

User Guidelines

1. Introduction

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| Title of Legal Notice | Veterinary Pharmacy Regulations, 2024 hereinafter referred to as the "legal notice". |
| Activity to be regulated | Retail of Veterinary Medicinal Products from Veterinary Pharmacies. |
| Responsible entity | The Veterinary Regulation Directorate within the Animal Health and Welfare Department. |

2. Objectives and Purpose of the Legislation

The legal notice aims to strengthening the control of retail of veterinary medicinal products from veterinary pharmacies. Together with Part X (specifically from article 62 to article 70) of the Veterinary Services Act (Cap. 437), it implements further Article 103 of Regulation (EU) 2019/6 of the European Parliament and of the Council of the 11th December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC. The legal notice implements to the full the legal provisions referred to in Part X (Articles 62 to 70) of the Veterinary Services Act (Cap. 437).

The need for better control of veterinary medicinal products, in particular regarding the rising threats of antimicrobial resistance, and the dangers of putting on the market ineffective medicines were the main drivers for this legal notice. In addition, the standards of animal care and expectations from the public have both risen significantly in recent years. Therefore, any new legislation must also live up to these expectations.

The standards established by this legal notice will ensure that the objectives are met. It is appropriate that the retail sale of high-risk products, such as veterinary medicinal products, is conducted only from a regulated and controlled environment that reduces the risk to animal and public health.

3. Commentary on parts and articles

The regulations are made up of fifteen (15) regulations as follows:



1. Citation, scope, applicability and commencement.
2. Interpretation.
3. Application for a licence.
4. Revocation of a licence.
5. Conditions for the granting of a licence.
6. Records of retail sale.
7. Obligations of the managing pharmacist.
8. Veterinary medicinal products kept at the veterinary pharmacy.
9. Opening hours.
10. Veterinary Pharmacy stores.
11. Obligations of the licence holder.
12. Acting in breach.
13. Offences, punishments and administrative penalties.
14. Right of appeal.
15. Consequential amendment.

Regulation 3 explains how and who can apply for a veterinary pharmacy. An application prescribed by the Director of the Veterinary Services must be submitted to the Director, who shall decide whether to grant a licence within 90 days. The procedure for granting a licence includes an inspection.

Regulation 4 explains that certain persons are disqualified from holding a veterinary pharmacy licence, namely medical practitioners, dental surgeons and veterinary surgeons. This regulation refers to the situation when a licence has to be revoked because an important condition is not satisfied with regard to economical agreement between a medical practitioner, dental surgeon or veterinary surgeon. These shall not enter into any agreement with any pharmacist or any other person for any share in the profits of a veterinary pharmacy.

Regulation 5 lists the conditions that must be fulfilled to grant a veterinary pharmacy. These range from the external appearance to the adequate premises that ensure that the quality of veterinary medicinal products is preserved. It also lists the requirements with regard of waste disposal and required facilities. The regulation mentions how a veterinary pharmacy must be managed and kept.

Regulation 6 refers to the record keeping requirements for the retail of veterinary medicinal product. These requirements may differ depending on whether retail is conducted in establishments which are under the official control of the Director or not.

Regulation 7 lists the obligations of the pharmacists working at the veterinary pharmacy, including the managing pharmacist and his substitute (*locum* pharmacist). The obligations range from what the pharmacists have to wear during their duty time to what standard operating procedures they should maintain.

Regulation 8 mentions how and what veterinary medicinal product shall be kept at the veterinary pharmacy.

Regulation 9 is about the opening times of veterinary pharmacies. The opening times may be ordered by the Director.

Regulation 10 relates to the stores that may form part of the veterinary pharmacy. The regulation makes it clear that what applies to veterinary pharmacy applies to its store, where applicable. For example, if a veterinary medicinal product should be stored at a temperature not exceeding 25 degrees Celsius in the pharmacy, it should be likewise kept in such conditions in stores.

Regulation 11 lists the obligations of the veterinary pharmacy licence holder and delve into subject matters like changes in the original application, access to the Director, provision of samples of veterinary medicinal product and provision of data on sales and use of veterinary medicinal products.

Regulation 12 explains the procedure that has to be followed when any of the parties is believed to be in breach of any of the provisions of the regulations, or Article 62 to 70 of the Veterinary Services Act (Cap. 437).

Regulation 13 provides the fines (*multa*) for breaches of the provisions of this legal notice. The fine (*multa*) shall not exceed four hundred euro (€400) while imprisonment penalty shall not exceed one (1) month. It also provides the possibility for the Director to proceed in accordance with article 61 of the Act, when administrative penalty is deemed more appropriate.

Regulation 14 provides that decisions of the Director in terms of these regulations shall be subject to a right of appeal before the Administrative Review Tribunal established by article 5(1) of the Administrative Justice Act. An appeal in terms of this regulation shall be filed within twenty (20) days from the service of the Director's 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: Provided that the Director's decision shall become



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

Disclaimer: The information contained within this document is intended only as guidelines and is not intended, nor should be construed, as legislation. Please refer to the related legal notice for a more comprehensive understanding.

For any other information kindly contact the Veterinary Medicines Unit of the Veterinary Regulation Directorate within the Animal Health and Welfare Department using the following contact details:

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