MINISTRY FOR AGRICULTURE, FISHERIES,
FOOD AND ANIMAL RIGHTS

Animal Health and Welfare Department

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

Version 2: 31-08-21

Information about the Licensing Scheme as of 31-08-2021

The 3 Licensing Schemes are:

- Parallel Import Licence
- Licence for Cascade Use
- Licence for Research Purposes

1. Parallel Import Licence

Parallel importation is 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. This can allow an authorised distributor to distribute a product even if he does not have an 'Access Letter' from the Marketing Authorisation Holder.

Parallel imports are a lawful form of trade within the Internal Market based on the principle of the free movement of goods. It benefits trade from the divergence in prices and so cannot be restrained.

The regulatory framework for Parallel Importation is built on case law. The EU Commission has prepared a communication (COM(2003)839) regarding this subject as a guide to this kind of trade in medicinal product.

A wholesale dealer can bring in Malta from another EU/EEA country a veterinary medicinal product which has a Marketing Authorisation in Malta and in that EU/EEA country. The product available in the EU/EEA country may be termed 'the reference product'. The product available in Malta may be termed 'the parent product'.

The 'reference product' may be available at cheaper prices and so consumers may benefit in divergence in prices.

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Points on Parallel Importation

1. Re-packaging and re-labelling are necessary as the 'Parallel Import Product' can only be in English or Maltese or both.

2. Both the Marketing Authorisation number of the 'reference product ' and the 'Parallel Import License number' assigned by the Veterinary Medicines Section should be clearly visible on the outer pack of the product.

3. Veterinary medicinal products that obtain their authorisation through the centralised procedure can be parallel imported/distributed in Malta. The Parallel Import License must be obtained from the European Medicines Agency (EMA).

4. Both the 'reference product' in Malta and that 'parent product' should have a valid Marketing Authorisation. Products registered according to 7 of Directive 2001/82 or that are Parallel Imports cannot be neither 'reference products' nor 'parent products'.

2. Licence for Cascade Use

A veterinarian can use an authorised veterinary medicinal product in ways that are different from those indicated on the product specifications. Under certain circumstances the veterinarian can even use a human medicine for veterinary use. At the last stage, when all preceding stages have been ruled out as an option, the veterinarian may get a veterinary medicinal product authorised in another EU/EEA country but not in Malta. All these are examples of cascade use. When using the last stage the veterinarian can apply for a 'Cascade License'.

Points on the Cascade Licence for all Species

1. It is applicable only for products which already have obtained a Marketing Authorisation. It cannot be used for products which have a provisional Marketing Authorisation or are still at an experimental stage.

2. Importation of veterinary medicinal products or human medicines for veterinary use from Third countries is not possible through this route.

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3. Importation of human medicinal products from EU/EEA for veterinary use is not strictly speaking 'cascade use'. However, in extreme situations veterinary surgeons can submit a request as per Regulation 10A(1) (for non-food animals) and 11A(1) (for food animals) to import veterinary medicinal products from Third countries. Such importation is strictly controlled and the veterinary surgeon must show the need for it.

4. It is the task of the veterinarian to clinically justify the application for a licence. The Veterinary Medicines Section must be satisfied that a positive benefit/risk balance exists before issuing the licence.

5. A cascade licence is never granted before it is ensured that all legislative requirements have been met and that the product will not pose a risk to the animal, user, consumers or the environment.

6. It is not needed for veterinary medicinal products that are already authorised in Malta but that have temporary supply issues.

7. It can be used to bring products present on the list of essential substance for the treatment of equidae present in Regulation (EU) No 1950/2006.

8. In the case of vaccines, veterinarians are advised to inform themselves on the vaccination policies/programmes for certain diseases. When a vaccine is for a variant strain, veterinarians must provide proof that the variant strain is actually present in the farm.

9. Pursuant to the above, veterinarians are advised to send swabs to appropriate laboratories to do differential Polymerase Chain Reaction (PCR) test to confirm presence of a variant strain.

10. It cannot be used for human medicines which may be cheaper than available veterinary medicinal products.

Points on the Cascade Principle for Food Producing Species

1. When writing a prescription according to the cascade a statement to that effect should be included on it.

2. The veterinarian must keep appropriate record.

3. Unless the veterinary medicinal product indicates a withdrawal period for the species concerned the statutory withdrawal periods shall not be less than:

- 7 days for eggs;
- 7 days for milk;
- 28 days for meat from poultry and mammals including fat and offal;
- 500 degree-days for fish meat

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3. Licence for Research Purposes

The Research Purposes Licence is a licence that authorises a veterinary medicinal product for research in the wide sense of the word.

The licence for Research Purposes is not:

- licence to procure/import/distribute veterinary medicinal products
- licence to conduct a clinical trial
- licence that authorise a premise to be used for the purpose of a clinical field trial
- licence to use animals for clinical trials

The Licence for Research Purposes is granted without prejudice to other requirements that the applicant must get from other sections of the Departments, other Directorates of the Department or any other entity.

A licence for research purposed is granted on the basis of Regulation 4A of Subsidiary Legislation 437.47. According to Regulation 4A (4) (h) The Veterinary Services shall set out the criteria for veterinary medicinal product which are obtained in accordance with sub-regulation (1) and make them public.

These criteria are as follows:

Criteria for Granting a Licence for Veterinary Medicinal Product for Research Purposes

1.	The quantities of veterinary medicinal product authorised are proportional to the scale of the research activity as described on the application form.
2.	The total quantity of veterinary medicinal product is the sum total of all the quantities of each different batch, if applicable.
3.	A different supplier or a different country of origin of the same or different batch numbers of the same veterinary medicinal product necessitate a separate application form.

4.	The licence holder can be supplied with the quantities indicated on the Licence in parts. However, the total quantity consigned during the validity period of the licence cannot exceed that indicated on the licence without the prior approval of the Veterinary Services.
5.	The Licence may be suspended or revoked in case of any breach of the Veterinary Services Act, Animal Welfare Act and the Protection of Animals for Scientific Purposes Regulations.
6.	The licence holder must observe all health and safety measures in accordance with the applicable laws.
7.	The licence is not a substitute or granted in lieu of a Marketing Authorisation.
8.	Veterinary medicinal products authorised in accordance with this licence cannot be distributed by way of wholesale dealing or retailed.
9.	The Licence is granted without prejudice to any other licence or the permit that may be needed in order to conduct the research activity in question.
10.	The licence holder, his activities and the premises were the products are kept and used are subject to official inspection by the Veterinary Services.
11.	The licence is valid for one (1) year from the date of first issue. Upon request, an administrative renewal is possible. In such cases , a new licence may not be re-issued. Provided, none of the particulars on the licence should differ from the original licence. Provided further that there is no new data on the risk-benefit ratio or safety use.
12.	If the licence holder becomes aware of any serious adverse reactions on the animal/s or on the person administering the medicine he must report the reaction to the Veterinary Services within fifteen (15) days from the day the serious adverse reaction was discovered.

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