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Summary of the Main Points related with Veterinary Prescription, Veterinary Pharmacy and Wholesale Distribution in S.L 437.47 as amended by LN 179/21

Summary of the Main Points related with Veterinary Prescription

SL 437.47 has a number of regulations directly about the veterinary prescription. It provides for a definition of a veterinary prescription and stipulates who has the right to issue it (Regulation 59A). Currently, in Malta these persons can only be veterinary surgeons.

S.L 437.47 also lays down the requirements for those veterinary medicinal product that require a veterinary prescription and those occasions when a veterinary prescription is not requires (Regulation 60). The AHWD has also prepared the criteria which are used to help determining the Distribution Category of Veterinary Medicinal Products (e.g. whether a VMP should be a POM or OTC). They are made public on the AHWD 's website. The usual procedure is that applicant 'suggest' a Distribution Category' on the application form but then it is up to the AHWD's to decide which Distribution Category to assign.

IN SL 437.47 there are also a number of regulations that somehow 'indirectly' refer to the veterinary prescription. These include obligations of dispensers with regard to record keeping for prescription-only-products (Regulation 59(2)) and prohibition to advertise prescription-only-products (Regulation 77A (1)) except for certain class of operators.

The legal obligations of the prescriber are laid out in regulation 59A(1) . Whoever conduct such an activity and is not a veterinary surgeon will be in breach of the regulations and subject to shall be guilty of an offence.

The official veterinary prescription on which veterinary surgeons can prescribe VMPs will be issued by the Veterinary Services. Currently this exists as a 4 colour coded carbon copy prescription. The white one is the original and kept by the dispenser the pink one retained by veterinary surgeon, the yellow one kept by the

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farmer in the farm and the blue copy is sent to the veterinary services. The Veterinary Services will be making the veterinary prescription available in electronic version.

Veterinary surgeons can only prescribe VMPs for animals which are under their care, Regulation 59A (4). Therefore, the extent of their responsibility lies within this sphere. A veterinary surgeon cannot take responsibility of treatment recommended by another veterinary surgeon.

Veterinary surgeons can only use one prescription for each recommended treatment, and only when a clinical examination is done by the veterinary surgeon. For example, a veterinary surgeon cannot write different VMPs for more than one diagnosed condition on the same veterinary prescription. In such cases 2 different veterinary prescriptions should be issued. It is also crucial for the veterinary surgeon to understand that the use of combination of antimicrobials should be scientifically supported as per Regulation 79A (9)

It is acknowledged that sometimes it is not possible for the veterinary surgeon to make a full diagnosis of a condition that affects an animal or a herd. The veterinary surgeon may have to wait for the results of sample or swab tests, e.g. for antimicrobial sensitivity tests or antibiograms. It these cases it can be acceptable that the veterinary surgeon starts with empirical treatment. However, before recommending such treatment the veterinary surgeon should be familiar with the health status of the animal or herd, especially in case of farms, Regulation 59A (4).

Whenever there is a reason for the veterinary surgeon to prescribe VMPs for prophylaxis or metaphlaxis use he should be able to provide a justification in case this is asked for by the authorities. It is advised that the veterinary surgeon keep a note when he prescribes product for such use. As per Regulation 79A(5) metaphylactic or prophylactic antimicrobial treatment may be allowed with conditions. Preventive use of antimicrobials veterinary medicinal products or medicinal products is not allowed. The veterinary surgeon should take care of not prescribing antimicrobials for preventive use on the pretext of metaphylactic or prophylactic use.

A veterinary prescription for antimicrobial medicinal products shall be valid for five days from the date of its issue as per Article 105 (10) of Regulation EU 2019/4

As in the case of dispensing, in prescribing the veterinary surgeon should also makes his best to ensure that whoever will be using the VMPs is informed properly about its proper use, including dosing information and any warnings or contra-indications. In particular, veterinary surgeons should always and at all times put in

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considerations factors that may adversary affect the effectiveness of antimicrobials. There are a number of antimicrobials that are classified as critically important antimicrobials. Regulation 59A (8) (d).The veterinary surgeon should put particular emphasis on these. He should keep himself updated on the latest developments in this and other regards.

When the veterinary surgeon administers himself the VMPs he can choose not to issue a veterinary prescription, provided this is not specifically asked for by the animal owner. However. this exemption should not be confused with the other obligation related with record keeping of retailed products. As a supplier of the VMP the veterinary surgeon is not exempted from record keeping obligations as per Regulation 59(5).

PRESCRIPTION ONLY MEDICINE AND OVER THE COUNTER MEDICINE

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 in order 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 in the legislation.

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 Regulation 60. The designation are POM-VP, POM-V, OTC, or GS

(a) Prescription-Only-Medicine, Veterinary surgeon and Pharmacist- abbreviated to POM-VP.

(b) Prescription-Only-Medicine, Veterinary surgeon- abbreviated to POM-V.

(c) Over- the- Counter –Medicine, abbreviated to OTC

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(d) General Sales, abbreviated to GS

(4) The supply of veterinary medicinal products for each distribution category shall be made as follows:

(a) POM-VP shall only be prescribed and/or dispensed by a veterinary surgeon or dispensed by a pharmacist according the terms of a veterinary prescription. Premises from where the products can be supplied are veterinary pharmacies, licensed veterinary establishments, and by the veterinary surgeon during an outcall.

(b) POM-V shall only be prescribed, dispensed and administered by a veterinary surgeon. Premises from where the products can be supplied are licensed veterinary establishments, and by the veterinary surgeon during an outcall.

(c) OTC, may be dispensed without a veterinary prescription. The persons who can dispense this category of veterinary medicinal products are veterinary surgeons, pharmacists and suitably qualified persons under the direction of a pharmacist or a veterinary surgeon. Premises from where the products can be supplied are veterinary pharmacies, licensed veterinary establishments, and by the veterinary surgeon during an outcall.

(d) GS, may be dispensed without a veterinary prescription. The persons who can dispense this category of veterinary medicinal products are veterinary surgeons, pharmacists and suitably qualified persons. Products that fall under this category 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:

Regulation 60 (4) provides for an exemption if it is deemed important that products on the ‘General Sales List' are also supplied from premises other than those mentioned above. The persons who dispense the VMPs from these other premises may not necessary be Suitably Qualified Persons but must have at least 2 years experience in handling these kind of products.

It is to note that S.L437.47 as amended by LN 179/21 does not go into the details with regard to the requirements of the veterinary prescription *per se.* For example, it does not stipulate its layout, its content, how it should be prepared, the logistical requirements, who should fill each part of it, to whom any copy thereof is sent, how should each player act in particular circumstances (e.g. incomplete dispensing, urgent situations), the validity of it depending on the type and

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class of veterinary medicinal product, what is considered as the *official* veterinary prescription and which entity issues it. These and more are planned to be included in a new Legal Notice on the Veterinary Prescription.

It is also to note also that the AHWD is planning to launch an electronic version of the veterinary prescription in November 2021. This will be subject to the same rules that apply to a paper based veterinary prescription but it is expected that it will facilitate the activities of prescribing and dispensing while allowing the regulatory entities to effectively oversee the whole dynamic process.

Summary of the Main Points related with Veterinary Pharmacy

LN 179/21 introduces a definition of veterinary pharmacy and there are various references to veterinary pharmacies in a number of Regulations and in some of the definitions, namely of 'dispensing [1], and veterinary pharmacy [2]. The point which emerges here is that a veterinary pharmacy is one of the premises where veterinary medicinal products can be retailed or supplied (Regulation 58A) [3] Some veterinary medicinal products categorised as requiring a veterinary prescription can only be retailed or supplied from veterinary pharmacies or veterinary surgeons but not from other premises where certain veterinary medicinal products categorised as on the General Sales list can be retailed or supplied.

In LN179/21 there is also a reference to a veterinary pharmacy when a pack of veterinary medicinal product is dividing up or changed (Regulation 39 (2) (b)) [4] This is normally done by the pharmacist for a pack or two in the pharmacy when the quantities required by the animal is much less than the pack size presented for sale. Apart from not being economically feasible this can result is a large amount of veterinary medicinal product going to waste. In these cases, and when the storage conditions of the veterinary medicinal product allow it. These packs can be opened and divided as necessary without a manufacturing authorisation.

S.L 437.47 has a reference to a pharmacy with respect to medicinal product prepared in a pharmacy in accordance with the prescriptions of a Pharmacopoeia and intended to be supplied directly to the end-user, commonly known as the officinal formula (Regulation 3 (2) (b)) [5] . In these cases the legislation exempts these products from the requirements of a Marketing Authorisation. This provision has been kept with the amendments of S.L 437.47.

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Veterinary pharmacies are also mentioned in Regulation 60 where the designation of the distribution category of the veterinary medicinal products are provided. Please refer to the first part of this document entitled ‘ Summary of the Main Points related with Veterinary Prescription’ for a more detailed description about this.

It is to note that S.L437.47 as amended by LN 179/21 does not go into the details with regard to the requirements of a veterinary pharmacy. For example, it does not stipulate how the premises should be, where the premises should be, who manages it, how it is managed, what are the qualifications of the person who manages it, what are the opening times, whether there are any licence requirements, the duties of the pharmacist and owner, conditions for application , what equipment is to be kept and storage conditions of the veterinary medical products. These provisions are planned to be included in the amendments of Chapter 437 and a new Legal Notice on Veterinary Pharmacies. The Regulations referred to in these paragraph are being reproduced below.

Extracts taken form S.L 437.47 as amended by LN 179/1

1. "dispensing" means the sale or supply of veterinary medicinal products. The products are sold or supplied from a veterinary pharmacy or by a veterinary surgeon in licensed veterinary establishments or during out calls;

2. "veterinary pharmacy" means the premises from where veterinary medicinal products are, dispensed directly to the public except for licensed veterinary establishments;

3. 58A. In the territory of Malta, the retail supply of veterinary medicinal products shall be conducted only from veterinary pharmacies, licensed veterinary establishments, other establishments mentioned in regulation 60(4)(d) and by veterinary surgeons during out call visits."

4. 39 (2) (b) A Manufacturing Authorisation shall not be required for preparation, dividing up, changes in packaging or presentation where such processes are carried out solely for retail supply by pharmacists in veterinary pharmacies, or by other persons legally authorised to carry out such processes

5. 3 (2) (b) Except for the provisions on the possession, prescription, dispensing and administration of veterinary medicinal products, these regulations shall not apply to any medicinal product prepared any medicinal product prepared in a pharmacy in accordance with the prescriptions of a Pharmacopoeia and intended to be supplied directly to the end-user, commonly known as the *officinal formula.*

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Summary of the Main Points related with Wholesale Distribution

Definition

Title VI is about possession, distribution and dispensing of veterinary medicinal products. Regulation 58 is dedicated solely to wholesale distribution and provides for the authorisation of these operators while listing the requirements and duties of the holders of such an authorisation. These requirements include those related with record keeping, batch recalls, the employment of a 'Responsible Person' and other technical staff, self-audits. This regulation also puts an obligation on the Veterinary Services to take all appropriate measures to ensure that wholesalers supply of veterinary medicinal products is only carried out according to the legislation. Article 5 is being reproduced below. The new or provisions that were amended by LN 179/21 are being reproduced in Table 1

Regulation 58 of S.L 437.47

58. (1) In the territory of Malta, the wholesale distribution of veterinary medicinal products is subject to the holding of an authorisation. The Veterinary Services shall take all appropriate measures to ensure that the time taken for the procedure for granting this authorisation does not exceed ninety days from the date on which it receives the application.

Supplies of small quantities of veterinary medicinal products from one retailer to another may be excluded from the scope of the definition of wholesale distribution under a decision to be laid down by the Veterinary Services.

(2) In order to obtain the authorisation for distribution, the applicant shall have at his disposal technically competent staff and suitable and sufficient premises complying with the requirements laid down in the territory of Malta as regards the storage and handling of veterinary medicinal products:

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Provided that for the purposes of this sub-regulation "technically competent staff" means responsible or qualified persons who shall be professionally responsible for the activity in question. Such person(s) must be in possession of qualifications as required by the Veterinary Services:

Provided further that, where more than one responsible or qualified person is nominated, the application will clearly specify the responsibilities of each respective person.

(3) The holder of the authorisation for distribution shall be required to keep detailed records. The following minimum information shall be recorded in respect of each incoming or outgoing transaction:

(a) date;
(b) precise identity of the veterinary medicinal product;
(c) manufacturer's batch number, expiry date;
(d) quantity received or supplied;
(e) name and address of the supplier or recipient.

At least once a year a detailed audit shall be carried out to compare incoming and outgoing medicinal supplies with supplies currently held in stock, any discrepancies being recorded.

These records shall be available for inspection by the Veterinary Services for a period of at least three years.

(3A) The holder of a distribution authorisation shall have an emergency plan guaranteeing the effective implementation of any recall operation ordered by the competent authorities or undertaken in cooperation with the manufacturer of the medicinal product in question or the holder of the marketing authorisation.

(4) The Veterinary Services shall take all appropriate measures to ensure that wholesalers supply veterinary medicinal products only to persons permitted to carry out retail activities in accordance with regulation 59, or to other persons who are lawfully permitted to receive veterinary medicinal products from wholesalers.

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(5) Any distributor, not being the marketing authorization holder, who imports a product from another Member State shall notify the marketing authorization holder and the Veterinary Services to which the product will be imported of his intention to import it. In the case of products which have not been granted an authorisation pursuant to European Regulation (EC) No 726/2004, the notification to the Veterinary Services shall be without prejudice to additional procedures provided for in the legislation of Malta.

Table 1: New or provisions that were amended by LN 179/21

Reg Number	Legal Text	Explanation
5(6)	The manufacturer, importer, wholesale dealer or retailer of a veterinary medicinal product shall declare that he will notify the Veterinary Services within fifteen (15) days of learning of any serious adverse reactions in accordance with sub-regulations (2) and (3) of regulation 68. A record of each adverse reaction and serious adverse reaction must be maintained on becoming aware of it. The records shall be kept for five (5) years.	This adds an obligation on veterinary wholesale dealers to notify the Veterinary Services in case he becomes aware of any Adverse Drug Reactions for the Veterinary Medicinal Products he distributes. The time frame is 15 days.
4(B) (1)	Veterinary medicinal products may be exempted from the provisions in regulations 5 to 8 if it can be demonstrated that the products are veterinary samples or demonstration packs distributed to veterinary surgeons or pharmacists by veterinary wholesale distributors.	This may exempt veterinary medicinal products from obtaining a Marketing Authorisation if they will only be distributed as samples or demonstration packs to the legally designated persons, i.e. veterinary surgeons or pharmacist. The veterinary services may make up procedures in order to keep the appropriate control over veterinary medicinal products that exempted from a Marketing Authorisation for this purpose.
4B (2)(e)	the maximum period of time the authorised veterinary wholesale dealer can procure a product from a Member State of the European Union as a free sample is one (1) year from the first consignment thereof	This also related to samples or demonstration packs. There is a limit as to how long a veterinary medicinal products can be procured as sample or demonstration pack. This is one year from the first consignment thereof. This also applies to any approvals granted by the Veterinary Services, e.g. for the exemption from a Marketing Authorisation.

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		It does not meant that the wholesale distributor cannot procure more sampled or demonstration packs after one year. It means that he has to submit a new request.
10 (9)	When a veterinary surgeon has recourse to the provisions in paragraphs (a), (b) and (c) of sub-regulation (1), the activity undertaken by the veterinary surgeon is excluded from the scope of the definition of wholesale distribution under a decision to be laid down by the Veterinary Services."	This related to those occasions when veterinary surgeons bring veterinary medicinal products from other countries under the 'cascade'. Most often veterinary medicinal products are obtained by wholesale distributors established in the other country. When this happens the rules regarding wholesale distribution (e.g. to have a Responsible Person, to obtain a Wholesale Distribution Authorisation) do not apply to veterinary surgeons. Veterinary surgeons cannot regularly obtain veterinary medicinal products from abroad on the pretext of this provision. It is also essential that the veterinary surgeon proofs that the veterinary medicinal products in question are not authorised Malta. This relates for veterinary medicinal products administered to **non-food animals.** An application form needs to be submitted as is normally done for 'cascade' use when products are obtained from other Member States of the EU.
11 (11)	When a veterinary surgeon has recourse to the provisions in sub-regulation (1) the activity undertaken by the veterinary surgeon is excluded from the scope of the definition of wholesale distribution."	This related to those occasions when veterinary surgeons bring veterinary medicinal products from other countries under the 'cascade'. Most often veterinary medicinal products are obtained by wholesale distributors established in the other country. When this happens the rules regarding wholesale distribution (e.g. to have a Responsible Person, to obtain a Wholesale Distribution Authorisation) do not apply to veterinary surgeons. Veterinary surgeons cannot regularly obtain veterinary medicinal products from abroad on the pretext of this provision. It is also essential that the veterinary surgeon proofs that the veterinary medicinal products in question are authorised in Malta. This relates for veterinary medicinal products administered to **food animals.** An application form needs to be submitted as is normally done for 'cascade' use when products are obtained from other Member States of the EU.

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39 (5)	A Manufacturing Authorisation shall include a licence to distribute by wholesale the veterinary medicinal products in respect of which the Manufacturing Authorisation has been issued.	When a holder of a Manufacturing Authorisation wants to distribute a veterinary medicinal product he manufactures himself, there is no need for him to obtain a Wholesale Distribution Authorisation. The Manufacturing Authorisation is sufficient to cover his wholesale distribution activity for those products as they would already be included in his Pharmaceutical Quality System.
50C(2)	The only exclusion in respect of the requirement in regulation 38, is when the operations of import for the sole purpose of re-export are effected within a freeport, free trade zone or customs warehouse. However, in such instances a veterinary wholesale dealer's licence is still required by the company engaging in the process.	This relates to imported products (meaning obtained from Third countries) without a Marketing Authorisation from operators that do not hold a Manufacturing Authorisatation. These products and this activity can only take place when the products are neither put on the EU market (in any EU members state including Malta) nor changed in any way (e.g. re-labelled). The reason why they are in Maltese territory should be because they are intended to be exported in a Third country, i.e. re-exported. The products should be kept in bonded stores or else transhipped. Operators should refer to the relevant Customs legislation for the meaning and requirements of bonded stores and trans-shipment.
50C(6)	The authorisation to engage in such an activity is only given to persons in possession of a veterinary wholesale dealer licence and without prejudice to other authorisations that the persons may have to obtain, particularly with respect to the requirements of the Importation Control Regulations.	For all intends and purposes the activity explained above in Regulation 50C(2) ('import for re-export') is legally considered as wholesale distribution. For this reason only holders of a wholesale distribution authorisation can engage in it. This ensures that this activity is still regulated and carried out in accordance with a Pharmaceutical Quality System. Wholesale distributors should inform the Veterinary Services about this activity in order to be included in their Pharmaceutical Quality System, and if necessary their authorisation modified. They have to be authorised for this activity and an inspection may be warranted. The application form for a wholesale distribution authorisation includes a part related with bonded stores were operators can fill in the necessary details.

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58(1)	second paragraph "When the market situation in Malta is such that it gives rise to a temporary supply issues for an authorised veterinary medicinal product, the procurement of small quantities of the same authorised veterinary medicinal product, or an essentially similar veterinary medicinal product, by a veterinary surgeon is permitted and is excluded from the scope of the definition of wholesale distribution:	This provision may seem similar to that present in Regulation 10 (9) and 11(11). The difference is that whereas those provisions relate to veterinary medicinal products not authorised in Malta this provision related to those veterinary medicinal products that **are** authorised in Malta but are either experiencing temporary supply issues (commonly known as out-of-stock) or are authorised but not marketed. It is important that the product is the same one authorised in Malta. It is not enough that the products bear the same name. They must be the same one (same name, same country, same Summary of Products Characteristics) otherwise the provisions of Regulation 10 (9) and 11(11) shall apply. This means that an application form needs to be submitted as is normally done for 'cascade' use when products are obtained from other Member States of the EU. This provision applies to both food and non-food animals.
60(13)	The holders of a wholesale distribution authorisation shall distribute veterinary medicinal products only to the premises authorised to retailed veterinary medical according to these regulations.	This is a new provisions which stipulates to whom and where wholesale distributors can supply veterinary medicinal products. These premises or persons are stipulated in the legislation and can be veterinary pharmacies, veterinary surgeons, other veterinary wholesale distributors and some other places (e.g. pet shops, medicated feed traders) according to the distribution category.
60 (14)	The holders of a wholesale distribution authorisation shall distribute to the premises authorised to retailed veterinary medical only the category/categories of veterinary medicinal products that are authorised to be retailed from each type of premises in accordance with these regulations."	This provision compliments Regulation 60 (13) Wholesale distributors can distribute the veterinary medicinal products according to their distribution category. For example, veterinary medicinal products classified as Prescription-Only-products (POM) can only be distributed to veterinary pharmacies and veterinary surgeons. Products on the General Sales List can also be distributed to other premises, e.g. pet shops.

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It is to note that S.L437.47 as amended by LN 179/21 does not go into the details with regard to the requirements of the Whole Sale Authorisation *per se*. For example, it does not stipulate how the premises should be, where the premises should be, who manages it, how it is managed, what are the qualifications of the person who manages it and of the 'Responsible Person', what are the opening times, whether there are any licence requirements, the duties of the 'Responsible Person' and owner, conditions for application, what equipment is to be kept and storage conditions of the veterinary medical products. These and more are planned to be included in a new Legal Notice on the Veterinary Wholesale Dealing. This upcoming Legal Notice is planned also to address the activity of Brokering.

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