MINISTRY FOR AGRICULTURE, FISHERIES,
FOOD AND ANIMAL RIGHTS

Animal Health and Welfare Department

National Veterinary Laboratory
Abattoir Street, Albertown, Marsa, MRS 1123 - Malta

Information about the Authorisation or Registration Routes

There are 5 Authorisation or Registration routes as follows:

- Community Marketing Authorisation
- National Marketing Authorisation
- MRP and DCP Marketing Authorisations
- Registration in accordance with Regulation 7 of S.L 437.47
- Authorisation in accordance with Regulation 4(2) of S.L 437.47

1. Community Marketing Authorisation

A Community Marketing Authorisation is obtained when the European Commission grants the product an authorisation through the Centralised Procedure in accordance with Regulation (EU) No 726/2004. The Marketing Authorisation obtained in this way is valid in all EU countries. These products are called Centrally Authorised Products (CAP)

Applicants are not required to get CAP through another national authorisation procedure. The notification application form for Centrally Authorised Product is used just to notify the Veterinary Medicines Section about CAP on the Maltese market.

The CAP still have to be placed on the Maltese market by way of wholesale dealing. A 'Community Authorisation' does not cover the authorisation for wholesale dealing.

For all more information about Parallel Importation of CAP, applicants are requested to contact the European Medicines Agency (EMA).

More detailed information and application forms can be found in EudraLex - Volume 3 Pharmaceutical Legislation Notice to applicants.

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2. National Marketing Authorisation

The National Procedure refers to the Marketing Authorisation procedure in accordance with regulation 5 of the Veterinary Medicines Regulations S.L 437.47, in accordance with Article 5 of Directive 2001/82/EC.

In order to obtain a National Marketing Authorisation for a veterinary medicinal product the standard application form used throughout the EU region has to be submitted to the Veterinary Medicines Section.

3. MRP and DCP Marketing Authorisations

This is commonly referred to as the European Procedure. It is an authorisation granted in line with Regulation 31 of the Veterinary Medicines Regulations S.L 437.47, in line with Article 31 of Directive 2001/82/EC.

- In cases where a Marketing Authorisation is required for a product that is already authorised in at least one EU/EEA country the Mutual Recognition Procedure (MRP) has to be used.

- In cases where a Marketing Authorisation is required for a product that will be authorised in more than one EU/EEA country for the first time the Decentralised Procedure (DCP) has to be used.

Detailed information on both procedures can be found on the CMD(v) website of the Heads of Medicines Agencies website.

This includes also information regarding authorisation, renewals, variations and transfers.

Documentation, application forms and templates can be found in Volume 6A Chapter 2 of the Notice to Applicants.

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Final National Phase

If Malta is a Concerned Member State (CMS) in a DCP/MRP the applicant is requested to send to the Veterinary Medicines Section an application form (*national stage)* once the procedure is concluded.

This is purely a national administrative step whereby a Marketing Authorisation (MA) number is assigned to the veterinary medicinal product. Malta accepts shared or combined packs with other Member States as long as the pack is in the English or Maltese language or both.

The MA number should be included on the outer pack of the product. When the Application form for National stage is submitted it won 't be possible for the Marketing Authorisation Holder (MAH) to know what is the Maltese Marketing Authorisation number, hence only the draft mock-ups *without* the Maltese MAH can be submitted. Once the National Stage application form is processed the MA number is assigned to the product and the MAH is informed of it. Once the MAH is informed of the number the mock-ups *bearing* the Maltese MA number can now be submitted by e-mail within a period of 3 months.

The MAH can print the details during production or also rely on the Malta representatives to include them locally through printing or the affixing of a label.

4. Authorisation in Accordance with Regulation 7 of S.L 437.47

4.1 Introduction

The legal basis for this authorisation is Regulation 7 of SL 437.47 which transposed Article 7 of Directive 2001/82/EC. Article 7 states:

"Where the health situation so requires, a Member State may authorise the marketing or administration to animals of veterinary medicinal products which have been authorised by another Member State in accordance with this Directive"

The main pre-requisite for this authorisation route is that the veterinary medicinal product has a valid Marketing Authorisation in the EU/EEA country from where it is sourced (source country) and placed on the market in Malta.

The Veterinary Medicines Section does not carry out any scientific assessment of the dossier.

The Veterinary Medicines Section assigns a unique number to the product once evaluation of the product is completed.

Applications are supported by a reduced dossier of the veterinary medicinal product. The most important parts of the dossier that should be submitted are Part 1A and Part 1B.

A veterinary medicinal product **cannot** be registered through this route in the following instances:

a) When the applicant wants to source it from an EU/EEA Member State where it is also registered in accordance with Article 7 of Directive 2001/82/EC.

b) When the applicant wants to source it from an EU/EEA Member State where it is licensed as a Parallel Import.

c) If the product is already authorised through the Centralised Procedure.

d) If the product is already authorized through a DCP/MRP where Malta is a CMS.

e) Veterinary medicinal products from Third countries.

4.2 Important supporting documentation of the application form

a. The Product Information (PI)

The Product Information (PI) is a collective term for the Summary of Products Characteristics (SmPC), Product Leaflet (PIL) and Labelling (outer and inner pack). The PI must be exactly the same as that approved in the source country. Product Information from countries other than the source countries are not acceptable.

b. The relevant extract from table 1 of Regulation (EU) No 37/2010 in the case of veterinary medicinal products intended for food-producing animals

Table 1 of Regulation 37/2010 lists those pharmacological active substances that can be used for food-producing animals together with the permissible maximum residual limits (MRLs). This extract must be annexed with the application form.

c. The proof of Marketing Authorisation in the source country

Proof that the veterinary medicinal product has a Marketing Authorisation in the country of source can be provided from Part 1 section A of the reduced dossier. This includes a copy of the Marketing Authorisation.

d. The proof of establishment of Registration Holder

The Registration Holder is that person/entity that holds the registration of Regulation 7. That person/entity should be indicated as such on the Application Form.

Proof of establishment of the Registration Holder can be provided in three ways.

- If the Registration Holder to be is the local wholesale distributor a copy of the wholesale distributor authorization will be accepted as a proof of establishment.

- If the Registration Holder to be is the owner of a veterinary pharmacy a copy of the approval of the veterinary pharmacy will be accepted as a proof of establishment.

- If the Registration Holder to be is the Marketing Authorisation Holder in the country of source, an authenticated copy of the Marketing Authorisation of the product in question will be accepted as a proof of establishment.

e. The EU Good Manufacturing Practice (GMP) License (*if available*)

A copy of the EU GMP License will confirm that the product has been manufactured according to EU GMP standards.

f. The letter of access.

It is important for the Veterinary Medicines Section to know who is designated to communicate with the section when a Marketing Authorisation Holder (MAH) has a representative. It is not always evident from the application form whether a local distributor has an agreement with an MAH, hence this may be a requirement is some cases.

4.3 Variations

If there is a variation in the country of source this must be notified to Malta by using the a national Application Form. This is the same Application Form used also for variations of Registration according to Regulation 4(2) of S.L 437.47

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Authorisation in Accordance with Regulation 4(2) of S.L 437.47

1. Introduction

The provisions of Regulation 4 (2) of SL 437.47 (in line with article 4(2) of Directive 2001/82/EC) have been applied to introduce this 'exemption scheme' which is intended only for small non-food animals and pets (not applicable to dogs and cats). This authorisation is only granted for products that are to be marketed in Malta.

Only products with active ingredients present in the List of Active Ingredients for Products to be authorised in accordance with Regulation 4(2) can be authorised through this route.

2. Description of important requirements

a. The small non-food producing animals kept exclusively as pets for which the products are intended are the following: aquarium animals, terrarium animals, cage birds, homing/racing pigeons, pet rabbits, small rodents and ferrets. This route is not applicable to cats and dogs.

b. A copy of a Manufacturing Import Authorisation or equivalent (if the product is from a Third country) must be submitted with the application form

c. Mock-ups of the pack (inner and outer) are always requested as part of the supporting documents. The pack must have the minimum information referred to in Regulation 4(9) of S.L 437.47

d. The Authorisation Holder who obtains this type of authorisation must label the product accordingly, i.e. a sticker or a label with a declaration such as:

"*This veterinary medicine has been authorised according to Regulation 4(2) of S.L437.47. Not for food animals*",

or a similar statement to that effect. The statement can be printed on the outer pack during production or else affixed as a label post production at the distributor 's end.

This label should also bear the Authorisation Number assigned to the product by the VMS

e. A separate application form needs to be completed for different strengths of the product.

f. A separate application form needs to be completed for dosage forms with variable volumes of the same strength and with a different target species;

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The same application form can be used for dosage forms with variable volumes of the same strength and with the same targets species.

g. This authorisation is a national authorisation and valid only in Malta. Applicants who would like to market the same product in another EU/EEA country are requested to consult the competent authority of that country in order to inform themselves of the proper authorisation route that is applicable for the product and the conditions of the licence.

h. As of 1-11-21 the product must not be classified as requiring a veterinary prescription.

3. Variations

In case of a variation this must be notified to the Veterinary Medicines Section by using the appropriate application form. This is the same Application Form used also for variations of Registration according to Regulation 7 of S.L 437.47