



Version 1 -16/03/26

CRITERIA FOR THE DISTRIBUTION CATEGORY OF VETERINARY MEDICINAL PRODUCTS

1. SCOPE OF THE DOCUMENT

The current national legislation dictates which are the classes/types of Veterinary Medicinal Product that require a veterinary prescription to be dispensed. It also mentions those instances when Veterinary Medicinal Products are exempted from the veterinary prescription.

Although the current national legislation also established four different Distribution Categories (POM-VP, POM-V, OTC and GS) it does not specify which Veterinary Medicinal Products should be assigned what Distribution Category.

The scope of this document is to set out the criteria for the categorisation of a Veterinary Medicinal Product into the 4 different Distribution Categories as required by Regulation 18 (7) of Subsidiary Legislation 437.115.

Applicants for the authorisation of Veterinary Medicinal Products are to consider these criteria when proposing a Distribution Category for a Veterinary Medicinal Products while the Veterinary Services Directorate will assess the application according to these criteria and determine the appropriate Distribution Category. This applies to any type of authorisation route (e.g. that based on Article 116 or Article 5(6) of Regulation (EU) 2019/6 but not for Centrally Authorised Products)

Although the Distribution Category is set during the assessment process of new applications, this does not exclude a change in the Distribution Category at some point during the life cycle of the product.

2. LEGISLATION

Although the Distribution Category of Veterinary Medicinal Products authorised in the EU is the competence of each Member State, the decision must be aligned with Article 34 of Regulation (EU) 2019/6.



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Article 34 (1) says the following:

The competent authority or the Commission, as applicable, granting a marketing authorisation as referred to in Article 5(1) shall classify the following Veterinary Medicinal Products as subject to veterinary prescription:

- (a) Veterinary Medicinal Products which contain narcotic drugs or psychotropic substances, or substances frequently used in the illicit manufacture of those drugs or substances, including those covered by the United Nations Single Convention on Narcotic Drugs of 1961 as amended
- (b) Veterinary Medicinal Products for food-producing animals;
- (c) antimicrobial veterinary medicinal products;
- (d) Veterinary Medicinal Products intended for treatments of pathological processes which require a precise prior diagnosis or the use of which may have effects which impede or interfere with subsequent diagnostic or therapeutic measures;
- (e) Veterinary Medicinal Products used for euthanasia of animals;
- (f) veterinary medicinal products containing an active substance that has been authorised for less than five years in the Union;
- (g) immunological Veterinary Medicinal Products;
- (h) without prejudice to Council Directive 96/22/EC (23), Veterinary Medicinal Products containing active substances having a hormonal or thyrostatic action or beta-agonists.

It is worth pointing out that nearly all vaccines are classified as requiring a veterinary prescription. It is a common misunderstanding that these do not normally require a veterinary prescription.

It is also to note, that for food-producing animals the classification is rather straightforward, i.e. they Veterinary Medicinal Product require a veterinary prescription.

In Malta, in accordance with Regulation 18 of S.L 437.115, there shall be the following four Distribution Categories for Veterinary Medicinal Product.



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(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"; and

(d) general sales, abbreviated to "GS".

The Veterinary Services Directorate shall categorise the Distribution Category is during the assessment of an application form of a particular Veterinary Medicinal Product.

Article 34 (2) of Regulation (EU) 2019/6 speaks of the instances when a Veterinary Prescription might not be required and Member States might classify the product as not requiring a veterinary prescription.

Article 34 (2) list the occasions mentioned below as the instances when a veterinary prescription might not be required:

- (a) the administration of the veterinary medicinal product is restricted to pharmaceutical forms requiring no particular knowledge or skill in using the products;
- (b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal or animals treated or to other animals, to the person administering it or to the environment;
- (c) the summary of the product characteristics of the veterinary medicinal product does not contain any warnings of potential serious adverse events deriving from its correct use;
- (d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent adverse event reporting;
- (e) the summary of the product characteristics does not refer to contra-indications related to the use of the product concerned in combination with other veterinary medicinal products commonly used without prescription;
- (f) there is no risk for public health as regards residues in food obtained from treated animals even where the veterinary medicinal product is used incorrectly;
- (g) there is no risk to public or animal health as regards the development of resistance to substances even where the veterinary medicinal product containing those substances is used incorrectly.

3. INTERPRATATION OF THE LEGISLATION



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Veterinary Medicinal Products that require a veterinary prescription are likely to present a risk, even if used correctly despite the animal not being under veterinary care. This can be related to toxicity, interactions and adverse drug reactions. These risks may be even indirect one. An example of such indirect risk is where symptomatic treatment might mask an underlying condition and so delay diagnosis and treatment. Other indirect risks include that related with resistance to the product, e.g. antimicrobial resistance.

On the other hand, those Veterinary Medicinal Products that do not require a veterinary prescription have a low general toxicity and no relevant reproductive toxicity, genotoxic or carcinogenic properties. They also have no or very few serious interactions with other substances. These Veterinary Medicinal Products are generally used for short term treatment,

For products that do not require a veterinary prescription the condition for which a Veterinary Medicinal Product is indicated must be those that can be correctly assessed by the animal owner without need of a veterinary surgeon 's assistance. The animal owner must be able to exclude other conditions which could appear to be similar to the indications but still unsuitable for treatment with that Veterinary Medicinal Product.

Therefore, to achieve this Distribution Category the product pack must provide sufficient and easily understood information to the animal owner. Information can also be provided to the animal owner through additional documents, e.g. leaflets (which can also be electronic)

4. EXCLUSIONS FROM THE CRITERIA

For centrally authorised products the categorisation is relatively straightforward as this is decided by the European Commission on the basis of a recommendation by the rapporteur who assessed the application. Therefore, these criteria do not apply for Centrally Authorised Products.

5. BASIC CRITERIA FOR EACH AUTHORISATION ROUTE

- As a general rule, unless the Veterinary Medicinal Product contains a new active substance it usually follows the Distribution Category of similar products.



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- For national Marketing Authorisations and Veterinary Medicinal Products authorised through the Decentralised or Mutual Recognition Procedure (DCP/MRP) (where Malta is a Reference Member State, RMS) the Distribution Category is decided on the basis of the products 's dossier.
- For Veterinary Medicinal Products authorised through the Decentralised or Mutual Recognition Procedure (where Malta is a Concerned Member State, CMS) the Distribution Category is decided from the information provided by the applicant and in line with similar products already on the markets in Malta and the EU.
- For Veterinary Medicinal Products registered according to Article 116 of Regulation (EU) 2019/6 the Distribution Category is decided from the information provided by the applicant and in line with similar products already on the Maltese market.
- For Veterinary Medicinal Products registered according to Article 5(6) of Regulation (EU) 2019/6 the Distribution Category is always OTC. The issue to decide is whether these can also be allowed on the General Sales list. The decision will be based on the information provided by the applicant, the risk factor on the use of the product and in line with similar products already on the Maltese and EU market.
- For parallel imports the Distribution Category must be exactly the same as of Maltese market reference product.

6. DETAILED CRITERIA FOR ALL AUTHORISATION ROUTES

Decision is taken on all four Distribution categories. The General Sales List can be considered as a sub-section of OTC products, i.e. products that can be supplied from places other than veterinary pharmacies can be supplied from these premises as well.

Apart from the basic conditions for each authorisation route mentioned above the following aspects are also taken into account:

- The requirements of the EU/National legislation
- The active substance
- Safety profile of the product
- Pharmaceutical form
- Strength



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- Indications
- Maximum dose, maximum daily dose
- Short/long term use
- Pack size and container (two different presentations of the same product may have different Distribution Category)
- Population of animals that may be administered the product
- Distribution Category in other Member States
- Outcomes of European referrals.
- Recommendations of relevant bodies, e.g. OIE, Council of Europe , on the classification of active substances
- Amount of information present on the pack
- Classification in other Member States of the EU, in particular in the Member State from where it is brought
- Availability and access to the product
- Historic evidence of low/high risk in the current distribution way

7. CHANGES IN THE DISTRIBUTION CATEGORY

If the Distribution Category determined by the Veterinary Services Directorate is different from the one proposed by the applicant, the Veterinary Services Directorate may ask the applicant to submit additional information in support of his original proposal for the Distribution Category.

The on-line form for Notification of changes/variation can be used for this purpose. The on-line form for Renewal of all authorisation/registration contains also a field that indicates the Distribution Category. A change may be proposed at the time of renewal as the option is also given on this on-line form.

Distribution Categories are not established indefinite and may change due to new information that related with the criteria. A variation to change the Distribution Category may be requested, unless the change is covered by a European Commission decision.