User Guidelines

1. Introduction

Title of Bill	A Bill entitled an Act to amend the Veterinary Services Act, Cap. 437 of the Laws of Malta (the "principal Act"/the "Act").
Activity to be regulated	The activities to be regulated are those related to veterinary medicinal products (VMPs), starting from their manufacture to their marketing, distribution, retail and use. This involves the activities undertaken by manufactures, wholesalers, pharmacists, veterinarians and animal owners (including farmers). The amendment provides for the possibility of products associated with VMPs to be also regulated in a similar way. These are namely active substances and veterinary medical devices. It also regulates those activities of the Veterinary Services related to official controls. The amendments shift the responsibility for veterinary medicinal products from the Head of National Veterinary Laboratory to the Director of Veterinary Services.
Entity that prepared the legislation	Animal Health and Welfare Department within the Ministry for Agriculture, Fisheries and Animal Rights

2. Objectives & Purpose of the Legislation

The amendments empower the Minister to make regulations on veterinary medicinal products (VMPs), active substances, and veterinary medical devices concerning their manufacture, importation, research, introduction, wholesale distribution, brokering, marketing, prescribing, dispensing, supply, retail, advertising and the provision of data on sales and use.

Amendments have also been carried out in relation to the functions of the National Veterinary Laboratory, the responsibilities of the Director of Veterinary Services, the slaughter of food-producing animals and the collaboration of the Veterinary Services with other entities. Amendments have also been affected to the provisions related to animal products as well as to the provisions that strengthen the enforcement actions that can be taken by the Veterinary Services.

Primarily the Act will introduce:

With regard to VMPs.

- Transfers responsibility for activities relating to the regulation of VMPs from the National Veterinary Laboratory to the Director of Veterinary Services;
- Deletes the 'Sixth Schedule' so that the Minister may make regulations on all types of VMPs and not only on the limited number and types of VMPs listed therein;
- Adds provisions related to enforcement action by officers of the Veterinary Services, including the right of entry and confiscation of any items suspected to be used in the commission of an offence;
- Adds the conditions required for the issuance of a marketing Authorisation of a Veterinary Medicinal Product and regulation of its life cycle, including cases of batch recalls, adverse drug reactions and suspensions;
- Adds 'Active Substances' of VMPs and 'Veterinary Medical Device' as new elements to be regulated;
- Aligns a number of terms and definitions with Regulation (EU) 2019/6;
- Includes a number of provisions related to the application for licences of veterinary pharmacies, veterinary wholesale distributor, research activities manufactures and importer of VMPs;
- Adds the necessary references to any regulations that may be made under the principal Act for any offences and penalties for infringements relating to VMPs;
- Enhances the scope of inspections carried out throughout the distribution chain of VMPs;
- Provides for the collaboration with other public authorities established by law, with specific reference to The Malta Medicines Authority;
- Includes a section in relation to the licencing of veterinary pharmacies.

Other changes not directly related to VMPs

- Empowers officers other than veterinary officers to be nominated by the Director, Veterinary Services, to conduct official controls;
- Adds articles related to the slaughtering of animals for human or animal consumption (animal by-products);
- Adds provisions related to the right of entry and enforcement action by officers of the veterinary services, including the right of entry, applicable fines and confiscation of any items suspected to be used in the commission of an offence;
- Removes the 'Second Schedule' which is replaced by a reference to the list of notifiable terrestrial and aquatic animal diseases issued by the World Organization for Animal Health (OIE);

- Transfers the roles of regulating additives which may be incorporated in feeding stuffs, the prohibition of undesirable substances and products used in animal nutrition, and the use and marketing of enzymes and micro-organisms and their preparation in connection with animal nutrition from the National Veterinary laboratory to Director, Veterinary Services;
- Deletes the function of the National Veterinary Laboratory related to *post-mortem* examinations.

Importance of Regulations

The lack of proper regulation of VMPs has been highlighted by the EU Commission in its Country Visit of 3-7 July 2017 DG (SANTE) 2017-6248 and audit of 19-23 February 2018 DG (SANTE) 2018-6342.

In an EU Commission audit (Joint Audit Programme (JAP) Ref Ares (2018)6454178-14/12/2018 of (28-Feb-1 March 2019) Malta has committed itself to enact a number of legal provisions related to manufacturing and distribution of VMPs by the end of 2020.

Furthermore, one of the main objectives (Objective 1) of the '*Strategy and Action Plan for the Prevention and Containment of Antimicrobial Resistance (AMR) in Malta 2020 – 2028'*, is to review the current legislation to strengthen governance to counteract AMR and address the gaps in legislation to ensure leadership, engagement and accountability for actions to combat AMR. Please refer to the following link for more information:

https://deputyprimeminister.gov.mt/en/nac/Documents/AMR%20Strategy%20Final%20Jul%202020.pdf

The changes are also deemed important to honour Malta's committments and to contribute to the safeguard of animal and human health.

The amended principal Act will empower the Minister to make the neccessary national legislation that will support Regulation (EU) 2019/6 for the full implementation of its requirements.

There could be an increased number of operators as a result of a clear legal framework on obligations and the creation of a level playing field. In certain areas (e.g. Gozo, north of Malta) there is a clear need for such operators, but SMEs may be reluctant to invest due to an unregulated environment that may lead to unfair competition. The increased predictability and resulting protection offered to the investments of operators brought about by the proposed legislation will encourage industry to flourish.

There is also a clear need to step-up enforcement action in order to better control this sector. Through these amendments, any authorised officer and not just an official veterinarian can take enforcement measures. It also provides the much needed

clarifications with regard to the right of entry, confiscations, co-operation from inspectees and provision of information.

3. Target Audience

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

- Veterinary medicinal products 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. Commentary on parts and articles

Article 1: Stipulates the title of the Act.

Article 2: Adds a number of new definitions to article 2 of the principal Act (e.g. active substance, data on sales, veterinary medical device) and amends other existing definitions (e.g. about Director, definition of withdrawal period). The amendment in the definition of 'Director' opens the possibility for enforcement action to be exercised more effectively, as all officers of the Veterinary Services will be empowered to take enforcement action and not only official veterinarians.

Article 3: Adds to the scope of the Act, active substances and veterinary medical devices. Currently these are either not fully regulated (active substances) or unregulated (medical devices). Once regulations (through legal notices) are made for these 2 elements there will be tightening of controls. Control of the former is especially important due to the rise of falsified medicines on the market.

Article 4: Amends the wording of Article 6 of the principal Act to replace references to the Second Schedule of the Act with the list of notifiable terrestrial and aquatic animal diseases issued by the World Organization for Animal Health (OIE). This was done for practical reasons, to avoid amending the principal Act every time a change is affected in the OIE list. This amendment is present in other articles for the same reason. It does not affect any of the obligations of the stakeholders, which remain the same.

Article 5: Amends the wording of Article 15 of the principal Act to replace references to the

Second Schedule of the Act with the list of notifiable terrestrial and aquatic animal diseases issued by the World Organization for Animal Health.

Article 6: Amends the wording of Article 16 of the principal Act to replace references to the Second Schedule of the Act with the list of notifiable terrestrial and aquatic animal diseases issued by the World Organization for Animal Health.

Article 7: Amends article 24 of the principal Act, to replace the words "Head of the National Veterinary Laboratory" by the word "Director". This will effectively shift the responsibility in relation to products used for animal nutrition from the National Veterinary Laboratory to the Director, Veterinary Services. There will be no apparent changes for stakeholders, apart from the administrative matters.

Article 8: Substitutes Article 29 of the principal Act to include all the activities related to veterinary medicinal products, active substances and veterinary medical devices. The activities to be regulated range from the manufacturing of active substances and veterinary medicinal products to their marketing and related post marketing activities, such as advertisement and provision of data on sales. Most of these activities are not currently regulated and the details in relation thereto shall be spelt out by means of regulations. This new provision includes also a reference to fees and procedures to be observed.

Article 9 and Article 10: Amend article 30 and article 32 of the principal Act respectively, to include the power of the minister to make legislation on all the requirements and authorisations related to veterinary medicinal products, active substances and veterinary medical devices without leaving any gaps in the system. Currently, the powers of the Minister do not cover all activities related to veterinary medicinal products, active substances and veterinary medical devices. These activities range from their manufacturing, marketing and related post marketing activities (including inspections), such as advertisement and provision of data on sales.

Article 11: Amends article 35 of the principal Act, to include the activities related to veterinary medicinal products, active substances and veterinary medical devices within the scope of this article. Obligations which currently pertain to certain stakeholders (e.g. owner, the keeper, the dealer or the importer, the consignee, the carrier, the retailer) will now be extended to others (e.g. those who manufacture, import, prescribe, wholesale distribute, broker, market or trade in VMPs and active substances). The fines shall also apply to the infringement of obligations (mostly already in place) by the added stakeholders. The amendments also strengthen the authority of the Veterinary Services with regard to the right of entry of regulators in the relevant establishments and confiscation of items.

Article 12: Amends article 36 of the principal Act to include all the activities related to veterinary medicinal products, active substances and veterinary medical devices within the scope of this article. The fines shall also apply to the infringement of obligations (mostly already in place) by the added stakeholders. Similar to the changes in Article 11 these amendments will also strengthen the authority of the Department with regard to the right of entry of regulators in relevant establishments and the confiscation of items. Moreover, this

amendment introduces provisions related to the slaughter of animals. Authorisation, as may be applicable, will be required for the latter activity.

Article 13: Amends the wording of article 37 of the principal Act to replace references to the Second Schedule of the principal Act with the list of notifiable terrestrial and aquatic animal diseases issued by the World Organization for Animal Health (OIE).

Article 14: Amends article 38 of the principal Act to include all the activities related to veterinary medicinal products, active substances and veterinary medical devices within the scope of this Article. The fines shall also apply to the infringement of obligations. These obligations are for the most part already in place, though new ones were added, principally the right of entry and the right for the Veterinary Services to ask for samples and to confiscate articles suspected to have been used in the commission of an offence against this article. The amendments also strengthen the authority of the Veterinary Services with regard to the right of entry of regulators in the relevant establishments and confiscation of items.

Article 15: Amends article 49 of the principal Act to include the power of Director, Veterinary Services to grant/recall/withdraw authorisations related to veterinary medicinal products (marketing authorisations/active substances/veterinary medical devices and activities related to it, e.g. wholesale distribution). The latter involves also the power of Director, Veterinary Services to inspect and/or supervise these activities, including taking samples and submitting them for testing. All stakeholders involved in veterinary medicinal products, active substances and veterinary medical devices will now be subject to the Veterinary Services' inspection. They must also comply with any decision that is taken by the Veterinary Services in this regard.

A provision has now been added to this article on the collaboration between the Veterinary Services and other entities. The Malta Medicines Authority has been included in the Article.

Article 16 and article 17: Amend articles 50 and 51 of the principal Act respectively to clarify the role of the National Veterinary Laboratory (NVL) with regard to veterinary medical products and other factors. The NVL will no longer be directly responsible for VMPs but will support the Director, Veterinary Services in its area of competence. The NVL will no longer be tasked with carrying out *post mortem* examinations.

Article 18: Deletes article 53 of the principal Act and therefore removes a number of responsibilities related to VMPs previously falling under the Head, NVL.

Article 19: Amends article 54 of the principal Act to include the power of inspection of the Veterinary Services related to the trade and movement of animals and their products. In this part of the Act, as in other relevant parts, all officers have been empowered to take enforcement action (not only the official veterinarians).

Article 20: Amends article 56 of the principal Act to include within the scope of this provision, the legislation that may be made under the Act. As in other instances, this has been affected by adding the phrase: "*or any regulations made thereunder"*.

Article 21: Amends article 57 of the principal Act and clarifies the powers of the Veterinary Services for confiscating articles. The subject-matter of the confiscation may include any of those related to the Act, including animals, products of animal origin, active substances, veterinary medical devices, veterinary medicinal products, feeding stuffs. These have been mentioned by name for added clarity.

Article 24: Amends article 61 of the principal Act to include a reference to the remedial steps to be taken by the person committing an infringement, in case of conviction. It also clarifies the applicability of the administrative fine referred to in article 61.

Article 25: Introduces new articles 62 to 72 to the principal Act, about Veterinary Pharmacies. Veterinary Pharmacies are currently unregulated. With these new articles these operators will be licenced and controlled. The basic standards of veterinary pharmacies will be established, amongst which the obligation for a veterinary pharmacy to be managed by a pharmacist. This is a major change that introduces a number of new obligations.

The new article 73 enlists the powers of the Minister to make regulations with regards to anything related to veterinary medicinal products, including the issuance of licences and the establishment of standards of practice.

Articles 26 and 27: These 2 articles delete the Second Schedule (about listed diseases) and the Sixth Schedule (about VMPs) respectively. These deletions are in line with the changes in Articles 6,15,16, 35, 37 for the deletion of the Second Schedule and Article 32 for the deletion of the Sixth Schedule.

Other general changes include the applicability of fines to any relevant regulation (in Legal Notices) that may be made under Chapter 437 and the empowerment of all officers to take enforcement action (besides the official veterinarian).

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 new 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,
- telephone number: 00356 22925100
- submit comments on on-line form: https://agrikoltura.gov.mt/en/nvl/Pages/contact.aspx
- Any feedback submitted on the Animal Health and Welfare Department website: https://agrikoltura.gov.mt/en/ahwd/Pages/feedback.aspx

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