No. 1748

MINISTRY FOR AGRICULTURE, FISHERIES AND ANIMAL RIGHTS

Explanatory Notes
(for the purpose of article 3(2)(c) of Cap. 512 of the Laws of Malta)

1. Introduction

Title of the Legal Notice	Veterinary Medicinal Products Regulations, 2024 hereinafter referred to as "the regulations"
Activity to be regulated	Strengthening the regulation and control of the retail, research, supply, distribution, dispensing, prescribing, manufacturing, data collection and use of veterinary medicinal products and active substances
Responsible entity	The Veterinary Regulation Directorate within the Animal Health and Welfare Department

2. Summary and Background

2.1 Aims & Objectives of the legislation

The regulations aim to supplement and give full effect to 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 (hereinafter "Regulation (EU) 2019/6"). They also regulate other matters falling under the subject matter as provided in Regulation (EU) 2019/6.

Apart from giving full effect and allowing the effective implementation of Regulation (EU) 2019/6, the regulations contain a number of national provisions that are essential to manage the regulatory environment that has emerged in the last couple of years. 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 these new legal provisions. 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.

2.2 Importance of Regulations

The improved control on the sale, manufacture, storage, distribution, data collection and use of veterinary medicinal products, in particular antimicrobials and narcotics/psychotropic drugs, will decrease the abuse, misuse or overuse of these products. This will directly affect animal health and indirectly human health because if they are not used correctly residues of these products may end up in the food chain. Imprudent use of antimicrobials increases the prevalence of antimicrobial resistance. This is one of largest threat to human and animal health worldwide. Additionally, improper use contributes to the rising threats of antimicrobial resistance. Not to mention the lack of control on drugs of abuse, which is not in line with the 1961 Single Convention Narcotic Drugs as amended by the 1972 Protocol. The new regulations address these issues.

The current situation may also lead to non-compliance with Malta's obligations to control the use of veterinary medicinal products and the prudent use of these products at EU level.

Furthermore, one of the main objectives of the 'Strategy and Action Plan for the Prevention and Containment of Antimicrobial Resistance in Malta 2020 – 2028 is to review current relevant legislation to strengthen governance to prevent and counteract antimicrobial resistance and address the gaps in legislation and regulations to ensure leadership, engagement and accountability for actions to combat antimicrobial resistance. The action plan for the mentioned strategy has been included as 'Budget Measure No 108, 2020 (Se tiġi implimentata l-Istrateġija dwar ir-Reżistenza Antimikrobika bil-għan li titjieb il-bijosigurtà fl-irziezet u l-użu prudenti tal-antimikrobiċi.)'.

2.3 Public Consultation

No public consultation was conducted. However, consultation took place with selected stakeholders.

Prior to the finalisation of the draft Legal Notice on the table a consultative session was held with the Veterinary Surgeon Council (VSC) on parts of the draft Legal Notice related with the veterinary prescription. The details are as follows:

On the Veterinary Prescription: Draft text sent on 7th of September 2021. Feedback received on the 22nd of September 2021. Meeting held on the 20th of December 2021

Following this session, the draft Legal Notice containing all provisions related with veterinary medicinal products was finalised and given to selected stakeholders as per below. The text was sent to all stakeholders on the 2nd of February 2023 with an extended deadline of 28th February 2023 (original deadline was the 17th of February 2023)

Pharmacy Council: feedback was provided on the 1st of March 2023;
Veterinary Surgeon Council: feedback was provided on the 28th of February 2023;
Malta Veterinary Association: no feedback reveived;
Malta Chamber of Pharmacists: no feedback received.

The Veterinary Surgeon Council and Pharmacy Council were not opposed to the draft Legal Notice.

The Pharmacy council 's comments centred on the perceived unalignment of the draft Legal Notice with Regulation (EU) 2019/6 on veterinary medicinal products and legal provisions thought to be about medicinal products for human use.

The Veterinary Surgeon Council 's comments centred on improvements in the text to increase the availability of veterinary medicinal products and the possibility to allow persons other than veterinary surgeons to issue veterinary prescriptions.

3. Overview of the structure of the instrument

The regulations are made up of thirty-nine (39) 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. Veterinary medicinal products obtained for personal use.
8. Registration in accordance with Article 116 of Regulation (EU) 2019/6.
9. Cascade use of veterinary medicinal products.
10. Registration of homeopathic veterinary medicinal products.
11. Parallel trade.
12. Manufacturing of veterinary medicinal products and active substances.
13. Qualified person.
14. Products in transit.
15. Retail supply of veterinary medicinal products.
16. Dispensing.
17. Prescribing.
18. Distribution categories of veterinary medicinal product.
19. Advertising.
20. Samples or demonstration packs.
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. Veterinary prescription.
31. Veterinary prescription established by the Director.
32. Administration of veterinary medicinal products and medicinal product to animals.
33. Complaints received by the marketing authorisation holder.
34. Safe disposal of veterinary medicinal products.
35. Access by the Director.
36. Offences, punishments and administrative ppenalties.
37. Right to appeal.
38. Repeal and saving.
39. Consequential amendment.

4. Commentary

Regulation 2 provides ddefinitions 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 specifies how the exemption from a Marketing Authorisation granted by Article 5(6) of Regulation (EU) 2019/6 will be and how it can be applied for. The regulation also lists the conditions of such an exemption, 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 on products for research purposes specifies that applicants shall apply for authorisation. It also lists 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 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 8 lays down the national regulations on the registration of veterinary medicinal products in accordance with Article 116 of Regulation (EU) 2019/6 with the Director. It also lists 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 9 specifies that applicants shall apply for authorisation when veterinary surgeons would like to procure the products from other countries. The regulation also lists 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 10 specifies that applicants have to apply with 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 11 specifies that applicants have to apply with 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 12 specifies that applicants have to apply with the Director to obtain a Manufacturing Authorisation that is in accordance with Articles 88 and 89 of Regulation (EU) 2019/6 . It also lists 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 13 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 14 provides legal cover for the authorised veterinary wholesale dealers who intend to obtain veterinary medicinal products without putting them on the EU Market but re-export them to Third countries, i.e. they are in transit. 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 the freeport, free trade zones, or customs tax warehouses. 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 15 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 16 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 17 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. This regulation 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 18 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 that 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 19 provides the regulatory coverage for activities related with advertising 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 20 specifies that applicants have to apply with the Director for registration of veterinary medicinal products to be brought in Malta to be distributed as free samples. 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 just obtain veterinary medicinal product and classify them as samples themselves. The status of a sample can only be acquired through this registration.

Regulation 21 has provisions that seek 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.

This set of regulations specify that applicants shall apply for a wholesale distribution authorisation and list 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 in 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 if requested to do so by the Director

Regulation 29 specifies that applicants shall register for brokering of veterinary medicinal products with 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 30-31 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 32 is about 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 33 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 34 refers to guidelines for the disposal of veterinary medicinal products waste to be issued by the Director.

Regulation 35 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 36 prescribes the fines (multa) and imprisonment periods 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 37 provides that decisions of the Director in terms of these regulations shall be subject to a right of appeal before the Administrative Review Tribunal. An appeal shall be filed within twenty (20) days from the service of the Director's decision.

5. Concluding Section

The regulations are an effective tool to provide increased safeguards to animal and public health while creating a level playing field for all parties, and do not introduce unnecessary bureaucratic burdens on the stakeholders concerned.

All the provisions of the regulations shall come into force two (2) months after the date of publication, except for regulation 17(2) which shall come in force two (2) years after the date of publication of the regulations.

N.B. These Explanatory Notes are not intended to be an exhaustive description of the instrument nor a substitute thereof or a legislative supplement to it. These Notes do not purport to be an authoritative ruling on the interpretation of the legislation.

10th December, 2024

User Guidelines

1. Introduction

Title of the Legal Notice	Veterinary Medicinal Products Regulations, 2024 hereinafter referred to as "the regulations"
Activity to be regulated	Strengthening the regulation and control of the retail, research, supply, distribution, dispensing, prescribing, manufacturing, data collection and use of veterinary medicinal products and active substances
Responsible entity	The Veterinary Regulation Directorate within the Animal Health and Welfare Department

2. Objectives and Purpose of the Legislation

The regulations aim to supplement and give full effect to 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 (hereinafter "Regulation (EU) 2019/6"). They also regulate other matters falling under the subject matter as provided in Regulation (EU) 2019/6.

Apart from giving full effect and allowing the effective implementation of Regulation (EU) 2019/6, the regulations contain a number of national provisions that are essential to manage the regulatory environment that has emerged in the last couple of years.. 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 these new legal provisions. 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 regulations are made up of thirty-seven (39) regulations as follows:

3. Commentary on parts and articles

1. Citation, scope, applicability and commencement.
2. Interpretation.
3. Languages.
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9. Cascade use of veterinary medicinal products.
10. Registration of homeopathic veterinary medicinal products.
11. Parallel trade.
12. Manufacturing of veterinary medicinal products and active substances.
13. Qualified person.
14. Products in transit.
15. Retail supply of veterinary medicinal products.
16. Dispensing.
17. Prescribing.

18. Distribution categories of veterinary medicinal product.
19. Advertising.
20. Samples or demonstration packs.
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.
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4. Commentary on the regulations

Regulation 2 provides ddefinitions 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 whenn words and phrases used are not defined in the regulations and the Act, the definition in Regulation (EU) 2019/6 shall apply.

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Regulation 9 specifies that applicants shall apply for authorisation when veterinary surgeons would like to procure the products from other countries. The regulation also lists 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.

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Regulation 13 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 14 provides legal cover for the authorised veterinary wholesale dealers who intend to obtain veterinary medicinal products without putting them on the EU Market but re-export them to Third countries, i.e. they are in transit. 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 the freeport, free trade zones, or customs tax warehouses. 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.

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Regulation 16 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 17 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. The regulation 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 18 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 that 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 19 provides the regulatory coverage for activities related with advertising 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 20 specifies that applicants have to apply with the Director for registration of veterinary medicinal products to be brought in Malta to be distributed as free samples. An important requirement is that the applicant shall be a holder of a wholesale distribution authorisation. Companies cannot just obtain veterinary medicinal product and classify them as samples themselves. The status of a sample can only be acquired through this registration.

Regulation 21 has provisions that seek 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.

This set of regulations specify that applicants shall apply for a wholesale distribution authorisation and list 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 in 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 if requested to do so by the Director.

Regulation 29 specifies that applicants shall register for brokering of veterinary medicinal products with 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 30-31 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 32 is about 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 33 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 34 refers to guidelines for the disposal of veterinary medicinal products waste to be issued by the Director.

Regulation 35 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 36 prescribes the fines (multa) and imprisonment periods 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 37 provides that decisions of the Director in terms of these regulations shall be subject to a right of appeal before the Administrative Review Tribunal. An appeal shall be filed within twenty (20) days from the service of the Director's decision.

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No. 1749

MINISTRY FOR AGRICULTURE, FISHERIES AND ANIMAL RIGHTS

Explanatory Notes
(for the purpose of article 3(2)(c) of Cap. 512 of the Laws of Malta)

1. Introduction

Title of the Legal Notice	Veterinary Medicinal Products and Veterinary Pharmacies (Fees) Regulations, 2024, hereinafter referred to as "the regulations"
Activity to be regulated	Fees for authorisations of all matters related with the authorisation or registration or notification of veterinary medicinal products, authorisation of wholesale distributors of veterinary medicinal products, issuance of free sale certificates, registration of brokers of veterinary medicinal products, registration for importation and distribution of active substances, licensing of veterinary pharmacies, issuance of a certificate for Good Manufacturing Practice (GMP) , issuance of a Manufacturing Authorisations, inspections related with pharmacovigilance, destruction of veterinary medicinal products or related products including supervision of destruction and assessment of dossiers for the authorisation of veterinary medicinal products
Responsible entity	The Veterinary Regulation Directorate within the Animal Health and Welfare Department

2. Summary and Background

2.1 Aims & Objectives of the legislation

The regulations aim to establish the fees payable to the Veterinary Services for services referred to in Regulation (EU) 2019/6, the Veterinary Pharmacy Regulations (S.L. 437.XX) and the Veterinary Medicinal Products Regulations (S.L. 437. XX). The services range from the issuance of authorisation, registration or licences to those related to inspections and supervision. The regulations shall provide legal certainty to stakeholders and increase predictability.

2.2 Importance of Regulations

The regulations create more robust regulatory procedures in a clearer and more predictable environment for the authorisation of any matter related with veterinary medicinal products, and any kind of permit that needs to be obtained. Apart from ensuring the sustainability of the whole system of regulatory control it shall induce greater responsibilities on the operator and allow for more efficient operations. Moreover, the proposed validity periods for most authorisations are longer than currently assigned. This shall decrease administrative burden on both regulatory entity (Veterinary Regulation Directorate) as well as the stakeholders. A longer validity period shall alleviate this pressure without increasing risks. Moreover, more time will be made available for the officers to dedicate on other tasks, of perhaps of more regulatory importance.

2.3 Public Consultation

No public consultation or consultation with targeted key stakeholders were carried out. Internal consultation was carried out.

3. Overview of the structure of the instrument

The regulations are made up of three (3) regulations and a Schedule and consist of the following:

1. Citation and commencement.

2. Interpretation.

3. Fees.

Schedule.

4. Commentary

Regulation 2: Provides a list of definitions.

Regulation 3: Provides that the fees specified in the Schedule shall be payable to the Director of Veterinary Services.

Schedule: Provides the fees and amounts to be paid and validity periods for the registration and authorisation of veterinary medicinal products.

5. Concluding Sections

The regulations establish reasonable and fair fees for services provided by the regulatory entity (Veterinary Regulation Directorate). The fees shall support the sustainability of the regulatory system and safeguards the safety and quality of veterinary medicinal products on the market in Malta.

It is also acknowledged that in many instances fees (even if in most cases these are nominal ones) install a sense of responsibility in stakeholders.

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

N.B. These Explanatory Notes are not intended to be an exhaustive description of the instrument nor a substitute thereof or a legislative supplement to it. These Explanatory Notes do not purport to be an authoritative ruling on the interpretation of the legislation.

10th December, 2024

User Guidelines

1. Introduction

Title of the Legal Notice	Veterinary Medicinal Products and Veterinary Pharmacies (Fees) Regulations, 2024, hereinafter referred to as "the regulations"
Activity to be regulated	Fees for authorisations of all matters related with the authorisation or registration or notification of veterinary medicinal products, authorisation of wholesale distributors of veterinary medicinal products, issuance of free sale certificates, registration of brokers of veterinary medicinal products, registration for importation and distribution of active substances, licensing of veterinary pharmacies, issuance of a certificate for Good Manufacturing Practice (GMP) , issuance of a Manufacturing Authorisations, inspections related with pharmacovigilance, destruction of veterinary medicinal products or related products including supervision of destruction and assessment of dossiers for the authorisation of veterinary medicinal products.
Responsible entity	The Veterinary Regulation Directorate within the Animal Health and Welfare Department

2. Objectives and Purpose of the Legislation

The regulations aim to establish the fees payable to the Veterinary Services for services referred to in Regulation (EU) 2019/6, the Veterinary Pharmacy Regulations (S.L. 437.XX) and the Veterinary Medicinal Products Regulations (S.L. 437. XX). The services range from the issuance of authorisation, registration or licences to those related to inspections and supervision. The regulations shall provide legal certainty to stakeholders and increase predictability.

3. Commentary on parts and articles

Regulation 2: Provides a list of definitions.

Regulation 3: Provides that the fees specified in the Schedule shall be payable to the Director of Veterinary Services.

Schedule: Provides the fees and amounts to be paid and validity periods for the registration and authorisation of veterinary medicinal products.

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No. 1750

MINISTRY FOR AGRICULTURE, FISHERIES AND ANIMAL RIGHTS

Explanatory Notes
(for the purpose of article 3(2)(c) of Cap. 512 of the Laws of Malta)

1. Introduction

Title of the 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. Summary and Background

2.1 Aims & Objectives 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.

2.2 Importance of the Regulations

The improved control on the retail of veterinary medicinal products, in particular antimicrobials and narcotics/psychotropic drugs, will decrease the abuse, misuse or overuse of these products. This will directly affect animal health and indirectly human health as human and animal health are intimately linked and effect each other (the 'One Health Principle'). Better control of narcotics/psychotropic drugs is also highly required and in line with the 1961 Single Convention on Narcotic Drugs as amended by the 1972 Protocol.

Furthermore, one of the main objectives of the 'Strategy and Action Plan for the Prevention and Containment of Antimicrobial Resistance in Malta 2020 – 2028', is to review current relevant legislation to strengthen governance to prevent and counteract antimicrobial resistance. This objective seeks to address the lacunae in legislation to ensure leadership,

engagement and accountability for actions to combat antimicrobial resistance. The action plan for the mentioned strategy has been included as 'Budget Measure No 108. 2020 (Tiġi implimentata l-Istrateġija tal-Antimicrobial Resistance 2020 – 2028)'.

2.3 Public Consultation

Prior to the finalisation of the draft legal notice, a consultative session was held with the Veterinary Surgeon Council on the said legal notice on veterinary pharmacies. The draft text was sent on 29th of October 2021. Feedback was received on 15th of November 2021, which was followed by a meeting on 10th January 2022.

Following this meeting, the amended text was integrated with another legal notice about all matters related to veterinary medicinal products, including those on veterinary pharmacies was re-drafted. This draft legal notice was given to the below selected stakeholders on the 2nd of February 2023 with an extended deadline of 28th February 2023 (original deadline was 17th February 2023):

Pharmacy Council: feedback provided on the 1st March 2023;
Veterinary Surgeon Council: feedback provided on the 28th February 2023;
Malta Veterinary Association: feedback was not received;
Malta Chamber of Pharmacists: feedback was not received.

No comments were received on those parts of the consolidated legal notice related with veterinary pharmacies.

Subsequently it was decided that it would be best if the legal provisions on veterinary pharmacies exist in a separate and dinstict text. Therefore, the legal text related with veterinary pharmacies within the legal notice about all matters related with VMPs was again removed and placed in the legal notice on the table.

3. Overview of the structure of the instrument

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 pharmacis.
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.

4. Commentary

Regulations 3 - The regulation 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 - 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 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 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 substitue (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 - This regulation is about the opening times of veterinary pharmacies. The opening times may be ordered by the Director.

Regulation 10 - This regulation 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 stores at a temperature not exceeding 25 degrees Celsius in the pharmacy, it should be likewise kept in such conditions its 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 products and provision of data on sales and use of veterinary medicinal products.

Regulation 12 - This regulation 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 62-70 of the Veterinary Services Act (Cap. 437.)

Regulation 13 - This regulation 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 an 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 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 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.

5. Concluding Section

The legal notice is an effective tool to provide increased safeguards to animal and public health while creating a level playing field for all parties. It does not introduce any unnecessary bureaucratic burdens on the stakeholders concerned.

This legal notice shall enter into force within two months from the date of its publication in the Gazette, in accordance with article 3(2)(b) of the Small Business Act (Chapter 512 of the Laws of Malta).

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10th December, 2024

User Guidelines

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