UNITED NATIONS

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LAWS AND REGULATIONS

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

In accordance with the relevant articles of the international treaties on narcotic drugs and psychotropic substances, the Secretary-General has the honour to communicate the following legislative texts.

MALTA

Communicated by the Government of Malta

NOTE BY THE SECRETARIAT

(a) Some editing of texts may be done by the Secretariat in the interest of clarity. In this connection, words in square brackets [ ] have been added or changed by the Secretariat.

(b) Only passages directly relevant to the control of narcotic drugs or psychotropic substances have been reproduced in this document. Non-relevant parts of laws and regulations have been deleted by the Secretariat; such deletions are indicated by [...].

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E/NL.1985/44

CIRCULAR DH No. 61/84, DEPARTMENT OF HEALTH,
17 August 1984

TO ALL MEDICAL PRACTITIONERS
DENTAL SURGEONS/DENTISTS
VETERINARY SURGEONS
APOTHECARIES
IMPORTERS/WHOLESALE DEALERS IN PHARMACEUTICAL PRODUCTS

Your attention is drawn to recent amendments to the Dangerous Drugs Ordinance, 1939, the Dangerous Drugs (Internal Control) Rules, 1939, 1/ and the Drugs (Control) Regulations, 1976, as well as to the new Rules regarding the prescribing and dispensing of Methadone, viz Legal Notices 32, 39, 40, 41 of 1984 2/ which are annexed.

These amendments provide for the use of the green form 'Prescription for Narcotic and Psychotropic Drugs' for all prescriptions for drugs falling under the relative legislation referred to above. The provisions in respect of prescribing, dispensing and importation of such drugs have also been updated. Special provisions apply to methadone.

In order to remove any doubts as to which drugs fall under the new requirements, I am annexing updated lists of narcotic and psychotropic drugs to which these legal provisions apply. Drugs not included in these lists, even though pharmacologically they may be in the class of, for example, psychotropic drugs, are not subject to these requirements.

I am now giving the details regarding the new provisions.

1. Prescribing of these Drugs

Medical practitioners and dental surgeons are now familiar with the prescription form for narcotic and psychotropic drugs as regulated by the Dangerous Drugs (Internal Control) Rules and the Drugs (Control) Regulations, which form was recently made compulsory by law in respect of prescriptions for free drugs. One of the provisions of the new amendments is to extend this legal requirement to all prescriptions for such drugs whether they are intended to be obtained free from government pharmacies or are intended to be dispensed on payment from private pharmacies. As a result of these amendments the old statutory form, 'Prescription for Dangerous Drugs' which has been in use for several years, is no longer valid.

It is the duty of a medical practitioner or dental surgeon or dentist issuing a prescription for these drugs:

(a) To fill in ink or other indelible material, and in a clear and legible hand, Part A of this form supplying all the details and information in the appropriate space of the form and to add his signature in full, his Medical Council registration number, and the date when the prescription was issued;

(b) To ensure that such drugs are required for the purposes of medical treatment;

(c) To ascertain the identity of the patient through his identity card (unless such person is well known to him);

(d) To take reasonably sufficient steps to ascertain that such person is not, at the same time of issuing the prescription, receiving treatment for such drugs and has not been supplied with any of such drugs on a prescription issued by another practitioner;

(e) To use a separate form in respect of each such drug; no other medicine may moreover be prescribed on the same prescription form;

(f) In order to meet the needs of his patients, to procure and use only booklets of forms duly bearing a serial number issued to him. [...]

1/ Note by the Secretariat: League of Nations document C.361.M.274.1939.XI.

2/ Note by the Secretariat: E/NL.1985/45, E/NL.1985/46, E/NL.1985/47 and E/NL.1985/48.

Whenever a medical practitioner has to issue a prescription for these drugs 'for professional use' the maximum amount at any one time shall be ten phials or twenty tablets of the drug and the practitioner shall keep a record in an appropriate register of the name, surname, age and address of the patients to whom the drug has been administered.

As stated further on in this circular, prescriptions for these drugs will no longer be 'repeat' prescriptions - they will only be dispensed once.

The prescribing of such drugs for in-patients in hospital is subject to hospital internal rules.

Special Provisions in respect of amphetamine preparations, etc.

The above amendments do not affect the special provisions already in force regarding preparations containing amphetamines, methaqualone, mecloqualone, phenmetrazine, methylphenidate as well as secobarbitone and combinations of amylobarbitone and secobarbitone in tablet or capsule form or in cachet or sachet. In such cases, prior authorization is required from the Chief Government Medical Officer in respect of each particular patient for whom these drugs are intended to be prescribed. Doctors are moreover required by law to inform the Chief Government Medical Officer within 24 hours of making a prescription for such drugs giving details on an ad hoc form. Pharmacists dispensing such prescriptions are also legally bound to inform the Chief Government Medical Officer within 24 hours of dispensing every prescription for such drugs on a separate form. These forms are obtained from the Department of Health.

2. Dispensing of these drugs

Under these rules and regulations:

(a) Dispensing of these drugs can only be carried out by an apothecary and only if prescribed on the form laid down by law and duly filled in all its details;

(b) The apothecary must take steps to acquaint himself with the signature of the prescriber and must take reasonable steps to satisfy himself that it is genuine. For this purpose the dispensing apothecary may (if necessary) contact the prescriber concerned;

(c) No such drug may be dispensed more than once on the same prescription;

(d) The apothecary dispensing a prescription for such drugs must request the identity card of the person in respect of whom the prescription has been issued and must fill in a clear and legible hand all details contained in Part C of the prescription form and must add his signature, the Pharmacy Board registration number and the date of dispensing. If a person other than the patient calls with the prescription, he must present his I.D. Card in addition to that of the patient. The provision in respect of the I.D. Card of the patient does not apply in the case of persons (e.g. under 16) who have not yet been issued with the relative card;

(e) The apothecary must retain the prescription, and it is his duty to send to the undersigned on the first day of each month all the prescriptions dispensed by him from his pharmacy during the preceding month. These should be addressed 'Superintendent of Public Health, Department of Health, Valletta', and shall be marked 'confidential'. No stamp is required when so addressed and marked.

Action should be taken by managing apothecaries to amend the last column of the registers of sales of drugs falling under the Drugs (Control) Regulations and the Dangerous Drugs Ordinance so as to ensure that the official serial number of the prescription and the name of prescriber are entered in the registers as provided for in the new amendments.

3. Addition to lists of drugs

Alfentanil has been included among the list of narcotic drugs falling under the Dangerous Drugs Ordinance, 1939 and Pentazocine among the drugs falling under the Drugs (Control) Regulations, 1976. (See annexed updated lists.)

4. Special Provisions in respect of Methadone - Methadone (Prescribing and Dispensing) Rules, 1984

On the prescription form, additional information is required when methadone is prescribed viz expected duration of treatment and the medical indication for such drug.

Moreover, under the new Rules:

- It is illegal for a practitioner who is not a Designated Practitioner working in a Designated Clinic to prescribe methadone to any person who has recently been, or will be, on methadone for a period in excess of two weeks;

- Methadone from Designated Clinics will be prescribed in liquid form (as linctus) and proper records are to be kept in respect of such patients;

- The importation, storage and supply, including dispensing, by or from private sources are prohibited. Such functions can only be carried out by the Chief Pharmacist from St. Luke's Hospital or Craig Hospital pharmacists;

- These provisions do not affect the prescribing of methadone in any form to patients suffering from terminal malignant disease provided the prescriber indicates this fact on the prescription which prescription can only be dispensed from Government pharmacies referred to above.

Since this drug can no longer be stocked or sold in private pharmacies, managing apothecaries are to send to the undersigned by the 30th August a return of stocks of such drug so that necessary action may be taken for their disposal.

Medical practitioners are hereby informed that the Psychiatric Unit at St. Luke's Hospital is the Designated Clinic for the purpose of these new rules. [...]

5. Notification of patients on long-term Pethidine

Medical practitioners/dental surgeons and dentists are now required to notify the undersigned of any patient under their care who has been on pethidine for a period in excess of four weeks (including those whom it is intended to start treatment in excess of this period), giving details as to the name, address, age and I.D. Card number of patient as well as the indication for long-term treatment with this drug.

6. Importation of drugs

Importation of drugs falling under the Dangerous Drugs Ordinance and the Drugs (Control) Regulations require a special import licence from the undersigned every time a consignment is imported, and their importation, storage and sale are the responsibility of an apothecary. As stated above special provisions are now in force in respect of methadone.

Veterinary Surgeons are bound (in so far as applicable) by the above provisions.

(Signed)

ALF. GRECH
Chief Government Medical Officer

DRUGS FALLING UNDER THE DANGEROUS DRUGS ORDINANCE 1939

SCHEDULE I

Preparations containing any of the drugs included in Parts I and II of this Schedule subject to the exceptions listed in Part III of this Schedule.

PART I

Acetorphine
Acetylmethadol
Alfentanyl
Allyprodine
Alphacetylmethadol
Alphameprodine
Alphamethadol
Alphaprodine
Anileridine
Benzethidine
Benzylmorphine
Betacetylmethadol
Betameprodine
Betamethadol
Betaprodine
Bezitramide
Cannabis
Clonitazene
Cocaine
Codoxime
Desomorphine
Dextromoramide
Diampromide
Diethylthiabutene
Difenoxin
Dihydromorphine
Dimenoxadol
Dimepheptanol
Dimethylthiabutene
Dioxaphetyl butyrate
Diphenoxylate
Dipipanone
Concentrate of poppy straw
Drotebanol
Ecgonine
Ethylmethylthiambutene
Etonitazene
Etorphine
Etoxeridine
Fentanyl
Furethidine
Heroin
Hydrocodone
Hydromorphinol
Hydromorphone
Hydroxypethidine
Isomethadone
Ketobemidone
Levomethorphan
Levomoramide
Levophenacylmorphan
Levorphanol
Medicinal opium
Metazocine
Methadone
Methadone-intermediate
Methyldesorphine
Methyldihydromorphine
Metopon
Moramide-intermediate
Morpheridine
Morphine
Morphine methobromide
Morphine-n-oxide
Myrophine
Nicomorphine
Noracymethadol
Norlevorphanol
Normethadone
Normorphine
Norpipanone
Oxycodone
Oxymorphone
Pethidine
Pethidine-intermediate-A
Pethidine-intermediate-B
Pethidine-intermediate-C
Phenadoxone
Phenampromide
Phenazocine
Phenomorphan
Phenoperidine
Piminodine
Piritramide
Proheptazine
Properidine
Racemethorphan
Racemoramide
Racemorphan
Sufentanil
Thebacon
Thebaine
Tilidine
Trimeperidine

Note: Dextromethorphan and Dextrophan are specifically excluded from this part of the Schedule.

The isomers, unless specifically excepted of the drugs in this Part of the Schedule whenever the existence of such isomers is possible within the specific chemical designation.

The esters and ethers, unless appearing in another part of this Schedule, of the drugs in this Part of the Schedule whenever the existence of such esters or ethers is possible.

PART II

Acetyldihydrocodeine
Codeine
Dextropropoxyphene
Dihydrocodeine
Ethylmorphine
Nicocodine
Nicodicodine
Norcodeine
Pholcodine
Propiram

The isomers, unless specifically excepted, of the drugs in this Part of the Schedule, whenever the existence of such isomers is possible within the specific chemical designation;

The salts of the drugs listed in this Part of the Schedule, including the salts of the isomers as provided above whenever the existence of such salts is possible.

PART III

Exemptions

1. Preparations of:

Acetyldihydrocodeine
Codeine
Dihydrocodeine
Ethylmorphine
Nicocodine
Nicodicodine
Norcodeine, and
Pholcodine

when compounded with one or more other ingredients and containing not more than 100 milligrammes of the drug per dosage unit and with a concentration of not more than 2.5 per cent in undivided preparations.

2. Preparations of propiram containing not more than 100 mg of propiram per dosage unit and compounded with at least the same amount of methylcellulose.

3. Preparations of cocaine containing not more than 0.1 per cent of cocaine calculated as cocaine base and preparations of opium or morphine containing not more than 0.2 per cent of morphine calculated as anhydrous morphine base and compounded with one or more other ingredients and in such a way that the drug cannot be recovered by readily applicable means or in a yield which would constitute a risk to public health.

4. Preparations of difenoxin containing, per dosage unit, not more than 0.5 mg of difenoxin and a quantity of atropine sulphate equivalent to at least 5 per cent of the dose of difenoxin.

5. Preparations of diphenoxylate containing, per dosage unit, not more than 2.5 milligrammes of diphenoxylate calculated as base and a quantity of atropine sulphate equivalent to at least 1 per cent of the dose of diphenoxylate.

6. Pulvis ipecacuanhae et opii compositus

10 per cent opium in powder
10 per cent ipecacuanha root, in powder well mixed with 80 per cent of any other powdered ingredient containing no drug.

7. Preparations conforming to any of the formulae listed in this Part of the Schedule and mixtures of such preparations with any material which contains no drug.

DRUGS FALLING UNDER THE DRUGS (CONTROL) REGULATIONS, 1976

SCHEDULE II

Amfepramone, diethylpropion
Amobarbital
Amphetamine
Barbital
Benzphetamine
Chloral hydrate
Chlordiazepoxide
Chlorphentermine
Cyclobarbital
Dexaphetamine
Diazepam and other compounds containing the chemical structure of Dihydro-1;4 Benzodizepine substituted to any degree
Ethchlorvynol
Ethinamate
Fencamfamin
Fenfluramine
Glutethimide
Mazindol
Mecloqualone
Mephentermine
Meprobamate
Methamphetamine
Methaqualone
Methylphenidate
Methylphenobarbital
Methyprylon
Paraldehyde
Pentazocine
Pentobarbital
Phentermine
Pipradrol
Phencyclidine
Phendimetrazine
Phenmetrazine
Phenobarbital
Secobarbital
SPA (Lefetamine)
and any salts or esters of the drugs listed.

L.N. 32 of 1984

E/NL.1985/45

DANGEROUS DRUGS ORDINANCE (CAP. 161)

Dangerous Drugs Ordinance (First Schedule) (Amendment)

Order, 1984

In exercise of the powers conferred by subsection (3) of section 10 of the Dangerous Drugs Ordinance, hereinafter referred to as "the Ordinance", the Minister of Health has made the following order:

1. This order may be cited as the Dangerous Drugs Ordinance (First Schedule) (Amendment) Order, 1984 and shall be read and construed as one with the First Schedule to the Ordinance. — Citation

2. In Part I of the First Schedule to the Ordinance, immediately after item "ACETYLMETHADOL" there shall be inserted the item "ALFENTANIL". — Amends the First Schedule to the Ordinance

E/NL.1985/46

L.N. 39 of 1984

MEDICAL AND KINDRED PROFESSIONS ORDINANCE (CAP.51)

Drugs (Control) (Amendment) Regulations, 1984

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:

1. These regulations may be cited as the Drugs (Control) (Amendment) Regulations, 1984, and shall be read as one with the Drugs (Control) Regulations, 1976 3/ hereinafter referred to as "the principal regulations". — Citation — L.N. 31 of 1976

2. In regulation 2 of the principal regulations, immediately before the definition of "register" there shall be inserted the following new definition: — Amends regulation 2 of the principal regulations

> "'identity card' means a valid identity card issued in accordance with the provisions of the Identity Card Act, 1975 and of any regulations made thereunder;". — Act LI of 1975

3. Regulation 4 of the principal regulations shall be amended as follows: — Amends regulation 4 of the principal regulations

(a) for paragraph (1)A thereof there shall be substituted the following:

> "(1A) (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 sub-paragraph shall be issued unless the drug or drugs in respect of which is issued are under the direct responsibility of an apothecary.";

and

(b) paragraph (6) thereof shall be deleted.

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

Substitutes regulation 7 of the principal regulations

4. For regulation 7 of the principal regulations there shall be substituted the following:

"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.

(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:

Provided that in the case of a medical practitioner authorized under section 4 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 paragraph (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 paragraph (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.

(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, 1939, 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; 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 the 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 paragraphs (1), (2), (7) and, in so far as applicable, paragraphs (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.".

Substitutes regulation 8 of the principal regulations

5. For regulation 8 of the principal regulations there shall be substituted the following:

Dispensing of prescriptions

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

(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 to 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 paragraph (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 paragraph and the relative part of the provisions of paragraph (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.".

Deletes regulation 10 of the principal regulations

6. Regulation 10 of the principal regulations shall be deleted.

Amends the First Schedule to the principal regulations

7. In the first column of the First Schedule to the principal regulations for the letters "DMPH" there shall be substituted the letters "D M H P".

Amends the Second Schedule to the principal regulations

8. Immediately after the item "PARALDEHYDE" in the Second Schedule to the principal regulations there shall be inserted the following:

"PENTAZOCINE 1,2,3,4,5,6-Hexahydro-6, 11-dimethyl-3-(3 methylbutyl-2-enyl)-2, 6-methano-3-benzazocin-8ol".

Amends the Third Schedule to the principal regulations

9. In Part II(b) of the Third Schedule to the principal regulations for the words "Where sale is on prescription, prescription number" there shall be substituted the words "When sale is on prescription, the name of the prescriber and the official serial number printed on the prescription form".

Adds new Schedules to the principal regulations

10. Immediately after the Sixth Schedule to the principal regulations there shall be added the following new Schedules: 4/

E/NL.1985/47

L.N. 40 of 1984

DANGEROUS DRUGS ORDINANCE, (CAP. 161)

Dangerous Drugs (Internal Control) (Amendment) Rules, 1984

In exercise of the powers conferred by section 9 of the Dangerous Drugs Ordinance, the Minister of Health, on the advice of the Council of Health, has made the following rules:

Citation

GN 292 of 1939

1. These rules may be cited as the Dangerous Drugs (Internal Control) (Amendment) Rules, 1984, and shall be read and construed as one with the Dangerous Drugs (Internal Control) Rules, 1939, hereinafter referred to as "the principal rules".

Substitutes rule 6 of the principal rules

2. For rule 6 of the principal rules there shall be substituted the following:

"6. (1) Every prescription for the supply of the drugs shall be written in ink or in other indelible material on the form set out in Schedule A to these rules.

4/ Note by the Secretariat: The "Schedules" (i.e. forms) referred to are not reproduced herewith but are available from the Secretariat on request.

(2) It shall be the duty of a medical practitioner issuing a prescription for the drugs to fill in a clear and legible hand Part A of the form set out in Schedule A, and to supply all the details and give all the information (including additional information in the case of prescriptions for methadone or for any salt or ester thereof) 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:

Provided that in the case of a medical practitioner authorized to practise the medical professional under section 4 of the Medical and Kindred Professions Ordinance but who is not yet registered with the Medical Council such practitioner shall insert the number given to him by the Superintendent of Public Health instead of the Medical Council registration number on the said prescription. Cap. 51

(3) Subject to the provisions of paragraph (11) of this rule, no medical practitioner shall issue a prescription for the supply of the drugs unless the prescription complies with the provisions of paragraphs (1) and (2) of this rule, and unless the drugs are required for the purpose of medical treatment:

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

Provided further that:

(i) In the case of a dental surgeon or a dentist a prescription may only be issued for the purposes of dental treatment and such prescription shall be marked 'for dental treatment only'; and

(ii) In the case of a veterinary surgeon a prescription shall only be issued for the purposes of treatment of animals and shall be marked 'for animal treatment only'.

(4) Every medical practitioner who obtains the drugs for professional use as provided for in the first proviso to paragraph (3) of this rule, shall keep, in accordance with, and without prejudice to, the provisions of rule 10 of these rules, 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 and the medical indication for administering the drug.

(5) No medical practitioner shall issue a prescription for the drugs to any person unless such person is well known to him or unless the medical practitioner has ascertained the identity of such person through the identity card issued under the Identity Card Act, 1975. Act LI of 1975

(6) No medical practitioner shall issue a prescription for the drugs 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 of the drugs or otherwise, and that such person has not been supplied with any of such drugs on a prescription issued by that other medical practitioner.

(7) A medical practitioner shall use a separate form in respect of every drug prescribed by him under these rules, and no drug other than a drug to which the provisions of the Ordinance or of the Drugs (Control) Regulations, 1976, apply, may be prescribed on these forms.

(8) A medical practitioner shall in prescribing the drugs use only prescription forms from the booklets of forms in serial number issued to him by the Superintendent of Public Health upon a request made on the form set out in Schedule B to these rules and it shall be the duty of a 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 a 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 personally to the Chief Pharmacist at the Government Medical Stores, Gwardamangia or sent by post to the Superintendent of Public Health at the Department of Health in Valletta; when sent by post 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 of Public Health 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 rule, unless the context otherwise requires, the expression 'medical practitioner' includes a dental surgeon, a dentist and a veterinary surgeon.

(11) The provisions of paragraphs (1), (2), (7) and, in so far as applicable, of paragraphs (8) and (9) of this rule shall not apply to the prescription of the drugs for administration to ward patients in Government hospitals, which prescription shall be controlled by the hospital internal rules.".

Substitutes rule 7 of the principal rules

3. For rule 7 of the principal rules there shall be substituted the following:

"7. (1) No person other than an apothecary shall dispense a prescription for the drugs.

(2) No apothecary shall dispense a prescription for the drugs 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 rule 6 of these rules.

(3) The drugs shall not be supplied more than once on the same prescription.

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

(5) For the purpose of paragraph (4) of this rule, it shall be the duty of an apothecary dispensing a prescription for the drugs 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 the drugs 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 provision of this paragraph, and the relative part of the provision of paragraph (4) of this rule 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 of Public Health in a sealed envelope on the first day of every month all the prescriptions for the 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.".

4. For Schedule A to the principal rules there shall be substituted the Schedules contained in the Schedule to these rules. — Substitutes Schedule A to the principal rules

5. In part (b) of the First Schedule to the principal rules, for the words in the last column thereof "When sale is on a prescription, specify the ingredients orthe prescription" there shall be substituted the words "When sale is on prescription specify the ingredients on the prescriptions and insert the official serial number printed on the prescription form". — Amends the First Schedule to the principal rules

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DANGEROUS DRUGS ORDINANCE (CAP. 161)

Methadone (Prescribing and Dispensing) Rules, 1984

In exercise of the powers conferred by section 9 of the Dangerous Drugs Ordinance, the Minister of Health has made the following rules:

1. These rules may be cited as the Methadone (Prescribing and Dispensing) Rules, 1984. — Citation

2. In these rules, unless the context otherwise requires: — Interpretation

"designated clinic" means a clinic in a government hospital or clinic designated by the Superintendent of Public Health for the treatment by methadone of drug addicts or other persons needing that drug for a period in excess of two weeks;

"designated practitioner" means any medical practitioner or dental surgeon authorized by the Superintendent of Public Health to work in a designated clinic;

"methadone" includes any salt or ester thereof.

3. No medical practitioner or dental surgeon shall issue a prescription for methadone in any form in respect of a patient who is an addict or who recently has had treatment with this drug for a period in excess of two weeks unless such medical practitioner or dental surgeon, as the case may be, is a designated practitioner and unless such prescription is issued from a designated clinic. — Restricted prescripion

4. No methadone may be prescribed or supplied from a designated clinic other than in mixture form or as linctus: — Form of methadone

Provided that in exceptional circumstances the psychiatrist in charge of a designicated clinic may in writing authorize the prescribing or supply of such drug in any other form as may be indicated for the patient under his care.

Register of persons under treatment

5. There shall be kept at each such clinic:

(a) A register of persons under methadone treatment at a designated clinic as provided for under rules 2 to 4 of these rules, and

(b) Individual records in which shall be entered details of every prescription and supply, the amount of the drug, and the name of the designated practitioner prescribing the drug, and which shall be countersigned by the person responsible for supplying the drug.

Responsibility for stocks

6. It shall be the duty of the psychiatrist in charge of a designated clinic to ensure that strict procedures are enforced in respect of the security and accountability of methadone preparations stocked at such clinic.

Restricted importation, etc.

7. Saving any other provision of these rules, no person other than the Chief Pharmacist employed with the Department of Health may import, stock or supply any methadone.

Form of prescription

8. (1) When any medical practitioner or dental surgeon issues a prescription for methadone to a patient he shall issue the prescription on the form set out in the Schedule to these rules.

(2) It shall be the duty of the medical practitioner or dental surgeon who prescribes methadone as provided for in this rule to enter in a legible manner all the details contained in Part A of the said form.

(3) It shall be the duty of the apothecary dispensing a prescription for methadone to enter in a legible manner all the details contained in Part C of the said form in accordance with any instructions contained therein.

Dispensing

9. (1) Any prescription for methadone as is referred to in rule 8 of these rules shall only be dispensed from a Government Pharmacy authorized for that purpose by the Superintendent of Public Health.

(2) No methadone may be dispensed unless the prescription is issued in conformity with the provisions of rule 8 of these rules:

Provided that when the prescription is not issued in conformity with the provisions of rule 8 of these rules or where the dose prescribed is in excess of the normal therapeutic dose for methadone, the apothecary in charge of such pharmacy may, if he considers the case as an emergency and after ascertaining the identity of the patient by means of the identity card, issue a supply for two days only and shall immediately inform the prescriber accordingly.

Prescription for pethidine

10. It shall be the duty of every medical practitioner or dental surgeon prescribing pethidine or any salt thereof to a patient who has commenced or is about to commence treatment with such drug for a period exceeding four weeks, to inform the Superintendent of Public Health giving particulars as to the name, age and address of the patient, the patient's identity card number and the indication for long term treatment with that drug.

Non-applicability of rules 2 to 6

11. The provisions of rules 2 to 6 of these rules do not apply in respect of methadone prescribed in terminal cases of malignant disease, provided that the prescriber indicates this fact on the prescription.