shall not apply, in respect of 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. Exemptions.

(2) These Regulations 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.

17. Any dispensed prescription, register, record, invoice or other document which, immediately before the coming into force of these Regulations, are preserved under the Drugs (Control) Regulations, 1976,* shall continue to be preserved and to be open for inspection and shall for these purposes be deemed to have always been preserved under these Regulations. Saving.

*Revoked by these Regulations.

Substituted by:
L.N. 70 of 1988.
Amended by:
L.N. 183 of 1999.

FIRST SCHEDULE

(Regulation 2)

<i>International or other nonproprietary name or other trivial name</i>	<i>Chemical name</i>
CATHINONE	(-)-a-aminopropiophenone
DET	<i>N,N</i> -diethyltryptamine
DMA	d1-2,5-dimethoxy-a-methylphenylethylamine
DMHP	3-(1,2-dimethylheptyl)-1-hydroxy-7, 8, 9, 10-tetrahydro-6, 6, 9-trimethyl-6Hdibenzo [b, d] pyran
DMT	<i>N,N</i> -dimethyltryptamine
DOB, BROLAMFETAMINE	2,5-dimethoxy-4-bromoamphetamine
(+) LYSERGIDE, LSD, LSD-25	(+)- <i>N,N</i> -diethyllysergamide (d-lysergic acid diethylamide)
DOET	d1-2, 5-dimethoxy-4-ethyl-a-methylphenylethylamine
ENTRYPTAMINE	3-(2-aminobutyl) indole
MDA, METHYLENE DIOXYAMPHETAMINE	3,4, methylenedioxyamphetamine
MDMA, TENAMFETAMINE	d1-3, 4-methylenedioxy- <i>N</i> , a-dimethylphenylethylamine
METHCATHINONE	2-(methylamino)-1-phenylpropan-1-one
MESCALINE, MESCAL BUTTON, PEYOTE, PEYOTL	3, 4, 5-trimethoxyphenethylamine
MMDA	d1-5-methoxy-3,4-methylenedioxy-a-methylphenylethylamine
PARAHEXYL	3-hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6, 6, 9-trimethyl-6H-dibenzo [b, d] pyran
PCE, ETICYCLIDINE	<i>N</i> -ethyl-1-phenylcyclohexylamine
PHP, PCPY, ROLICYCLIDINE	1-(1-phenylcyclohexyl) pyrrolidine
PMA	4-methoxy-a-methylphenylethylamine
PSILOCINE, PSILOTSIN	3-(2-dimethylaminoethyl)-4-hydroxyindole
PSILOCYBINE	3-(2-dimethylaminoethyl)-indol-4-yl dihydrogen phosphate
STP. DOM	2-amino-1-(2, 5-dimethoxy-4-methyl) phenylpropane
TETRAHYDROCANNABINO-LS, ALL ISOMERS	1-hydroxy-3-pentyl-6a, 7, 10, 10a-tetrahydro-6, 6, 9-trimethyl-6-H-dibenzo [b, d] pyran
TCP, TENOCYCLIDNE	1-[1-(2-thienyl) cyclohexyl] piperidine
TMA	d1-3, 4, 5-trimethoxy-a-methylphenylethylamine

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

SECOND SCHEDULE
(Regulation 2)

Amended by:
L.N. 26 of 1987.
Substituted by:
L.N. 70 of 1988.
Amended by:
L.N. 103 of 1989;
L.N. 78 of 1998;
L.N. 183 of 1999.

<i>International or other nonproprietary name or other trivial name</i>	<i>Chemical name</i>
ALLOBARBITAL	5, 5-diallylbarbituric acid
AMFEPRAMONE, DIETHYLPROPION	2-(diethylamino) propiophenone
AMINOREX	2-amino-5-phenyl-2-oxazoline
AMOBARBITAL	5-ethyl-5-(3-methylbutyl) barbituric acid
AMPHETAMINE	(±)-2-amino-1-phenylpropane
BARBITAL	5, 5-diethylbarbituric acid
BENZPHETAMINE	N-benzyl-N, ∞ -dimethylphenethylamine
BROTIZOLAM	2-bromo-4(o-chlorophenyl)-9-methyl-6H-thieno [3,2-f]-s-triazolo [4,3-a] [1,4] diazepine
BUPRENORHINE	21-cyclopropyl-7-alpha-[(S)-1-hydroxy-1,2,2-trimethylpropyl]-6,14-endoethano-6,7,8,14-tetrahydrooripavine
BUTALBITAL	5-allyl-5-isobutylbarbituric acid
BUTOBARBITAL	5-butyl-5-ethylbarbituric acid
CATHINE	d-threo-2-amino-1-hydroxy-1-phenylpropane
CHLORAL HYDRATE	2, 2, 2-trichloroethane-1, 1-diol
CHLORDIAZEPOXIDE	7-chloro-2-(methylamino)-5-phenyl-3H-1, 4benzodiazepine-4-oxide
CHLORPHENTERMINE	p-chloro-∞ -dimethylphenethylamine
CYCLOBARBITAL	5-(1-cyclohexen-1-yl)-5-ethylbarbituric acid
DEXAMPHETAMINE	(+)-2-amino-1-phenylpropane
DIAZEPAM and other compounds containing the chemical structure of DIHYDRO-1:4 BENZODIAZEPINE or of DIHYDRO-1:5 BENZODIAZEPINE substituted to any degree	7-chloro-1, 3-dihydro-1-methyl-5-phenyl-2H-1, 4-benzodiazepine-2-one
DRONABINOL delta-9-tetrahydrocannabinol and its stereochemical variants (This item refers to only one of the stereochemical variants of delta-9-tetrahydrocannabinol, namely (-)-trans-delta-9-tetrahydrocannabinol.)	(6aR, 10aR)-6a7, 8, 10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo [b,d] pyran-1-ol
ETHCHLORVYNOL	ethyl-2-chlorovinylethynylcarbinol
ETHINAMATE	1-ethynylcyclohexanolcarbamate

FENCAMFAMIN	dl-N-ethyl-3-phenylbicyclo (2,2,1)-heptan-2amine
FENETYLLINE	dl-3,7-dihydro-1, 3 dimethyl-7-(2-[(1-methyl-2-phenylethyl) amino] ethyl)-1H-purine-2, 6-dione
FENFLURAMINE	N-ethyl-∞ -methyl-m(trifluoromethyl)phenethylamine
FENPROPorex	dl-3-[(a-methylphenethyl)amino]propionitrile
GLUTETHIMIDE	2-ethyl-2-phenylglutarimide
KETAMINE	(±)-2-(2-Chlorophenyl)-2-methylaminocyclohexanone
LEVAMPHETAMINE	1-a-methylphenethylamine
LEVOMETHAMPHETAMINE	l-N, a-dimethylphenethylamine
MAZINDOL	5-(p-chlorophenyl)-2, 5-dihydro-3H-imidazo [2, 1-a] isoindol-5-ol
MECLOQUALONE	3-(o-chlorophenyl)-2-methyl-4 (3H)-quinazolinone
MEFENOREX	dl-N-(3-chloropropyl)-a-methylphenethylamine
MEPHENTERMINE	N-∞ -trimethylphenethylamine
MEPROBAMATE	2-methyl-2-propyl-1, 3-propanediol dicarbamate
MESOCARB	3-(∞ -methylphenethyl)-N-phenylcarbamoyl sydnone imine
METHAMPHETAMINE	(+)-2-methylamino-1-phenylpropane
METHAMPHETAMINE RACEMATE	
METHAQUALONE	2-methyl-3-o-tolyl-4(3H)-quinazolinone
METHYLPHENIDATE	2-phenyl-2 (2-piperidyl) acetic acid, methyl ester
METHYLPHENOBARBITAL	5-ethyl-1-methyl-5-phenylbarbituric acid
METHYPRYLON	3, 3-diethyl-5-methyl-2, 4-piperidine-dione
N-ETHYLAMPHETAMINE	dl-N-ethyl-a-methylphenylethylamine
PARALDEHYDE	acetaldehyde trimer
PEMOLINE	2-amino-5-phenyl-2-oxazolin-4-one or 2-imino-5-phenyl-4-oxazolidinone
PENTAZOCINE	1, 2, 3, 4, 5, 6, hexahydro-6, 11-dimethyl-3-(3-methyl-2-butenyl)-2, 6-methano-3benzazocin-8-ol
PENTOBARBITAL	5-ethyl-5-(1-methylbutyl) barbituric acid
PHENCYCLIDINE	1-(1-phenylcyclohexyl) piperidine
PHENDIMETRAZINE	(+)-3, 4-dimethyl-2-phenylmorpholine
PHENMETRAZINE	3-methyl-2-phenylmorpholine
PHENOBARBITAL	5-ethyl-5-phenylbarbituric acid
PHENTERMINE	a,a-dimethylphenethylamine
PIPRADROL	1,1-diphenyl-1-(2-piperidyl) methanol
PROPYLHEXEDRINE	dl-1-cyclohexyl-2-methylaminopropane

PYROVALERONE	dl-1-(4-methylphenyl)-2-(1-pyrrolidinyl)- lpentanone
SECBUTABARBITAL	5-sec-butyl-5-ethylbarbituric acid
SECOBARBITAL	5-allyl-5-(1-methylbutyl) barbituric acid
SPA, LEFETAMINE	(-)-1-dimethylamine-1, 2, diphenylethane
VINYLBITAL	5-(1-methyl-butyl)-5-vinylbarbituric acid
ZIPEROL	∞ -(∞ -methoxybenzyl)-4- (β -methoxyphenethyl)-1- piperazineethanol

And any salts or esters of the above.

THIRD SCHEDULE
(Regulations 3 and 4)

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 from whom obtained	Amount obtained	Form in which obtained	Purpose of use	Date of Authorisation from S.P.H.	Signature of Authorised Person
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(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 where used whichever applicable	Amount sold or used	Form	Prescription No. or authorisation from S.P.H.	Quantity remaining in stock	Signature of Authorised Person
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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 from whom obtained	Amount obtained	Form in which obtained
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(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 number, the name of the prescriber and the official serial number printed on the prescription form
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III (a) Manufacture of Restricted Drugs

Name of substance manufactured	Date of manufacture	Amount manufactured	Form	Signature of Authorised Person	Date of authorisation

(b) Manufacture of Specified Drugs

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

FOURTH SCHEDULE

(Regulation 13(4))

CONFIDENTIAL

(Return in terms of regulation 13 - Prescriptions for amphetamine and its isomers, flunitrazepam, mecloqualone, methaqualone, methylphenidate and phenmetrazine and secobarbital or a combination of secobarbital and amobarbital in tablet or capsule form or in sachet or cachet 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

.....

.....

IDENTITY CARD NUMBER

.....

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 13(5))

CONFIDENTIAL

(Return in terms of regulation 13 - Prescriptions for amphetamine and its isomers, mecloqualone, methaqualone, methylphenidate and phenmetrazine and secobarbital or a combination of secobarbital and amobarbital in tablet or capsule form or in sachet or cachet and their respective salts or esters)

NAME AND ADDRESS OF PATIENT

IDENTITY CARD NUMBER

NAME OF PREPARATION AND STRENGTH

QUANTITY PRESCRIBED

DATE OF PRESCRIPTION

NAME OF PRESCRIBER

SIGNATURE OF APOTHECARY

NAME (Block Letters)

DH LICENCE NUMBER

ADDRESS (of Pharmacy)

DATE OF DISPENSING

SIXTH SCHEDULE

(Regulation 13)

Name and address of patient

Identity Card Number

Date of prescription

Name of drug

Amount prescribed

Name of medical practitioner, dental surgeon or dentist who has prescribed the
drug

SEVENTH SCHEDULE

(Regulation 7)

PRESCRIPTION FOR NARCOTIC AND PSYCHOTROPIC DRUGS
 (Only one item may be prescribed on this Form)

A. TO BE FILLED BY PRESCRIBER	
PATIENT	
Name and Surname	
Address	
ITEM (incl. Form & Dose)	Quantity
Directions for use	
Additional information in respect of Prescriptions for METHADONE	
Expected Duration of Treatment	
Medical Indication	
PRESCRIBER	Med Council Reg. No. [][][][][]
Name and Surname	
Address	
Signature Date	

B. FOR OFFICIAL USE ONLY	
To be filled by Government Dispenser	
PRESCRIPTION TYPE	
Pink Form <input type="checkbox"/>	Schedule III <input type="checkbox"/> Others <input type="checkbox"/>
Direct <input type="checkbox"/>	Postal <input type="checkbox"/>
LOCATION DISPENSER	[][][][][]
To be filled by Coder	
Item No.	[][][][][][] Prescription Origin [][][]

C. TO BE FILLED BY DISPENSING APOTHECARY	
PATIENT	
Surname [][][][]	Name [][][][]
I.D [][][][][][][][][]	
Male <input type="checkbox"/>	Female <input type="checkbox"/>
ITEM	
Quantity Supplied	
Total Quantity in Units	
Total Quantity in Weight/Measure	
PRESCRIPTION ORIGIN	
Hospitals	
Govt. Clinics
Private
DISPENSER	
Signature.....	
Pharmacy Board Reg. No [][][][]	
Dispensary Address	
Dispensary	
DH Licence No. [][][][]	
Date [][][][][][][][][]	

Serial No.

EIGHTH SCHEDULE

(Regulation 7)

**REQUEST FOR PRESCRIPTION FORMS FOR NARCOTIC AND
PSYCHOTROPIC DRUGS**

I request booklet/s by prescription forms.

Name and surname of prescriber
(IN BLOCK LETTERS)Private address
(IN BLOCK LETTERS)

Signature Med. Council Reg. No.

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FOR OFFICIAL USE

Supplied booklet/s by prescription forms.

Serial No. to

(a) If withdrawn personally by prescriber.

.....
Signature of Prescriber Date

(b) If forwarded by mail.

Forwarded by on

A.R. Card to be attached.

Added by:
L.N. 65 of 1986.

TENTH SCHEDULE

(Regulation 9)

**REQUEST FOR THE ISSUE/RENEWAL OF A CONTROL CARD
FOR NARCOTIC AND PSYCHOTROPIC DRUGS**

Superintendent of Public Health

I hereby request that Mr/Ms..... aged

I. D. No. * residing at

- (i) be issued with a control card for narcotic/psychotropic drugs (§)
- (ii) have the control card for narcotic/psychotropic drugs renewed.(§)

(§) Delete whatever is inapplicable.

Signature of Medical Practitioner

Name and Address of
Medical Practitioner

Medical Council Reg. No.

Date

* In case of non-Maltese citizens not holding an I.D. Card, the Passport No., is to be inserted; in the case of a minor the particulars inserted are to be in relation to the I. D. Card or passport of the father, mother or guardian.

