

TO: Pharmacy Licence Holders
Managing Pharmacists
Pharmacists

RE. STANDARDS, REPORTING AND ADMINISTRATIVE ISSUES FOR PHARMACIES

The Medicines Authority, which was set up in November 2003 as the National Competent Authority to regulate medicinal products for human use, has now taken over all regulatory obligations and responsibilities pertaining to pharmaceutical activities, including pharmacies.

Your attention is brought to previous circulars in respect of the pharmacy roster (I 02/2005), payment of fees (I 004/2006) and national surveillance program for medicines (DH 127/05). This circular is now aimed at summarising the obligations of licence holders and pharmacists so that reporting and compliance with legislation is achieved in a consistent manner.

Legal Basis

Pharmacies are regulated by the Medicines Act 2003 and the various subsidiary legislations published as legal notices. Licence holders and pharmacists are urged to become familiar with the obligations and standards specified in legislation and achieve compliance accordingly.

Legislation regulating pharmacies include:

1. Medicines Act, Act III of 2003, Part III Title IV.
2. L.N. 31 of 1984 – Dispensaries Licensing Regulations.
3. L.N. 354 of 2002 – Opening Hours of Dispensaries Order.
4. L.N. 200 of 2004 – List of active Substances in a Medicinal Product (requirement for prescription) Regulations.
5. L.N. 22 of 1985 – Drugs (Control) Regulations.
6. L.N. 292 of 1939 – Internal Control of dangerous Drugs Rules.
7. L.N. 380 of 2005 – Medicinal Products (Advertising) Regulations.
8. L.N. 393 of 2005 – Medicinal products (Labelling and Packaging) Regulations.
9. L.N. 143 of 1998 – Licensing Fees for Private Medical Premises Regulations.
10. L.N. 486 of 2004 – Pharmacy Licences (Fees) Regulations.

Obligations and Responsibilities

Pharmacists and Licence Holders are responsible to abide by the applicable standards with respect to pharmacy practice and pharmacy premises as defined and stipulated by law. In particular, your attention is being brought to the following:

- a) the 30 minute concession, for a pharmacist to be temporarily absent from a pharmacy, is no longer applicable. Pharmacists are required to be present within the pharmacy at all times. This requirement is, and will be, strictly enforced.
- b) pharmacists are obliged to wear a clean white overall and to wear the identity tag that will be issued by the Pharmacy Council in due course (L.N. 31 of 1984 art. 10 (5)).
- c) pharmacists should have easy access to pharmaceutical information to enable them to perform their duties diligently.
- d) record keeping is an essential requirement that should be strictly observed. Electronic registers can be kept provided that a reliable back-up is available and that print outs are issued, duly signed and filed.

Administrative Duties

Pharmacists and Licence Holders need to comply with various administrative obligations and reporting duties, including:

1. An application for variation to a pharmacy licence is to be lodged for any change pertaining to the licence, such as change in licence holder (i.e. transfer of licence), change in premises (temporary or permanent), change in name of pharmacy.
2. Authorisation must be obtained prior to initiation of any alteration works. New plans together with the relevant MEPA permits, if applicable, are to be submitted.
3. Any change in managing pharmacist must be notified and the Managing Pharmacist Declaration Form must be duly completed by the new incumbent. A resignation letter is to be submitted by the managing pharmacist leaving the post, at least one week prior to termination.
4. Authorisation must be obtained for any change in the assigned roster. The two pharmacies that would like to swap must agree in writing and submit the request three weeks in advance.
5. Notification is to be submitted in cases where a pharmacy cannot open. Unless authorised, pharmacies are required to abide by the opening hours stipulated in L.N. 354 of 2002 (i.e. Mondays to Saturdays from 9.00 – 12.00 and from 16.00 – 19.00, Sundays 9.00 – 12.00 according to roster).
6. Records should be kept of locum pharmacists substituting the managing pharmacist.
7. Any pharmacy technician employed with a pharmacy should be notified.
8. An end of year stock-taking report in respect of narcotic drugs and psychotropic substances must be submitted.

You are also being reminded of your legal obligations to cooperate with inspectors and enable easy access to premises during inspections, spot checks, collection of samples for analysis and investigations. A serious view will be taken in those instances where the inspectorate duties are hampered or resisted.

All applications, correspondence, and notifications with respect to pharmacies and the above mentioned points are henceforth to be submitted to the Medicines Authority. Prescriptions for narcotic and psychotropic drugs (green prescriptions) should be sent to the Government Pharmaceutical Services at the end of each month according to the present system.

Information, links to legislation and application forms can be found on the Medicines Authority's website www.medicinesauthority.gov.mt. Application forms can also be obtained directly from the Medicines Authority.

Should you require any further information you are kindly requested to contact the Inspectorate Directorate.

Regards

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