Department of Agriculture, Food and the Marine

Application for a Veterinary Medicinal Product Retailers Licence to Solicit Orders

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

Part 1 - The Applicant*

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

Veterinary Medicinal Product Retailers Licence No.: _____ or
Pharmacist Details: _____

* 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 will only be considered by a licensed Veterinary Medicinal Product (VMP) Retailer or pharmacist.
(b) Applications for Companies, Co- Operatives, Partnerships must be submitted in the official name of the Business
(c) A licence cannot be issued to a 'Trading as' entity.

Part 2 - Representatives

In respect of all representatives*, please indicate:

Name: _____

Address: _____

Telephone: _____

Email: _____

Vehicle Type: _____

Registration Number: _____

Area of Operation: _____

*Additional representatives can be listed on 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, 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 undertake to comply with the conditions as set out in Annex 1.

I enclose licence fee of €76.00 _____

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
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 – Conditions of Licence

(1) Orders may only be solicited for products with a route of sale of LM (Licensed Merchant) and CAM (Companion Animal Medicine). Orders may not be solicited for products with a route ofsale of POM (Prescription Only Medicine).

(2) A licence, if granted, will be subject to the following conditions:

(a) The licence applies to the soliciting and collecting and/or obtaining of orders for theVMPs listed in (1) above the application and does not apply to the sale of a VMP.

(b) The licence authorises the making of farm-to-farm visits for the purposes set out in paragraph (a) above.

(c) The licence authorises the licensee to solicit, collect or obtain orders using the representative(s) and vehicles, named in part 2 and in the area of operation mentioned in part 2 of the application.

(d) The representative soliciting, collecting or obtaining orders may not carry any VMPs with him/her in the course of his/her duties.

(e) The order taken by the representative must be in the form of an offer from the farmerto purchase the VMPs, acceptance of which is not in the power of the representative.

(f) The order must be signed and dated by the farmer at the time of collection of theorder. The order must be completed in duplicate.

(g) The representative must return the order to the VMP Retailer's Licensed Premises for checking by the nominated person.

(h) The contract of sale must be concluded at the point when the Retail Responsible Person is satisfied that the supply of the VMPs in question is

lawful.

(i) The Retail Responsible Person must sign and date the order to confirm acceptance. A copy of the order must be retained at the point of sale for at least five years from date of dispatch of the order.

(j) A signed order form must be received at the point of sale before any VMPs are dispatched.

(k) Each consignment of VMPs must, insofar as is feasible, be packaged as an individual consignment for and addressed to the farmer/purchaser. The delivery documents shall include a copy of the order.

(l) 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.

(m) The VMPs so sold must be delivered to the farmer/purchaser by a means of distribution which does not involve the use of the representative.

(n) The farmer/purchaser must sign the delivery documents to confirm receipt of the goods. These documents must be returned to the point of sale and retained with theorder for at least five years.

(o) Each representative must keep a separate record of the itinerary of calls made to solicit, collect and/or obtain orders, and lists of products so ordered. The record mustinclude all premises visited including those where no order was obtained.

(p) Officers of the Minister for Agriculture, Food and the Marine shall have access to allrecords and documents relating to activities subject to the licence.

(q) Any change in the particulars supplied in support of this application must be approvedin writing by or on behalf of the Minister for Agriculture, Food and the Marine.

(r) If the Minister for Agriculture, Food and the Marine has reasonable grounds to believethat the conditions for a licence are not being observed, he/she may by a notice in writing suspend a licence pending further investigation of the complaint and if satisfied that the conditions applicable to a licence are contravened, may revoke or amend the licence.

Annex 2

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.

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.