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

Licensed Retailer Application

Department of Agriculture, Food and the Marine

Application for a Veterinary Medicinal Product Retailers Licence

REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 11TH DECEMBER 2018

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

Part 1 - The Applicant

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

Veterinary Practitioner Yes ☐ No ☐
(Please tick as appropriate) If Yes, VCI No. Required: _____

* Name/Business Name: _____

* Trading As: _____
(where applicable)

Address: _____
(of retail premises)

Website: _____

Telephone No: _____

Email Address: _____

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

Company Registration No.: _____

If you wish you / your company to be included on a list of retailers on the Department of Agriculture, Food and the Marine Website please tick box Yes ☐ No ☐

* (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 - Internet Sales

Do you wish to sell veterinary medicinal products (VMPs)on the internet: Yes ☐ No ☐
If yes, please supply website address:

Please note there are additional requirements for those selling on the internet in order to comply with EU Regulation 2019/6. (see annex 2)

Address of premises where VMPs are stored and /or kept for sale, where the contract will be concluded and relevant records maintained **(if different from the above):**

Part 3 – Training

Have you or a member of your staff successfully completed the FETAC approved training course to become a retail responsible person?* Yes ☐ No ☐ or

are you or a member of your staff a Veterinary Nurse registered by the Veterinary Council of Ireland (VCI)? Yes ☐ No ☐

If yes, please give details of the person(s) as follows.

Name: _____

Cert. No. / VCI Reg. No.: _____

Course Provider: _____

Name: _____

Cert. No. / VCI Reg. No.: _____

Course Provider: _____

*Please note veterinary medicinal products may only be sold by a retail responsible person from your retail premises.

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, 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 declare that the premises to which this application relates conforms to the conditions set down in Annex 1 to this application, and does not constitute part of a domestic dwelling.
5. I declare that I will adhere to the conditions as set out in Annex 2 for internet sales (if applicable).
6. I undertake to have in place arrangements to receive and return to the person from whom he or she purchased them, a veterinary medicinal product that is unused or has reached its expiry date and in addition take steps to ensure that customers are aware of the arrangements.
7. I understand that a licence will not issue until an inspection of the premises has taken place.

I enclose licence fee of €150.00 (retailer fee) _____

Please click here for Payment Options

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. The licence fees made payable to the Department of Agriculture, Food and the Marine must accompany this application.
3. 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

REQUIREMENTS FOR A VETERINARY MEDICINAL PRODUCT (VMP) LICENSED MERCHANT'S PREMISES AND SALE AND STORAGE OF VMPS

PREMISES

1. The premises shall be a permanent structure of sound construction.

2. The premises shall be capable of being adequately secured.

3. Premises contained within the curtilage of a domestic dwelling shall not be considered suitable. If a premises is attached to the dwelling, the limits of the premises to be used as a retail premises shall be clearly defined and it shall be possible to access the premises directly without trespass into the dwelling.

SALE AND STORAGE OF VMPS

4. All activities concerning the sale, supply, display and storage of VMPs shall take place in a separate designated area.

5. The premises shall have adequate storage space to store VMPs in accordance with good pharmaceutical practice and in accordance with manufacturer's directions.

6. VMPs shall not be stored or kept for sale or supply outside the confines of the licensed premises.

7. VMPs shall be stored in a manner that will facilitate proper rotation of stock.

8. The premises shall have a designated area for the storage, prior to return or disposal, of expired, returned and damaged stock. This area shall also be used for the temporary storage of products subject to recall due to quality defect or for reasons relating to the pharmacovigilance system provided for under these regulations.

9. The premises shall have refrigerated storage and display facilities for VMP which require to be kept under controlled temperature conditions.

10. All VMPs shall be stored in accordance with the manufacturer's instructions and the summary of product characteristics.

11. Storage and display facilities shall be adequate to ensure that VMPs do not become contaminated by other VMP or stock on the premises or cause such contamination.

Annex 2 Conditions for Internet Sales

1. Only VMPs designated with a route of sale of LM (Licensed Merchant) and CAM (Companion Animal Medicines), may be sold under an internet sales licence, unless determined otherwise in national law

2. VMPs not subject to a prescription may be sold across the EU, provided they are authorised, as verified by the seller, for use in the destination country.

3. VMPs subject to a prescription (if they are permitted to be sold in accordance with national law) may only be sold within the State. They may not, under any circumstance, be sold to another Member State or 3rd country.

4. The location from which the internet site is controlled, where the contract will be concluded and the records maintained shall be a premises licensed for the retail sale of VMPs.

5. The common logo for internet sales is required to be displayed on every page of the website that sells or offers for supply VMPs. The guidelines provided by the Department of Agriculture, Food and the Marine for the use of the common logo must be followed.

6. The contract of sale shall only be entered into (i.e., acceptance of the order) when the retail responsible person is satisfied that the supply of a VMP is in order. A record of this process, which shall include the signature of the retail responsible person and the date shall form part of the record referred to in paragraph (12).

7. Each consignment of VMPs dispatched shall be packaged securely and safely and shall be addressed to the purchaser identified on the order. In the case of VMPs that require temperature control, the licensee shall ensure, in particular, that the delivery system used shall guarantee that temperature parameters specified for the products in question are observed. A documented risk assessment should be

performed in these instances.

8. The delivery documents accompanying the order shall include a hard copy of the order whichshall contain a section enabling the purchaser to confirm receipt of the consignment.

9. The receipted order form shall be returned without delay by the purchaser to the retail responsible person. It shallbe the responsibility of the seller to ensure that subsequent orders are not accepted from a purchaser who has not returned a receipted order form relating to a previous consignment.

10. The record-keeping requirements of Article 103(3) of EU 2019/6 in relation to an internet business shall apply to all categories of VMPs sold.

11. With the exception of incoming stock records, separate records shall be maintained for all aspects of the internet business.

12. All records and documents relating to the internet business shall be retained for at least five years.

13. Access shall be afforded to authorised officers of the Minister for Agriculture, Food and theMarine to the records and documents related to the internet business.

14. Any changes in the particulars supplied in support of the application shall be notified in writing to the Department of Agriculture, Food and the Marine and any proposed material changes affecting the operation of the business shall first be submitted to the said Department for approval.

15. If the Minister for Agriculture, Food and the Marine, has reasonable grounds to believe that the conditions applicable to a licence are not being observed, he/she

may by a notice in writing, suspend a licence pending further investigation and if satisfied that the conditions applicable toa licence are contravened, may amend or revoke the licence.

16. In the case of internet sales to destinations outside the State, the holder of an internet sales licence shall only sell or supply a VMP which is authorised for sale in this State, to aperson/s who is/are lawfully permitted to receive the VMP, in accordance with the legislation of the destination country. Any specific enquiry about the status of a particular product which it is intended to sell to another country, or about rules applying to sale of veterinary medicines in that country, should be addressed to the regulatory authority in that country.

Annex 3

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 VPMs.

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 Department of Agriculture, Food and the Marine 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.