

**SUBSIDIARY LEGISLATION 101.02****INTERNAL CONTROL OF DANGEROUS DRUGS  
RULES**

1st September, 1939

*GOVERNMENT NOTICE 292 of 1939, as amended by Government Notices 449 of 1942 and 545 of 1957; Legal Notices 4 of 1974, 40 of 1984, 23 of 1985, 64 of 1986 and 33 of 1989.*

- 1.** The title of these Rules is Internal Control of Dangerous Drugs Rules. Title.
- 2.** (1) For the purposes of these Rules, unless the context otherwise requires - Interpretation.
- "medical practitioner", "dental surgeon", "dentist", "veterinary surgeon", "apothecary" mean in each case a person holding a licence to practice in Malta the profession indicated;
- "Ordinance" means the Dangerous Drugs Ordinance; Cap. 101.
- "register" means a bound book and does not include any form of loose-leaf register or card index.
- (2) The drugs to which these Rules apply are those to which Part V of the Ordinance applies, unless the context otherwise requires.
- 3.** No person shall manufacture or carry on any process in the manufacture of any of the drugs - Prohibition.
- (a) unless he is licensed by the Minister responsible for Health or is authorised by these Rules or by any authority granted by the Minister responsible for Health to do so;
- (b) except on premises licensed for the purpose by the Minister responsible for health;
- (c) otherwise than in accordance with the terms and conditions of such licence or authority.
- 4.** No person shall supply or procure, or offer to supply or procure, the drugs to or for any person and whether in these Islands or elsewhere, or advertise the drugs for sale - Prohibition unless authorised.
- (a) unless he is licensed by the Minister responsible for Health or is authorised by these Rules or by authority granted by the Minister responsible for Health to supply the drugs, or unless he is in possession of an import or export authorisation issued by the Chief Government Medical Officer in pursuance of the provisions of Part VI of the Ordinance, or unless he is licensed or otherwise authorised to manufacture the drug or (but so far only as regards procuring) unless he is licensed to procure the same;
- (b) otherwise than in accordance with the terms and

conditions of such licence or authority.

Drugs lawfully  
dispensed to  
licensed or  
authorised persons.

**5.** Except when the drugs are lawfully dispensed in pursuance of a prescription given by a medical practitioner, dental surgeon, dentist, or veterinary surgeon, in accordance with the conditions hereinafter in these Rules specified, no person shall supply or procure, or offer to supply or procure, any of the drugs to or for any person in these Islands who is not licensed or otherwise authorised to be in possession of the drug nor to any person so licensed or authorised except in accordance with the terms and conditions of such licence or authority:

Provided that the administration of the drug by or under the direct personal supervision of a medical practitioner, or by a dental surgeon or by a dentist in dental treatment, or by, or under the direct personal supervision of a, veterinary surgeon in the treatment of any animal, shall not be deemed to be supplying the drug within the meaning of these Rules.

Prescription for  
drugs.  
*Amended by:*  
*G.N. 448 of 1942;*  
*G.N. 545 of 1957.*  
*Substituted by:*  
*L.N. 40 of 1984.*

**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 the First Schedule to these Rules.

(2) A medical practitioner issuing a prescription for drugs shall fill in a clear and legible hand Part A of the form set out in the First Schedule, 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); 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 to practise the medical profession under article 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.

(3) Subject to the provisions of sub-rule (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 sub-rules (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 sub-rule (3), shall keep, in accordance with, and without prejudice to the provisions of rule 11, a record in an appropriate register, of the name and surname, 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 his Identity Card.

(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, apply, may be prescribed on these forms. S.L. 31.18

(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 the First Schedule 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 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 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, the expression "medical practitioner" includes a dental surgeon, a dentist and a veterinary surgeon.

(11) The provisions of sub-rules (1), (2), (7), (8) and (9) 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.

Conditions to  
dispense drugs.  
*Amended by:*  
*G.N. 545 of 1957.*  
*Substituted by:*  
*L.N. 40 of 1984.*

**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, and 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.

(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 the First Schedule, 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 sub-rule (4), an apothecary dispensing a prescription for the drugs shall request the identity card of the person in respect of whom the prescription has been issued, the person who intends to acquire the drugs whether for himself or on behalf of the person to whom the drugs have been prescribed shall present the said identity card as well as his own identity card together with the prescription:

Provided that the provision of this sub-rule, and the relative part of the provision of sub-rule (4) shall not apply in respect of a person who has not yet been issued with an identity card.

(6) Every managing apothecary of a licensed dispensary shall 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.

Control card.  
*Added by:*  
*L.N. 64 of 1986;*  
*Amended by:*  
*L.N. 33 of 1989.*

**8.** (1) (a) No medical practitioner may prescribe any drug to any person unless such person is in possession of a control card, as per the Fifth Schedule, issued for the purpose by the Superintendent of Public Health.

(b) In prescribing any 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 Sixth Schedule, also issue a prescription for a supply of a 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-rule (2) 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 Sixth Schedule:

Provided that in the case of a prescription for a supply of a drug as provided for in the provisos to sub-rule (1), 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 of Public Health following a request by a medical practitioner, on the form set out in the Sixth Schedule.

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

(5) On dispensing a drug, the apothecary shall, in addition to other duties laid down by these Rules 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) Notwithstanding the provisions of this rule, 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 Rules; and
- (iv) the prescriber notifies the Superintendent of Public Health within forty-eight hours of issuing such prescription, giving full particulars of the patient, the name, form and dose and amount of drug prescribed and reasons 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).

(7) The provisions of this rule shall not apply to the prescription of a drug 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 rule 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 rule, the expression "medical practitioner" includes a dental surgeon and a dentist but does not include a veterinary surgeon.

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

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

Possession of drugs.

**9.** No person shall be in possession of or attempt to obtain possession of any of the drugs unless -

- (a) he is in possession of an import or export authorisation issued by the Chief Government Medical Officer in pursuance of the provisions of Part VI of the Ordinance; or
- (b) he is licensed or otherwise authorised to manufacture or supply such drug; or
- (c) he is otherwise licensed by the Minister responsible for the Department of Health or authorised by these Rules or by any authority granted by the Minister responsible for health to be in possession of the drug; or
- (d) he proves that the drug was supplied for his use in accordance with such a prescription:

Provided that the qualification contained in paragraph (d) shall not apply in the case of any drug supplied to a person for his use in accordance with a prescription if that person was at the time of the supply in course of receiving treatment from another medical practitioner in respect of addiction to any of the drugs or otherwise, and of being supplied with any of the drugs on a prescription given by that last-mentioned practitioner and did not disclose that fact to the first-mentioned practitioner before the drug was supplied to him.

Package or bottle to be plainly marked.  
Amended by:  
G.N. 449 of 1942.

**10.** (1) No person shall supply any of the drugs unless the package or bottle is plainly marked in ink or in other indelible manner with the nature and amount of the drug contained therein.

(2) No person shall supply any preparation, admixture, extract or other article containing any of the drugs unless the package or bottle is plainly marked in ink or other indelible manner-

- (a) in the case of a powder, solution or ointment with the total amount thereof in the package or bottle and the percentage of the drug in the powder, solution or ointment; and
- (b) in the case of tablets or other articles with the amount of the drug in each article and the number of articles in the package or bottle:

Provided that this rule shall not apply to any preparation supplied in accordance with the prescription of a medical practitioner, dental surgeon, dentist or veterinary surgeon.

**11.** (1) Every person who supplies any of the drugs shall comply with the following provisions: Compliance.

- (a) he shall enter or cause to be entered in a register kept for this sole purpose all supplies of the drug purchased or otherwise obtained by him and all dealings in the drug effected by him (including sales or supplies to persons outside these Islands) in the form, with such variations as circumstances may require, and containing the particulars shown in the Second Schedule;
- (b) he shall make the entry with respect to any of the drugs purchased or otherwise obtained by him on the day on which the drug is received, and with respect to any sale or supply by him of the drug on the day on which the transaction is effected; or, where that is not reasonably practicable, on the day next following the day on which the drug is received or the transaction is effected;
- (c) where he carries on business at more than one set of premises he shall keep a separate register or registers in respect of each set of premises;
- (d) he shall keep the register or registers in some part of the premises to which it relates, so that it or they shall at all times be available for inspection in accordance with the provisions of the Ordinance;
- (e) he shall not cancel, obliterate or alter any entry in the register or make therein any entry which is untrue in any particular; any mistake in an entry may be corrected by a marginal note or footnote giving the correct particulars and dated;
- (f) every entry required to be made and every correction of such an entry must be made in ink or otherwise so as to be indelible;
- (g) he shall furnish to the Chief Government Medical Officer such particulars as the said Chief Government Medical Officer may require in regard to any purchases by him of the drugs, all stocks held by him of the drugs, and all transactions effected by him in the drugs.

(2) A drug or preparation administered by, or under the direct supervision and in the presence of, a medical practitioner or dental surgeon or dentist shall not be deemed to have been supplied by him.

(3) With the approval of the Chief Government Medical Officer, separate registers may be kept for separate departments of a business.

Apothecary.

- 12.** (1) An apothecary is hereby authorised -
- (a) to manufacture in the ordinary course of his retail business any preparation, admixture or extract of any of the drugs; and
  - (b) to carry on the business of retailing, dispensing or compounding the drugs, but subject always to the provisions of these Rules.

(2) Every drug in the actual custody of a person authorised by virtue of this rule shall be kept in a locked receptacle which can be opened only by him.

(3) Where under the provisions of article 9(2) of the Ordinance any such authorisation has been withdrawn, notice of such withdrawal shall be published in the Gazette.

Authorised persons.

**13.** Notwithstanding anything to the contrary contained in these Rules, any medical practitioner, dental surgeon, dentist, veterinary surgeon or apothecary, or any person in charge of a laboratory used for research or instruction and attached to any public hospital or other institution approved by the Minister responsible for Health for the purpose, is hereby authorised, so far as may be necessary for the practice of his profession or employment in such capacity and in accordance with the provisions of any law relative to such profession or employment, to be in possession of and to supply the drugs.

Conviction for an offence.

**14.** (1) If any person authorised by these Rules or by an authority granted by the Minister responsible for Health to manufacture, supply or possess the drugs or any of them is convicted of an offence against the Ordinance or these Rules, the Minister responsible for Health may, if he is of opinion that that person ought not to be allowed to manufacture, supply or possess the drugs, withdraw the authority of such person and notice of such withdrawal shall be published in the Gazette:

Provided that nothing in this rule shall be taken to prejudice any power otherwise vested in the Minister responsible for Health of withdrawing any authority previously given by him.

(2) Where the person whose authority is withdrawn under sub-rule (1) of this rule is a medical practitioner, dental surgeon, dentist or veterinary surgeon, it shall not be lawful, if the Minister responsible for Health so directs, for that person to give prescriptions for the purposes of these Rules, and notice of any such direction shall be given to the person affected thereby and shall be published in the Gazette.

(3) If the Minister responsible for Health has reason to suspect that a medical practitioner or dental surgeon or dentist is supplying or prescribing drugs to or for either himself or any other person otherwise than is properly required for the purpose of medical or dental treatment of himself or that of any other person, the Minister responsible for Health may refer the matter to the Tribunal constituted in the manner specified in the Third Schedule, and, if the Tribunal so recommends, the Minister responsible for Health may withdraw the authority of the practitioner or dental surgeon or

dentist to supply, procure or possess the drugs and give the like direction with respect to him as may be given under sub-rule (2) of this rule, and notice of any such withdrawal or direction shall be given to the person affected thereby and shall be published in the Gazette.

**15.** (1) No person shall deliver any of the drugs to any person not licensed or otherwise authorised to be in possession of the drugs who purports to be sent by or on behalf of a person so licensed or authorised unless such person produces an authority in ink or in other indelible manner, signed by the person so licensed or authorised, to receive the drug on his behalf, and unless the person supplying the drug is satisfied that the authority is genuine. This rule shall not be deemed to apply to medicines dispensed in accordance with the provisions of these Rules.

Delivery and supply of drugs.  
Amended by:  
G.N. 449 of 1942.

(2) A person to whom a drug is lawfully delivered in the circumstances mentioned in sub-rule (1) shall be deemed to be a person authorised to be in possession thereof, but for such period only as in the circumstances of the case is reasonably sufficient to enable the delivery to the recipient to be effected.

**16.** Any of the drugs in the order or disposition of any person shall be deemed to be in his possession.

Possession of drugs.

**17.** These Rules shall not apply to the preparations named in the Fourth Schedule, nor to any such preparations when mixed with an inert substance required to render the medicament suitably coherent.

Preparations.

**18.** Prescriptions, records, registers or other documents required to be retained or kept in pursuance of the Ordinance or of any of these Rules shall be preserved for not less than two years from the date of the prescription or document or the last entry in the record register, as the case may be, and shall be kept at all times available for inspection in accordance with the provisions of the Ordinance.

Prescriptions, records, etc.







## THIRD SCHEDULE

*Substituted by:  
L.N. 4 of 1974.*

(Rule 14)

The Medical Council constituted under article 20 of the Department of Health (Constitution) Ordinance shall be the tribunal for the purposes mentioned in sub-rule (3) of rule 14 of these Rules.

## FOURTH SCHEDULE

(Rule 17)

**Preparations exempt from the Rules**

- Cereoli Idoformi et Mophineae, B.P.C. '23  
Elixir Diamorph. et Terpin. c. Apomorph., B.P.C.  
Emp. Opii, B.P. '98.  
Linctus Diamorph. Camph., B.P.C.  
Linctus Diamorph. c. Ipecac., B.P.C.  
Linctus Diamorph. et Scill., B.P.C.  
Lin. Opii, B.P. '14.  
Lin. Opii Ammon., B.P.C. '23.  
Pasta Arsenicals, B.P.C.  
Pil. Digitalis et Opii Co., B.P.C. '23.  
Pil. Hydrarg. c. Cret. et Opii, B.P.C.  
Pil. Hydrag. c. Opio, B.P.C. '23.  
Pil. Ipecac. c. Scill., B.P. '14.  
Pil. Plubi c. Opio. B.P. '14.  
Pulv. Cret. Aromat. c. Opio, B.P.  
Pulv. Ipecac. et Opii, B.P (Dover's Powder).  
Pulv. Kino Co. B.P., '14.  
Suppos. Plumbi c. Opio, B.P.  
Tabellae Plumbi c Opio, B.P.C.  
Ung. Gallae c. Opio, B.P.C. (Ung. Gallae Co.).  
Mixtures of Emp. Opii, B.P. '98 with other plasters of the British Pharmacopoeia 1914 and 1932, and of the British Pharmaceutical Codex.  
Mixtures of Lin. Opii, B.P. '14 with other liniments of the British Pharmacopoeia 1914 and 1932, and of the British Pharmaceutical Codex.  
Mixtures of Pulv. Ipecac. Co., B.P. '14 and of Pulv. Ipecac. et Opii, B.P. with any of the following:  
Hydrarg. c. Cret., B.P.



SIXTH SCHEDULE

Added by:  
L.N. 64 of 1986.

(Rule 8)

**DRUGS (CONTROL) REGULATIONS AND DANGEROUS DRUGS  
(INTERNAL CONTROL) RULES**

**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.

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