MINISTRY FOR AGRICULTURE, FISHERIES,
FOOD AND ANIMAL RIGHTS
Animal Health and Welfare Department
National Veterinary Laboratory
Abattoir Street, Albertown, Marsa, MRS 1123 - Malta

User Guidelines

References:

S.L437.47: https://agrikoltura.gov.mt/en/nvl/Documents/usefulInfo/medicFeed.pdf

LN179/2021: https://agrikoltura.gov.mt/en/nvl/Documents/home/legalNotice179.pdf

1. Introduction

Title of Regulations	LN 179 of 2021, Veterinary Medicinal Products (Amendment), Regulations

2. Objectives and Purpose

The regulations in the proposed Legal Notice aim to fine tune the transposition of Directive 2001/82/EC which was originally made through Subsidiary Legislation 437.47 in 2004. The consolidated legislation is Subsidiary Legislation 437.47 on Veterinary Medicinal Products. This will be done in the light of new elements that have emerged since its transposition in 2004 regarding the necessity for the increase in control of veterinary medicinal products, in particular the rising threats of antimicrobial resistance brought about by the imprudent use of antimicrobials and the increase in number of companion animals and higher expectations of the owners. To achieve these aims the regulations have been formulated with the intend to:

- Add new provisions and regulations to the current legislation; most importantly those related with antimicrobial use, manufacturing, and the authorisations of veterinary medicinal products

- Add new provisions related with the authorisation of veterinary medicinal products, mostly notably those authorised through an exemption from a Marketing Authorisation, e.g. when the health situation requires it (Reg 7), for small non-food animals (Reg 4(2)), under the cascade (Reg 10 and 11) and products for research purposes (Reg 4D). These provisions will ensure the integrity of the distribution chain and facilitate pharmacovigilance and batch recalls in case of defective products/batches.

- Introduce new rules and regulations for dispensing, distribution, procuring for personal use, retail and prescribing of Veterinary Medicinal Products.

- Clarify and set rules on categorisation of veterinary medicinal products, i.e. whether they are prescription-only-medicine (POM) or can be given over-the-counter (OTC).

- Establish the requirement for all establishments where animals are kept (not only farms) to have an adequate and fit for purpose Health Plan under the responsibility of a 'professional registered with the Veterinary Surgeons Council'.

- Add provisions for effective inspection and supervision by the competent authority

- Create a level playing field amongst interested parties that increase interest in the area and more willing investors and professionals in this sector.

Primarily these regulations will regulate activities that are already taking place but are inadequately controlled. There are provisions related with the following:

- The requirement that a veterinary prescription can only be issued by a veterinary surgeon.

- The requirements for the dispensing of veterinary medicinal products only from trained and qualified persons depending on their distribution classification. In this regard dispensing of veterinary medicinal products can only take place from veterinary pharmacies, from veterinary surgeons and, for a very limited type of products, from certain other establishments, e.g. pet shops.

- Requirements related with the manufacture and distribution of veterinary medicinal products and active substances

- The legal designation of veterinary medicinal products as prescription only medicines, over the counter medicines (but still pharmacy only medicine) or those on a general sales list (e.g. sold also from registered pet shops, registered aquarium fish product retailers and approved feed traders where animal medicated feeds are produced, sold or traded.

- Penalties for breaches of the legal requirements set in the regulations

- More robust regulatory procedures for the authorisation of veterinary medicinal products that install greater responsibilities on the operator and allow a more efficient operation of post licensing activities, such as batch recalls and detection of adverse drug reactions

- Possibility for veterinary surgeons to import veterinary medicinal products from Third countries in exceptional circumstances and for the general public to procure these products for personal use

- Requirements on the prudent use of antimicrobials that benefits both animal and human health.

- Requirements on the advertisement of veterinary medicinal products.

- Requirements related with the Health Plan under the responsibility of a professional registered with the Veterinary Surgeons Council' for establishments were animals are kept. This does not only apply to farms but also for zoos, breeders, and animal sanctuaries.

3. Target Audience

The target audience of these user guidelines are persons dealing with veterinary medicinal products. These are as follows:

- Veterinary wholesale dealers
- Veterinary medicinal products manufacturers
- Veterinary medicinal products distributors
- Veterinary medicinal products brokers
- Veterinary Pharmacies
- Pharmacists
- Veterinary Surgeons
- Animal keepers (farmers, breeders, zookeepers)
- Active substance manufacturers and distributors
- Owners of pet shops
- Medicated feed producers/traders

4. Specific conditions under which the rules apply

Regulation No.	**Meaning & obligations placed on user** (where applicable)
4 to 4D, 7, 10, 10A, 11 and 11A	The new provisions detail how applicants can apply for different types of authorisation. This includes VMP that are obtained for research purposes (4A), disseminated as samples (4B), or obtained for private use or donations (4D). The provisions stipulate when, how and which is the most suitable authorisation for the kind of VMP and its intended use. The holder of the authorisations will have obligations related with the authorisation of the product and its sale/distribution on the market. Amongst the most important there are the ones related with reporting of adverse reactions resulting from the administration of the

	VMP, record keeping obligations, labelling of the VMP, quantities to be authorised and conditions imposed for each type of authorisation. Currently applicants are not required by law to maintain such records although any approvals that are issued by the Department are conditional to that. An important requirement is that the manufacture of products exempted from a Marketing Authorisation by virtue of Regulation 4(2) must still hold a Manufacturing Authorisation. If the manufacturer is established in the EU the Manufacturing Authorisation must be in line with the EU legislation. Those manufactures that are established in Third countries must hold an equivalent authorisation granted by the authorities is that country. The Veterinary Services shall prepare and publish a list of active substances that can be used in veterinary medicinal products authorised under subregulation (2 Also, products authorised un this way must not be prescription-only-medicine. A transitional provision was added 4(11) so that the provisions of sub-regulation 5 come into force on the 1st November 2021. This means that after this date only VMPs that do not require a veterinary prescription can be authorised according to Regulation 4(2) In the case of Regulation 7, 10 and 11 the current provisions where augmented with new provisions that increase the obligations on both the holders of authorisations and the competent authorities in relation with pharmacovigilance, reporting of product defects and antimicrobial resistance. The new provisions also aim and obliging the authorisation holders to provide more information to the user of the VMP. Authorisations holders will be obliged by law to keep themselves informed of any reports of adverse drug reactions or product defects and report it to the authorities. In the case of Regulation 10A and 11A the opportunity is being given in cases of highly restricted and regulated occasions where veterinary surgeons can import VMPs from Third countries. On these occasions the veterinary surgeons must provide detailed justification.
38 to 50C	This set of regulations are all related with the manufacturing and importation of veterinary medicinal products and manufacturing and distribution of active substances. These regulations replace the previous ones (38 to 50) on manufacturing and importation of veterinary medicinal products. The new set of Regulations provide a more comprehensive and cohesive rules for the regulation of this subject matter. The provisions are all in line with the

	recommendations of the Compliance Group of the Good Manufacturing Practice inspection The obligations in the provisions are linked with the penalties whereby manufacturer and/or other relevant persons are liable in case of any breaches in them. The legislation provides for prosecution and/or penalties upon conviction.
39(1)(a) (b)	Companies that manufacture or import veterinary medicinal products are required to hold a manufacturing authorisation. This shall also apply for the manufacture of veterinary medicinal products intended for export and biological active substance, or active substance to be used directly as an investigational veterinary medicinal product
43(2)(g)	The legislation now prohibits the sale and processing of active pharmaceutical ingredients and medicinal products under unsanitary conditions or leading to adulteration.
43(4)(a)	This provision gives the legal authority for an inspector to enter at any reasonable time in any place where active pharmaceutical ingredients and veterinary medicinal products are manufactured, imported, and exported.
43(4)(d)	The provision gives legal authority for the veterinary services to open and examine any article subjected to legislation.
43(4)(g)	The scope of jurisdiction of legislation is now available for companies that will be inspected by the veterinary services.
44(1) (g)	There is the added obligation on the holder of the manufacturing authorisation to notify the veterinary services of significant changes or of conditions, which may affect the quality, safety, or efficacy of the veterinary medicinal product.
44(1) (k)	The provision requires a marketing authorisation holder and a manufacturer of veterinary medicinal product to record and report to the regulatory authority any serious adverse medicinal product reactions.
44(1) (l)	

	This provision requires the manufacturer to implement a system for recording and reviewing complaints together with an effective system for recalling promptly and at any time the veterinary medicinal products or the active substance in the distribution network
44(1) (m)	The provision requires a marketing authorisation holder and a manufacturer of active pharmaceutical ingredients or of medicinal product to document any product defect impacting its quality
50(B) (1)	This new provision stipulates that companies that distribute active substances are registered with the veterinary services. It explains how the registration process works in practice and what obligations the applicants and authorised entities gave in this regard.
50(B) (3)	This provision stipulated how the applicants for the distribution of active substances may be inspected according to a risk assessment. If no inspection is warranted the applicant may consider his application as successful after 60 days.
50(B) (4)	This provision adds the requirement that the holder of the manufacturing authorisation is required to notify the regulatory authority of significant changes or of conditions, which may affect the quality, safety or efficacy of a medicinal product.
58A	An important provision that stipulates from where the retail supply of veterinary medicinal products shall be conducted. Retail sale can now be carried out only from veterinary pharmacies, licensed veterinary clinics/hospitals or other establishments stipulated in the legislation according to the distribution status assigned to the VMP in question (e.g. POM or OTC). Retail can also be carried out by veterinary surgeon during out call visits for patients under their care. Whoever conduct such sale in places not indicated in the legislation will be in breach of the regulations and subject to a fine.
59	An important change in the existing regulation which gives the legal direction as to who is allowed to carry out dispensing of VMPs. This can only be done by pharmacist, veterinary surgeons and in for certain VMPs on the 'General Sales List'(e.g. flea collars) from other premises (registered pet shops, registered aquarium fish product

	retailers and approved feed traders where animal medicated feeds are produced, sold or traded. Whoever dispenses a VMP and is not part of this profession (or pharmacy) will be in breach of the regulations and will be subject to a fine. The legal obligations of the dispenser are laid out in this regulation under several sub-regulations. Sub-regulation 59(5) is about record keeping obligations by the dispenser. These obligations shall come into force on the 1st November 2021 Veterinary surgeons may dispense veterinary medicinal products during an in-call or out-call visits to the animals under their care. The quantities so dispensed should be those required for the treatment of an urgent condition.
59A	An important provision that stipulates how only veterinary surgeons can prescribe veterinary medicinal products. The legal obligations of the prescriber are laid out in this regulation under several sub-regulations. Whoever conduct such an activity and is not a veterinary surgeon will be in breach of the regulations and subject to a fine.
60	The regulation was changed to include provisions that stipulate the way VMP shall be prescribed and dispensed. Some VMPs need to be prescribed on a veterinary prescription to be dispensed. Such requirement should be indicated on the outer pack of the product. The way this indication shall be conveyed is also stipulated. Other VMPs whose use is considered as less risky can be obtained without a veterinary prescription. This status should also be indicated on the outer pack. Other important additions include the places from where VMPs can be dispensed. Depending on the distribution categories VMPs can be supplied from veterinary pharmacies, veterinary establishments, registered pet shops, registered aquarium fish product retailers and approved feed traders where animal medicated feeds are produced, sold, or traded. The designated abbreviations for each distribution classification are stipulated in this regulation (i.e. POM-VP, POM-V, OTC, or GS)

62	The changes here include intensified obligations on keepers of animals about record keeping and proof of purchase of VMPs. There are also new provisions for the tighter use of antimicrobials especially when these are not used for treatment but for metaphlactic and prophylactic use. Observation of the sector indicate that the practice of using antimicrobials for metaphlaxis or prophylaxis is quite common. With this new legislation a solid justification by the veterinarian will be required to do this.
72 (1)	This provision gives the legal authority for an inspector to enter at any reasonable time in any place where active pharmaceutical ingredients and veterinary medicinal products are manufactured, imported, distributed, used, and exported.
77A	Currently the legislation prohibits the advertising to the general public of veterinary medicinal products that are available on veterinary prescription only; or contain psychotropic drugs or narcotics. Exceptions to the former will be made under certain conditions while regulations related with the advertisements of all type of veterinary medicinal products have been added. The provision stipulates which, how and in what way VMPs can be advertised. It takes into consideration the class of VMPs and the target audience of the advertisement. Attention has been given to the fact that advertisement can be misleading and not properly formulated. It is desirable that certain VMPs (vaccines, medicines against worms) are used frequently and so the provisions facilitate the advertisement of these products in the correct way.
79(2)	Currently every licensed, registered farm in Malta shall nominate a veterinary surgeon responsible for animal health and animal welfare on the farm. Changes were made in this provision to include also other places where animals are kept (zoos, breeders, animal sanctuaries) and possibility for other professional registered with the Veterinary Surgeons Council' to be responsible for the animal health plan. Moreover, the responsibility of the veterinary surgeon will be made through an animal health control programme that is appropriate to the farm. The Veterinary Services will issue official requirements related to animal health control programme. These will take in consideration the type, size, and scale of the establishment.

	A provision was added 79(3) so that this requirement comes into force 2 years from the date of coming into force of these Regulations.
79A	New provisions related with the administration of medicines were added. These provisions cater for those urgent situations where it is not possible for a veterinary surgeon to be on site. The provisions also stipulate the requirements related with the administration of VMP, e.g. that only authorised VMPs should be used. There are also requirements regarding record keeping and proof of purchase by animal owners. This means that the farmer must keep the invoices or receipts that are given to him when he obtains the medicine. Important provisions related with antimicrobials were added to ensure prudent use. Fines were introduced for whoever is in breach of these provisions.
82	The regulation was amended to require a marketing authorisation holder and a manufacturer of active pharmaceutical ingredients or of medicinal product to document any product defect impacting its quality.
87	The regulation was augmented to add the obligations on several operators (companies, large establishments, and professional bodies) to prepare SOPs describing the way they dispose of expired/unused or unsuitable VMPs. These operators are to follow the guidelines issued by the veterinary services and keep up to date with the instructions issued by Maltese competent authority responsible for waste management for the safe disposal of hazardous material.
88 to 93	These regulations prescribe the penalties for the obligations mentioned in the Legal Notice. The enforcement provisions found in the current regulations are those which envisage the suspension or revocation of the marketing authorisation if certain conditions are not met such as in regulations 55 and 75. In the amended legislation when breaching any of the obligations mentioned in it will incur a penalty. When reading these Regulations, the reader should also refer to Article 38 and 61 of Chapter 437.

5. The Regulator

Throughout the years the Animal Health and Welfare Department through the Veterinary Medicines Section (part of the National Veterinary Laboratory) has always maintained an effective and open relationship with its stakeholders and it is committed to pursue this principle. The amended legislation will ensure it honours its role as the regulator of all matters related

with veterinary medicinal products to safeguard animal and public health while keeping its good relationship with stakeholders. Controls will be stepped-up as this will be crucial for the correct application of the new regulations, which despite not radically changing the existing framework, it will include several requirements. To note that some of these requirements are already being applied although up until now they have been unregulated.

6. Channels of Communication

To provide continous help and support, the Veterinary Medicines Section can be reached via:

- an email on veterinarymedicine@gov.mt,
- submit comments on on-line form: https://www.servizz.gov.mt/en/Pages/Environment_-Energy_-Agriculture-and-Fisheries/Animal-Welfare/Veterinary-Services/WEB2454/default.aspx
- leave any feedback on the AHWD website: https://agrikoltura.gov.mt/en/nvl/Pages/feedback.aspx