An Roinn Talmhaíochta,
Bia agus Mara
Department of Agriculture,
Food and the Marine

Department of Agriculture, Food and the Marine

Application by a Veterinary Practitioner or a holder of a Wholesale Distribution Authorisation for an import licence in accordance with Articles 112,113 or 114 of Regulation EU 2019/6

PLEASE COMPLETE PART 1 OR PART 1a AS APPLICABLE (BOTH SHOULD NOT BE COMPLETED)

Part 1 – The Applicant – Veterinary Practitioner/Veterinary Practice (see note 1)

Name: _____

Address: _____

VCI Number: _____

Email: _____

Phone: _____

Part 1a – The Applicant – Wholesale Distribution Authorisation Holder (WDA) (if relevant)
*** If the Veterinary Medicinal Product (VMP) is being imported from a 3rd Country this section MUST be completed. (see note 1)**

Name: _____

Address: _____

WDA Number: _____

Email: _____

Phone: _____

Part 2 – Details of Veterinary Medicinal Product (VMP) to be imported

Name of VMP: _____

VMP Marketing Authorisation No: _____

Country where Marketing Authorisation (MA) is held: _____

Expiry Date of MA (must be currently authorised): _____

Proof that MA is currently authorised (in English) enclosed: (tick to confirm)

Copy of SPC (in English) enclosed: (tick to confirm)

Target Species: _____

Indications for use covered by the MA: _____

Active Substances(s): _____

Pharmaceutical Form: _____

Strength: _____

Pack Size: _____

Part 3 – Detail for Licence

Quantity to be imported (see note 2): _____

Do you intend to supply only to the veterinary practitioners supporting the application?

_____

Period for which licence is requested (see note 3): _____

Part 4 – Reasons for Import

Is this import required to prevent unacceptable suffering? _____

Reasons for Import: _____

_____

_____

Letters of veterinary justification for import enclosed tick to confirm (See note 4 for WDA applications)

Indication for use for which VMP is required: _____

Species for which VMP is required: _____

Food-producing animal? (step 3 below relevant) Yes No

The following steps are required to be followed under EU 2019/6 in order for use to be considered. Please indicate each step below has been followed before proceeding to the next step. The necessary proof must accompany the application to demonstrate the actions detailed at each step have been completed.

Please highlight the point at which you require the import licence:

1. There is no authorised VMP in Ireland or the authorised VMP is unavailable.
   (If reason for application is authorised VMP is unavailable evidence of this must be provided)
   Has confirmation from the manufacturer or HPRA of shortage been provided? Y/N

2. VMP authorised in Ireland or another Member State for same/another species for same/another indication.
   Has HPRA and EU's Product Database been checked and evidence of same provided? Y/N

3. VMP authorised in Ireland for a non-food-producing species for same indication.
   Has HPRA and EU's Product Database been checked and evidence of same provided? Y/N

4. Medicine authorised for human use in any EU Member State.
   (The EMA provides information on authorised human medicines - European Medicines Agency | (europa.eu)
   Has the EMA website been checked and evidence of same provided)? Y/N

5. VMP prepared extemporaneously on foot of a prescription

6. 3rd country authorised VMP for same species/indication. (Immunologicals are not permitted under this provision)

Part 5 - Previous Applications

Have you made a previous application (whether granted or refused) for this product? Please outline details below.

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: _____

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. Only a WDA is permitted (under licence) to import from a 3rd country.

2. The quantity should be a 'best estimate' based on the need for the product. 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. For applications made by a WDA, if their intention is to supply more than 1 veterinarian, there should 1 letter of justification per practice and if more than 4 practices are to be supplied, a minimum of 4 letters of justification will suffice, all letters should be on practice letterhead and should be dated.

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

6. 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.

7. 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 or special imports of veterinary medicinal products.

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.