

SUBSIDIARY LEGISLATION 458.49**PRESCRIPTION AND DISPENSING
REQUIREMENTS RULES**

1st December, 2006

LEGAL NOTICE 292 of 2006, as amended by Legal Notices 303 of 2013 and 401 of 2014.

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| <p>1. The title of these rules is the Prescription and Dispensing Requirements Rules.</p> <p>2. (1) These rules apply to medicinal products and to products or substances not classified as medicinal products but which have been deemed by the Medicines Authority to require a medicinal prescription for their use.</p> <p>(2) The provisions of these rules are without prejudice to those stipulated in the Free Medicinals (Prescription Forms) Regulations, in respect of prescription forms for free medicinals.</p> <p>3. Every prescription shall:</p> <p>(a) be easily legible and written in ink or in other indelible manner;</p> <p>(b) bear the date on which it is written, clearly indicate in a legible manner and in block letters the full name, professional qualification, work address (including the name of the relevant Member State) and contact details (e-mail and telephone or fax, the latter both with international prefix), such as the telephone number, of the prescriber as well as the registration number assigned by the relevant council, and shall be signed accordingly in original;</p> <p>(c) bear the name, date of birth, age and locality of current residence of the patient and the 'Common name' as defined in article 2 of the Medicines Act; the brand name if (i) the prescribed product is a biological medicinal product, as defined in Part I, point 3.2.1.1. of the Schedule to the Medicines (Marketing Authorisation) Regulations, or (ii) if the person authorised in accordance with article 81 of the Medicines Act to issue a prescription deems it medically necessary; in that case the prescription shall shortly state the reasons justifying the use of the brand name; the strength, dosage form, quantity and duration of treatment of each prescribed product included in the said prescription, together with clear instructions on how the prescribed product is to be taken or used. Repeat prescriptions are to be marked accordingly indicating the total period of duration of treatment;</p> <p>(d) in the case of electronically generated prescriptions, bear the details in paragraphs (a), (b) and (c) and must be</p> | <p>Title.</p> <p>Interpretation.</p> <p>S.L. 458.24</p> <p>Form and content of prescription.
<i>Amended by:</i>
<i>L.N. 303 of 2013;</i>
<i>L.N. 401 of 2014.</i></p> <p>Cap. 458.</p> <p>S.L.458.34</p> |
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officially signed by the prescriber, which may include digital signatures; and

- (e) if the product prescribed qualifies under the criteria for prescribing a brand name as specified in paragraph (c), the pharmacist dispensing the product shall dispense the product with the brand name as prescribed.

Dispensing of prescription.

4. (1) It shall not be lawful for any person, not being a pharmacist duly licensed to practise in Malta, to dispense a prescribed product against a prescription.

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(2) It shall not be lawful for any pharmacist to dispense any product to which these regulations apply except on a prescription issued from persons duly authorized under article 81 of the Medicines Act, unless the product is deemed by the Licensing Authority not to require a prescription.

(3) Verbal instructions over the telephone shall not be accepted and honored unless the following conditions are satisfied:

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(a) that the pharmacist is satisfied that the verbal instruction over the telephone is being requested by a person duly authorized under article 81 of the Medicines Act, who by reason of an emergency is unable to furnish a prescription immediately;

(b) that the prescriber undertakes to furnish the pharmacist with a prescription complying with the provisions of rule 3 within forty-eight hours of the verbal instructions;

(c) that the product is dispensed in accordance with the directions of the prescriber; and

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(d) that an entry is made into any record kept under the Medicines Act:

Provided that these conditions shall not apply to narcotic or psychotropic substances.

(4) It shall not be lawful for any pharmacist to dispense a product against a prescription after the expiry of six months from the date specified in rule 3(b), unless it is a repeat prescription, in which case it shall only be dispensed other than in accordance with the directions contained in the repeat prescriptions.

(5) If a prescription is more than six months old, the patient shall be referred to the prescriber for reassessment.

(6) In the case of antibiotics, the prescription shall not be dispensed after ten days from the date of issue of the prescription.

Dispensed prescriptions, repeat prescriptions and partially dispensed prescriptions.
Substituted by:
L.N. 303 of 2013.

5. (1) The dispensing pharmacist shall write clearly and legibly thereon in ink or any other indelible manner the word "dispensed", date of dispensing, the quantity supplied, the Pharmacy Council registration number, signature and endorse the prescription with the pharmacy stamp.

(2) For repeat prescriptions and partially dispensed prescriptions, which are given back to the patient, the dispensing

pharmacist shall write clearly and legibly thereon in ink or any other indelible manner the word "dispensed", date of dispensing, the quantity supplied, the Pharmacy Council registration number, signature and endorse the prescription with the pharmacy stamp.

6. (1) A pharmacist dispensing a repeat prescription or partially dispensed prescription shall enter into any record kept under the Medicines Act the following particulars:

Particulars to be noted.
Amended by:
L.N. 303 of 2013.
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- (a) the date on which the prescription is dispensed;
- (b) the name, quantity and the pharmaceutical form and strength of the product;
- (c) the full name of the prescriber and his registration number;
- (d) the date of the prescription; and
- (e) in the case of medicinal products dispensed in compliance with rule 4(3), the date on which the prescription is received.

(2) The requirements of sub-rule (1) shall be satisfied in the case of computerized records, provided that the information is also retained in the form of a print-out for each day on which the pharmacy is open. Such print-out shall be dated and certified by the managing pharmacist on the day to which the print-out relates or within a period of twenty-four hours thereafter.

7. The provisions stipulated in the Dangerous Drugs Ordinance, and in the Medical and Kindred Professions Ordinance, in respect of prescriptions for narcotic and psychotropic substances, shall also apply.

Applicability of other laws.
Cap. 101.
Cap. 31.