



**Submission to Joint Oireachtas Committee on
Agriculture, Food and the Marine
on Veterinary Medicinal Products, Medicated Feed
and Fertilisers Regulation Bill 2022**

7th October 2022

Introduction

The Irish Farmers' Association is Ireland's largest farming organisation with approximately 77,000 members nationwide representing farmers across all farming sectors. IFA represents all farming sectors at National, European and International level.

Through our office in Brussels, the IFA represents Irish farmers on the European umbrella body of farm organisations COPA/COGECA. IFA officers are democratically elected from our membership which stems from over 970 branches. In addition, the IFA is the representative for Irish farmers on the World Farmers' Organisation.

The IFA structure provides for direct engagement with and support services to farmers who experience difficulties on their farms, including reflecting the issues associated with this **Veterinary Medicinal Products, Medicated Feed and Fertilisers Regulation Bill 2022**.

Multiple stakeholders, including prescribers and suppliers of the products under the remit of this Bill have expressed their views as to how the Bill will impact on their business model and the economic viability of their businesses. However, farmers are the end users of the products covered by this Bill and as a result will be most impacted by the legislative obligations which this Bill will establish.

IFA has a clearly set out long standing policy in relation to veterinary medicine usage on farms. Veterinary Medicines are vital tools for us as farmers to ensure we meet our animal health and welfare legislative obligations as identified keepers of our animals and to ensure we maximise the productive capacity of our animals. Access to these products in a competitive market is vital for farmers.

IFA fully support the targeted and appropriate use of all veterinary medicines and have proactively participated in the stakeholder groups set up by the Minister for Agriculture to deliver this objective at farm level including the Antiparasitic Stakeholder Group.

To deliver this objective takes a multi-faceted approach with the active participation of all stakeholders, vets, pharmacists, licensed merchants and advisors with consistent scientifically based advice. The HPRA reflected the importance of multi stakeholder involvement in the process in their *'Report of the Task Force on the method of supply of antiparasitic veterinary medicinal products that are intended for food-producing species'* including in the prescribing process.

While the issue of prescribing of antiparasitic products is a significant issue to be addressed in this Bill there are a number of other areas of concern for farmers including the proposed compulsory electronic prescribing and the responsibilities for compliance and associated proposed sanctions.

The Bill, if framed correctly, can address these issues in a positive and proactive way for farmers and deliver on the key objective of targeted and appropriate medicines usage on farms, however the current draft fails to deliver the framework to achieve this and places Irish farmers at a distinct disadvantage in comparison to farmers in Northern Ireland by creating a two-tiered system of access to antiparasitic products on the island.

Regarding the fertiliser sales database section of the Bill, IFA strongly believe that the following key principles should be adhered to in the final legislation.

- I. The provisions in the Bill must seek to minimise any additional extra costs and administration being placed on professional fertiliser end users
- II. The Bill must not disincentivise the purchase or spreading of fertiliser(s) at farm level by professional end users.
- III. Data protection of information gathered by the database is of critical importance. Individualised farm data on fertiliser usage should be treated in the strictest confidence.

Executive Summary

Throughout the drafting stages of the EU Veterinary Medicine Regulation, IFA identified key areas of concern for Irish farmers which included, in particular, the prescribing process and categorisation of veterinary medicinal products. The changes sought by IFA were not provided by the Department of Agriculture in the final draft of the EU Regulation and as a result these issues must now be addressed in this Bill.

The substantive point raised related to the categorisation of Antiparasitic Products and as result brought into focus the prescribing process for these products. The current draft of the Bill facilitates only registered veterinary practitioners in prescribing antiparasitic products.

This approach removes competition from the supply chain for farmers and critically removes a significant stakeholder from proactively supporting national efforts to promote better and more targeted usage of antiparasitic products. The demise of licensed merchant stores and veterinary pharmacies that will occur as a result will have an even more profound impact on the rural communities and the farmer's they serve due to the loss of economic activity in these regions.

There will be a two-tier system created by this Bill in its current format on the island of Ireland in relation to sourcing antiparasitic products, placing Irish farmers at a competitive disadvantage while creating strong incentives for illegal trade in these products.

The Bill must facilitate prescribing for antiparasitic products by Qualified Persons. This can be achieved by recognising the procedures currently in place where Responsible Persons have fulfilled this function in national law since 2007 under accreditation from the Department of Agriculture which meets the criteria set out in the EU Veterinary Medicines Regulation.

The opportunity to provide this is also attainable under the context of uniformity of approach on the island of Ireland for animal health and welfare measures.

The proposal for all veterinary medicine prescriptions to be issued on line through the NVPS raises significant farmer concerns in relation to the level and type of data that will be stored relating to each individual farm and the accessibility of that data by DAFM and others.

This information is private farmer data and the Bill cannot seek to compile and use this information in a format that provides ease of access to individual identifiable farmer medicine usage information in a more detailed or comprehensive way than is already available. This has the potential to be used by DAFM and industry to categorise farms and/or animals for potential inspections and/or price penalties on animals or produce from farms.

The sanctions for non-compliance with measures in this Bill must be proportionate and farmers cannot be accountable for or sanctioned where prescribers or suppliers of veterinary medicines have failed to comply with their obligations in this area. Farmers are end users and dependant on prescribers and suppliers to meet their obligations, as farmers we do not have oversight of these service providers, this is the responsibility of DAFM and therefore we cannot be liable for their failures to comply with their legal obligations.

The power provided to those charged with implementing this Bill must not extend to farmers. Farmers can only access veterinary medicines when they are prescribed by a qualified person and supplied by a DAFM approved outlet. Entry by force onto farms is not acceptable and must be removed from the Bill. Entry to farms under this Bill must require a warrant and be by arrangement with the herdowner. Farms are also family homes.

Submission

Part 2: Regulation of veterinary medicinal products and medicated feed

Chapter 2: Veterinary Medicinal products and medicated feed – prescriptions and dispensing – national database

5. Prohibitions

- (1) Must be amended to provide for Qualified Persons to prescribe Antiparasitic Products.

The recommendations for the HPRA *'Report of the Task Force on the method of supply of antiparasitic veterinary medicinal products that are intended for food-producing species'* are;

- a) The available scientific evidence shows that antiparasitic veterinary medicines that are intended for use in food-producing species do not comply with the criteria for derogation from veterinary prescription specified in Regulation 2019/6. A consequence of this determination is that any such products that are supplied without veterinary prescription would need to be upregulated to supply under veterinary prescription. The TF recommends that the Authority of the HPRA carefully consider this recommendation.
- b) The TF recommends that a multi-actor stakeholder approach be taken to elaborate national guidelines for sustainable parasite control, including the development of consistent scientifically-based advice on targeted selective treatments.
- c) The TF recommends that those involved in the prescribing and dispensing of antiparasitic veterinary medicinal products are provided with access to training/CPD on sustainable parasite control.
- d) Given that a number of policy options have been identified in this report regarding the development of an appropriate regulatory framework for the supply of antiparasitic veterinary medicinal products that are designated veterinary prescription control, it is recommended that DAFM carefully considers the merits of the various options.
- e) Given the expression of interest by certain stakeholders in providing parasitological diagnostic services to farmers, it is recommended that DAFM consider elaborating the system for veterinary prescription of antiparasitic medicines which support evidence-based prescribing.
- f) Given the known rationalisation of the text of the labelling and outer packaging of veterinary medicinal products that will take place from January 2022 as a consequence of Regulation 2019/6, there is a need for MAHs and other stakeholders to consider how best to disseminate the specific information on dose banding and instructions for use of antiparasitic veterinary medicinal products to the end-users.
- g) In the event that the Authority accepts the conclusions of this report, there will be a need for existing stakeholders to adapt to the requirement for a veterinary prescription for antiparasitic veterinary medicinal products. It is recommended that the HPRA provides the maximum flexibility and allows a period until 1 January 2022 to comply with this report. It is also recommended that stakeholders, including veterinarians, other health care professionals and licensed merchants be informed of this report in order to be able to engage with DAFM in relation to the elaboration and implementation of any new regulatory framework.
- h) Given the status of the honey bee and its importance in pollination, it is recommended that special status be given to antiparasitic veterinary medicinal products that are indicated for bees (in line with that applying to centrally authorised products for bees).

Following finalisation of the Report by the Task Force in early October 2019, it was reviewed and adopted by the ACVM on 23 October 2019. Subsequently, the Report was discussed and endorsed by the Authority of the HPRA at their meeting on 5 December 2019.

It is this report that established the need to categorise antiparasitic products as POM's. However, in doing so the experts recognised this one-dimensional approach was neither suitable for the conditions that prevail in this country or the optimum approach to deliver better antiparasitic medicine usage and as a result included the following key recommendations;

b) The TF recommends that a multi-actor stakeholder approach be taken to elaborate national guidelines for sustainable parasite control, including the development of consistent scientifically-based advice on targeted selective treatments.

c) The TF recommends that those involved in the prescribing and dispensing of antiparasitic veterinary medicinal products are provided with access to training/CPD on sustainable parasite control.

d) Given that a number of policy options have been identified in this report regarding the development of an appropriate regulatory framework for the supply of antiparasitic veterinary medicinal products that are designated veterinary prescription control, it is recommended that DAFM carefully considers the merits of the various options.

e) Given the expression of interest by certain stakeholders in providing parasitological diagnostic services to farmers, it is recommended that DAFM consider elaborating the system for veterinary prescription of antiparasitic medicines which support evidence-based prescribing.

Restricting prescribing to only registered veterinary practitioners significantly reduces the involvement of other stakeholders and service providers, removes competition in the supply chain and creates a two-tier system on the island of Ireland.

This approach has the capacity to severely undermine National efforts to implement better and more targeted usage of antiparasitic products while providing significant incentives for illegal trade in these products.

Farmers will be faced with higher charges for medicines and rural communities will lose economic activity in their regions.

Prescribing by Qualified Persons can be facilitated in the Bill by recognising the existing qualifications and effective prescribing role Responsible Persons have been charged with since 2007.

The opportunity also exists to provide for this in the context of ensuring consistency of approach on the island of Ireland.

This wider prescribing base would ensure the active participation of additional stakeholders in parasite control advice to farmers, maintain a competitive supply chain for farmers, protect rural jobs and economic activity in rural areas and ensure there is a uniform approach in access to antiparasitic products on the island for Irish farmers.

6. Regulations - prescriptions and dispensing

(a) The validity period of the prescription for all products with the exception of antibiotics must be 12 months to align with standard herd health planning on the farm and minimise costs and bureaucracy associated with short validity periods for these products while also maximising farmers opportunity to competitively source their on-farm medicine needs.

7. National database

This section proposes the establishment of a National database for all veterinary medicine prescriptions and sets out the information that will be held, its format and those who will have access to it.

IFA has consistently raised concerns with this proposal and the access it provides for DAFM and others to individual farm and animal specific information.

This information is and should remain private to the herdowner and the decision must rest with each individual herdowner as to who can access the data and the level of detail and information they can access.

IFA has raised concerns at two levels in relation to the visibility of this data.

1. In the first instance farmers who are purchasing products from more than one supplier must have the opportunity to identify that product on the prescription to the supplier, having all products on the prescription visible to the dispenser would severely limit farmers ability to source their various medicines from the most competitive outlets.

The Bill must clearly set out in law the right of the farmer to decide who can have access to the personal data on the National database and the level and type of information that is visible to them.

2. The second and most substantive concern in relation to the storing of this data and the access that the Minister is proposing to provide to outside agencies has the potential to severely impact on individual farmers.

DAFM accessing this data can use it to flag herds for inspections, milk and meat processors can request it and use it to categorise herds and potentially devalue animals and produce from farms based on the usage of important medicines for the health and welfare of the animals.

The Bill must ensure the National database is developed in a way that does not provide DAFM or any outside agencies with access to individual farmer data at a level or in a format than what is currently available.

This information is private individual farmer data and the choice as to who can access it and in what format must rest solely with the herdowner.

Part 3. Enforcement

Farmers cannot source veterinary medicines unless they are prescribed by a Qualified person and supplied by a person approved by the Department of Agriculture.

It is not acceptable or appropriate the Bill seeks to provide the right of entry (if necessary, by force) to authorised officers or others to farmland, farms or homes of farmers.

The Bill must require a warrant and arranged entry with the farmer concerned. Farms are also family homes and this approach, while adopted in the past by DAFM officials, must be prohibited by the Bill.

Sanctions

Throughout the Bill there are references to sanctions for failure to comply with various aspects.

Sanctions must be proportionate and reasonable with opportunity provided to rectify the issue to avoid sanction.

In the event prescribers or suppliers have failed to meet their obligations in the Bill farmers cannot be held accountable. The current Veterinary Medicines Regulation incorrectly sanctions farmers where others have not met their obligations, this is not acceptable and must be addressed in the Bill.

It is the responsibility of the DAFM to ensure compliance of prescribers and suppliers with their obligations in the Bill, farmers do not have oversight of these service providers and cannot be liable for their failures to adhere with their obligations of the Bill.

This Bill must provide clarity and certainty for farmers on this issue.

Part 4: Amendment of Fertiliser Feeding Stuffs and Mineral Mixtures Act 1955

IFA would like included the following comments and clarifications on the fertiliser register and sales data section of the General Scheme of Veterinary Medicines Medicated Feeds and Fertilisers Regulation Bill 2022.

62. Fertiliser Registers and sales data

7A. Fertiliser Economic Operators Register

- 1) An exact definition of a *fertiliser product* must be provided in the Bill.
- 2) A definition of fertiliser product manufacturing must also be provided
- 3) IFA firmly believe that it is unfair and unreasonable to consider farmers who source or pay for fertiliser in Northern Ireland or the United Kingdom as fertiliser importers and therefore liable for inclusion or categorisation under both the *Fertiliser Economic Operators Register* and the *Professional Fertiliser End Users Register*. There must be flexibility and ease of use in the database for fertiliser economic operators in Northern Ireland to sell and transfer fertiliser products to professional users in the ROI. Farmers who choose to purchase fertiliser from suppliers in Northern Ireland must not be unfairly disadvantaged for doing so.
- 4) Throughout the Bill there are references to fines and sanctions, in the event fertiliser economic operators fail to meet their obligations in the Bill, farmers cannot be held accountable.

7D. National Fertiliser Database

(6) & (11) Returns of details of fertiliser products held on a premises. The submission of fertiliser product details and quantities owned or held on a premises by end users at regular intervals of time or even in real time has potential to be onerous and overly demanding for farmers. IFA has concerns over the ability of older and less technologically literate farmers to comply with these requirements. To this extent, many farmers now employ agents and consultants for any submissions that require online completion on agfood.ie and IFA believe this trend would likely extend to the national fertiliser database. This will increase administrative costs for farmers with no direct economic return. Taking this into account, IFA believe the submission of fertiliser information or statistical returns should be kept to a minimum and take place within the closed spreading period and away from the major farm payment scheme deadlines.

(8) Further clarifications are needed on what additional details could be required for submission to the database by professional fertiliser end users.

7E. Processing of Information

- (1) The use of the information compiled under a national fertiliser database to inform policy and control programmes and to reduce inorganic fertiliser usage is clearly stated. IFA is concerned that 2023 would be used as a baseline or reference year to inform this decision making. Given the unprecedented increase in fertiliser prices in 2022 and widespread predictions for more

restricted fertiliser availability and demand in 2023, IFA believe this must be considered by the Minister and his officials.

- (4) Clarification must be provided on which third parties anonymised data from the National Fertiliser Database could be shared with.

7F. Service of Notice and Notifications

Should an inspection of a premises be required, sufficient notice must be provided by officials and entry must be strictly by arrangement only.

ENDS.