

L.N. 337 of 2024

**VETERINARY SERVICES ACT
(CAP. 437)**

Veterinary Pharmacy Regulations, 2024

IN EXERCISE of the powers conferred by articles 30 and 70 of the Veterinary Services Act, the Minister responsible for veterinary services, after consultation with the Director Veterinary Services, has made the following regulations:-

1. (1) The title of these regulations is the Veterinary Pharmacy Regulations, 2024. Citation, scope and commencement.

(2) The scope of these regulations is to establish standards to be complied with by veterinary pharmacies licensed in accordance with article 62 of the Veterinary Services Act and to further implement Article 103 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC. Cap. 437.

(3) These regulations shall come into force within two (2) months from their publication in the Gazette.

2. (1) In these regulations, unless the context otherwise requires: Interpretation.

"Act" means the Veterinary Services Act; Cap. 437.

"Director" shall have the same meaning as assigned to it in the Act;

"licence" means a veterinary pharmacy licence issued in accordance with article 62 of the Act;

"licensed veterinary establishment" shall have the same meaning as assigned to it in the Private Veterinary Establishments (Licensing) Regulations; S.L. 437.106.

"managing pharmacist" means the pharmacist managing the pharmacy referred to in article 63(1)(d) of the Act;

"narcotic drugs" means the substances present on the Yellow List established by the International Narcotics Control Board in accordance with the Protocol of 25 March 1972 amending the Single Convention on Narcotic Drugs, 1961;

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Cap. 464.

"pharmacist" means a person who is enlisted in the Register of Pharmacists kept by the Pharmacy Council in accordance with article 17 of the Health Care Professions Act;

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"premises" means the premises used for, or in connection with, any premises licensed by the Director to carry out the business of a veterinary pharmacy;

"psychotropic drugs" means the substances listed in the Third Schedule to the Medical and Kindred Professions Ordinance and those substances listed on the Green List prepared by the International Narcotics Control Board in accordance with the Convention on Psychotropic Substances of 1971, as amended from time to time;

"Regulation (EU) 2019/6" means Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC;

"relocation" means the transfer of a veterinary pharmacy premises from a physical premises within a locality to another physical premises within the same or different locality, upon the approval of the Director;

"Single Convention" means the Single Convention on Narcotic Drugs adopted at New York on the 30th March 1961, as subsequently amended by the Protocol adopted in Geneva on the 25th March, 1972;

"suitably learned person" means any person included in the Register for the Professions and Trades Supplementary to the Veterinary Profession mentioned in the Act who can dispense veterinary medicinal products of category OTC under the supervision of a veterinary surgeon or pharmacist and dispense others of category GS without this supervision;

S.L. 437.106.

"veterinary consultancy practice" shall have the same meaning as assigned to it in the Private Veterinary Establishments (Licensing) Regulations;

"veterinary medicinal products" shall have the same meaning as assigned to it in Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC;

"veterinary pharmacy" means any premises licensed in

accordance with article 62 of the Act in which any veterinary medicinal product is kept or from where it is sold, dispensed or supplied directly to the public by retail but shall not include dispensing of treatments from veterinary establishments and dispensing during out calls by veterinary surgeons;

"veterinary surgeon" means a person who has a warrant granted in accordance with article 43 of the Act.

(2) Unless the context otherwise requires, words and phrases used in these regulations which are not defined herein shall have the same meaning as assigned to them in the Act:

Provided that words and phrases used in these regulations which are not defined herein nor in the Act shall have the same meaning as assigned to them in Regulation (EU) 2019/6.

3. (1) Any person not being a medical practitioner, dental surgeon or a veterinary surgeon may apply to the Director for the issuance of a licence in accordance with article 62 of the Act. Application for a licence.

(2) The said person shall submit an application with the Director in the prescribed form as provided by the Director and shall pay the applicable fee in accordance with the Veterinary Medicinal Products and Veterinary Pharmacies (Fees) Regulations. L.N. 336 of 2024.

(3) The Director shall, within ninety (90) days from the date of receipt of the said application, decide on the application as referred to in article 63(2) of the Act.

(4) Unless otherwise determined by the Director based on the conclusions of an inspection, the licence shall be valid for five (5) years and renewed in accordance with article 66 of the Act.

(5) The licence shall pertain only to the premises and the address listed on the application for a veterinary pharmacy submitted to the Director in accordance with article 64(2) of the Act:

Provided that if the licence holder intends to relocate the veterinary pharmacy, he shall apply for a new licence.

4. (1) No medical practitioner, dental surgeon or veterinary surgeon shall enter into any agreement with a pharmacist or any other person for any share in the profits of a veterinary pharmacy, or to have any direct or indirect interest of whatever nature in any veterinary pharmacy in accordance with article 68 of the Act. Revocation of a licence.

(2) Any person who:

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(a) carries on the business of a veterinary pharmacy on account of, or in partnership with a medical practitioner, dental surgeon or veterinary surgeon;

(b) enters into any agreement with a medical practitioner, dental surgeon or veterinary surgeon for any share in the profits of a veterinary pharmacy; or

(c) allows any other person to use his name in order that the business may be carried out by such person,

shall have his licence revoked.

Conditions for
the granting of a
licence.

5. The Director shall, in accordance with article 64(1) of the Act, inspect the premises and shall not issue a licence unless the following conditions are satisfied:

(a) the licence shall be displayed in a prominent position in the premises at all times;

(b) the external appearance shall reflect the professional character of the veterinary pharmacy and makes it clear to the public that the business of a veterinary pharmacy is the primary activity of the establishment;

(c) the premises shall be kept orderly and clean in such manner that every surface present shall be kept with the least amount of clutter, impermeable and easy to wipe;

(d) the premises shall have a clear area set aside for the unpacking of goods, preparation and compounding of veterinary medicinal products and testing activities;

(e) all products present on the premises shall be protected from the adverse effects of extremes of temperature, sunlight and excess humidity in a manner that the maximum and minimum temperature and humidity and any other condition specified on the packaging by the manufacturer are always complied with:

Provided that records shall be kept for daily readings of thermometers indicating the highest and lowest temperatures reached in different parts of the pharmacy, including any refrigerators;

(f) all access points to the premises shall be securely locked when the veterinary pharmacy is closed;

(g) the premises shall be equipped with toilet facilities which shall be kept clean and in good working order:

Provided that the said facilities shall include warm and cold water, soap and nail brushes and a hand drying facility:

Provided further that the said facilities shall not be used as a source of water dispensing or as storage areas;

(h) all waste derived from veterinary medicinal products or other sources, and expired or deteriorated products shall be segregated from veterinary pharmacy stock and placed in a designated quarantine area:

Provided that the safe disposal of all types of waste shall be made in accordance with regulation 7(d);

(i) psychotropic and narcotic drugs shall be kept in a secure non-conspicuous cabinet which shall be locked at all times when not in use:

Provided that access to the cabinet shall be the responsibility of the managing pharmacist;

(j) 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 Director;

(k) a high level of cleanliness shall be observed in all places and regular cleaning schedules shall be kept;

(l) a pest control programme shall be prepared and records thereof shall be kept:

Provided that the said records shall be retained for a period of at least one (1) year and shall be available for inspection upon request by the Director;

(m) the premises shall not form part of a premises used for habitation and no veterinary pharmacy shall be used for sleeping purposes;

(n) every veterinary pharmacy shall have its own separate and independent entrance for the public and any connection with any other premises which is used for any commercial activity shall be kept to a minimum:

Provided that the provisions of this regulation shall

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not apply in respect of an existing veterinary pharmacy before the coming into force of these regulations and which cannot be structurally altered as to comply with this regulation:

S.L. 437.106.

Provided further that if the commercial activity being carried out from the same premises is that of a veterinary consultancy practice licensed in accordance with the Private Veterinary Establishments (Licensing) Regulations, such consultancy shall be allowed to continue operating only in cases where the veterinary consultancy practice licence holder held such licence prior to the coming into force of these regulations;

(o) a licence holder shall not carry out, cause to permit, or suffer to be carried out on the premises any activity which is not related to:

(i) the storage, the preparation, the dispensing, the sale or supply of veterinary medicinal products; or

(ii) the storage or sale of other articles and all other activities related to veterinary medicinal products and other animal care products or activities as allowed by these regulations; and

(p) the veterinary pharmacy shall have access to reference sources of information and equipment as the managing pharmacist may require in the exercise of good pharmacy practice within the premises.

Records of retail sale.

6. (1) Without prejudice to the professional responsibility of the managing pharmacist to maintain records in accordance with the obligations of Article 103(3) of Regulation (EU) 2019/6, records in respect of each transaction of veterinary medicinal products requiring a veterinary prescription shall include:

(a) the species of animals to which the veterinary medicinal products are to be administered;

(b) the type of veterinary medicinal product;

(c) the broken, damaged or expired veterinary medicinal products; and

(d) the copies of invoices or receipts given by suppliers of veterinary medicinal products or issued to clients for providing veterinary medicinal products, in electronic or hard copy format. The minimum particulars present on the invoices or receipts shall be the following:

- (i) in cases of establishments which are under the official control of the Director, the identity of the client;
- (ii) date of supply;
- (iii) name and pharmaceutical form of the veterinary medicinal product; and
- (iv) quantity supplied.

(2) The detailed audit which shall be carried out in accordance with Article 103(5) of Regulation (EU) 2019/6, may also include information obtained from the veterinary prescriptions.

(3) The information mentioned in sub-regulations (1) and (2) shall be kept for a period of not less than five (5) years and be readily available for inspection by the Director upon his request.

7. The managing pharmacist or his temporary substitute being a *locum* pharmacist, shall fulfil the following obligations:

Obligations of
the managing
pharmacist.

(a) be present at all times during the veterinary pharmacy's opening hours to the public.

(b) keep written records in a register of any pharmacist and suitably learned person working at the veterinary pharmacy. Such records shall be signed by the managing pharmacist, and countersigned by the other *locum* pharmacists or suitably learned persons. The records shall be retained for a period of at least five (5) years and be available for inspection by the Director upon his request.

(c) wear a white lab coat while attending to his professional duties and shall have an identity tag issued by the Pharmacy Council attached to their coat clearly showing his name, designation and the Pharmacy Council registration number.

(d) prepare standard operating procedures for the effective running of the veterinary pharmacy which shall at least include procedures to follow in case of batch or product recalls, management of expired veterinary medicinal products and their proper disposal, maintenance of proper storage conditions, collection of data on sales of antimicrobials and procedures for the unloading and verification of veterinary medicinal products.

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Veterinary medicinal products kept at the veterinary pharmacy.

8. Veterinary medicinal products can only be retailed from the veterinary pharmacy under the following conditions:

(a) veterinary medicinal products shall be appropriately kept in their original boxes, fully labelled and with no loose blister or mixed batches;

(b) unauthorised veterinary medicinal products shall not be kept at the veterinary pharmacy;

(c) veterinary medicinal products shall be kept at appropriate temperature, light and humidity levels in accordance with the summary of products characteristics; and

(d) expired or unused veterinary medicinal products shall be kept segregated in designated areas.

Opening hours.

9. A veterinary pharmacy shall be kept open on such days and on such times as the Director may order in accordance with the provisions of article 70 of the Act.

Veterinary pharmacy stores.

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

Obligations of the licence holder.

11. A licence holder of a veterinary pharmacy shall:

(a) immediately inform the Director of any changes in the details given in the original application within one (1) working day;

(b) provide the Director access to his premises, documents and equipment at any reasonable time to carry out inspections as necessary;

(c) enable the Director to carry out his duties established by the Act and these regulations;

(d) provide any samples of the veterinary medicinal products which have been retailed or available from the veterinary pharmacy at the request of the Director;

(e) provide any information about veterinary medicinal products, including data on sales and use of veterinary medicinal products, as requested by the Director;

(f) inform the Director of any intention to relocate the veterinary pharmacy three (3) months prior to relocation and shall apply for a new licence in accordance with regulation 3;

and

(g) abide by other responsibilities as may be established from time to time by the Director.

12. (1) When the Director has valid reason to believe that the licence holder, any pharmacist or suitable learned person working in the veterinary pharmacy are acting in breach of any of the provisions of these regulations or article 62 of the Act, he shall notify the said person in writing through a notice, specifying the type of breach and a time frame during which a valid justification for his actions is to be provided:

Acting in breach.

Provided that when the notice is sent to any pharmacist or suitable learned person working in the veterinary pharmacy, a copy of the notice shall also be sent to the licence holder.

(2) Where the said person referred to in sub-regulation (1) fails to provide a valid justification within such time as specified in the notice, or if the reply is unsatisfactory, the Director may suspend the activity of the said person through a written notice specifying the reasons for the said suspension until such person is in compliance.

(3) The Director may report any breach of these regulations to the relevant national body that regulates the said professional.

(4) Any license issued in accordance with article 62 of the Act shall not be renewed unless remedial measures as specified in the notice are taken by the person to whom such notice is addressed.

13. Any person who contravenes or acts in violation of any of these regulations shall on conviction be liable to a fine (*multa*) of not less than two hundred euro (€200) and not more than four hundred euro (€400), or to imprisonment for a term not exceeding one (1) month, or both such fine and imprisonment:

Offences, punishments and administrative penalties.

Provided that the Director shall not be precluded from proceeding in accordance with the provisions of article 61 of the Act.

14. Decisions in terms of these regulations shall be subject to a right of appeal before the Administrative Review Tribunal established in terms of article 5(1) of the Administrative Justice Act by not later than twenty (20) days from the service of the decision, wherein the person aggrieved by the said decision shall specify the reasons on the basis of which the said decision of the Director should be cancelled or modified:

Right of appeal.

Cap. 490.

Provided that the decision shall become immediately

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applicable and enforceable and shall remain applicable throughout the term of appeal until final judgement by the Administrative Review Tribunal, unless such decision is reversed by the said Tribunal and, or the Court of Appeal or cancelled or modified by the Director:

Cap. 490. Provided further that any party, who feels aggrieved by a decision of the Tribunal, may on a point of law, appeal to the Court of Appeal in accordance with article 22 of the Administrative Justice Act.

Consequential
amendment.
Cap. 490.

15. Immediately after the last item of the Second Schedule to the Administrative Justice Act there shall be added the words "Veterinary Pharmacy Regulations, S.L. 437.116, Superior/Inferior Competence".
