



**Written Submission by Macra na Feirme President John
Keane to the Joint Oireachtas Committee on Agriculture,
Food and the Marine
7th October 2022**

Chairman and Committee Members,

On behalf of Macra na Feirme I would like to thank you for the opportunity to provide a written submission on the topic of Veterinary Medicinal Products Medicated Feed and Fertilisers Regulation Bill 2022. We also look forward to future engagements with the committee on the topic and welcome any opportunity to provide written submissions and physical evidence at a committee meeting. The overarching ambition is set out in the aim of the EU Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6. The Regulation followed the adoption of a proposal in 2014 to develop a fit-for-purpose veterinary legislation which would no longer be based on the equivalent human medicines authorisation system.

As set out by the EU the ambitions and core objectives of the regulation is to:

- Harmonise the internal EU market for veterinary medicinal products
- Reduce the administrative burden on companies and regulatory authorities
- Enhance the availability of veterinary medicinal products
- Stimulate innovation of new and existing medicines
- Strengthen the EU response to fight antimicrobial resistance

Harmonisation with EU Regulation

Macra has some initial observations regarding the current bill and its effectiveness in ensuring that the ambitions of the EU regulation are achieved. With regards to the harmonisation of the Internal EU market for veterinary medicinal products, how does the Bill propose to share the data that is contained within the National Database to meet this objective. The Bill makes provision for sharing data for the purposes of Audit, Food Safety, Veterinary regulation, fit for practice hearings but does not mention how the data on the National Database will be used to effect the market. This in turn asks the question regarding sharing the data with market actors, such as wholesalers and manufacturers. Without clear guidelines for provision for control and access what is the procedure for harmonising the internal market?

Data Analysis

The Bill also refers to using the data for the purposes of Bord Bia quality assurance inspections. Clarity is needed regarding this aspect of the regulation. Farmers who voluntarily sign up and partake in the Bord Bia quality assurance schemes are now going to be faced with cross checks to the Bill. The natural next question is what penalties are proposed under the Bill for those found in breach of the Bord Bia quality assurance scheme? The next question is will this undermine the confidence that farmers have in the Bord Bia quality assurance schemes? Comparisons can be made with the ASSAP programme and Nitrates Inspections. There is an agreement that data is not passed from one to the other so as to ensure the buy in of farmers in the ASSAP programme. Macra fears that this backdoor examination and enforcement will undermine confidence in the Bord Bia quality assurance schemes.

Regarding the data being shared with The Veterinary Council Of Ireland for fit for practice hearings, what are the specific data sets that are envisaged will be required in such a hearing? Macra also has questions regarding sharing data with such other persons specified by the Minister in regulations. To comply with this part and end user obligations under the VMP Regulation and the Medicated Feed Regulation and having regard to the need to adequately safeguard public and animal health and the environment. The issue is in relation to the last element, adequately safeguard the environment. Is there a risk that many interest groups claiming to be proponents of good environmental practices could gain access to the data? There is an obvious concern here from farmers that their data could become publicly available and used against them.

The second aim of the EU regulation is to reduce the administrative burden on companies and regulatory authorities. It fails to mention the veterinary practitioners and the farmers who will be directly affected by many of the proposals contained within the Bill. For example the of the National Database, uploading of information, additional training for staff in veterinary practices, more frequent prescriptions along with many other additional process will only add to the administrative burden that vets and farmers face. What supports have the Department of Agriculture planned to put in place to facilitate this transition and additional workload on vets and farmers?

Antimicrobial Resistance

Macra support the reduction of antimicrobial resistance across the EU and in Ireland. All efforts must be made to ensure that our strongest and most effective medicines remain as effective in humans. However there must be a conscious effort to monitor the affect of reducing the supply of certain products to vets. Some severe clinical cases will still require strong medication to ensure survival. It cannot become the norm that critical medicines become unavailable to vets with the result being higher mortality rates on farm. All efforts must be made to ensure preventative practices and products are supported across farms to ensure animal health and welfare along with the health and wellbeing of the farmer. A severe health breakdown on farm can often have a devastating impact on the health and wellbeing of the farmer and in many cases these health issues are directly correlated.

Data Sharing with ICBF

Macra also raises the question as to why the data collected would not be shared with the National Cattle Breeding Federation? Given the focus on improving the reliability of data sets around the health sub-index, maintenance sub-index and fertility sub-index in our breeding indexes it makes logical sense that the body charged with gathering, accessing, evaluating and developing the national breeding indexes would have access to the data. It would give greater reliability of figures to farmers and create greater confidence in the figures produced. It would also link together the desire of farmers to improve profitability on farm and the impact that genetics can have on individual animal health along with herd performance. Macra would request that this issue be addressed and evaluated.

Market Competition

Macra also has reservation regarding the impact that the Bill may have on competition in the market. The potential result of the Bill may be that the numbers of suppliers in the market of medicinal products for animals becomes reduced. This will obviously have an effect on availability of products in certain areas and regions but will also have a larger impact on all farmers in relation to the price point of products should competition in the market become reduced. Given the requirements laid out in the Bill in relation to premises, advertisement, prescriptions and training this additional burden may become too much for smaller retailers and vets. It may well be the case that many smaller retailers leave the market.

Impact on Vets

There is also the national of distribution of vets to issues prescriptions and the likelihood of retailers servicing prescriptions they have not issued or indeed retailers/vets on servicing prescriptions that they themselves have issued. This will also result in a smaller market and limited options for farmers. A second challenge that vets have highlighted to Macra is around the time that meeting the requirements of the Bill will take. Having to administer prescriptions for an additional number of

medicinal products will add an extra time burden on an already overworked practitioner. There is also the question around the need for an on farm visit or knowledge of the farm and its health status. The likelihood that a vet unknown to the farm or farmer issuing a prescription for a medicinal product is slim. This may be the case should a farmers normal vet be unavailable or be too busy to get to satisfy the needs of all their clients. There is a need for detailed support and continuous engagement with veterinary practitioners around the impact the Bill will have on their workload. It cannot be the case that vets become so busy with paperwork and form filling that they are restricted in the number of farm call outs they can manage.

Labelling

Within the EU Regulation there is specific mention to a simplified labelling system for veterinary medicinal products. How does this Bill hope to achieve this given the list contained within it regarding the information that a product label must contain? The list is:

- (a) supplier information,
- (b) prescription identification information,
- (c) details of the prescribing veterinary practitioner,
- (d) the date of retail,
- (e) the dosage and duration of treatment (unless indicated on a proprietary label),
- (f) withdrawal period (unless indicated on a proprietary label),
- (g) special import licence information, if applicable, and
- (h) and any other information specified in regulations made by the Minister necessary to safeguard public and animal health and the environment.

The regulation at EU level refers to simplified systems with species specific icons etc on the label which it is envisaged would reduce the detail on the labels. Macra would like to see further consideration as to how the labelling of the products can be streamlined.

Fertilizer Register

As set out by the EU the three broad principles of the element of the Bill that covers fertiliser are:

- Establishment of National Fertiliser Database
- Fertiliser Economic Operators ie. merchant, retailer, importer, etc
- Professional Fertiliser End User ie. farmer

Sale of fertilizer using an identifier number

Under the Bill merchants and retailers can only sell fertilizer to professional end user who are identified by an identifier such as a herd number. Macra poses the question how will the Fertilizer Register apply to those with no herd number or not involved in farming eg GAA clubs, golf courses etc.

Minimum threshold

In the case of very small scale users of fertilizer will they be required to complete the register or will a minimum threshold below which there is no requirement to report be introduced.

Records

As proposed for the fertilizer register the date on which the fertiliser is despatched is when it's recorded on the register. The supply chain for fertilizer is quite perilous at the moment. Challenges present for farmers around the availability of P and K fertilizers. This could result in farmers not having products they need to meet requirements for Nitrates. The question is how will the register facilitate farmers in such a scenario.

Imports from Northern Ireland

All fertiliser coming into the state will have to be recorded. Fertiliser coming from NI will be recorded as import. However the register will not be applied to merchants and retails in Northern Ireland. Many questions remain regarding how importing fertilizer from Northern Ireland will be addressed.