Frequently Asked Question (FAQ) on Veterinary Medicinal Products and the Veterinary Medicines Unit (VMU)

1. What products are regulated by the Veterinary Medicines Unit?

The Veterinary Medicines Unit only regulates products that are classified as Veterinary Medicinal Products (VMPs)

These products must have a Marketing Authorisation (MA) in order to be placed on the market. The Marketing Authorisation must have been granted in Malta or in EU/EEA country.

Medicated Feed are partially regulated by the Veterinary Medicines Unit. These products are the remit of both the Feeding Staff and Animal Nutrition Section and the Veterinary Medicines Unit since these are made of 2 components, i.e. the feed part and the medicated pre-mix part (the medicinal part). The latter is classified as a veterinary medicinal product.

2. What products are not regulated by the Veterinary Medicines Unit?

Products that just maintain the healthy function of a physiological system and do not claim any curative effects may not necessary be classified as veterinary medicinal products. Therefore, they are not regulated by the Veterinary Medicines Unit and there is no need for these products to obtain a Marketing Authorisation.

Such products include vitamins/minerals complexes, non-medicated rubs/creams/linaments, shampoos, and certain non-medicinal stimulants.

Feeds (excluding Medicated Feeds) and feed additives are also not regulated by the Veterinary Medicines Unit. These products are regulated by the Animal Feed Section within the Veterinary Regulations Directorate (VRD).

Other products which are not regulated by the Veterinary Medicines Unit include the following:

1. Biocides (disinfectants, preservatives, insecticides, pesticides, repellents)
2. Plant Protection Products
3. Diagnostic tools and veterinary medical devices
4. Other types of veterinary equipment (e.g. horse harnesses, dog collars, non-medical veterinary devices and veterinary medical devices etc.)

These products are either not yet regulated, e.g. medical and non-medical veterinary devices, or regulated by other entities e.g. biocides regulated by the Malta Competition and Consumer Affairs Authority (MCCAA).

Sometimes the dividing line between biocides and veterinary medicinal products may be very fine. One classification may not necessary exclude another, e.g. most flea collars contain a biocide as an active ingredient yet the product is usually classified as a veterinary medicinal product. The active ingredient of a product may have biocidal activity, yet it may still be classified as a medicine. The classification depends on various factors, especially on the clinical indications given and the mode of application.

As a general rule the regulation of medicines is usually more stringent than that of biocides. Therefore, when in doubt or to be ‘on the safe side’, the classification of a product as medicine most often than not takes precedence

Commission guideline 7 Doc-Biocides-2002/01 Version 08.01.2008 can be a useful aid to distinguish between the two.

3. How is the use of products that are not veterinary medicinal products but can be used for therapeutic purposes controlled?

Checks on their use is made by the relevant Unit of the Animal Health and Welfare Department (AHWD) in charge of the primary production of the species that is treated with the product in question. The Veterinary Medicines Unit will collaborates with the relevant Units to give its advice and technical input.

There are many substances in common use that can be administered to animals due to their professed or proven therapeutic properties. Although these substances may have therapeutic qualities they are not veterinary medicinal products in accordance with the official definition of veterinary medicinal products in Regulation (EU) 2019/6. This means that they have not been through the stringent requirements of the

medicines legislation and have obtained a Marketing Authorisation. The fact that they do not have a Marketing Authorisation does not mean that they are harmful, useless or banned from use.

4. How can I distinguish between a medicinal product and a non-medicinal product?

Article 4 of Regulation (EU) 2019/6 defines a veterinary medicinal product as:

'veterinary medicinal product' means any substance or combination of substances which fulfils at least one of the following conditions:

(a) it is presented as having properties for treating or preventing disease in animals;

(b) its purpose is to be used in, or administered to, animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action;

(c) its purpose is to be used in animals with a view to making a medical diagnosis;

(d) its purpose is to be used for euthanasia of animals;

Bearing in mind this definition, a product may be considered as medicinal either by function or by presentation.

A product is medicinal by function because it possesses recognised properties for treating or preventing disease and by presentation because the product is placed on the market with that claim (through labelling, leaflets, and advertisements) even though its clinical efficacy may not have been sufficiently proven.

Not all products can be straightforwardly classified as medicinal. There are a number of ingredients that have accepted usage in a range of different categories besides the treatment of disease.

The Veterinary Medicines Unit will determine the classification of the product.

5. What are the other main roles of Veterinary Medicines Unit besides the authorisation/registration of veterinary medicinal products?

The Veterinary Medicines Unit is involved in the control of a number of other activities related to the retail, wholesale dealing, brokering import, export and use of veterinary medicinal product.

The following is a non- exhaustive list:

- Oversees that only authorised veterinary medicinal products are distributed, sold and/or administered to animals;
- Oversees that the manufacturing, retail, wholesale dealing and brokering of authorised veterinary medicinal product occurs from the proper premises. This included inspections—even at farm level;
- Oversees that no activity side steps the acceptable retail chain;
- Oversees that veterinary prescriptions are issued when due and treatments are listed on the animal treatment records (commonly known as herd book) and;
- Liaises with the border inspection posts/customs/commerce Departments on relevant matters regarding importation, in particular of medicinal products (human medicines, veterinary medicinal products or products used to manufacture or test these products) that may contain animal by-products;
- Involved in the enforcements procedures after residues of veterinary medicinal products/banned substances are found in foodstuffs of animal origin;
- Involved in inspection together with other officers of VRD e.g. farms and checking on the Animal Health Programme in all places where animals are kept and the premises regulated by VRD;
- Vetting of postal parcels/containers containing veterinary medicinal products or products suspected of being such products.
- Discussing with foreign counteparts to strike agreements e.g. technical agreements for GMP Inspections;
- Participating in meetings at international and EU level;
- Collecting sales and use data on antimicrobials;
- Proposing and drafting legislation on VMPs.

6. How are veterinary medicinal products authorised or registered?

The authorisation/registration route depends on several factors. Questions that should be asked when deciding which authorisation/registration route to choose include the following:

- Is the provenance of the product from an EU/EEA country or Third country?
- Are the products for food animals or non-food animals?
- If they are for non-food animals, do they include cats and dogs?
- Are the products antimicrobials? Are they medicated pre-mixes?

Although some industries rely heavily on veterinary medicinal products to make production viable, this must not be done at the expense of safety. The type of authorisation/registration route depends on the risk of using a particular product and the level of control which is deemed necessary.

The website of the Veterinary Medicines Unit contains a vast amount of information to help applicants choose the best authorisation/registration route for their products.

7. What are Unauthorised veterinary medicinal products?

Unauthorised veterinary medicinal products can be either one of the following products:

- Products which do not have or have never had an authorisation/registration. The trader of the product places the product on the market without seeking an authorisation/registration from the Veterinary Medicines Unit or else before this Unit has completed a positive evaluation of an application form.

- Products which have an outdated 'validity period' but are still kept on the Maltese market, i.e. the authorisation holder does not extend the validity period.

8. Why is it important that veterinary medicinal products are authorised/registered?

Authorisation/registration of the products is necessary so that both the regulator and the regulated can meet their respective legal obligations and in this way good use of the veterinary medicinal products can be promoted.

The safety and efficacy of a product cannot be guaranteed if it bypasses the normal retail chain. It all boils down to the simple but important principle that 'what cannot be measured cannot be controlled'.

Effective control of authorised veterinary medicinal products includes the following processes:

1. To follow up any variations in the Product Information (Summary of Products Characteristics (SmPC), Product Information Leaflet (PIL) and outer/inner packaging).
2. To know who is responsible for what in case of a rapid alert, batch recall or product defect report.
3. To know to whom to send a notification letter in case of an EU Commission (or other EU institution) recommendation/opinion/decision.
4. To take the appropriate action in response to pharmacovigilance obligations. If the data available locally is incorrect the resulting action would be more harmful than no action at all.
5. To detect trends in the improper use of veterinary medicinal products, e.g. use, misuse or overuse of antimicrobials.
6. To be able to compile and update the list of authorized/registered veterinary medicinal products.
7. To have a thorough picture of veterinary medicinal products usage not a sketchy and misleading one.

9. Who can deal in veterinary medicinal products?

Only veterinary wholesale dealers are approved by the Veterinary Medicines Unit to import, procure and/or distribute veterinary medicinal products. Only veterinary pharmacies are approved by the Veterinary Medicines Unit to sell these products.

The Veterinary Medicines Unit encourages its stakeholders or any other person to put it in the know of any irregular undertakings, so that an inquiry can be held.

Depending on the results of the inquiry this Unit will either tackle the issue itself or task another department/entity to intervene.

All reports are treated with the strictest of confidentiality.

During the course of the inspection or investigation the inspectors may retrieve samples when there is reason to believe that these are necessary as evidence in a possible court proceeding or to safeguard public and/or animal health.

10 . Are there any requirements for immunological veterinary medicinal products (vaccines)?

The manufacture, import, possession, sale, supply and/or use of certain vaccines may be prohibited in Malta, on the whole or part of its territory, pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply any immunological veterinary medicinal products must consult the Animal Health Unit of the VRD within the Animal Health and Welfare Department (AHWD) on the current vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.

In order for an individual to procure a vaccine from an EU/EEA it must be proven that the variant strain is present in Malta or at least in that particular farm. This is particularly important when there is no cross protection between the variant and the classical strain. There is no be benefit of using vaccines blindly and can cause more harm than benefits.

The VMU suggests that if a veterinary surgeon wants to use a live or attenuated vaccine for a variant that the veterinary surgeon suspects is present in Malta he/she liaises with the company manufacturing the vaccine and sends the company swabs of the dead animal (suspected of contamination by the microbe) to do differential PCR. Provided, if the microbe and/or strain is present and the vaccine is not available the veterinary surgeon could bring it under the cascade from another Member State of the EU.

The VMU can request all the information as may be needed from both the company and the individual and veterinary surgeon who wants to use the vaccine. In exceptional circumstances and in line with Article 110 of Regulation (EU) 2019/6, vaccines form Third countries can also be obtained.

11. What are the most common misconceptions encountered by the Veterinary Medicines Unit?

CONCEPT/TERM	CONCEPT/TERM
Veterinary Medicinal Product Article 4 of Regulation (EU) 2019/6 defines this as: 'veterinary medicinal product' means any substance or combination of substances which fulfils at least one of the following conditions: (a) it is presented as having properties for treating or preventing disease in animals; (b) its purpose is to be used in, or administered to, animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; (c) its purpose is to be used in animals with a view to making a medical diagnosis;	**Veterinary Products which are not Veterinary Medicinal Products** A product which does not claim to cure or treat a disease. It supports a physiological function. Such products could be shampoos, non-medicated rubs, vitamins/nutrients and certain stimulants. However, a product could not just be classified as such through its description or labelling. The claims on the use of the product should be supported by the nature of the active ingredients and its mode of administration. These products do not currently need any pre-notification to any local authority for their authorisation or availability on the market. Still, the Veterinary Medicines Unit encourages traders to notify it when these products are placed on the market.

(d) its purpose is to be used for euthanasia of animals;	
Veterinary Medicinal Product Article 4 of Regulation (EU) 2019/6 defines this as: 'veterinary medicinal product' means any substance or combination of substances which fulfils at least one of the following conditions: (a) it is presented as having properties for treating or preventing disease in animals; (b) its purpose is to be used in, or administered to, animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; (c) its purpose is to be used in animals with a view to making a medical diagnosis; (d) its purpose is to be used for euthanasia of animals;	**Biocides** Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means. Biocides are regulated by Malta Competition and Consumer Affairs Authority (MCCAA) Sometimes active ingredients with biocidal activity are present in products classified as veterinary medicinal products. The classification as a veterinary medicinal product of such products is made without prejudice to any other classifications carried out other Departments, e.g. by customs Department during custom release through the TARIC code classification.
Marketing Authorisation It is obtained by the full/partial assessment of the product's dossier. It can be National, Subsequent Authorisation, Mutual Recognition (MRP), and Decentralised (DCP). The product has a Marketing Authorisation Holder (MAH). There is a considerable fee involved in the whole	**Registration in accordance with Article 116 of Regulation (EU) 2019/6** It is obtained by the evaluation of a reduced dossier. No assessment of the product dossier is carried out. It is a regulatory procedure where Malta, one-sidedly, 'recognises' the Marketing Authorisation (MA) as granted in the EU/EEA country from where it is sourced. It is a national procedure with a nominal fee

procedure. The word 'national' in this context must not be confused with the word 'national' as used when explaining Registration in accordance with Article 116 of Regulation (EU) 2019/6.	(currently 60 Euro./per year). The validity is currently of one (1) year.
Mutual Recognition Procedure (MRP) It is a European Procedure where the principle of mutuality is essential. It is one of the routes by which a product obtains a Marketing Authorisation. It involves the input of the Committee for Medicinal Products for Veterinary Use (CMDv)	**Registration in accordance with Article 116 of Regulation (EU) 2019/6** It is a national, one-sided recognition. It can be obtained regardless of the Marketing Authorisation Holder (MAH) 's consent.
Parallel Trade The distribution of the veterinary medicinal product by a distributor who is someone other than the distributor appointed by the Marketing Authorisation Holder of the Veterinary Medicinal Product. The Parallel traded product should have a reference product in Malta. If the reference product is not authorised through a DCP/MRP, or National procedure a Parallel Import is not applicable. Parallel Trade is Regulated through Article 102 of Regulation (EU) 2019/6	**Registration in accordance with Article 116 of Regulation (EU) 2019/6** The registration of a product whose main pre-requisite is that the product must have a valid Marketing Authorisation in the EU/EEA country from where it is sourced. The local distributor may or may not have contractual agreement with the MAH. If contractual agreements exist, the MAH from the source country may or may not choose to be the registration holder of the product. There are no restrictions on the number of authorisation holders that can submit an application for the same product from a different or same source country.
Market exclusivity of Marketing Authorisation Holders A Marketing Authorisation can decide to give an Access Letter to only one local distributor and consent for the distribution of his products only for that distributor. Third parties can only distribute those product	**Market exclusivity of Registration in accordance with Article 116 of Regulation (EU) 2019/6** The same product coming from the same or a different EU/EEA country can be distributed by more than one local distributor. As long as all the distributors satisfy the local requirements no one has the market exclusivity.

through a Parallel Import Licence	Each registration holder pays his own fee and is responsible for his registration. This means also that each registration holder for the 'same product' is responsible for his own batch recalls, product defects, reporting of adverse drug reactions and notification of change.
Authorisation of an activity An activity can be a wholesale dealing activity, retail activity, acquisition under the cascade, import for re-export activity etc. The products that are transacted during these activities must all be authorised/licensed products except when the product are not intended to be placed on the Maltese market, e.g. import for re-export.	**Authorisation/Registration of a product** It is granted to a product. The entity that wants to distribute or sell the product must still obtain an authorisation for this activity, e.g. a centrally authorised product may already have an authorisation, but it cannot be sold by anyone. The entity which sells it must be authorised to carry out that activity.
Import Licence (IL) It is currently issued from the Commerce Department for Third Country Imports and for certain EU/Third countries' products. The Commerce Department acts as a 'co-ordinator' and requests the endorsement of the IL from the relevant government departments as agreed between the Commerce Department and the other Departments. The Legal basis is SL 117.14. It is not an authorisation for the licensing of a veterinary medicinal product. It does not fall within the EU veterinary medicinal products legislation. It falls within the Commerce and Custom legislation. It cannot be used ***instead of*** a MIA. An Import Licence is only endorsed by the VPRD when the product is a veterinary medicinal product which ***has already obtained*** an Authorisation. If the product is not a veterinary medicinal product a note to this effect is written on the IL, which is signed	**Manufacturing/Import Authorisation(MIA)** It is issued by the authority which regulates veterinary medicinal products in accordance with the EU veterinary medicinal products regulations. It is given without prejudice to other national/EU requirements (e.g. customs, commerce). It is given to the importer of the product in the EU, which is the Batch Release Site (BRS). The responsibility of the MIA's terms and conditions lies on the Qualified Person (for manufacturing, for batch release etc.) To ascertain conformance with the MIA, the emphasis is more on official inspections and market surveillance rather than border control. A MIA is granted in line with Article 88 of Regulation (EU) 2019/6.

and stamped nonetheless.	
Manufacturing Site/s These are the manufacturing sites where the different components of the product, from the API/excipients to the immediate packaging material, are manufactured or assembled. They may or may not be carried out in EU/EEA country. However, manufacturing must be done according to EU GMP (and not just any GMP) and the sites are inspected and certified EU GMP by EU/EAA authorities. GMP stands for Good Manufacturing Practice The manufacturing site may or may not be owned by the MAH. The Active Pharmaceutical Ingredient (API) formula may not even be disclosed to the MAH. The authorative bodies will then have to get this information directly from the manufacturers.	**Batch Release Site** The site must always be located in an EU/EEA country. Tests are performed by the Qualified Person Responsible for Batch Release to ensure that the finished product complies with the specifications as approved in the Marketing Authorisation. The Batch release site may or may not be owned by the MAH. In essence the Batch release site 'takes on the responsibility' of all the manufacturing sites which were needed to produce the finished product. Its name and address can be found in the Product Information Leaflet (PIL), most often this is phrased on the PIL as: 'manufactured by *(*name of Batch Release) If the finished products is imported from a Third Country and is manufactured according to the EU GMP Batch, re-analysis may or may not be carried out depending on mutual agreements (MRA) in place between the Third country in question and EU/EEA.
Custom Release Endorsement Custom release papers are sent by the customs department for the endorsement of the relevant department as stipulated by certain legislations (Chapter 30 of Decision 275/2007 Positive Checks) e.g. this is needed in order to exclude ingredients originating from certain animals or to ascertain their safety These may not necessary be veterinary medicines intermediates or reagents. In fact finished veterinary medicinal products are not on the positive list.	**Import Licence Endorsement** An Import Licence is issued from the Commerce Department for Third Country Imports and specific EU/Third products. The Commerce Department acts as a 'co-ordinator' and requests the endorsement of the IL from the relevant government departments as agreed between the Commerce Department and the other Departments in accordance with SL 117.14.
Free Sale Certificate of VMPs	**VMPs that have Free Circulation Status**

It is issued by the Veterinary Medicines Unit as a kind of export Licence on request. It indicates that the product is freely available on the market. The legal basis for this is Article 98 of Regulation (EU) 2019/6	It 's a term that described a product originating from outside the EU but which attains this status once it has passed through the custom declaration. It does not mean that the product does not need to attain other types of authorisations according to relevant legislations.
Off label Use The use of a product not in accordance with the SPC. Under certain conditions it can be an acceptable activity if no other viable alternatives exist.	**Cascade Use** The use of a product which has not obtained an authorisation in Malta. However it may or may not be used 'off label'. The legal basis for this is Articles 110 and 112 to 115 of Regulation (EU) 2019/6
Maximum Residual Limit (MRL) The maximum residual amount of a substance that can be found in a particular animal produce. It is detected through various laboratory tests. It does not detect AMR but since misuse/abuse/overuse of antibiotics can result in an exceeded MRL it may be a useful parameter in AMR studies. However AMR can still develop even though MRL results are negative.	**Antimicrobial Resistance (AMR)** It is the phenomenon whereby microorganisms develop resistance to previously effective antimicrobials. The prevalence and extent can be measured by taking microbial isolates from the animal and perform sensitivity testing. Isolates can also be taken from indicator microbes other than the actual pathogens.
Line Extension It is the use of an established product brand name for a new item in the same product category. Line extensions occur when a company introduces additional items in the same product category under the same brand name such as new flavours, forms, colours, added ingredients, package sizes.	**Renewal of an national Authorisation in line with Regulation 5(6) and Registration in accordance with Article 116 (<u>not</u> renewals of Marketing Authorisation (national/DCP/MRP)** An Authorisation in line with Regulation 5(6) and Registration in accordance with Article 116 has a validity period of one (1) year; after which it can be renewed by means of an on-line application form. National fees is applies (60 Euro/year) Note that Market Authorisations (National/DCP/MRP) have an indefinite in line with Article 5 of Regulation (EU) 2019/6. The payment of

	an annual administrative fee of 60 Euro/year still applies. This can also be made by means of an on-line form. Previously we used to call this process 'extension' of a registration/authorisation. However, it was decided that this increase confusion with the term 'line extension'. Therefore the term 'extension' is no longer in use.
Withdrawals Period on SmPC Withdrawal periods set on the Marketing Authorisation and listed on the SPC. They may be different depending on the Member State.	**Withdrawal Period under the Cascade** Statutory withdrawal period listed in Article 115 of Regulation (EU) 2019/6 for foodstuffs when veterinary medicinal products are used on target species not mentioned on the SmPC.