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

Version 30-07-21

Guidelines on the Prescribing and Dispensing of Veterinary Medicinal Products and the Good Use of Antimicrobials for Wholesale dealers, Pharmacists and Medicated Feed Mills/Traders/Distributors

1.1 Prescribing of Veterinary Medicinal Products

Regulation 59A of S.L 437.47 concerns those persons that have the right to prescribe Veterinary Medicinal Products (VMPs). In Malta these persons can only be veterinary surgeons as stipulated by the same regulation.

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

Currently the veterinary prescription is made up of 4 colour coded copies which veterinary surgeons order through an on-line form. It is planned that by November 2021 an electronic veterinary prescription will be available for prescribers. Each player retains a copy of the prescription as explained in section 2.1 of these guidelines.

PRESCRIPTION ONLY MEDICINE AND OVER THE COUNTER MEDICINE

S.L 437.47 was modified to include provisions that stipulate the way VMP can be prescribed and dispensed. Certain VMPs are classified as prescription-only-medicine and this requirement should be indicated on the outer pack of the product. The way this indication shall be conveyed is also stipulated in S.L437.47. Other VMPs whose use is considered as less risky can be obtained without a veterinary prescription. This status should also be indicated on the outer pack. Other important additions include the places from where VMPs can be dispensed. Depending on the distribution categories VMPs can be supplied from veterinary pharmacies, veterinary establishments, registered pet shops, registered aquarium fish product retailers and approved feed traders where animal Medicated Feeds are produced, sold, or traded.

The designated abbreviations for each distribution classification are stipulated in this regulation. These are: POM-VP, POM-V, OTC, or GS. The meaning of each abbreviation is as follows:

(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

(d) General Sales, abbreviated to GS

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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 the qualifications for the 'Suitably Qualified Persons' are envisaged to be stipulated in the changes in Chapter 436, The Veterinary Services Act.

1.2 Dispensing of VMPs

Legal Notice LN179/2021 that was published on 23.04.2021 amends S.L 437.47 , Veterinary Medicinal Products Regulations. A number of provisions that are related with prescribing and dispensing have been introduced by this LN. In the section of these guidelines one can find a number of notes which focus on wholesale dealers and pharmacists. Particular emphasis is given for the use of antimicrobials.

In Regulation 58A of S.L 437.47 a provision was introduced that stipulates from where the retail supply of VMPs can be conducted. Retail sale can be carried out only from veterinary pharmacies, licensed veterinary clinics/hospitals or other establishments stipulated in the legislation according to the distribution status assigned to the VMP in question (e.g. POM , OTC and their sub-categories). Retail can also be carried out by veterinary surgeon during out call visits for animals under their care. Whoever conduct such sale in places not indicated in the legislation will be in breach of the regulations and shall be guilty of an offence.

In Regulation 59 important changes in the existing regulation as regard dispensing were made. Pharmacist can dispense all type of VMPs, except those that can be administered only by veterinary surgeons.

In accordance with Regulation 2, Definition 17 of S.L 437.47 wholesale dealing is distinguished from retail supply. Wholesale dealing does not include the retail supply (so also includes dispensing) of veterinary medicinal products by persons entitled to carry out such supplies in accordance with regulation 59, i.e. pharmacies, veterinary surgeons and Suitably Qualified Persons from other premises, e.g. pet-shops.

Dispensers should be able to ask diligent and to-the-point questions to the animal owners. Dispensers should always explain in a clear and easily understandable manner any specific warning about the VMP and advise them on the dosing of the product. Special attention should be given to antimicrobials in all aspects in order to minimise the risks of antimicrobial resistance. There should be close collaboration between dispenser and prescriber. Any misunderstandings should be resolved and any disagreements discussed on scientific grounds. This is particularly important when a dispenser is presented with a veterinary prescription containing a critical antimicrobial but without any justification. As per Regulation 59 (9) the dispenser has to be satisfied that all necessary precautions have been taken in these cases.

2.1 Prescribing of Medicated Feed

Veterinary surgeons have to prescribe Medicated Feed on the prescription forms that are provided by the veterinary services. These can be hard copies on in an electronic form. The prescription must be filled in ink, using block letters and in legible handwriting. Currently this prescription consists of 4 copies: white, yellow blue and pink. The veterinary surgeon's stamp or full name and registration number in block letters has to be placed upon every copy of the prescription form.

1. The white original copy is to be kept by the manufacturer/distributor/trader/pharmacy

2. The yellow copy is to be kept by the farmer/producer

3. The blue copy is to be sent to the Veterinary Services

4. The pink copy is to be retained by the veterinary surgeons

The content of the prescription is dictated by Regulation 8 (1) of S.L 437. 73 (Conditions Governing the preparation, placing on the market and use of Medicated Feeding stuffs Rules). A specimen of the prescription is shown in Schedule I of Subsidiary Legislation. S.L 437. 73 transposed EU Directive 2001/82/EC. The

Veterinary Services has prepared prescription booklets based on this specimen. In it there are a number of modifications in the format and content in order to have an easier to understand prescription. (Photo 1)

Part A of the prescription is filled by the veterinary surgeons. Part B is completed by manufacturer or authorised distributor. The prescription must be made available at all times to the Veterinary Services during official inspections. It cannot be used for more than one treatment.

The prescription may be used only for animals treated by the veterinary surgeons. The veterinary surgeons must be satisfied that the use of the Medicated Feed is justified for the species concerned, administration is not incomplete or incompatible with a previous treatment and that there is no contra-indication or interaction between different medicated premixes.

The veterinary surgeons must prescribe such quantities necessary for treatment. Currently it is only possible to manufacture Medicated Feed only with a prescription. With the coming in force of Regulation (EU) 2019/4 in 22-01-23 it will be possible to manufacture Medicated Feed without prescription under certain circumstances. (Article 8). This is called 'anticipated production' and it is a provision intended to commence treatment of the animal as soon as possible.

As in all veterinary medicinal products or product containing them, the appropriate withdrawal period should be assigned by the veterinary surgeons.

An important consideration is for the veterinary surgeons is to make sure that the Medicated Feeding stuff does not contain a coccidiostat which is also contained in another feeding stuff that may be given to the animals. This also applies to antibiotics and to human medicine.

Medicated pre-mixes are veterinary medicinal products. Therefore, medicated pre-mixes must be registered with the Veterinary Services before they can be used for the manufacture of Medicated Feed.

Medicated Feed should not contain substances with hormonal or thyrostatic effect as per Directive 96/22/EC. The administration thereof is also subject to the controls of Directive 96/23/EC regarding the monitoring of residues in animal products.

The manufacturer must take in consideration that the prescription is valid for a period not exceeding 3 months and can be used only once. Each copy shall be kept for a period of not less than three years from the date it is issued by the respective party. The prescription must be made available at all times to the Veterinary Services during official inspections.

Currently a veterinary prescription prepared by a veterinary surgeons working in another EU Member State is not valid in Malta. With the coming in force of Regulation (EU) 2019/4 in 22-01-23 the prescription can be recognised between each Member State.

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2.2 Distribution of Medicated Feed

In these guidelines the term Medicated Feed traders and Medicated Feed distributors are being used synonymously.

Only manufacturers of the same Medicated Feeding stuff and approved distributors can supply farmers with Medicated Feed. The former usually manufactures the Medicated Feed according to need while the latter is authorised to supply pre-packed Medicated Feed ready for use manufactured elsewhere (e.g. authorised Medicated Feed mill outside Malta. In both cases they should comply with the same conditions regarding the keeping of registers, storage, transport and issue of the Medicated Feedstuff. Medicated feeds can be retailed from veterinary pharmacies too.

Like the manufacturer, then distributor must also take in consideration that the prescription is valid for a period not exceeding 3 months and can be used only once. Each copy shall be kept for a period of not less than three years from the date it is issued by the respective party. The prescription must be made available at all times to the Veterinary Services during official inspections.

Apart from the prescription, the distributor is required to have a certificate issued by the competent authority from where the Medicated Feed is brought with each consignment. The specimen of this form is in Schedule II of Subsidiary Legislation. S.L 437.73. This sample of this certificate is being reproduced in these guidelines (see Photo 2)

A copy of these certificated should be sent to the Veterinary Services together with the blue copies of the prescription that are in current use.

Medicated Feeds can be brought from Third countries and distributed in Malta. However, it is imperative that they are manufactures in accordance with the requirements that are equivalent with those of the EU. Same rules for prescription, preparation, use and distribution apply.

2.3 VMPs Dispensing Guidelines for Dispensers

Sometimes a veterinary prescription is required as a matter of urgency. In these cases it is suggested that instructions can also be given verbally. However, it is suggested that verbal instructions to the dispenser are not accepted and honored unless the following conditions are all satisfied:

a) that the dispenser is satisfied that the verbal instruction come from a veterinary surgeon , who by reason of an emergency is unable to furnish a veterinary prescription;

b) that the veterinary surgeon undertakes to furnish the dispenser with a veterinary prescription within forty-eight hours of the verbal instruction;

c) that the product is dispensed in accordance with the directions of the veterinary surgeon

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Sometimes a veterinary prescription may contain more than one prescribed veterinary medicinal products and not all of them are available from the same place of dispensing. Or else it is not possible for the same place of dispensing to furnish the full prescribed quantities. In these cases it is suggested that the dispenser follows this procedure:

a) In case more than one product is listed on the veterinary prescription and not all of them are dispensed from a single place the dispenser can make a note on the veterinary prescription to that effect.

b) The dispenser can mark on the veterinary prescription which and how much of the product/s were dispensed.

c) The dispenser can keep an accurate account of the course of action he has taken.

d) The veterinary prescription can then be given to another dispenser by the customer, whereupon, if the rest of the products are dispensed, it will be considered as completely honored.

e) This procedure can also be applied to products which are only partially dispensed from a single place with the remaining quantities of the same product dispensed from another place.

A veterinary prescription for products other than antimicrobial products should be valid for a period not exceeding (6) months from the date of issue.

A veterinary prescription for antimicrobial products should be valid for five days from the date of issue.

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PHOTO 1

VETERINARY PRESCRIPTION FOR THE PREPARATION OF MEDICATED FEEDINGSTUFFS

PART A: TO BE COMPLETED BY THE PRESCRIBING VETERINARIAN								
Name of veterinarian								
Address (residence / clinic)					Post-code			
Name and address of business manufacturing or supplying the medicated feedingstuff					Post-code			
Name and address of stockfarmer or holder of animals / Churn no. / stamp / stable no					Post-code			
Identification and number of animals being treated								
Number	Species	Stamp / Tag / Tattoo / Microchip	Breed	Sex	Category			
1.								
2.								
3.								
Disease to be treated (*indicate if cascade principle applied*)								
Authorisation number of the medicated premix								
Quantity of medicated feedingstuff in kilograms								
Special instructions for the stockfarmer or holder of the animal(s)								
Percentage of medicated feedingstuff in the daily ration		Frequency of treatment		Duration of treatment in days	Withdrawal Period			
					Eggs	Meat	Milk	
1.								
2.								
3.								
Date when prescription was issued			Signature of veterinarian		Stamp and Registration Number of veterinarian			
Day	Month	Year						

PART B: TO BE COMPLETED BY MANUFACTURER OR AUTHORISED DISTRIBUTOR						
Prescription presented on	Day		Month		Year	
Date of delivery	Day		Month		Year	
To be used before	Day		Month		Year	
Signature and Stamp of manufacturer or supplier						

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PHOTO 2

Schedule II

ACCOMPANYING CERTIFICATE IN RESPECT OF MEDICATED FEEDINGSTUFFS FOR ANIMALS INTENDED FOR TRADE

Name and address of the manufacturer or approved distributor: .....
.....
.....

Name of the medicated feedingstuff: .....
.....

Type of animal for which the medicated feedingstuff is intended: .....

Name and composition of the authorised medicated pre-mix: .....
.....

Dosage of the medicated pre-mix authorised in the medicated feedingstuff: .....
.....

Quantity of medicated feedingstuff: .....

Name and address of the recipient: .....
.....
.....

It is hereby certified that the medicated feedingstuff as described above has been manufactured by an authorised person in accordance with Directive 90/167/EEC.

Done at ....., on .....
(place) (date)

.....
(Signature)
(Name and position)

Stamp of the veterinary authority
or other competent authority

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