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

Regulatory Impact Assessment	
Department: **Department of Agriculture, Food and the Marine**	Title of Legislation: **Veterinary Medicinal Products, Medicated Feed and Fertiliser Regulation Bill 2022**
Related Publications:	• Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 • Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 • S.I.36 of 2022: European Union (Veterinary Medicinal Products and Medicated Feed) Regulations 2022 • Fertilisers Feeding Stuffs and Mineral Mixtures Act, 1955
Available to download at:	
Contact for enquiries:	Vetmedregs@agriculture.gov.ie

Introduction

The regulatory impact assessment sets out the background and policy objective of the Bill. It details the current regulatory framework. The purpose of this Bill is to make provision for the regulation of veterinary medicinal products and medicated feed; the repeal of the Animal Remedies Act 1993; and to provide for matters within the governing EU regulations which were left to the discretion of Member States. Details of the consultative process engaged in by Veterinary Medicines section are also given. The Department recognises that certain areas of the Regulation will have large impacts on stakeholders and below some of these are discussed.

In addition, an amendment to the Fertilisers, Feeding Stuffs and Mineral Mixtures Act 1955 is proposed to provide for a National Fertiliser Database which will encompass the registration of fertiliser economic operators and end users.

Description of Policy Context and Objectives

This Bill has two objectives:

First, to introduce a legal framework pursuant to which the Minister will regulate and monitor the manufacture, import, sale and supply of veterinary medicinal products and medicated feedstuffs.

Second, to amend the Fertilisers, Feeding Stuffs and Mineral Mixtures Act 1955 by inserting new registration requirements and related provisions into that Act to enable the Minister to capture and process information on the manufacture, import, sale, supply and use of fertiliser in the State.

EU legislation Governing Veterinary Medicines

Regulation EU 2019/6 of the European Parliament and of the Council on veterinary medicinal products, which replaced Directive 2001/82/EC on the Community Code relating to veterinary medicinal products, and Regulation EU 2019/4 on the manufacture, placing on the market and use of medicated feed, were agreed in 2018 and came into effect in January 2022.

These Regulations set out rules for the manufacture, import, export, sale, supply, distribution, advertisement, control and use of veterinary medicinal products and medicated feed, aiming to:

1. modernise legislation,
2. stimulate innovation in and increase the availability and safety of veterinary medicinal products, and
3. strengthen and enhance the EU's action against antimicrobial resistance.

National discretion is permitted in a limited number of areas in these EU Regulations, and these will be provided for in the proposed Bill.

Irish Legislation Governing Veterinary Medicines

The European Communities (Animal Remedies) (No 2) Regulations 2007 (SI 786/2007) transposed Directive 2001/82 and provided a comprehensive legislative basis for authorising veterinary medicines and controls on their distribution.

In addition, the Animal Remedies Act 1993, provided for the regulation of Animal Remedies and other matters.

S.I.36 of 2022: European Union (Veterinary Medicinal Products and Medicated Feed) Regulations gave effect in part to the provisions of the Regulation EU 2019/6 and Regulation 2019/4 and repealed SI 786/2007.

.

Policy Problem and Objectives of New Proposal

General objective

The objective of the Veterinary Medicinal Products, Medicated Feed and Fertilisers Regulation Bill 2022 is to:

1. Provide the Minister with powers to make Regulations on areas of the EU Regulations that may be determined by national law.
2. Provide for a national database maintained by the Minister establishing a system to record prescriptions of veterinary medicinal products
3. Provide for rules on the retailing of Veterinary Medicinal Products and Medicated Feeds.
4. Repeal the Animal Remedies Act 1993 and modernise the legislation governing veterinary medicinal products and medicated feed.
5. To amend the Fertilisers, Feeding Stuffs and Mineral Mixtures Act 1955 by inserting new registration requirements and related provisions into that Act to enable the Minister capture and process information on the manufacture, import, sale, supply and use of fertiliser in the State.
6. To provide for the introduction of a National Fertiliser Database.

The provisions of this Bill and the subsequent regulations made in accordance with the provisions of this Bill will ensure a high level of public health protection,

high standards of quality and safety of veterinary medicines and the optimal functioning of the veterinary medicinal products and medicated feed market.

The size of the animal pharmaceutical industry is only a small fraction of the size of the pharmaceutical industry for human medicines. The European Commission, prior to the introduction of Regulations (EU) 2019/4 and 2019/6, therefore considered it appropriate to develop a regulatory framework addressing the characteristics and specificities of the veterinary sector, which cannot be considered as a model for the human medicines market.

The EU Regulations seek to put in place, while safeguarding public health, animal health, food safety and the environment, an up-to-date, proportionate body of legislation tailored to the specificities of the veterinary sector, aiming in particular to:

- increase the availability of veterinary medicinal products;
- reduce administrative burdens;
- stimulate competitiveness and innovation;
- improve the functioning of the internal market; and
- address the public health risk of antimicrobial resistance (AMR).

The Bill, when enacted, will also enable the capture and processing of information on the import, manufacture, sale, supply and use of fertiliser in the State. It will enable data related to fertilisers and lime to be collected from the point of import into the country until sale to end user. It will provide for the establishment of a National Fertiliser Database which will encompass the registration of fertiliser economic operators and end users. The data collected will be used to inform the integrated policy and control programmes in the areas of Nitrates, Biodiversity, Climate Change and deliver on several strategies which are prioritised by Government.

Commission Impact Assessment on Veterinary Medicinal Products Legislation

The European Commission have highlighted that the needs of the veterinary sector differ substantially from those of the human sector in relation to medicines. In particular, the drivers for investment for the human and the veterinary medicines markets are different.

Stakeholders and Member States have previously expressed concern that the governing legislation did not fully deliver a single market in veterinary medicinal products and failed to meet the EU's needs as regards the regulation of veterinary medicines. In particular, the following areas were identified as needing improvement:

- regulatory burden;
- the lack of availability of veterinary medicinal products, especially for small markets; and
- the functioning of the internal market.

In response to this, the Commission carried out a detailed impact assessment prior to the drafting of the regulation on veterinary medicinal products. This included a wide online public consultation which took place from April to July 2010. The full text of the Commission's impact assessment is available at EUR-Lex - 52014SC0273 - EN - EUR-Lex (europa.eu)

The policy options that have been considered:

1. Do nothing
2. Introduce legislation to allow the Minister to:
   a) make regulations concerning matters left to national discretion by the governing EU regulations
   b) provide for a national database maintained by the Minister establishing a system to record prescriptions of veterinary medicinal products
   c) provide for rules on the retailing of Veterinary Medicinal Products and Medicated Feeds
   d) capture and process information on the import, manufacture, sale, and supply and use of fertiliser in the State.
   e) establish a National Fertiliser Database which will encompass the registration of fertiliser economic operators and end users.

Options	Costs	Benefit	Impact
1) Do nothing	None	None	Failure to provide legislation could result in inappropriate use of veterinary medicinal products with subsequent impact of animal health through increased

			antimicrobial resistance and antiparasitic resistance. The State will not be able to keep track of fertiliser sales which will prevent the effective operation of certain agricultural schemes and delay payments. Doing nothing will also increase the administrative burden placed on farmers as they will have to complete manual records to verify compliance. These will then have to be physically checked by the Department of Agriculture, Food

			and the Marine (DAFM) before payment can issue.
2) Introduce legislation to allow the Minister to make regulations concerning matters left to national discretion by the governing EU regulations and provide for a national database establishing a system to record prescriptions of veterinary medicinal products as well as fertilisers and provide for rules on retailing of veterinary medicinal products.	There are costs associated with introducing and the enforcement of legislation and the development of a database.	This legislation will allow the Minister to provide for matters left to national discretion under the governing EU regulations through the introduction of subsequent Statutory Instruments. This legislation also provides a national database establishing a system to record prescriptions and dispensing of veterinary medicinal products and medicated feed for the benefit of	This legislation will allow the Minister to effectively govern the import, sale, possession, administration and storage of veterinary medicinal products and medicated feeds protecting animal health as well as providing for an effective functioning market within Ireland for these products. The Bill will facilitate the recording of fertiliser sales data and will not

		all stages of the supply chain and provides for the retailing of veterinary medicinal products in Ireland. The legislation will allow the Minister capture and process fertiliser data whereby collecting such information will improve traceability regarding fertiliser use. It will facilitate improved compliance with nitrogen and phosphorous use limits. In addition, it will inform policy making around the use of chemical	impact on the ability to purchase fertiliser.

		fertilisers and our national targets.	

Option 1: Do nothing.

The option to do nothing is not a realistic option due to the importance of animal health and the correct use of veterinary medicinal products and medicated feed both to Ireland's agri-food economy but also the close relationship between antimicrobial resistance in people and animals.

In addition, it is not an option as it would not be possible for Ireland to deliver on its commitments to the European Commission arising from the recent review of Ireland's Nitrates Action Programme and the extension of the Nitrates Derogation. Furthermore, the Climate Action Plan 2021, Food Vision 2030 and the EU Farm to Fork strategy have all set ambitious targets to reduce fertiliser use. Establishing fertiliser use will be an important first step in the process of developing policy to address these targets.

Option 2: Introduce legislation to allow the Minister to make regulations concerning matters left to national discretion by the governing EU regulations on veterinary medicinal products and medicated feed, provide for a national database establishing a system to record prescriptions of veterinary medicinal products and provide for rules on retailing of veterinary medicinal products in addition to introducing legislation to capture and process information on the import, manufacture sale and supply and use of fertiliser in the State and establish a National Fertiliser Database which will encompass the registration of fertiliser economic operators and end users.

Cost:

There are costs associated with introducing and the enforcement of legislation and the development of databases.

In addition to the Department of Agriculture, Food and the Marine's costs to development of the database there will be some costs for Private Veterinary Practitioners, as well as dispensers of veterinary medicinal products and those involved in the supply of fertiliser who have existing software that will be required to interact with the system. For private veterinary practitioners or dispensers who do not have existing prescribing or dispensing software there will be no cost associated with using the system. Additionally, there will be no costs for farmers associated with the systems.

Benefits:

The benefits of the Bill will be that the Minister will be able to introduce legislation in areas left to national discretion in a manner that is most appropriate to Irish agriculture with the view to protecting animal health and ensuring that the market for veterinary medicinal products and medicated feeds is an effective, equitable and functioning market. The introduction of the proposed prescribing database will facilitate the direct upload of all generated veterinary prescriptions to a centralised cloud-based database. Once generated the animal keeper will be sent a copy of the prescription or token via email or SMS. This prescription can then be either dispensed by the prescribing vet or by other dispensing parties, such as Licenced Merchant operators, Pharmacists or Medicated Feed Mill upon presentation of the electronic prescription, token, bar code or PIN etc.

The legislation will also allow the Minister capture and process fertiliser data whereby collecting such information will improve traceability regarding fertiliser use. It will facilitate improved compliance with nitrogen and phosphorous use limits. In addition, it will inform policy making around the use of chemical fertilisers and our national targets. In addition, the proposed database will provide reliable data back to farmers which they can then use to qualify for possible voluntary industry sustainability initiatives that will reward farmer actions – for example, in

relation to the use of lime or the use of protected urea rather than alternative forms of chemical nitrogen. Establishment of this fertiliser database will be critical to facilitating timely farmer payments under Ireland's proposed Eco-Scheme. It will also allow Ireland to meet its commitments to the European Commission arising from the recent review of the Nitrates Action Programme and the extension of Ireland's Nitrates Derogation.

Impacts:

The making of regulations under this Bill will provide the animal keeper/farming community with a much greater choice on where they may obtain their veterinary medicinal products (VMPs). It will also potentially reduce the administrative burdens, a key objective of the EU Regulation, for those prescribing, dispensing, and purchasing VMPs as well as positively impacting on animal and human health.

The introduction of a national database and a system to record prescriptions of veterinary medicinal products can potentially simplify record keeping for those purchasing VMPs. In addition, it will provide greater regulatory oversight of those parties involved in the general prescribing, dispensing and use of VMPs. Greater oversight will ultimately protect those parties who are meeting their regulatory functions. It will also allow Ireland to meet its reporting requirements under EU regulations

The Bill will facilitate the recording of fertiliser sales data and will not impact on the ability to purchase fertiliser. It will reduce the administrative burden for farmers participating in the proposed Eco-Scheme and those that chose to avail of a Nitrates Derogation.

Consultation Process

DAFM has continuous consultations with regard to the implementation of the Bill with the HPRA, who are a competent authority for the veterinary medicinal products component of this Bill and the Veterinary Council of Ireland (VCI) who are the statutory body that regulate the practice of veterinary medicine in Ireland, in the public interest.

Veterinary Medicines division of DAFM initiated a consultative process in December 2019 on the governing EU Regulations and invited key stakeholders to make written submissions on the draft proposals. Submissions were invited from all interested parties in the following sectors:

- Farming Sector
- Agricultural Advisory Sector
- Marketing and Manufacturing Authorisation Holders
- Retailers of Veterinary Medicines
- Veterinary Sector
- Wholesalers of Veterinary Medicines

15 submissions were received from interested stakeholders. These submissions informed further individual stakeholder meetings and the wider public consultation process.

In addition ongoing consultation in respect of the implementation of different aspects of the governing EU Regulations is carried out with the Animal Health Implementation Committee which is tasked with overseeing the animal health actions outlined in Irelands National Action Plan (iNAP) for Antimicrobial Resistance as well as an Antiparasitic Resistance Stakeholder Group chaired by DAFMs Chief Veterinary Officer.

The Department has also established a National Fertiliser Database Stakeholder Consultative Committee. This Committee consists of representatives from the fertiliser industry, fertiliser retailers, agricultural contractors, farm organisations, Teagasc and the Agricultural Consultants Association. It will continue to meet over the coming months as the Department works to establish the national fertiliser database.

Public Consultation

A public consultation process on the veterinary medicines proposals was undertaken which aimed at posing specific questions to a wider audience. This process was launched in June 2020 and closed in July 2020. 108 submissions were received from interested stakeholders and members of the public.

Publication

It is intended that the RIA will be published on the gov.ie website on publication of the draft legislation.