



Department of Agriculture, Food and the Marine

**Application by a Feed Business Operator for an authorisation to
manufacture medicated feedingstuffs and intermediate products.**

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

N.B. A separate form *must* be used in respect of *each* premises.

Part 1 - The Applicant

Status of Business:	Company	Limited Company	Partnership
(Please tick as appropriate)	Sole Trader	Co-Operative	

1. Are you manufacturing to place on the market and supply others: Yes No

2. Are you manufacturing for your own use only: Yes No

If yes, what species of animal are you manufacturing for? _____

Name/Business Name: _____

* Trading As: _____
(where applicable)

Address: _____
(of premises)

Website: _____

Telephone No: _____

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Email Address: _____

PPS No: _____ (sole trader only) Vat No: _____ (if available)

Company Registration No.: _____

Herd No (if applicable): _____

- * (a) Applications for Companies, Co- Operatives, Partnerships must be submitted in the official name of the Business
- (b) A licence cannot be issued to a 'Trading as' entity.

Part 2 - Premises

Manufacturer's address; if different from details provided in Part 1: _____

Are the premises to be used for any commercial activity relation to veterinary medicinal products (i.e. wholesale or retail of veterinary medicinal products): Yes No

(If yes please give details):

Are the premises currently *registered/authorised under the [European Union \(Food and Feed Hygiene\) Regulations, 2020, \(SI No.22 of 2020\)](#): Yes No

Please provide registration details and approval certificate (if applicable) with this application:

*Note: Consideration for a licence to manufacture Medicated Feedingstuffs is dependent on the manufacturer's premises being registered under the provisions of these regulations.

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.

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3. I am aware that a licence may, if granted on foot of false or misleading particulars supplied by me, be revoked.
4. I understand that a licence will not issue until an inspection of the premises has taken place.

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.

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 manufacture of medicated feed or intermediate product.

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>