Department of Agriculture, Food and the Marine

Application to import a Veterinary Medicinal Product in accordance with Article 116 of EU 2019/6 from EU Member State Only

Part 1- THE APPLICANT – *see note (1)*

Note: 'The applicant' should be the holder of the current marketing authorisation or in exceptional circumstances a "Sponsor Co".

Name: _____

Address: _____

Phone No.: _____

Email Address: _____

Part 2 - VETERINAY MEDICINAL PRODUCT (VMP) TO BE IMPORTED

1. Name of VMP: _____
2. VMP Marketing Authorisation No: _____
3. Member State where Marketing Authorisation (MA) is held:

   _____
4. Expiry Date of MA (must be currently authorised): _____
5. Proof that MA is currently authorised (in English) enclosed: [ ] tick to confirm
6. Copy of SPC (in English) enclosed: [ ] tick to confirm

7. Target Species: _____

8. Indications for use covered by the MA: _____

_____

9. Active Substances(s): _____

10. Pharmaceutical Form: _____

11. Strength: _____

12. Pack Size: _____

Part 3 - DETAILS OF LICENCE BEING REQUESTED

Quantity of Product to be imported: _____
see note (3)

Period for which licence is requested: _____
see note (4)

Part 4 - REASON FOR IMPORTATION

1. Description of health situation to be addressed:

_____

_____

_____

_____

2. Letter of veterinary justification for import enclosed ☐ tick to confirm

3. If reason for application is authorised VMP is unavailable evidence of this must be provided (confirmation from manufacturer or HPRA of shortage, EU's Product Database should be checked)

4. Justification as to why a **full marketing authorisation** has not been applied for in Ireland:

_____

_____

_____

_____

Part 5 - WHOLESALE DISTRIBUTION AUTHORISATION HOLDER (WDA) NOMINATED TO IMPORT* THE VMP (see note 4)

Name: _____

Address: _____

WDA Holder Authorisation Number: _____

Email: _____

Phone: _____

***If multiple WDAs are to import please list on separate page**

Part 6 - REGISTERED VETERINARY PRACTITIONER(S) TO BE SUPPLIED WITH THE PRODUCT

Name: _____

Address: _____

VCI No: _____

Name: _____

Address: _____

VCI No: _____

Additional veterinary practitioners may be listed on a separate page

Part 7- FARMS/SITES TO BE SUPPLIED WITH THE PRODUCT

1. Farm/Site Name: _____

Address: _____

_____

2. Farm/Site Name: _____

Address: _____

_____

3. Farm/Site Name: _____

Address: _____

Additional farms/sites may be listed on a separate page

DECLARATIONS AND UNDERTAKINGS

1. I undertake to comply with Regulation (EU) 2019/6 of the European Parliament and of the Council of 11th December 2018 and with any conditions attached to a licence granted as a result of this application.

2. I understand that this application is for a product for use in the State only, and if successful the product requested may not be exported or used except in accordance with the circumstances of this application.

3. I undertake to furnish details if requested, in the manner and within the timescale prescribed by the Minister for Agriculture, Food and the Marine, of quantities imported on foot of any licence granted as a result of this application.

4. I recognise that any licence granted on foot of this application is exceptional and is for the purposes described in this application and that the grant of any such licence will not confer any right on the applicant in respect of the grant of any future licence for the product concerned.

5. I am aware that a licence may, if granted on foot of false or misleading particulars supplied by me, be revoked.

6. The Minister is not liable for any losses arising from the import of this product or any losses arising from the revocation of or amendment to the licence issued.

In relation to personal data supplied with this application, please see attached Annex.

Signature of Applicant: _____

Applicant's Name in Block Capitals: _____

Applicant's Position in Company: _____

Date of application: _____

Checklist

Have you included the following:

SPC in English

MAH in English

Required number of letters of justification,
on practice letterhead and dated

Notes relevant to completion of the application:

1. 'The applicant' should be the holder of the current marketing authorisation or in exceptional circumstances a "Sponsor Co". Where "Sponsor Co" is named as the applicant reason for doing so should be provided.

2. The quantity should be a 'best estimate' based on the need for the product. The Department of Agriculture, Food and the Marine (DAFM) reserve the right to specify an upper ceiling on the licence for control purposes.

3. The period requested should be based on the need and may be for up to 1 year.

4. This application is for the **import** of the VMP, and any WDA listed will be entitled to import. If you intend to supply other WDA's within Ireland after import they should not be listed on this application. The conditions on the licence should be noted in relation to other WDA's being supplied with the product.

5. For applications made by a WDA, if their intention is to supply more than 1 veterinarian, there should be at least 3 letters of justification from veterinarians accompanying this application, all letters should be on practice letterhead and should be dated.

6. Applications that are incomplete or if applicant fails to provide additional requested information or misleading information the application will be refused.

7. Applications will be acknowledged within 3 working days of receipt. If further information is requested this will be done within 14 working days of initial receipt. Decision will be made within 28 working days of initial receipt of completed application.

8. Applications may be forwarded to veterinarymedicinesWMC@agriculture.gov.ie or to

Veterinary Medicines
Department of Agriculture, Food and the Marine
Backweston Campus
Celbridge, Co. Kildare, W23 X3PH

Annex

General Data Protection Regulation (GDPR)

Further information provided on how your data is handled is available here:
https://www.gov.ie/en/organisation-information/ef9f6-data-protection/

Information specific to the collection of personal data

The following data is specific information in relation to the personal data processed for the licencing of wholesale, retail, special imports of veterinary medicinal products or manufacture of medicated feed.

1. **Specified purpose:**

   Information is collected for the purposes of authorising Wholesale Distributors, Retailers and special import licences for veterinary medicinal products.

2. **Legal basis:**

   Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018, and the European Commission implementing and delegated acts referred to in the following regulations adopted thereunder.

   S.I. No 36 of 2022 European Union Veterinary Medicinal Products and Medicated Feed Regulations 2022

3. **Recipients:**

   Information may be shared with:

   The Health Products Regulatory Authority in their role as a competent authority for the regulation of the veterinary medicines sector;

   The Veterinary Council of Ireland in their role as regulator of the veterinary profession;

   External EU Auditors for the purposes of satisfying EU and national audits and control requirements;

   The Courts in the event of prosecutions for non-compliances with legislative requirements.

4. **Transferred outside the EU:**

   No personal data will be transferred outside the EU.

5. **Retention Period:**

   The data collected for this purpose will be held by the Department only as long as there is a business need to do so in line with the purpose(s) for which it was collected. After this time it will be marked for destruction and will be destroyed in line with internal guidelines or guidelines for destruction received from the National Archives Office or associated permissions received from them.

6. Data provision being statutory or contractual obligation:

Data is provided on a statutory basis in order to be permitted to distribute, possess, sell or supply veterinary medicinal products or manufacture mediated feed and intermediate products. The processing is necessary for compliance with a legal obligation to which DAFM is subject and is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller. If the applicant chooses not to provide this information his/her application cannot proceed.

7. Automated Decision Making:

Not applicable.

8. Information from Third Party:

In circumstances where this Department did not gather your personal data you are still entitled to exercise your rights in relation to this personal data and the details on how to exercise individuals rights are available at the following link: https://www.gov.ie/en/organisation-information/ef9f6-data-protection/

9. Technical information on data collected:
Technical information on the cookies used on the Gov.ie website is available at the following link: https://www.gov.ie/en/help/privacy-policy/?section=cookies

Freedom of Information

Information provided by you may be subject to disclosure under the FOI Acts 1997 and 2003. If you wish to have any of the records concerned protected under the Confidentiality, Commercially Sensitive, Personal Information or other exemption provisions of that legislation you should mark those records accordingly and state your reasons. The relevant exemptions will then be considered in the event of an FOI request relating to those records.