

Community Pharmacy: Legislation & Regulations

Pharmacy Information
Session



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Content:

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- Requirements, why?
- Legislation – Medicines Act 2003
- Legal notices: Rules and regulations
- Conditions of licence



Requirements

Health care professions and the services they render have been regulated with strict requirements since antiquity.

Pharmaceutical Industry/ Pharmaceutical Chain: Manufacturers – Importers & Wholesale dealers – Pharmacies



Requirements

All activity players in the pharmaceutical industry are regulated, some such as manufacturers heavily regulated and these together with importers and wholesalers managed to achieve and now maintain high levels of standards.

This must be so also at the pharmacy level.

Knowledge of the governing laws, rules and regulations by the Licence Holder and Pharmacists (managing pharmacists and locum pharmacist).

Pharmacy Licence

Before 2003 :The Medical & Kindred Professions Ordinance.
In 2003 the Medicines Act was published and came into force.



Medicines Act 2003

Medicines Act, Act III of 2003, Chapter 458 of the Laws of Malta, *Amended by Acts III of 2004 and XI of 2007* which came fully into force on 1/12/03.

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Medicines Act 2003

Medicines Act, Act III of 2003 (*continued*):

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Medicines Act 2003

Pharmacies and related pharmaceutical activity: Part III Title IV Articles 66-89

Articles 66 – 69 : processing of applications for & issue of new pharmacy licences (*Interesting to note article 66 (6) – Licensee must comply with licence conditions.*)

Article 70 - 72: speaks about the pharmacy licence; its content, validity, transfer, suspension or revocation.

Article 73 : Temporary closure authorised by LA except in force majeure. Closure for > 5days without authorisation there is automatic revocation;

Article 74 : Obligations of Pharmacy Licence Holder (*listed & amplified/explained in conditions of licence*);



Medicines Act 2003 (*continued*)

Article 75 – 76: (75) Managing pharmacist, duties & obligations of pharmacists (*listed & amplified/explained in conditions of licence*), mention here responsibility to have locum pharmacist and keep locum register + all other registers & if managing pharmacist is absent for >5 days, must nominate to LA a temporary managing pharmacist; can be a managing pharmacist of only 1 pharmacy;

(76) Dispensing & preparation done solely by a pharmacist or by a pharmacy technician under **direct** supervision of pharmacist;



Medicines Act 2003 (*continued*)

Article 77: Interest in a pharmacy: medicinal doctors, vet. surgeons or dentists cannot have any interest in a pharmacy

Article 78 : Employment of managing pharmacist free from any interference.

Articles 79-84: Dispensing and dealings with medicinal products:

Articles 80 – Pharmacist cannot refuse dispensing except in justified reasons which are: suspicion of falsification, misuse or abuse, medicine not available, other professional reasons; generic substitution possible except when doctor lists ® near name or writes word “branded”;

In suspected errors pharmacist is **bound** to inform prescriber;
Pharmacists takes full responsibility for the OTC;

Articles 81 – 83: dispensing against a prescription for POM and correct labelling;



Medicines Act 2003 (*continued*)

Article 84: cannot sell damaged, deteriorated, harmful or expired products;

Article 85: managing is to ensure correct storage of medicinal products and has facilities to ensure storage with recommended storage conditions;

Articles 85-88: Premises & equipment in good order and up to standard (*amplified by LN 279/2007*), and mention powers of entry and inspections

Article 89: Opening of pharmacies (*LN 364 of 2002*)



Legal Notices : Rules & Regulations

Medicines Act supplemented by subsidiary legislation – the Legal Notices

LN 236 of 2008 – Pharmacy Licences (Fees) Regulations

LN 364 of 2002 – Opening hours

L.N. 22 of 1985 (*as amended*) – Drugs (Control) Regulations (psychotropic drugs)

L.N. 292 of 1939 (*as amended*) – Internal Control of Dangerous Drugs Rules (narcotic drugs)

LN 292 of 2006 – Prescription & Dispensing Requirements Rules

LN 279 of 2007 (*as amended by LN 81 of 2008 & LN 198 of 2010*) – Pharmacy Licence Regulations.

Accessible through links in the Medicines Authority website:

www.medicinesauthority.gov.mt under heading Regulatory Affairs/Maltese legalisation. LINK to website page:

<http://www.medicinesauthority.gov.mt/legislation.htm>



L.N. 22 of 1985

L.N. 22 of 1985 (as amended) – Drugs (Control) Regulations (psychotropic drugs) (in particular regulations 4, 7, 8, 9(4,5,6b), 11 & 12).

Regulation 4: Content & Upkeep of purchase & sale registers

Regulation 7: use & contents of a prescription – specific form; all fields filled in; 1 form for each drug; issued to known persons (use of ID cards) etc.

Regulation 8: Dispensing of green prescriptions - Only pharmacists can dispense these; prescription should comply with regulation 7; no repeats; filled in full and only to known patients or against ID card.

Regulation 9 (4) : Must have control card (except in emergency cases);

Regulation 9 (5) : all details clear & legible;

Regulation 9 (6b): In emergency prescription supply must not exceed 7 days; & prescription must be labelled as URGENT.



L.N. 22 of 1985 (*continued*)

Regulation 11: delivery shall only be made to pharmacist only against a receipt (must be signed) or to an authorised (written) person by the pharmacist, who shall handle these personally.

Regulation 12: Registers (purchase & sale) must be on the premises



L.N. 292 of 1939

L.N. 292 of 1939 (as amended) – Internal Control of Dangerous Drugs Rules (narcotic drugs) (in particular regulations 6,7 (1,2,4&5) , 8, 11 & 15).

Regulation 6: use & contents of a prescription – specific form; all fields filled in; 1 form for each drug; issued to known persons (use of ID cards) etc.

Regulation 7(1), (2), (4) & (5) : Dispensing of green prescriptions - Only pharmacists can dispense these; prescription should comply with regulation 7; no repeats; filled in full, legible and only to known patients or against ID card.

Regulation 8 : Must have control card (except in emergency cases);



L.N. 292 of 1939 (*continued*)

Regulation 11: Content & Upkeep of purchase & sale registers

Regulation 15: delivery shall only be made to pharmacist only against a receipt (must be signed) or to an authorised (written) person by the pharmacist, who shall handle these personally.



LN 292 of 2006

LN 292 of 2006 – Prescription & Dispensing Requirements Rules

Regulation 3: Full, legible & in indelible ink; repeat prescriptions should be indicated so by the prescriber and for the indicated duration;

Regulation 4: Dispensing of POMs against a prescription by a pharmacist; prescriptions made only by medical doctors, dentists or veterinary surgeons; verbal instructions cannot be taken except in emergency cases and instructions made by authorised persons, directions for administration must be clear and a prescription to be eventually done within 48 hours (This is not applicable to narcotics & Psycho tropics); prescription is valid for 6 months except for antibiotics where a prescription cannot be dispensed after 10 days of its issue date.



LN 292 of 2006 – Prescription & Dispensing Requirements Rules (*continued*)

Regulation 5: If prescription is not retained, dispensing pharmacist must write clearly on prescription that it was dispensed, indicating date, quantity supplied and by whom (signature, name and registration number of Pharmacy Council), plus the pharmacy stamp.

Regulation 6 (1): Upkeep of a daily register showing date of prescription & name of prescriber, date dispensed, name/quantity/form & strength of product dispensed.

Regulation 6 (2): Computerised systems are acceptable if above information is retained and is printed out (and retained) on a daily basis with signature and date by the pharmacist.



LN 279 of 2007 – Pharmacy Licence Regulations

LN 279 of 2007 – Pharmacy Licence Regulations (as amended by LN 81 of 2008 & LN 198 of 2010)

In particular of utmost importance for community pharmacy practice regulations 9 to 13.

Regulation 9: Standards relating to a pharmacy – Easy access, reflects a professional character, premises compatible with workload, all surfaces clean, premises secure; toilet facilities available and clean with hot and cold water, compounding & preparation area available; pharmacy is kept in orderly & organised manner; environment safe and acceptable for staff and patients in terms of light, temperature, humidity and noise; products protected from adverse effects by excess or extremes of temperature, humidity and sunlight in line with maximum and minimum temperature & humidity specified on packaging by the manufacturer, whilst last but not least expired and deteriorated medicinals must be kept segregated from stock and safe disposal made according to laws of Malta.



LN 279 of 2007 – Pharmacy Licence Regulations (continued)

Regulation 10 Pharmacy Premises should:

- Be in a good state of repair & structural changes first to be approved by LA
- Does not communicate with or be used for habitation
- Activity allowed is that associated with dispensing and healthcare activity
- Can have access to the clinics used only for health care providing services
(*amendment introduced by LN 81 of 2008*)

Regulation 11 – Pharmacy shall be equipped with equipment, utensils and reference sources required by pharmacist to exercise his daily duties.

Regulation 12 – Registers to be kept showing:

- Sale of every medicinal product & poisonous substances;
- Purchase & sale of Narcotics & Psychotropics;
- Electronic records acceptable as long as they are secured, preventing tampering of data and audit trails of entries and deletions are possible.



LN 279 of 2007 – Pharmacy Licence Regulations (continued)

Regulation 13 Duties of managing pharmacist:

- Keep a register of persons working in the pharmacy including a locum pharmacist register;
- Pharmacist must wear a white coat with an identity tag issued by the Pharmacy Council at all times when carrying out his /her professional duties.

-Regulation 14 – Managing pharmacist should ensure that pharmacy is opened in line with the law and when not kept open (in line with the legislation), must affix a notice clearly visible with names and address of pharmacies open in that district.



Pharmacy Licence Conditions

Conditions of pharmacy licence mentioned in article 66(6) i.e. must be complied with and in article 68 (1) states that grant of licence is made conditional to the carrying out of such obligations as imposed.

Obligations.

The Licence Holder has 10 listed conditions which in summary:

- Maintain premises adequate for their use with all required facilities & equipment,
- Have one managing pharmacist and must provide him with all that is required including additional staff to help him in his daily duties,
- Have and give access to authorised persons (inspectors) to any record
- Help in recalls if so instructed
- Shall not close the pharmacy without authorisation except in cases of force majeure & in such cases must immediately & as soon as possible inform the LA
- Shall apply for a variation of licence if any detail on licence is or will be changed



Pharmacy Licence Conditions (*obligations continued*)

The managing pharmacist has 19 listed obligations in the list of conditions which in summary are:

- Shall be present at all times unless substituted by a pharmacist in which case must keep a locum register,
- If s/he or locum is not possible to be present must keep pharmacy closed & inform LA immediately
- Areas adequate for storage as per manufacturers labelling and must monitor all environmental areas used for storage
- shall not take up or abandon one's duties without giving prior notice to the Licensing Authority.
- shall not allow the promotion, by any means including discounts or other promotional offers, of medicinal products to the public.
- shall keep the pharmacy and all surfaces in a clean state and keep appropriate records of cleaning



Pharmacy Licence Conditions (*pharmacist obligations continued*)

- shall keep pharmacy free from cluttering and store medicines in such a way to ensure proper rotation of stock.
- shall ensure proper labeling of all dispensed medicinal products.



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