

SUBSIDIARY LEGISLATION 458.16**PHARMACY LICENCE REGULATIONS**

5th October, 2007

LEGAL NOTICE 279 of 2007, as amended by Legal Notices 81 of 2008, 198 of 2010, 305 of 2013 and 400 of 2014.

1. The title of these regulations is the Pharmacy Licence Regulations. Citation.

2. In these regulations, unless the context otherwise requires - Interpretation.
Amended by:
L.N. 400 of 2014.
Cap. 458.

"Act" means the Medicines Act;

"Cruise Liner Sea Terminal" means the site within the boundaries of the emphyteutical concession granted by Parliamentary Resolution 323 of 2003;

"drug" includes any medicinal product as defined in the Act;

"licence" means a licence granted under article 66 of the Act;

"Licensing Authority" means the Superintendent of Public Health in terms of article 3(1) of the Act;

"Malta International Airport" means the site within the boundaries of the emphyteutical concession granted by Parliamentary Resolution 298 of 2011;

"the Minister" means the Minister responsible for health;

"pharmacy" means any premises from which any medicinal products are sold, dispensed or otherwise supplied directly to the public by retail, irrespective of whether such sale, dispensing or supply is carried out on the presentation of a prescription given for the purpose by a medical practitioner, dental surgeon or veterinary surgeon, or otherwise;

"relocation" means the transfer of pharmacy premises from one place within a locality to another place within the same locality;

"Smart City" means the site within the boundaries of the emphyteutical concession granted by Parliamentary Resolution 281 of 2007;

"special designated areas" means the sites indicated in regulation 4A;

"town" means a locality, including all hamlets and outlying areas, having a local council or committee so designated under the Local Government Act and qualifying as such under this Act and "village" shall be construed to be the same; Cap. 363.

"walking distance" means the shortest walking distance.

3. (1) No person shall qualify for a licence if he is a medical practitioner, dental surgeon or veterinary surgeon. Disqualification from holding a licence.

(2) It shall not be lawful for any medical practitioner, dental surgeon or veterinary surgeon or any other person authorised to

issue prescriptions under the Act or any other Act, to enter into any agreement with any pharmacist or any other person for any share in the profits of a pharmacy, or to have any direct or indirect interest of whatever nature in any pharmacy.

(3) It shall not be lawful for any person:

- (a) to carry on the business of a pharmacy on account of, or in partnership with any medical practitioner, dental surgeon or veterinary surgeon or any other person authorised to issue prescriptions under the Act or any other Act;
- (b) to enter into any agreement with any medical practitioner, dental surgeon or veterinary surgeon or any other person authorised to issue prescriptions as aforesaid, for any share in the profits of a pharmacy;
- (c) to lend his name in order that the business may be carried out by some other person.

(4) If a pharmacy is kept closed for a period of six months or for any aggregate period of six months within one calendar year, the licence thereof shall be considered as being no longer valid and on completion of any such period the Licensing Authority shall give notice accordingly to the person to whom the licence has been issued.

Restrictions on the granting of a licence.
Amended by:
L.N. 198 of 2010.

4. (1) The number of pharmacies that may be licensed within the boundaries of any town or village shall not be less than two, and such pharmacies shall be situated no less than three hundred meters walking distance from each other:

Provided that such distance shall not apply in the case of pharmacies already holding a licence on the day of coming into force of these regulations:

Provided further that no pharmacy can open within three hundred meters walking distance from a pharmacy in a neighbouring town or village.

(2) In every town or village the number of pharmacies shall not exceed the ratio of one pharmacy for every two thousand five hundred inhabitants.

(3) The number of inhabitants of a town or village shall be taken to be the number of inhabitants of that town or village as published by the National Office of Statistics.

Special designated areas.
Added by:
L.N. 400 of 2014.

4A. The provisions of regulation 4 shall not apply to special designated areas which for the scope of these regulations shall be: Smart City, the Malta International Airport and the Cruise Liner Sea Terminal.

Application for a second licence.

5. (1) A licence for a pharmacy in a town or village shall not be granted to an applicant who already holds a licence for a pharmacy in the same town or village.

(2) An applicant who already holds a licence in a town or village may be granted another pharmacy licence in another town or village provided that there are no pending applications for a

pharmacy in that locality from persons who hold no licence for a pharmacy:

Provided that the provisions of this regulation shall not apply in respect of renewals of existing pharmacy licences but shall be taken into account if and when a request for the transfer of such a licence or an application for relocation is made.

(3) Any licensee may transfer an existing licence to another person by means of an application to the Licensing Authority.

(4) Any licensee may after authorisation by the Licensing Authority relocate the pharmacy to other suitable premises within the same town or village provided that the conditions of regulation 6 are adhered to.

6. A licensee may apply for the relocation of a pharmacy as long as the relocation is within the same town or village and the proposed new premises:

Relocation of pharmacy.
Amended by:
L.N. 81 of 2008.

- (a) offer better facilities in terms of these regulations than the existing premises;
- (b) are situated no less than three hundred meters walking distance from any other existing pharmacy or not more than 50 meters from the current premises:

Provided that in the case of an application for a pharmacy licence submitted before the application for relocation of an existing pharmacy, and where, as a result of such relocation, the distance between the proposed new pharmacy and the relocated pharmacy is less than 300 metres, then the requisite of 300 metres shall not apply in determining the validity or otherwise of the pending application.

7. The provisions of regulation 5 shall not apply to an application for a licence for a hospital in-patient pharmacy:

Hospital pharmacies.

Provided that such pharmacy may be bound by the Licensing Authority to provide service to the public on a twenty four hour, seven days a week basis, excluding normal pharmacy retail hours:

Provided further that such provisions shall not apply to any pharmacy which forms part of the Government health service.

8. Any licence granted after the coming into force of these regulations shall have as a condition of the licence the obligation to participate in any national pharmaceutical distribution or dispensing system that the Minister may at any time wish to introduce.

National pharmaceutical system.

9. A licence for a pharmacy shall only be granted if the pharmacy complies with the following standards:

Standards relating to a pharmacy.

- (a) easy access to the public;
- (b) the external appearance reflects the professional character of the pharmacy and make it clear to the public that the practice of pharmacy is the main

- purpose of the establishment;
- (c) the premises are compatible with the workload carried out within it whilst ensuring efficient and effective communication between the pharmacy staff and members of the public;
 - (d) the walls, floors, ceiling, windows and all other parts of the premises are kept clean in such manner that any surfaces present shall be impervious and may be easily wiped clean;
 - (e) the premises have a clear area set aside for the preparation and compounding of medicinal products and diagnostic testing;
 - (f) the pharmacy premises are kept in an orderly, organised condition;
 - (g) the premises provide an environment, in respect of space, temperature, lighting, humidity, noise levels and other factors, which is in conformity with occupational health and safety requirements, thereby providing a safe environment for staff and members of the public visiting the premises;
 - (h) all products present on the premises are protected from the adverse effects of extremes of temperature, sunlight and excess humidity in a manner that there shall be always followed the maximum or minimum temperature and humidity and any other condition specified on the packaging by the manufacturer;
 - (i) all openings to the outside of the premises are securely locked when the pharmacy is closed;
 - (j) the toilet facilities are kept clean and in good working order. Facilities must include hot and cold water, soap and nail brushes and a hand drying facility. The toilet area must not be used as a source of water for dispensing or as a storage area;
 - (k) all pharmaceutical and non-pharmaceutical waste and expired and deteriorated products are to be segregated from pharmacy stock and placed in a designated quarantine area. The safe disposal of pharmaceutical and non-pharmaceutical waste is to be made according to regulations under this Act or any other law.

Pharmacy
premises.
Amended by:
L.N. 81 of 2008.

10. (1) The premises shall be kept in a good state of repair at all times and no structural alterations shall be carried out without the prior approval of the Licensing Authority.

(2) No pharmacy shall form part or communicate with premises used for habitation and no pharmacy shall be used for sleeping purposes:

Provided that the provisions of this sub-regulation shall not apply in respect of a pharmacy existing before the coming into force of these regulations and which cannot be structurally altered as to comply with such provisions.

(3) It shall not be lawful for a licensee to carry out or cause to permit, or suffer to be carried out on the premises any activity which is not strictly that of storage, preparation, dispensing, sale or supply of medicinal products or that of storage or sale of other articles and all other activities related to pharmaceutical and other healthcare services as allowed by these regulations.

(4) Without prejudice to sub-regulation (2), there shall be no communication between the premises of a pharmacy and any other premises which is used for any commercial activity whatsoever, except in accordance with sub-regulation (3).

11. The pharmacy shall be provided with reference sources and equipment and other utensils as the managing pharmacist may require for the practice of good pharmacy within the premises.

Equipment, stock and appearance.

12. (1) Without prejudice to the professional responsibility of a pharmacist to maintain records as deemed fit and necessary for good patient care, all medicinal products dispensed against prescriptions shall not need to be registered and documented, except for those referred to in sub-regulation (4).

Registers and report of sales and stock of drugs.
*Substituted by:
L.N. 305 of 2013.*

(2) Pharmacists shall retain all prescriptions dispensed for a period of three months from date of dispensing; such prescriptions shall be retained in a manner that, in case of need, reference to a particular prescription can be made. At the end of the three month period, the said prescriptions may be disposed of in a manner that safeguards the patient's confidentiality.

(3) The dispensing pharmacist shall record on the prescription the date upon which the prescription was dispensed, his/her signature and Pharmacy Council registration number.

(4) It shall be the duty of the managing pharmacist to keep separate written records or electronic records into which shall be entered -

- (a) the sale of every medicinal product dispensed against a repeat prescription;
- (b) the sale of every medicinal product dispensed against a partially dispensed prescription.

The requirements of sub-regulations (1) and (2) shall be applicable when the prescription is fully dispensed.

(5) The provisions of this regulation shall not apply for narcotic drugs and psychotropic substances whose purchase and sale shall continue to be registered in line with the requirements of the Dangerous Drugs Ordinance and any subsidiary legislation made thereunder.

Cap. 101.

13. (1) The managing pharmacist shall supply the Licensing Authority with a list of pharmacists working in the pharmacy and of pharmacy technicians working under the supervision of a pharmacist within the pharmacy. He shall also inform the Licensing Authority when any such pharmacist or pharmacy technician ceases to be employed within the pharmacy which falls under his responsibility.

Duties of managing pharmacist.

(2) The managing pharmacist shall keep written records of any pharmacist or pharmacy technician engaged to work in the pharmacy on a locum basis and such records shall be signed by the managing pharmacist and countersigned by the locum pharmacist or pharmacy technician as the case may be and shall be available at all times for inspection by the Licensing Authority or his delegate.

(3) The managing pharmacist or any pharmacist employed within a pharmacy shall be obliged to wear a white coat while attending to his professional duties and shall have an identity tag issued by the Pharmacy Council attached to his coat clearly showing his name, designation and Pharmacy Council registration number.

(4) The name and Pharmacy Council registration number of the managing pharmacist shall be kept affixed in the pharmacy premises in such a way as to be visible at all times during which the pharmacy is open.

Opening times.

14. (1) Each pharmacy shall be kept open on such days and on such times as the Licensing Authority may from time to time order in accordance with the provisions of article 88 of the Act.

(2) The managing pharmacist of the pharmacy which is not required to be kept open in terms of subregulation (1) shall affix to the door of the pharmacy under his management, a notice clearly visible from the street indicating the name and address of the pharmacy or pharmacies required to be kept open in that particular district.

Stores.

15. The provisions of these regulations shall so far as applicable, apply also to stores used in connection with any pharmacy.
