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

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

Import Licence under Regulation 16

Licence no: AR16/04/22/WS1

1. The Minister for Agriculture, Food and the Marine, in exercise of the powers conferred by Regulation 16(1) and 49(1) of the European Communities (Animal Remedies)(No. 2) Regulations 2007, hereby grants:

Name: **INTERCHEM (IRELAND) LTD**
Address: **UNIT 29 SECOND AVENUE**
COOKSTOWN INDUSTRIAL ESTATE
TALLAGHT
DUBLIN 24
Dublin
D24 V9FP

a licence to possess, sell and supply the animal remedy described in Schedule 1 to a Registered Veterinary Practitioner who by virtue of this licence is authorised to possess, sell and supply the animal remedy described in Schedule 1 in accordance with Regulation 4 of the Animal Health and Welfare (Animal Remedies Veterinary Practice and Veterinary Medicines) Regulations 2007 and a Registered Pharmacist from a Registered Pharmacy who by virtue of this licence is authorised to possess, sell and dispense (but not expose for sale) the animal remedy described in Schedule 1 in accordance with Regulation 4 of the Animal Health and Welfare (Animal Remedies Veterinary Practice and Veterinary Medicines) Regulations 2007.

2. This licence is subject to the provisions of the said Regulations and the conditions set out in the attached Schedule 2.

3. This licence, unless previously suspended, revoked or varied shall continue in force until **1 June 2022**.

OFFICIAL STAMP

Dated this 26th day of January 2022

For the Minister for Agriculture, Food and the Marine

AN ROINN TALMHAÍOCHTA, BIA AGUS MARA
DEPT. OF AGRICULTURE, FOOD AND THE MARINE
IRELAND

J Roberts

An officer authorised in that behalf by the said Minister

Schedule 1 to Licence no: AR16/04/22/WS1

Name of Animal Remedy	Marketing Authorisation Holder	Marketing Authorisation No.	Member State	Target Species	Route Of Supply	Quantity
Fascionix	Kepro B.V.	0022-1195-22.06.209	Bulgaria	Ovine Bovine	Prescription Only Medicine	3000 L

Schedule 2 to Licence no: AR16/04/22/WS1

1. The licensee shall keep a dedicated record of purchases and sales in respect of each incoming and outgoing transaction, detailing at least:
   (a) the date of transaction
   (b) the precise identity of the animal remedy, including name, pharmaceutical form and pack size
   (c) the manufacturers batch number and expiry date
   (d) the quantity received or supplied and batch numbers of incoming and outgoing stocks of animal remedy
   (e) the name and address of the supplier or consignee
   (f) the quantity of each animal remedy received or returned, in accordance with Regulation 30(5)(j) of the European Communities (Animal Remedies)(No. 2) Regulations 2007.

2. The licensee shall retain a copy of this licence at the wholesaler premises and it shall be produced on request to an authorised officer.

3. The licensee shall, every six months carry out a detailed audit to reconcile incoming and outgoing supplies etc., of the product and the audit shall be retained and made available at the premises for inspection by an authorised officer.

4. The licensee shall return any unused product in stock at the expiry date of this licence to the person who supplied it.

5. When selling the product on this licence, veterinary practitioners and licenced merchants supplied with the product, must be informed of the expiry date of this licence and that at this date any existing product must be returned to the supplier and cannot be continued to be sold. Any product already purchased by the end user may be used until the expiry date of the product.

6. The licensee shall store the animal remedy separately from other animal remedies.

7. The licensee shall not advertise or promote the animal remedy for sale in accordance with Regulation 37 of the European Communities (Animal Remedies)(No. 2) Regulations 2007 as amended.

8. The Licensee shall notify any adverse reactions **immediately** to veterinarymedicinesWMC@agriculture.gov.ie