

User Guidelines

1. Introduction

Title of Legal Notice	Veterinary Medicinal Products Regulations, 2023 hereinafter referred to as "the regulations"
Activity to be regulated	Strengthening the regulation and control of the retail, research, supply, distribution, dispensing, prescribing, manufacturing and use of veterinary medicinal products and active substances..
Responsible entity	The Veterinary Services within the Animal Health and Welfare Department of the Ministry for Agriculture, Fisheries and Animal Rights

2. Objectives and Purpose of the Legislation

The regulations are made up of forty-six (46) regulations as follows:

1. Citation, scope, applicability and commencement.
2. Interpretation.
3. Languages.
4. Package Leaflet.
5. Exemptions from a Marketing Authorisation.
6. Authorisation for Research and Development Purposes.
7. Samples or demonstration packs.
8. Veterinary Medicinal Products obtained for personal use.
9. Registration in accordance with Article 116 of Regulation (EU) 2019/6.
10. Cascade use of veterinary medicinal products.
11. Registration of homeopathic veterinary medicinal products.
12. Parallel Trade.
13. Manufacturing of Veterinary Medicinal Products and Active Substances.
14. Qualified Person.
15. Import for re-export.
16. Retail supply of veterinary medicinal products.
17. Dispensing.
18. Prescribing.
19. Distribution Categories of Veterinary Medicinal Product.



20. Advertising.
21. Promotion.
22. Wholesale Distribution and Brokering of Veterinary Medicinal Products.
23. Application for a Wholesale Distribution Authorisation.
24. Granting of a Wholesale Distribution Authorisation.
25. Obligations of the Wholesale Distributor of veterinary medicinal products.
26. Renewal, Validation, Suspension or Revocation of a Wholesale Distribution Authorisation.
27. Duties of the Responsible Person.
28. Other medicinal products.
29. Brokering of Veterinary Medicinal Products.
30. Disqualification from holding a veterinary pharmacy licence.
31. Standards relating to a pharmacy premises and obligations of the holders of a veterinary pharmacy licence.
32. Structural alterations.
33. Equipment, stock and appearance.
34. Obligations of the managing pharmacist.
35. Veterinary medicinal products kept at the Veterinary Pharmacy.
36. Opening times.
37. Stores.
38. Obligations of the Veterinary Pharmacy licence holder.
39. Veterinary Prescription.
40. Veterinary prescription established by the Director.
41. Administration of Veterinary medicinal products and medicinal product to animals.
42. Complaints received by the Marketing Authorisation Holder.
43. Safe disposal of veterinary medicinal products.
44. Access by the Director.
45. Offences, punishments and administrative penalties.
46. Repeal and saving.

3. Commentary on parts and articles

Regulation 1 establishes the citation, the scope, the applicability and the commencement date of these regulations.

Regulation 2 provides definitions for terms found in the regulations. It is to be noted that definitions that are already present in the Veterinary Services Act (Chapter 437 of the Laws of Malta) shall apply when words and phrases used in the regulations are not defined, and that when words and phrases used are not defined in the regulations and the Act, the definition in

Regulation (EU) 2019/6 shall apply.

Regulation 3 specifies how the Director can decide which languages of the packs are acceptable to be marketed in Malta, as per Article 7 of Regulation (EU) 2019/6.

Regulation 4 specifies the acceptability of an electronic package information leaflets as per Article 14(3) of Regulation (EU) 2019/6.

Regulation 5 supports the exemption from a Marketing Authorisation granted by Article 5(6) of Regulation (EU) 2019/6. The applicants shall apply for these exemptions and the conditions thereof, including a number of obligations, e.g. reporting of adverse reactions. Companies should note that active substances which are antimicrobials cannot be authorised through this route. The requirements include the information about the product that have to be given to the user. Companies are obliged to include this information on the packs. Products authorised in this way cannot be prescription-only-medicine. Therefore, antimicrobials are excluded from the use of this exemption.

Regulation 6 specifies how applicants shall apply for authorisation and the conditions thereof, including a number of obligations, e.g. reporting of adverse reactions. The products might not necessarily be veterinary medicinal products with a Marketing Authorisation but even investigational veterinary medicinal products or active substances. Companies should take note that this provision regulated the product in question rather than the activity *per se*.

Regulation 7 specifies how applicants have to make a request to the Director for registration and the conditions thereof. An important requirement is that the applicant shall be a holder of a wholesale distribution authorisation. Companies should note that that it is through this provision that samples are registered as such. Companies cannot bring veterinary medicinal product and classify them as samples themselves. They can use the medicine as such a sample after its registration.

Regulation 8 specifies the conditions for any person to procure veterinary medicinal products from any country for personal use. Important requirements include that the products shall not be sold or re-sold for monetary gain and that the products themselves, or their indications, are not illegal in Malta. Live or attenuated Immunologicals products (vaccines), Psychotropic drugs or narcotic drugs cannot be obtained in this way. A veterinary prescription may be needed in some cases. To note that this provision does not apply for getting medicinal product manufactured for human use but intended by the person in question to be used on animals.

Regulation 9 specifies how applicants shall apply for the registration in accordance with Article 116 of Regulation (EU) 2019/6 and the conditions thereof. Products registered in accordance with Article 116 are exempted from a Marketing Authorisation. Therefore, to counteract any shortcoming in this registration a number of safeguards have been created based

on the requirements of a proper Marketing Authorisation. This can ensure sustainability of this widely used registration route.

Regulation 10 specifies how applicants shall apply for authorisation when veterinary surgeons procure the products from other countries and the conditions thereof. An important point is that when veterinary surgeons procure veterinary medicinal product through this route, they are excluded from the legal obligation of wholesale distribution. However, there are still other obligations, e.g. record keeping and issuing of a veterinary prescription in all cases. Veterinary Surgeons should note that an application to the Director should only be made when they would like to procure a veterinary medicine (not a medicine for human use) from outside Malta. There is no need for them to use any application form if they apply the cascade for product that are already available locally but which will not be used according to the terms of the Marketing Authorization.

Regulation 11 specifies how applicants have to make a request to the Director to obtain the registration of homeopathic veterinary medicinal products to be authorised in accordance with Article 86 of Regulation (EU) 2019/6. Companies should note that ‘regular’ homeopathics should obtain a Marketing Authorisation. No exemptions apply for these. Therefore, the regulations for Marketing Authorisation (including packaging/labelling) requirements and manufacturing (include GMP licences and Manufacturing Authorisation) apply.

Regulation 12 specifies how to make a request to the Director for registration for Parallel Trade of veterinary medicinal products to be authorised in accordance with Article 102 of Regulation (EU) 2019/6. Companies should note that in the veterinary sector the technical word used is ‘Parallel Trade’ as opposed to ‘Parallel Import’ in the human medicines sector. In the veterinary sector Parallel Trade is regulated by Regulation (EU) 2019/6.

Regulation 13 specifies how applicants apply for a Manufacturing Authorisation in accordance with Articles 88 and 89 of Regulation (EU) 2019/6 and the conditions thereof. It also stipulates that a manufacturing authorisation shall not be required for preparation, dividing up, changes in packaging or presentation where these processes are carried out solely for retail directly to the public by pharmacists in veterinary pharmacies, or by other persons legally authorised to supply veterinary medicinal products to the public, e.g. veterinary surgeons (Article 88(2) of Regulation (EU) 2019/6).

Regulation 14 clarifies the requirements of the Qualified Person and adds crucial obligations. These will also form the basis of the administrative procedures (Article 97(5) of Regulation (EU) 2019/6) that the competent authority will make in relation with the Qualified Person. The position of a Qualified Person is a legally designated position. Any manufacturer/importer of veterinary medicinal product should have at least one person as a Qualified Person in line with Article 97(1) of Regulation 2019/6.

Regulation 15 provides legal cover for the authorised veterinary wholesale dealers who intend to ‘import’ veterinary medicinal products without putting them on the EU Market but re-export them to Third countries. In these cases, if no manufacturing activity takes place on the products (including re-labelling) these may be exempted from a Marketing Authorisation and the applicant may be exempted from obtaining a Manufacturing Authorisation. The activity will be considered solely as an act of export that authorised wholesale dealers can duly conduct. It is to note that certain conditions apply, e.g. the activity should be carried out in a freeport, free trade zone, bonded stores or customs warehouse. A very important condition is that the products are not changed in any way. Simple labelling is also classified as manufacturing. Therefore, if this activity is carried out the consignment is disqualified from this provision.

Regulation 16 stipulates from where the retail supply of veterinary medicinal products shall be conducted. Retail sale shall be carried out only from veterinary pharmacies, licensed veterinary clinics/hospitals or the other establishments (pet shops, medicated feed business operators, and registered animal care product stores). Supply by veterinary surgeons can be done during their professional visits or when clients visit them.

Regulation 17 stipulates who can dispense veterinary medicinal products. In this regulation there are the standards that the dispenser must follow when dispensing; for example, veterinary surgeons may dispense veterinary medicinal products during in-call visits by the person bringing the animal to the licensed veterinary establishment and during their out-call visits. The quantities should be those required for the treatment where delay in the administration of the product may adversely affect the health and welfare of the animal. Veterinary surgeons should take note that this provision does not allow them to honour each other’s veterinary prescription on a routine manner. This does not mean that in certain exceptional cases they cannot co-operate with each other to fulfil the treatment requirement for the patients under their care. When veterinary surgeons perform retail activity, they will automatically be subject to the retail requirements, even though the veterinary establishment is not classified as a veterinary pharmacy. It is to be emphasised that the retail requirements apply to any kind of retail no matter where performed, i.e. in a veterinary pharmacy, pet-shop or veterinary surgeon from a veterinary establishment or independent of it.

Regulation 18 stipulates who can prescribe veterinary medicinal product and issue veterinary prescriptions in Malta. These can only be veterinary surgeons. In this regulation there are the standards that the person prescribing must follow; such as for example, it stipulates which is the only legally valid veterinary prescription in Malta, how a veterinary medicinal product should be prescribed, what are the obligations of veterinary surgeons in this regard. It goes into detail on what are the conditions for prescribing, e.g. before prescribing a veterinary surgeon shall carry out a clinical assessment of the animal under his care. There is also an obligation for veterinary surgeons to take in consideration factors related with antimicrobial resistance.

Regulation 19 stipulates the way veterinary medicinal products shall be prescribed and dispensed. Some need to be prescribed on a veterinary prescription to be dispensed. These are classified as Prescription-Only-Medicines (POM). POMs are in turn further classified depending on whether they can only be dispensed by a veterinary surgeon (POM-V) or dispensed by both veterinary surgeons and pharmacist (POM-VP). Other products are considered as less risky and may be obtained without a veterinary prescription. These are classified as Over-The-Counter (OTC). Both OTCs and POMs have to be dispensed from a veterinary pharmacy or obtained from a veterinary surgeon. Furthermore, there is a category of veterinary medicinal products that is considered as the least risky of them all. These veterinary medicinal products are classified on the ‘General Sales List’ (GS). Only these products can be dispensed from premises other than veterinary pharmacies, veterinary clinic/hospitals and veterinary surgeons, e.g. registered pet-shops, authorised medicated feed business operators and registered animal care product shops, Aquarium fish shops. Apart from pharmacists and veterinary surgeons, these can be supplied by Suitably Learned Persons. It is the responsibility of the wholesale distributor to ensure that only veterinary medicinal products with the appropriate category are distributed to each type of premises.

Regulation 20 provides the regulatory coverage for activities that are in common practice in Malta today. Attention has been given to the fact that advertisement can be misleading and not properly formulated.

Regulation 21 seeks to minimise any undue pressures that companies might exercise on prescribers and suppliers of veterinary medicinal products. It is considered as an important regulation with regard to decrease in the misuse, abuse and overuse of antimicrobials. It regulates the relationship between pharmaceutical companies and professional persons.

Regulations 22 - 28 provide comprehensive and cohesive legal coverage about enforcement, inspection, supervision and recall procedures that wholesale dealers should have in place.

The regulations specify how applicants shall apply for a wholesale distribution authorisation and the conditions for this authorisation. They also detail how this can be renewed, suspended or even revoked. Each procedure is described in some detail. The processing of an application shall not exceed ninety (90) days starting from the date on which the application is received. The Responsible Person must be a pharmacist who has a number of responsibilities (e.g. 24 hrs/7 days contact detail, provide details on sales data). The regulations specify that the wholesale distributor must have a permanent address in Malta, and that the Distributor shall comply with good distribution practices for veterinary medicinal products. The premises shall not be interconnected with any other premises which are used for other commercial activities or for habitation (exceptions apply), and the Distributor shall provide to the Director the ‘Letter of access’ by the marketing authorization holder granting him the use of such Marketing Authorisation.

Regulation 29 specifies how applicants shall register for brokering of veterinary medicinal products by means of a request to the Director. An inspection to grant this registration may or may not take place according to a decision by the Director. There are also details how the registration of the broker is renewed, suspended or even revoked. The broker should not be in any way involved in the distribution or storage of the products. If at some point, he does get involved directly in these activities he ceases to be a broker and becomes a wholesale distributor. In this case he needs to be covered by a wholesale distribution authorisation.

Regulations 30 - 38 specify how certain persons are disqualified from holding a veterinary pharmacy licence (medical practitioner, dental surgeon or veterinary surgeon). Nevertheless it is to note that veterinary surgeons can still retail veterinary medicinal products under certain conditions. The regulations delve into the standards relating to a pharmacy premises and obligations of the holders of a veterinary pharmacy licence. They include provisions on the appearance of pharmacy and how this should be planned, managed and kept. It also goes in the details for the approval of any structural alterations and management of pest and temperature controls. The regulations specify how applicants shall apply for a veterinary pharmacy licence and the conditions for this licence. They also detail how this licence can be renewed, suspended or even revoked. The minimum equipment that should be kept at the veterinary pharmacy are described. The processing of an application shall not exceed ninety (90) days starting from the date on which the application is received. The regulations provide comprehensive and cohesive regulations about enforcement, inspection, supervision and recall procedures that have to be in place. The storage conditions are also specified (appropriate light, temperature and humidity levels) that safeguard the quality of the products. The regulations also list the obligations of the managing pharmacy and the pharmacy owners. The consequences of any infringements are mentioned.

Regulations 39 - 40 establish the national legal basis of the veterinary prescription. In the case of the electronic veterinary prescription, the same regulations apply as the printed version apply. The regulations explain the procedure to follow in case of incomplete dispensing of the prescription, and establish how the electronic veterinary prescription (both paper and electronic) should be established by the Director and used by the persons authorized to prescribe and dispense. The procedure to follow in urgent situations when it is not possible to immediately issue a prescription or to alter it, including when verbal instructions are acceptable are prescribed. They make it illegal for any person not being a veterinary surgeon to issue a veterinary prescription. The validity of a veterinary prescription is also provided for.

Regulation 41 provides for the administration of veterinary medicinal products and also other substances to animals. The regulation also provides legal coverage for urgent situations when a veterinary medicinal which should only be prescribed and/or administered by a veterinary surgeon cannot be administered or given by the veterinary surgeon. There are also new provisions for the tighter use of antimicrobials especially those which are classified as critically

important antimicrobials. Every registered or licensed establishment where food producing animals are kept and are not excluded from the provisions of Regulation (EU) 2017/625 and the establishments where animals are kept for display to the public or for breeding purposes should have an appropriate animal health control programme designed and implemented under the responsibility of a professional registered with the Veterinary Surgeons Council. The Director shall keep a register of the professionals responsible for each animal health control programme and publish guidelines on the expected Animal Health programmes. The requirements may also be published in the Government Gazette.

Regulation 42 specifies the requirement for marketing authorisation holder to tackle any complaints (e.g. product defect) he received in an effective and transparent way. It speaks also about the aftermath of such an investigation (e.g. recalls) and the records to be kept. This regulation ensures that any product defect that impact the quality of products are tackled effectively.

Regulation 43 specifies the requirement for all those who generate waste that is derived from veterinary medicinal products to dispose of it in a safe way. It is a legal obligation for them to follow the directions of the relevant authorities in this regard. It obliges all parties who are regulated by Regulation (EU) 2019/6 and by the regulations to have a standard operating procedure for the safe disposal. Companies should keep themselves abreast of the latest directions from the current entity in Malta that tackles waste disposal.

Regulation 44 gives the legal authority to the Director to enter at any reasonable time the premises where the activities of all parties who are regulated by Regulation (EU) 2019/6 and by these regulations take place. It obliges these parties to provide documents, installations and any equipment necessary for the inspection.

Regulation 45 prescribes the fines (*multa*) for the infringements of the obligations mentioned in the regulations and in Regulation (EU) 2019/6. To note that although the fines (*multa*) are imposed upon conviction, suspension of any licences/authorisations may take place even during investigation.

Regulation 46 repeals the Veterinary Medicinal Products Regulations – Subsidiary Legislation 437.47.

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:

Animal Health and Welfare Department
(Attn: The Pharmacist - Veterinary Medicines Unit
Veterinary Regulation Directorate
Animal Health and Welfare Department
Triq il-Biccerija, Albertown, Marsa, MRS1123, Malta
Tel no: +(356) 23397043

Email: stephen.spiteri@gov.mt