

Superintendence of Public Health Sovrintendenza tas-Saħħa Pubblika

Ministry for Health, the Elderly and Community Care

Conditions of Licence for Pharmacy Licences

In line with and in addition to obligations and responsibilities listed in Medicines Act 2003 a pharmacy Licence Holder:

- shall provide and maintain such premises, equipment, facilities and staff for the handling, storage and dispensing of
 the medicinal products which s/he handles and stores under this licence as are necessary and according to
 manufacturers' storage conditions and instructions to avoid deterioration of such products. A pharmacy Licence
 Holder shall not use pharmacy premises for such purposes other than those specified in the Medicines Act and any
 subsidiary legislation. In particular pharmacy premises shall primarily be used for activities associated with
 medicinal products and medical devices storage and sale as per legislation and other professional healthcare
 services.
- 2. shall notify the Licensing Authority in writing before making any material alteration in the premises or any change in equipment which may impact the quality of medicines used under this licence, or in the operations in which they are used, and s/he shall notify the Licensing Authority in writing of any change that s/he proposes to make in qualified personnel in connection with this licence.

3.

- (1) shall have at his disposal the services of a managing pharmacist, who is registered with the Pharmacy Council, to carry out the functions specified in sub-paragraphs (11-29) of these licence conditions
- (2) shall at all times provide and maintain such staff, premises and facilities as will enable the managing pharmacist to carry out the said functions
- 4. shall keep readily available for inspection by officers authorized by the Licensing Authority as responsible for the enforcement or execution of these conditions non perishable records of each purchase and dispensing of a product, whose sale according to law should be recorded, in a manner that ensures traceability of the origin.
- 5. shall, if so directed by the Licensing Authority, immediately withhold any product from sale or supply and, immediately facilitate the recall of all supplies of such product already sold or supplied when these are returned to the pharmacy.
- 6. shall keep the pharmacy adequately equipped with any equipment that is required for the proper maintenance of storage conditions for the medicinal products, for pharmacy security and for proper and efficient disposing of medicines and record keeping as required by the managing pharmacist. Such equipment must be of such standard and kept properly maintained so as to be suitable for its intended purpose.
- 7. shall enable access to current reference material in hard copy or electronically for consultation by the pharmacists within the pharmacy.
- 8. shall not close the pharmacy, unless authorisation is given from the Licensing Authority for a planned closure after requesting permission with at least three days notice. For urgent closures immediate notice, or as soon as is possible in force majuere situations, has to be given to the Medicines Authority stating reason for such an urgent closure.
- 9. shall abide by the provisions of the Medicines Act 2003, its subsidiary legislation and the licence conditions made in this document.
- 10. Shall lodge an application for variation of licence if any details appearing on the licence shall change. Such changes cannot be carried out unless the varied licence is issued.

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In line with and in addition to obligations and responsibilities listed in Medicines Act 2003 a managing pharmacist:

- 11. shall ensure that all these licence conditions are adhered to.
- 12. shall be present at the pharmacy at all times it is open to the public, unless substituted by another pharmacist.
- 13. shall not open a pharmacy if no locum pharmacist is available in his/her absence and must inform immediately the Licensing Authority in such a case.
- 14. shall keep a proper register of locum pharmacists attending in his/her absence.
- 15. shall ensure that the dispensing of medicinal products is in accordance with the provisions of the Medicines Act and its subsidiary legislation.
- 16. shall ensure that the conditions for storage of medicinal products are in accordance with the requirements of the marketing authorization and labeling.
- 17. shall monitor all environmental conditions and areas used for storage and dispensing.
- 18. shall maintain records for any transaction in medicinal products as required by the Medicines Act 2003 and its subsidiary legislation.
- 19. shall comply with good practice as established by the Medicines Act 2003 and its subsidiary legislation.
- 20. shall only act as managing pharmacist for one pharmacy, unless otherwise authorized by the Licensing Authority.
- 21. shall not take up or abandon one's duties without giving prior notice to the Licensing Authority.
- 22. shall supervise the dispensing of medicinal products by persons other than pharmacists, that are authorized to perform such duties under the Medicines Act 2003.
- 23. shall wear a clean white overall bearing the tag issued by the Pharmacy Council at all times.
- 24. shall not allow the promotion, by any means including discounts or other promotional offers, of medicinal products to the public.
- 25. shall keep the pharmacy and all surfaces in a clean state and keep appropriate records of cleaning. Shelves must be of a material that can be easily wiped clean and are impervious to moisture.
- 26. shall keep pharmacy free from cluttering and store medicines in such a way to ensure proper rotation of stock.
- 27. shall keep adequate procedures for waste disposal and waste material must not be allowed to accumulate on the premises.
- 28. shall ensure proper labeling of all dispensed medicinal products.
- 29. shall comply with all provisions of the Medicines Act 2003 and its subsidiary legislation.

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