



6 October 2021

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

I would like to thank the Chairman, Deputies and Senators for inviting the Department here today. I am joined today by Director Rob Doyle and Peter Collins Assistant Principal Officer both of whom are engaged in the policy and proposed implementation of the Veterinary Medicinal Products (VMP) Regulations 2019/6. We welcome the opportunity to appear before the Joint Oireachtas Committee on Agriculture, Food and the Marine to provide updates and contribute to Committee discussions related to the new EU Veterinary Medicinal Products Regulation 2019/6 which will come into force in January 2022.

The Department is conscious that the legislation is complex, and that regulation of veterinary medicinal products is itself complex. It is important to recall that the main objectives of these new Regulations are to free up availability of veterinary medicines across the EU, whilst also introducing some additional control to address the clear evidence of the sustained escalating resistance to certain veterinary medicinal products. Highlighting the additional controls which Ireland is implementing to address this global concern only helps to provide greater international market confidence in Ireland's ability to produce the safest highest quality export from our agri-sector. As you will know, Ireland exported some €14.2 billion worth of agri-food in 2020 with dairy produce at €5.1 billion and beef at €2.3 billion. Irish agri-food sector makes a significant contribution to employment, accounting for 7.1% of total employment – or 163,600 jobs – in rural and coastal areas. Meeting the higher level of controls in the EU Vet Med Regs will be pivotal in Ireland's ability to maintain these agri-business employment and food export figures.

In ensuring that all concerns, associated with the various elements and processes required or introduced under the new Regulations, have the opportunity to be considered, the Department has undertaken extensive stakeholder engagements since 2019 – these are ongoing. We have met regularly with the multiple representative bodies in the sector



representing farmers, licensed merchants, pharmacists, veterinarians, co-ops, dairies, wholesalers, feed mills, educational groups and software companies. We have listened to their concerns, researched suggestions they have made as to possible options and included their suggestions in our planning for the implementation of Regulation 2019/6 wherever possible. Some suggestions however were not legally feasible. We have also established regular contact and information sharing links between Department officials on both sides of the border.

The Department is therefore working

- On enabling the continuation of all retail outlets, (and associated jobs) available to farmers, thus supporting competition in the marketplace and jobs in rural areas,
- On ensuring that farmers have control over where they purchase anti-parasitics as heretofore, notwithstanding they will be prescription only products,
- With stakeholders on a range of activities to reduce and reverse, wherever possible, the increased resistance patterns in both antibiotics and anti-parasitics for the benefit of farmers and society,
- With the Health Product Regulatory Authority (HPRA) to maximise the availability of veterinary medicinal products on the Irish market
- With the Veterinary Council of Ireland (VCI) to ensure alignment between our respective regulatory functions in the context of these new regulations.

Department officials have been before this Committee on this matter on two previous occasions and I do not wish to repeat much of what you have already considered, in this opening statement. However, the Department welcomes the Committee's recent comprehensive Report on the matter and we appreciate the opportunity today to discuss the recommendations, observations and findings of the Report along with the chance to provide updates outlining the progress made in the intervening period on related matters pertaining to Veterinary Medicine Regulation in Ireland.

The Committee's report highlighted the importance of the role that Licensed Merchants and Veterinary Pharmacists play in particular in rural Ireland and recommended that this continues. The Department wholeheartedly supports this view and wishes to assure Members



that all existing retailers of veterinary medicines (including Licensed Merchants and Veterinary Pharmacists) will continue to be legally permitted to sell antiparasitic medicines, as well as other veterinary medicinal products, as they have done heretofore. It is the Department's view that responsible persons employed in Licensed Merchants, veterinary pharmacists and veterinary practitioners will all continue to play an important advisory role in supplying veterinary medicines to farmers thereby safeguarding animal health and welfare and supporting jobs in the agri-sector.

When Department officials last appeared before the Committee in February, legal advices were awaited from the Office of the Attorney General (AGO) on the issue of the availability of the derogation in article 105(4) of the EU Regulation. Those comprehensive advices were subsequently received within the Department on April 12th and the outcome was subsequently shared with this Committee and the Antiparasitic Resistance Stakeholder Group. This confirmed that the derogation provided for in Article 105(4) is not available to Ireland – this means that only registered veterinary practitioners may issue a veterinary prescription in Ireland.

Veterinary practitioners have a key role to play in seeking to mitigate the problem of resistance to both antibiotics and anti-parasitics. In that context, the Veterinary Council of Ireland (VCI), is the independent statutory body that regulates the practice of veterinary medicine and veterinary nursing in Ireland. The VCI is currently reviewing its Professional Codes of Conduct. These are the rules that veterinary practitioners and nurses must comply with in order to practice veterinary medicine and veterinary nursing in the State. The objective of the Codes is to ensure a consistent ethical and professional provision of veterinary service in the public interest.

This updated VCI draft code, which takes into account various elements and objectives of these Veterinary Medicines Regulations, is currently open for public consultation. In the draft Code, it is set out that in order for a Veterinary Practitioner to prescribe veterinary medicines (including anti-parasitics) they must have established a relationship with a client/farmer. This is defined as an agreement between an animal owner (or designated keeper) and a veterinary



practitioner(s) within a veterinary practice to provide veterinary services that demonstrate real and ongoing clinical veterinary practitioner/animal contact at the owner's farm premises. This is designed to ensure that the best prescription choices are made in respect of the animals to be treated – for the benefit of the animal, its owner and indeed wider society, mitigating the risk of the continued development of resistance to antibiotics and anti-parasitics. The draft Code recognises that farmers may choose to have, and often do have, such working relationships with more than 1 veterinary practitioner.

As highlighted by the Committee, greater access and choice of VMPs for farmers, along with maintaining fair competition of products is hugely important to ensuring retention of competitive veterinary medicine supply channels such as Licensed Merchants and Pharmacies. The Department's objective is to place the farmer at the centre of decision-making as to where he or she purchases anti-parasitics and indeed other relevant VMPs through the introduction of a National Veterinary Prescription System (NVPS) which is currently being developed. Without going into the technical details, essentially veterinary practitioners will electronically issue a prescription for animals under their care to a centralised Department system. Prescription details will then be made available to farmers by email or text. The farmer can then produce the Prescription ID details contained in the email or text directly to the dispenser of their choice, Licensed Merchants, Pharmacist or Co-OP, or indeed from the prescribing vet if they so choose. This will allow greater access and management of prescriptions as required. The introduction of the system provides the farmer with greater control of where they choose to purchase their medicines from.

All dispensers registered for the NVPS will have equal access to dispensing antiparasitics. As per recommendations of this Committee the system is currently being developed to allow for alternative or generic products, based on the active substances detailed on the prescription, to be dispensed as an alternative to a named product, as necessary. This is a welcome suggestion by the Committee and one we are happy to be able to deliver on for the benefit of Irish farmers and retail suppliers alike. This will likely reduce costs to farmers and provide more choice and opportunities to retailers in the area.



While acknowledging the increased global risk of resistance to antimicrobial and anti-parasitic VMPs, the Department is acutely aware of the economic burden of parasites on Irish agriculture in general. A recent scientific paper suggested that this burden could be in the region of up to €237million per annum. In order to support the farmers and agribusinesses potentially impacted by these factors the Department has in the past and continues now to provide and develop support schemes such as the Sheep Welfare scheme and BEEP scheme, which include faecal egg counting for some of those parasites. The Department is currently working to develop a further anti-parasitic measure to be introduced under the Targeted Advisory Service on Animal Health (TASAH) scheme to assist farmers.

In growing the awareness of the issues surrounding resistances, the work of Ireland's National Action Plan (iNAP) on antimicrobial resistance stakeholder group and the Antiparasitic Resistance Stakeholder Group are both informed by extensive work plans. Each plan consists of a range of measures which aim to educate all actors in the production chain on addressing both antimicrobial resistance and anti-parasitic resistance. Appropriate strategies will be implemented to deal with each kind of resistance. The iNAP group only recently met whilst the Antiparasitic Resistance Group will meet again in the near future. Between meetings, work continues in following through on the extensive action lists.

In addressing the recommendation in the Committee Report on the issue that is known as decoupling, which is breaking the link between the prescriber and dispenser, the Department sought legal advice on the issue. The advice received was that for such decoupling to be permissible, a sound evidential basis in veterinary medicine is required to justify any partial or full prohibition on veterinarians selling the veterinary medicines that they prescribe. Such decoupling could not be solely for the purpose of economically assisting one sector of an industry over another. This would be seen as providing State Aid to one sector over another. The Department's view is that there is an absence of such sound veterinary medicine evidential basis and therefore decoupling is not an option legally available to us. This aspect was also considered by the EU Parliament during negotiations on the Regulations and it concluded, similar to the Department, that there is no substantive evidence which shows a correlation between decoupling and improved animal/human health or a reduction in



resistance development. DAFM shared the outcome of these advices with members of the Antiparasitic Resistance Stakeholder Group in advance of its meeting on April 15<sup>th</sup>

Before I conclude, the Department noted that the Committee also raised concerns about access to veterinary practitioners - we also note more recent commentary on this matter. Whilst this concern is not directly linked to the introduction of the new EU 2019/6 Veterinary Medicinal Product (VMP) Regulations, the matter was addressed as an action arising under the National Farmed Animal Health Strategy. The Department carried out research and analysis into the distribution and accessibility to farmers of large-animal veterinary services in rural Ireland. The outcome of this analysis was relatively positive, in that it identified that large-animal veterinary services are available within 20km to over 95% of Irish livestock farms. Whilst the provision of veterinary services to members of the public in Ireland is a private sector activity, nonetheless the Department will, from a public policy perspective continue to monitor this position closely, recognising that it is critical that Irish farmers are adequately supported with the provision of veterinary services in the best interests of animal health and welfare.

### **Conclusion**

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