Opening Statement,
Department of Agriculture, Food and the Marine (DAFM),
09.02.21

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

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RE: Opening Statement to Joint Committee on Agriculture, Food and the Marine

I would like thank the Chairman, Deputies and Senators for inviting the Department to appear before them today. I am joined today by Colm Forde, Head of Division with responsibility for the Veterinary Practice Act and Superintending Veterinary Inspector Caroline Garvan, and both of whom are engaged in the policy and proposed implementation of the Veterinary Medicines Regulations 2019/6. We welcome the opportunity to appear before the Joint Oireachtas Committee on Agriculture, Food and the Marine to contribute to the discussions the Committee has been having related to the new EU Veterinary Medicines Regulation 2019/6 which comes into force in January 2022.

Regulation 2019/6

Regulation 2019/6, legislates for the authorisation, use and monitoring of veterinary medicinal products (VMPs) in the European Union (EU). The legislation came into effect on 28 January 2019, and applies in all EU Member States (MSs) on 28 January 2022. The Regulation followed the adoption of a proposal in 2014 to develop fit-for-purpose veterinary legislation which would no longer be based on the equivalent human medicines authorisation system.

The overarching objectives of the Regulation are to:

- harmonise the internal EU market for veterinary medicinal products
- reduce the administrative burden on companies and regulatory authorities
- enhance availability of VMPs
- stimulate innovation of new and existing medicines; and
- strengthen the EU response to fight antimicrobial resistance.

In order to prepare for implementation of the new Regulations, the competent authorities in Ireland responsible for the regulation of veterinary medicine have been engaging extensively with stakeholders over the past two years. The Health Products Regulatory Authority (HPRA) have been liaising with Marketing Authorisation Holders who supply VMPs to Ireland in relation to changed requirements; DAFM has been engaging with wholesalers, prescribers, retailers and end-users; while the Veterinary Council of Ireland is actively meeting with stakeholders as they develop prescribing guidance for registered persons.

The Regulation is 125 pages in length and contains 160 articles. This highlights why it has been so important for the competent authorities to work collectively with stakeholders in addressing the challenges represented by the Regulation.

In the first half of 2020, DAFM completed a public consultation related to the Regulation. While many issues were highlighted in the responses, the clear area of most concern is related

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to the future requirements associated with the prescribing, dispensing and use of antiparasitic veterinary medicines (AVMPs). AVMPs include products commonly referred to as dosing products or wormers as well as topical products such as sheep dips and pour-ons.

EU and domestic legislative position of AVMPs

European legislation currently in force for Veterinary Medicines is Directive 2001/82/EC which is transposed through S.I. No. 786/2007 - European Communities (Animal Remedies) (No. 2) Regulations 2007. By default, existing legislation, provides that all VMPs for food-producing animals require a veterinary prescription before they can be supplied. However, there are certain exceptions where the VMP can be supplied without a veterinary prescription. Availing of this derogation, Ireland has permitted the supply of AVMPs without a veterinary prescription for many years. These have been commonly supplied by Responsible Persons employed in Licenced Merchants around Ireland. AVMPs are also available from other stakeholders such as veterinary practitioners and pharmacists.

In negotiating the 2019 Regulation, DAFM officials were satisfied that essentially the same criteria which allowed AVMPs to be supplied without a veterinary prescription was carried across into Regulation 2019/6.

Therefore, there has largely been no change in EU legislation as it applies to the supply of AVMPs.

Role of HPRA

Part of the HPRA's remit in Ireland is to ensure VMPs are as safe as possible and do what they are supposed to do. Clearly, this objective is in the interest of all stakeholders in the agrifood sector.

Following the completion of the negotiation process for Regulation 2019/6, the HPRA established an Expert Task Force to determine whether AVMPs continued to meet the criteria in EU law which allowed them to be supplied without a veterinary prescription. Their findings concluded that AVMPs no longer meet these criteria and therefore from January 2022 can only be supplied on foot of a veterinary prescription. The Task Force found evidence of the development of resistance to AVMPs, and also evidence of environmental damage associated with their use.

The threat of resistance to AVMPs, particularly for livestock, in Ireland is of major concern. APR is recognised as a threat to global food security. It is not in the interests of farmers, vets, VMP retailers or manufacturers if the efficacy of these important products is compromised. Failure to manage parasitic disease will result in greater animal losses, poor welfare, reduced profits and reduced farm sustainability. There is no pipeline of new products in development which can replace our existing stock of AVMPs. That is why we must endeavour to protect them.

Stakeholder concerns

The imminent upregulation of AVMPs has caused considerable concern and this is understandable. This Department is fully aware of the potential impact of these changes on stakeholders and the rural economy. In recognition of this, DAFM established an Antiparasitic Resistance Stakeholder Group last year. It is attended by farming organisations, Licensed Merchants, ICOS, Veterinary Ireland, the HPRA, VCI, Teagasc and others.

This Group is working through an action plan with over 30 actions aligned with 6 overarching objectives. The objectives are to:

1. Improve knowledge and awareness of APR
2. Enhance Surveillance of antiparasitic resistance and antiparasitic usage
3. Reduce the spread of infection and disease
4. Optimise the use of antiparasitics in human and animal health
5. Promote research and sustainable investment in new medicines, diagnostic tools, vaccines and other interventions; and
6. Facilitate an efficient, competitive supply chain through effective regulation and innovation

DAFM understands at present that Licensed Merchants and pharmacists account for a significant portion of the sales market for AVMPs in Ireland. There is a concern that these stakeholders may lose market share when AVMPs require a veterinary prescription before they can be supplied. DAFM is working with all stakeholders under Objective 6 of the APR Action Plan to provide for a competitive environment that supports all suppliers of these products. This includes the development of a secure national electronic prescribing system where all farmers, prescribers and retailers will have online access to veterinary prescriptions. Such a system will promote greater choice for the farmer with regard to the supply of these products once they have become prescription only medicines. DAFM has commenced work on this with a team of business analysts, policy officials and IT developers.

Legal queries

At the Department's last appearance in front of the Committee in late 2020 on veterinary medicines, the focus was on the interpretation of Article 105(4) of the Regulation. This Article allows veterinary prescriptions to be issued by someone other than a veterinary practitioner if a Member States' national legislation provided for that when the Regulation came into force in January 2019. The Chief Veterinary Officer wrote to the Commission seeking clarity on this point in 2020. His correspondence with the Commission is entirely consistent with a parliamentary question raised by Mr Chris McGuinness MEP at the European Parliament in early November 2020.

As noted earlier, the existing legislation in Ireland related to veterinary medicines is Statutory Instrument 786/2007 until it is repealed next January. It defines a veterinary prescription to mean a written prescription issued by a ***registered veterinary practitioner*** in respect of an animal under his or her care that provides for the administration of an animal remedy to the animal. Therefore, DAFM's clear interpretation of Article 105(4) is that Ireland is not in a position to avail of this derogation to allow people other than registered veterinary practitioners to issue veterinary prescriptions. This view has been informed through consideration by policy officials, consultation with the EU Commission and with internal legal advisors.

However, given the range of views on Article 105(4), DAFM committed to seeking definitive legal advice from the Attorney General's Office (AGO) which was submitted in late 2020. In advance of the committee hearing today, DAFM officials did seek if these advices from the AGO could be expedited but understand due to significant resource pressures this was not possible.

Conclusion

I want to assure the Committee that DAFM officials will continue to engage with all stakeholders at length as we develop the policy solutions that meet the requirements of Regulation 2019/6 in the broader interest of stakeholders in the agrifood sector. As a country, we have a proud record of promoting animal health and welfare which allows us to trade successfully across the world. Ensuring we have access to an appropriate supply of veterinary medicines that are as safe as possible and do what they are supposed to do is central to that.

I would like to thank the Chair and the Committee for the invitation to speak today and my officials and I are happy to address and questions the committee may have on the topic.