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

Department of Agriculture, Food and the Marine

Application by a Feed Business Operator for a licence to import a medicated feedingstuff for own use.

(EU) 2019/4 of the European Parliament and of the Council of 11 December 2018

Part 1 - The Applicant

Name: _____

Address: _____

Location where medicated feed will be administered (if different from the above):

_____

Medicated Feed Licence Number: _____

Feed Business Operator Registration Number: _____

Telephone No: _____

Email Address: _____

Veterinary Practitioner: _____

Part 2 – Particulars of Medicated Feed to be imported

*Name of authorised premix to be used for the manufacture

_____

VPA/EU Number: _____

Target Species (as per authorisation): _____

Quantity of premix to be incorporated (per the prescription): _____

Total tonnage of medicated feed to be manufactured: _____

Prescription reference/ID number: _____

Name of Compounder (Mill):_____

Address of Compound Mill: _____

Veterinary justification for this application: _____

_____

Indications for use of medicated feed: _____

Species to which feed will be administered: _____

Quantity of Product Required (including quantity of feed to be manufactured):

_____

Copy of prescription provided ☐ (tick to confirm)

The following information shall be forwarded post manufacture to veterinarymedicineswmc@agriculture.gov.ie (tick to confirm) ☐

a. Batch production records
b. Dispatch and delivery documentation
c. Records of administration of medicated feed.

***It is only permitted to use a premix authorised for use in Ireland**

DECLARATIONS AND UNDERTAKINGS

1. I undertake to comply with Regulation (EU) 2019/4 of the European Parliament and of the Council of 11th December 2018, S.I. 36 of 2022 and with any conditions attached to a licence granted as a result of this application.
2. I undertake to notify, in writing, the Department of Agriculture, Food and the Marine of any changes in or addition to the aforementioned particulars.
3. I am aware that a licence may, if granted on foot of false or misleading particulars supplied by me, be revoked.
4. I recognise that I will be fully and directly responsible for use of the medicated feed covered by this application in accordance with EU 2019/4 and S.I. 36/22 and that no

liability shall attach to the Minister for Agriculture, Food and the Marine for any adverse events which may arise in the treated animal(s).

5. I am aware of my obligations arising from my role as a Feed Business Operator and have complied with the requirements with regard to Third Country Representation.
6. I am aware that all the import requirements for compound feed apply to medicated feed and if the feed contains an Animal By-Product (ABP), ABP requirements also apply. I have ensured that all these requirements have been met.
7. 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.
8. The Department will consider the issuing of a licence permitting the import of the requested feed for own use only. The licence shall be valid for a maximum period of 31 days, corresponding to the period of validity of the prescription directing the manufacture and administration of the feed.
9. Applicants can access a list of all veterinary medicines authorised in Ireland by the Health Product's Regulatory Authority, and centrally authorised by the European Medicines Agency by accessing the appropriate listings on the Health Products Regulatory Authority website at www.hpra.ie and the European Medicine's Agency website, www.ema.europa.eu

Signature(s) of/on behalf of Applicant(s)
(in the case of a company or co-operative, a person authorised for such purpose on behalf of the applicant or if a partnership, all partners must sign).

_____

Names(s) in block capitals: _____

Position: _____

Date: _____

This form, when completed, can be emailed to veterinarymedicineswmc@agriculture.gov.ie or posted to:

ERAD (Veterinary Medicines)
Department of Agriculture, Food and the Marine
Backweston Campus
Young's Cross
Celbridge
Co Kildare

1. Applications that are incomplete or if applicant fails to provide additional requested information or misleading information the application will be refused.
2. 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.

Annex 1

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 personal data being collected:
The following data is specific information in relation to the personal data processed for the licencing of the manufacture of medicated feed.

1. Specified purpose:

Information is collected for the purposes of authorising the import of medicated feed.

2. Legal basis:

Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018.
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