# Guidance when applying for an animal remedies wholesaler's licence

This document is aimed at those persons who wish to wholesale supply veterinary medicinal products. Wholesale dealing means the procurement, holding, storage or distribution of a veterinary medicinal product to retailers or other wholesale dealers.

Possession and distribution of veterinary medicinal products is subject to the requirements laid down in Article 65 of Directive 2001/82/EC of the European Parliament and of the Council Regulation 30, "Wholesale of an animal remedy" of S.I. No. 786 of 2007, European Communities (Animal Remedies)(No.2) Regulations 2007.

In order to obtain an animal remedies wholesaler's licence, a person must have :

- A suitable premises
- Suitable equipment and staff
- Suitable arrangements for record-keeping
- Suitable arrangements for handling, storage and distribution of an animal remedy
- An effective emergency recall plan

Wholesale distribution of veterinary medicinal products is subject to the holding of an authorisation granted by the Minister, and as detailed under Regulation 30(1) of S.I. No. 786 of 2007, "A person shall not sell or supply an animal remedy by wholesale except in accordance with a licence ("animal remedies wholesaler's licence").

This guide should be read in conjunction with the relevant application form, WS/APPL.

The current application form is available on https://www.agriculture.gov.ie/animalhealthwelfare/veterinarymedicinesresidues/veterinarymedicines/veterinarymedicinesforms.

The application form should be completed and the fee of €634 paid to DAFM accounts on submission of the application. This fee can be paid by cheque or electronic transfer. If electronic transfer is preferred, please contact veterinarymedicineswmc@agriculture.gov.ie for further details.

Applications will be considered incomplete if the applicant is not ready for inspection at the time of submission of the application, and this will subsequently delay the time for approval.

Note- This document is for information purposes only and does not purport to be a legal instrument. For details of specific legal provisions, please refer to the relevant legislation.

A satisfactory inspection of a proposed animal remedies wholesaling premises is required prior to granting of an animal remedies wholesaler's licence.
A second inspection within a timeframe of approximately 12 months will be carried out, once the premises is fully operational. Thereafter, inspections of the premises are carried out on a risk basis.

The time taken for granting an animal remedies wholesaler's licence, upon receipt of a valid application and fee will not exceed 90 days. If the application is not complete, DAFM, Veterinary Medicines administration team will contact the applicant within 2 working days of receipt.

Licences are issued to a premises only and are non transferable. Licences issued are of an indefinite duration. However, licences will be revoked if the holder has not traded in animal remedies in the previous 3 years. A compliance document must be completed by the licensed animal remedies wholesaler annually and returned to the Department of Agriculture, Food and the Marine. (Appendix 2). This is a condition of your licence. DAFM will e-mail this document in the first quarter of each year for completion. It is important that it is ensured that the contact details held by DAFM are correct and up to date.

Any variations or changes required under the licence should be submitted in advance to veterinarymedicineswmc@agriculture.gov.ie for approval. Some variations may require inspection of the site, whereas others may only require administrative changes to existing documents.

## Material to be provided in support of an application

In recent times, some changes to the inspection process have been implemented to align wholesaling of veterinary medicines with international best practice. Key aspects of the quality management system of the operation will now be requested in advance of the inspection and reviewed in detail prior to visiting the site. We anticipate that the changes we have made will align with the requirements for Good Distribution Practice standards for veterinary medicinal products that have yet to be defined under new veterinary medicines legislation that will come into force in January 2022 (Regulation (EU) 2019/6 of the European Parliament and of the Council)

Prior to any inspection or visit to the proposed wholesaling site, it is required to complete a Documented Procedures Check List, Form 12 (Appendix 1), and to supply the requested copies of documented procedures which are or will be put in place.

Note-there is a very useful guide to quality systems for Wholesale Distribution on the HPRA website that can be used for reference. This specifically relates to human medicines but the general principles are also applicable to veterinary medicines.
https://www.hpra.ie/homepage/about-us/publications-forms/guidance-documents/item?id=6860f925-9782-6eee-9b55-ff00008c97d0&t=/docs/default-source/publications-forms/guidance-documents/ia-g0038-guide-to-quality-system-for-general-sale-wholesale-distributors-v5

To support Procure and Supply activities, the company must have evidence available to demonstrate that proposed activities meet the requirements of the definition of 'Procure' and/or 'Supply'. The wholesale entity must be able to demonstrate that it is in fact performing wholesale activities at the site and that it is "in ownership" of the product at some point in the supply model proposed.

## General Requirements for Approval of animal remedies wholesaler's licence

An applicant of an animal remedies wholesaler's licence must be able to satisfy the Minister that the proposed wholesaling premises is suitable, and that suitable equipment and staff, and suitable arrangements are in place for record-keeping, handing, storage and distribution of an animal remedy.

## Suitable premises

An animal remedies wholesaler's licence may not relate to a premises used for the retail sale of an animal remedy or companion animal remedy. The premises must be a secure premises. There must be adequate separation between receipt and dispatch areas and general storage areas. The premises must be suitable from the point of view of temperature control.

## Suitable staff and equipment

At present there is no statutory requirement for a named Responsible Person. However, this may be a requirement under the new Regulations.

## Suitable arrangements for record keeping

Holders of an animal remedies wholesaler's licence must keep, at the premises to which the licence refers, records of all incoming and outgoing transactions for at least 5 years.
Records must include :-

- The date of transaction
- The precise identity of the animal remedy including name and pharmaceutical form and pack sizes
- The manufacture's batch number
- The name and address as appropriate, of the supplier or consignee
- The quantity received or supplied (including quantities of product received or returned for disposal).

The holder of an animal remedies wholesaler's licence shall, at least once a year carry out a detailed audit to reconcile incoming and outgoing supplies with supplies currently held in stock and any discrepancies shall be specifically recorded.

**Customers**

The holder of an animal remedies wholesaler's licence may only sell or supply an animal remedy to a person who holds an animal remedies wholesaler's licence, an animal remedies merchant's licence, a person registered to sell CAM (Companion Animal Medicine) products, a pharmacist or a registered veterinary practitioner.

Exact customers may not be known at the time of submission of a new application but as much information as possible relating to the categories of potential customers and suppliers should be provided.

It is the responsibility of the licence holder to check bone fides of customers.

## Suitable arrangements for handling, storage and distribution of an animal remedy

The holder of an animal remedies wholesaler's licence must undertake procedures for adequate storage and rotation of stock.

A system must be in place to receive from a registered veterinary practitioner, a pharmacist, the holder of an animal remedies merchant's licence or a person registered to sell CAM (companion animal medicine) products, animal remedies which were unused or reached their expiry date, for return to the marketing authorisation holder.

Transport
Transportation does not require any standalone certification in relation to GDP. The holder of an animal remedies wholesaler's licence is however responsible in ensuring that transport used is compliant under GDP.

Controlled drugs
To stock, sell, supply controlled drugs (Drugs coming under the Misuse of Drugs Regulations 2017), the wholesaler must be licenced by the Health Products Regulatory Authority (HPRA). Note- Special Requisition/order forms are required from Veterinary Practitioners to be supplied with controlled drugs.

## An effective emergency recall plan

The holder of an animal remedies wholesaler's licence must have a system in place to be in a position to immediately withdraw, if directed by the Minister, the HPRA or the marketing authorisation holder, from sale or supply any quantity and, in so far as is practicable, immediately recall any quantity of an animal remedy sold or supplied (a batch or part of a batch) that does not conform with an animal remedies authorisation, or the strength, quality or purity does not conform with the specification of that animal remedy, or an animal remedy which has given rise to unacceptable adverse reactions.

The Inspection Process
The purpose of the inspection is to assess suitability for new applicants and to monitor compliance with the regulations. Inspections can be announced or unannounced. All inspectors are Authorised Officers of the Department of Agriculture, Food and the Marine. A typical inspection will follow the format below. It is essential that key personnel and all relevant documented procedures and records are available. It is difficult to predict how long an inspection will take but it advisable to have people available for a full day.

**Typical Format of an Inspection**

- Opening Meeting with key personnel - scope will be outlined
- Inspection of Quality System and Records
- Physical checks on facilities and stock
- Closing meeting outlining any findings

## References and further reading

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products. (Article 65)

S.I. No. 786 of 2007 European Communities (Animal Remedies)(No. 2) Regulations 2007.

HPRA Guide to Quality System for General Sale Wholesale Distributors;
https://www.hpra.ie/homepage/about-us/publications-forms/guidance-documents/item?id=6860f925-9782-6eee-9b55-ff00008c97d0&t=/docs/default-source/publications-forms/guidance-documents/ia-g0038-guide-to-quality-system-for-general-sale-wholesale-distributors-v5

**Appendix 1**



## Please complete this list of documented procedures and return in Word format.

| | |
|---|---|
| **Company Name:** | |
| **Date:** | |
| **DAFM Reference No: (to be completed by DAFM)** | |

| | Documented Procedure (Yes/No) | Name/Reference No. of Documented Procedure | Copy Received by DAFM (to be completed by DAFM) |
|---|---|---|---|
| **Responsible Person** | | | |
| **Document Control** | | | |
| **Deviations from Good Distribution Practice** | | | |
| **Change control** | | | |
| **Management review and monitoring of QS** | | | |
| **Training** | | | |
| **Pest control** | | | |
| **Receipt of medicinal products** | | | |
| **Establishing authority of suppliers to supply medicinal products** | | | |
| **Establishing authority of customers to receive medicinal products** | | | |
| **Temperature mapping and monitoring** | | | |
| **Storage of medicinal products** | | | |
| **Order processing, picking and dispatch** | | | |
| **Return of medicinal products to inventory** | | | |
| **Customer complaints** | | | |
| **Recall procedure** | | | |
| **Outsourced activities** | | | |
| **Self-inspections (internal audits) - at least annually.** | | | |
| **Waste management of medicinal products** | | | |
| **Transfer of medicinal product between branches** | | | |
| **Transportation** | | | |

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

**Appendix 2**

## 2019 COMPLIANCE DOCUMENT

## ANIMAL REMEDIES WHOLESALERS LICENCE

1. Please complete all relevant sections to this document. Please complete in block capitals legibly using black ink.
2. **If no wholesaling of animal remedies was carried out at the premises during the year 2019, you must state this under Section A below.**
3. Electronic version of the completed document is acceptable.
4. The completed document should be returned **no later than 7th June 2020**.
5. Failure to submit the completed document by this date will result in the Wholesaler being scheduled for a non-routine inspection.

### Section A. General Details

| | |
|---|---|
| Wholesale Licence Number | WS/ / |

| Name of Licensee | Address of Licensed Wholesale Premises | Wholesaled Animal Remedies during 2019 | |
|---|---|---|---|
| | | **YES** | **NO*** |

*If No what was last date animal remedies were wholesaled: _____

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| | |
|---|---|
| Have you traded as Animal Remedy Wholesaler in 2019? | |
| Have you traded as Animal Remedy Wholesaler in 2018? | |
| Have you traded as Animal Remedy Wholesaler in 2017? | |

## Section B. Changes

Any **significant changes** in relation to:

(1) Category of veterinary medicines sold,
i.e. VPO or controlled drugs: **YES** ☐ **NO** ☐

(2) Standard Operating Procedures **YES** ☐ **NO** ☐

(2) Facilities-i.e. physical modification **YES** ☐ **NO** ☐

(3) Equipment i.e. automated picker **YES** ☐ **NO** ☐

(4) Senior Personnel or Management **YES** ☐ **NO** ☐

(5) Workload, i.e. increase or decrease in throughput **YES** ☐ **NO** ☐

(6) Address or expansion to another Premises where additional stock is held **YES** ☐ **NO** ☐

**Please outline any significant changes in relation to (1) to (6) above on a separate sheet**

## Section C. Stock Control

**Detailed Audit undertaken at least once a year as required under Regulation 30 (7) of the European Communities (Animal Remedies) (No 2) Regulations 2007.**

| | **DATE OF AUDIT** |
|---|---|
| (1) Date Audit undertaken in **<u>2019</u>** to reconcile incoming and outgoing supplies with supplies currently held in stock: | |
| (2) Were discrepancies found*****: | **YES** ☐ **NO** ☐ |
| (3) Were discrepancies recorded and what remedial follow up action was taken*****: | **YES** ☐ **NO** ☐ |
| (4) Are details of discrepancies retained and available at the premises for inspection? | **YES** ☐ **NO** ☐ |
| *** Discrepancies must be outlined on a separate sheet to include the name of product(s), quantity, reason why and follow - up remedial action. <u>A copy of the annual audit is not required</u>.** | |

## Section D. Records

| | |
|---|---|
| (1) Do Purchases and Sales invoices contain all the information as prescribed under Regulation 30(5)(e)? | **YES** ☐ **NO** ☐ |
| (2) Is every purchaser supplied with the information prescribed under Regulation 30(5)(h)? | **YES** ☐ **NO** ☐ |

**DECLARATION**

**To the best of my knowledge and belief, the particulars I have given in this document are correct, truthful and complete and I declare that I am operating in accordance with the European Communities (Animal Remedies) (No.2) Regulations 2007 and the conditions specified in the schedule to my licence.**

**Signed: _____**

**Name: _____ (BLOCK CAPITALS)**

**Date: _____**

**Position: _____**

**Contact Phone No. _____**

**Email address: _____**

Note- This document is for information purposes only and does not purport to be a legal instrument. For details of specific legal provisions, please refer to the relevant legislation.

**The signatory shall take all reasonable precautions, to ensure that any information provided, is not false or misleading. It is an offence to provide false and misleading information.**

Please return this document to Veterinary Medicines Section, Floor 1 Department of Agriculture, Food and the Marine, Backweston Campus, Celbridge, Co. Kildare

Electronic documents may be emailed to veterinarymedicineswmc@agriculture.gov.ie

For information on data protection please see the following: https://www.agriculture.gov.ie/dataprotection/. The Data Protection Officer can be contacted at dataprotectionofficer@agriculture.gov.ie or, Data Protection Officer, Data Protection Unit, Department of Agriculture, Food and the Marine, Grattan Business Park, Dublin Road, Portlaoise, Co Laois R32 K857.

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