Department of Agriculture, Food and the Marine

Application for a Veterinary Medicinal Product Wholesale Distribution Authorisation

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

'Wholesale Distributor' means all activities consisting of procuring, holding, supplying or exporting veterinary medicinal products whether for profit or not, apart from retail supply of veterinary medicinal products to the public.

Part 1 - The Applicant

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

Activity to be undertaken: (Please tick as appropriate) Procuring ☐ Holding ☐ Supplying ☐ Exporting ☐

* Name/Business Name: _____

* Trading As: _____
(where applicable)

Address: _____
(of Wholesale premises requiring licence)

_____

Website: _____

Telephone/Mobile No: _____

Email Address: _____

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

Company Registration No.: _____

Name and Address to which all correspondence concerning the licence should be forwarded (if different than above): _____

_____

If you wish your company to be included on a list of wholesaler distribution authorisation holders on the Department of Agriculture 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.

Personnel

Name of Responsible Person: _____

Address: _____

Email: _____

Telephone: _____

Name of Deputy Responsible Person (if applicable): _____

Address: _____

Email: _____

Telephone: _____

Premises

Location of Wholesale premises: _____

Is this premises suitable and sufficient for the safe and secure storage and handling of Veterinary Medicinal Products (VMPs)? Yes ☐ No ☐

Are VMPs stored at this premises? Yes ☐ No ☐

Are VMPs stored elsewhere? Yes ☐ No ☐
If yes, please provide detail

Is this premises used for or in connection with any other purpose or business?
Yes ☐ No ☐
If yes, please specify: _____

Good Distribution Practice

Are you in compliance with GDP as per EU2021/1248? Yes ☐ No ☐

Have you supplied a copy of all SOPs as per Annex 1? Yes ☐ No ☐

Is an appropriate record keeping system in place? Yes ☐ No ☐

Do you confirm that you can fulfil all requirements as laid out in Article 101 of EU 2019/6?
Yes ☐ No ☐

Recall Plan

Do you confirm that you have a plan guaranteeing effective implementation of any withdrawal or recall ordered from the market of a VMP? Yes ☐ No ☐

Veterinary Medicinal Products

Categories of VMPs wholesaled: _____

Manner of delivery of products, including provisions for the transport of vaccines:

_____

_____

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, EU 2021/1248 on Good Distribution Practice and S.I. 36 of 2022 and with any conditions attached to an authorisation 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 an authorisation may, if granted on foot of false or misleading particulars supplied by me, be revoked.
4. I declare that the Standard Operating Procedures (SOPs) in Annex 1 attach to this application.
5. I understand that the licence to wholesale VMPs may be revoked by the Minister if I am no longer involved in the wholesale of VMPs within the timeframe as laid out by Department officials.
6. I understand that an authorisation will not issue until an inspection of the premises has taken place.

A licence fee of €634 is applicable. 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. Final decisions on applications will be made within 90 days of receipt of completed application.
4. In accordance with Article 100(5) of EU 2019/6 relevant information from this authorisation if granted will be uploaded on to the EU's manufacturing and wholesale distribution database.

Annex 1 SOPs Required to accompany application

	Documented Procedure (Yes/No)	Name/Reference No. of Documented Procedure
Overview of quality system (QS)		
Management review and monitoring of QS		
Deviations from Good Distribution Practice (GDP)		
Change control		
Responsible Person (RP) and role/responsibilities of RP and employees in key positions		
Training		
Personnel hygiene – PPE etc.		
Security of premises		
Cleaning programmes		
Pest control		
Temperature mapping and monitoring (incl. alarm systems)		
Maintenance of equipment –(incl. calibration)		
Computer/IT system		
Key equipment qualification and key process validation of activities		
Document Control		
Records of sales/purchases		
Receipt of medicinal products		
Establishing authority of suppliers to supply medicinal products		
Establishing authority of customers to receive medicinal products		
Storage of medicinal products		
Order processing, picking and dispatch		
Return of medicinal products to inventory		
Stock inventories		
Controlled drugs		
Waste management of medicinal products		
Transfer of medicinal product between branches		
Export of VMPs		
Customer complaints		
Returns		
Falsified VMPs		
Recall procedure		
Outsourced activities		

Audit procedure of companies to whom activities are outsourced – compliant with GDP		
Self-inspections (internal audits) - at least annually.		
Transportation/Delivery/Distribution		
Temperature control during transport		
Operation and maintenance of vehicles		
Security during transport (incl. reference to narcotic substances)		
Emergency out of hours deliveries		

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.