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Meitheamh 2021

Joint Committee on Agriculture, Food and the Marine

Proposed Regulation of Veterinary Medicines in Ireland

June 2021

33/AM/004

Membership

The following Deputies and Senators are members of the Joint Committee on Agriculture, Food and the Marine of the 33rd Dáil Éireann and the 26th Seanad Éireann.

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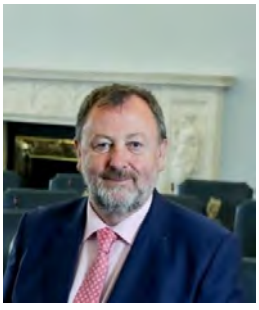

Sen. Denis O'Donovan
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Foreword

On 28 January 2022, a new regulation in relation to veterinary medicines will be enacted. Regulation EU 2019/6 legislates for the authorisation, use and monitoring of veterinary medicinal products (VMPs) in the European Union (EU). This Regulation has a significant impact on stakeholders of the animal healthcare industry. The Committee recognises the role of Veterinary Practitioners, Veterinary Pharmacists and Licensed Merchants in the provision of advice and animal healthcare products.

As Cathaoirleach of the Committee, I would like to Members for their input and their commitment in bringing forward this important Report. On behalf of the Committee, I would like to express my sincere gratitude to every stakeholder that came before the Committee to give evidence in person or remotely, especially under the current circumstances. These discussions with stakeholders were critical to the development of this Report. From the series of Committee meetings, the shared commitment of all stakeholders in providing excellent services and looking after the health of animals is commendable.

Jackie Cahill

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Jackie Cahill T.D.
Cathaoirleach
June 2021

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Introduction

The Joint Committee of Agriculture, Food and the Marine ('the Committee') held a series of meetings in relation to the regulation of veterinary medicines, including EU Regulation on Veterinary Medicinal Products EU 2019/6 ('the Regulation').

The Regulation legislates for the authorisation, use and monitoring of veterinary medicinal products (VMPs) in the European Union (EU). It came into effect on 28 January 2019 and applies in all EU Member States on 28 January 2022. The Regulation follows 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.

Context in Ireland

EU Directive 2001/82/EC which is transposed through S.I. No. 786/2007 is the legislation that is in force for veterinary medicines. This provides that all veterinary medicines products (VMPs) for food-producing animals require a veterinary prescription before they can be supplied, however, there are certain exceptions where the VMPs can be supplied without a veterinary prescription. Ireland at the time availed of an available derogation and permitted the supply of antiparasitic veterinary medicine products (AVMPs) without a veterinary prescription. As well as veterinary practitioners, AVMPs have been commonly supplied by Responsible Persons employed in Licenced Merchants and veterinary pharmacists around Ireland.

Under SI No. 786/2007, a person responsible for the retail sale or supply of animal remedies, and who is not a vet, a pharmacist or a registered nurse, must undergo

adequate training in the proper and safe handling and storage of animal remedies. A Responsible Person (RP) has obtained a QQI Level 6 qualification which has been approved and accredited by Department of Agriculture, Food and the Marine (DAFM) as being appropriate for the supply of VMPs. At the time of negotiating the Regulation (2019/6) DAFM was satisfied that the same criteria which allowed AVMPs to be supplied without a veterinary prescription was carried across into Regulation 2019/6.

In 2019, the Health Products Regulatory Authority (HPRA) adopted a Report on compliance of antiparasitic veterinary medicines with the criteria in the new regulation. This Report states that 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. It also states that a consequence of this determination is that any such products that are supplied without veterinary prescription will need to be upregulated to supply under veterinary prescription. In accordance with existing national legislation, antiparasitic veterinary medicinal products for use in food-producing species that are supplied under prescription may be dispensed by veterinary practitioners, pharmacists and licensed merchants. This means that all current providers that already supply such products will be entitled to stock them in the future, however, from 28 January 2022 onwards a veterinary prescription will be needed to dispense them. This means that AVMPs which had been previously labelled as licensed merchant products (LM) will now be labelled as Prescription-only medicines (POM).

Given the significance of this change the Committee agreed to prioritise this issue and hold a series of meetings to examine the challenges facing stakeholders and the changes it will bring to the Agriculture Sector.

Stakeholders

The Joint Committee on Agriculture, Food and the Marine held four days of hearings between November 2020 and April 2021 and engaged with relevant stakeholders to

discuss the Veterinary Medicines Regulation which will commence in January 2022. Table 1 below provides details on these meetings with stakeholders.

Table 1 - Joint Committee Hearings - Stakeholders / Witnesses

12 November 2020	
Irish Pharmacy Union (IPU)	Mr Daragh Quinn Mr D.J. Barry
Independent Licensed Merchants Association (ILMA)	Mr Terence O'Shea Mr Ian Scott
Department of Agriculture, Food and the Marine (DAFM)	Mr Colm Forde: Head of ERAD & Veterinary Medicines Division Mr Rob Doyle: Senior Superintendent Veterinary Inspector Ms Caroline Garvan: Veterinary Inspector

9 February 2021	
Irish Co-operative Organisation Society (ICOS)	Mr T.J. Flanagan: CEO Mr John O'Gorman, Chairman of the Dairy Committee Mr Ray Doyle, Livestock Executive
Department of Agriculture, Food and the Marine (DAFM)	Mr Colm Forde: Head of ERAD & Veterinary Medicines Division Dr Paula Barry Walsh: Deputy Chief Veterinary Officer Ms Caroline Garvan: Veterinary Inspector

23 March 2021	
UCD School of Veterinary Medicine	Professor Simon More Dr Catherine McAloon Ms Finola McCoy: Animal Health Ireland
Veterinary Ireland	Mr Conor Geraghty: President Mr Finbarr Murphy: Chief Executive Mr Tadhg Gavin: Food Animal Chair

27 April 2021	
Health Products Regulatory Authority (HPRA)	Dr J. Gabriel Beechinor: Director of Veterinary Sciences Dr David Murphy: Manager, Committee for Medicinal Products for Veterinary Use
Veterinary Council of Ireland (VCI)	Ms Niamh Muldoon: Registrar and CEO Mr Joe Moffitt: President Dr Ailis Ní Riain: Deputy President

Transcripts

The transcripts of the meetings of 12 November 2020, 9 February 2021, 23 March 2021 and 27 April 2021 are available online.

Presentation and Submission

The presentations and submissions made to the Committee for the meetings of 12 November 2020, 9 February 2021, 23 March 2021 and 27 April 2021 are available online. The Committee received supplementary evidence from the ILMA and DAFM after their presentations to the Committee.

Findings

The following presents the position of each stakeholder that attended a Committee meeting on this topic.

Irish Pharmacy Union (IPU)

The Irish Pharmacy Union (IPU) appeared before the Committee on 12 November 2020. There are over 300 veterinary pharmacists' premises in Ireland.

Role:

Current process for IPU members in administrating veterinary medicines prescriptions (VMPs):

- All VMPs are supplied with appropriate advice from the pharmacist regarding administration to the animal, safety for the user, withdrawal periods, environmental concerns, disposal of surplus product and containers.
- A written or printed document is provided with each transaction.
- Pharmacists maintain a computerised Client Medication Records and scanning system to create databases of the various VMPs used by animal owners for both companion and commercial animals. This allows them to record the use of anthelmintics, flukicides, coccidiostats, ectoparasiticides, vaccines and nutraceutical VMPs obtained by the animal owner. This information is utilised to create a healthcare programme for the animals concerned for parasite control.

According to IPU, the benefits of this process include:

- reduction of inappropriate and unnecessary treatments; and
- improved safety for the user, animal, the consumer and the environment.

Position on the Regulation:

- **Prescription Only Medicine (POM)** – According to IPU, this has effectively excluded Veterinary Pharmacists from their dispensing function. It is claimed that it is not economically viable for some marginal rural pharmacies to

continue to practice Veterinary Pharmacy and the numbers involved in VMP provision have decreased substantially already throughout the country.

- **Absence of competition** – IPU is concerned that supply of antiparasitic VMPs will result in price inflation to the farmer if a monopoly is permitted to develop under the new regulations. This will add further cost burden to Irish farmers reducing the viability of industry.
- **Responsible Persons (RP)** - They provide a similar service to Veterinary Pharmacists. RPs obtain a professional QQI Level 6 qualification which has been approved and accredited by DAFM as being appropriate for the supply of VMPs and associated advice to the purchaser.
- **Loss of jobs** – Employment opportunities can be limited in rural Ireland, and this will impact rural merchants, pharmacies, co-ops and the farming community. According to IPU, if this regulation is applied as proposed it could cause the loss of jobs in this sector.
- **Cross border –** IPU has raised the concern that when the regulation is enacted in January 2022 the trade in VMPs cross border will increase with no accountability and no transparency. This could undermine the quality assurance associated with Irish food products.

Solution:

IPU recommends that the Minister of Agriculture, Food and the Marine authorises Pharmacists & Suitably Qualified Responsible Persons including Agriculture Merchants & Co-ops to issue prescriptions for anti-parasitic VMPs.

Independent Licensed Merchants Association (ILMA)

The Independent Licensed Merchants Association (ILMA) appeared before the Committee on 12 November 2020. There are over 900 Licensed Merchants premises in Ireland.

Role:

ILMA members who are qualified Responsible Persons (RPs) currently follow a comprehensive prescribing protocol in dispensing veterinary medicines prescriptions (VMPs). This process includes discussion and advice in relation to age, type, breed and weight of animals, suitable product, knowledge of local situations, administration, dosing, withdrawal period, interpretation of laboratory tests, labelling, storage etc. The ILMA highlighted that RPs obtain a professional qualification (QQI level 6) and argued that by virtue of their previous role of administrating antiparasitic medicines they should be considered as suitably qualified to administrate under this new regime.

Position on the Regulation:

- **Article 105** – This Article states that all medicines for food producing animals including horses are subject to a veterinary prescription. Article 105(4) was included to allow professional persons other than vets who up to now have empowered to issue veterinary prescriptions. ILMA criticised DAFM for not adopting the specially written derogation in Article 105(4).
- **S.I. No. 786/2007** – At the time of entry of this SI it enables a RP the option to dispense antiparasitic veterinary medicine products (AVMP) without a veterinary prescription. A Licenced Merchant is a retail premises licenced by DAFM to retail veterinary medicinal products and is subject to regulation, inspection and control by DAFM.
- **Responsible Person (RP)** – This is a professional Level 6 QQI qualification and taking this exam costs the individual €995. This qualification is recognised and approved by DAFM and establishes the RP as a professional.
- **Absence of competition** – By visiting the vet premises the vet has an immediate, and in the ILMA's opinion, unfair advantage to prescribe and dispense the medicine in a one stop shop scenario. According to ILMA, this will inevitably result in sales of these products being largely undertaken by vets. There are identical generic LM medicines licensed but a vet's prescription has to specify a branded medicine and vets could prescribe brands only available from themselves. The consequence of this change of route of supply would be to remove the currently competitive environment for

the supply of these products and open the door for a pricing monopoly that could damage livestock and equine industries.

Solution:

ILMA's recommended solutions to enable DAFM to avail of Article 105(4) in the regulation:

- **Regulatory body -** Form a regulatory body for RPs with a Code of Practice that would enshrine their prescribing process to ensure responsible use, address environmental matters and ensure the long-term viability of the limited pool of active ingredients available. Areas such as responsible use, environmental protection, supervision at point of sale dispensing, continuous professional development, compulsory advice on Antiparasitic Resistance (APR) and include a disciplinary process.
- **Prescription classification** – ILMA proposes that DAFM to form a specific prescription classification just for LM medicines separate to a full veterinary prescription.

Department of Agriculture, Food and the Marine (DAFM)

Officials from the Department of Agriculture, Food and the Marine appeared before the Committee on this matter on two occasions, 12 November 2020 and 9 February 2021.

Role:

DAFM informed the Committee that it has been important to work collectively with stakeholders in addressing the challenges represented by the Regulation. DAFM held a public consultation related to the regulation in 2020.

Position on the Regulation:

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.

- **Legal Advice** - 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. At the meeting of 9 February 2021, DAFM stated that they did seek if these advices from the AGO could be expedited but understand due to significant resource pressures this was not possible.

Position on Antiparasitic Veterinary Medicines (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 antiparasitic veterinary medicine products (AVMP) 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.

- **Loss of competition** - At present Licensed Merchants and Veterinary Pharmacists account for a significant portion of the sales market for AVMPs in Ireland and there is a concern that these stakeholders may lose market share when AVMPs require a veterinary prescription before they can be supplied. DAFM stated that they are working with all stakeholders 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. According to DAFM, 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.

Irish Co-operative Organisation Society (ICOS)

The Irish Co-operative Organisation Society (ICOS) appeared before the Committee on 9 February 2021. ICOS member co-operatives and their associated companies collectively have over 150,000 individual members and employ over 12,000 people in Ireland.

Position on the Regulation:

ICOS highlighted their concern with HPRA's Report recommending the upregulating of antiparasitic medicines to Prescription Only Medicines (POMs),the future status of Co-op Mastitis Control Programmes and, connected with that, the transition from Blanket Dry Cow Therapy (BDCT) to Selective Dry Cow Therapy (SDCT).

- **BDCT transition to SDCT** - Article 107(3) of the Regulation states that "Antimicrobial medicinal products shall not be used for prophylaxis other than in exceptional cases". BDCT is considered to be an example of prophylaxis or preventative use. After January 2022, Irish milk suppliers will have to adopt SDCT and transition away from BDCT. SDCT involves administering just teat sealer to a selected proportion of suitable cows at drying off, with the rest receiving an antibiotic and a teat sealer. The transition to SDCT will take time, education and resources across the milk production supply chain with milk recording a key component to proper SDCT management.

- **Milk Quality Standards** – If the requirement to move from Blanket Dry Cow Therapy (BDCT) to Selective Dry Cow Therapy (SDCT) is rushed this could negatively impact the national milk quality standards.

- **Absence of competition** – ICOS is concerned that the Regulation could create a dramatic shift in the veterinary medicines supply chain, in favour of

Private Veterinary Practitioners (PVPs) to the detriment of Co-ops, Veterinary Pharmacists and Independent Licenced Merchants, and could narrow the distribution channel and reduce choice and in turn increase the costs of medicines.

- **Changing the route of supply** – ICOS claim this will undermine the sustainability of Co-op store networks, as a pillar of their offering will be weakened, and footfall will be diminished.

Solutions:

- Ensure the continuation of the existing LM network as a recognised route of supply, as expertly administered by trained Responsible Persons to ensure maximum and fair competition and availability for farmers, ICOS recommend that if an appropriate legal solution cannot be found, the option of breaking the link between the dispenser and prescriber needs to be actively considered by DAFM as an alternative but practical, fair and transparent solution to this issue. Other EU Member States such as Denmark, Sweden and Italy have implemented this option.
- Maintain and strengthen the holistic approach to herd health management as implemented by Co-ops through multi-disciplinary teams and veterinary oversight.
- Prescriptions to be available electronically on the AIM database or other national database. Prescriptions can be generated on the basis of data assisted decisions (milk recording, milk culturing & sensitivity testing, faecal egg count results, antibody detection tests) under the any other assessment method.
- Implement the transition from BDCT to SDCT, that will not result in a decline in milk quality standards, placing the Irish dairy industry at a competitive disadvantage compared to international milk processors. Recognise that the transition from BDCT to SDCT will result in a substantial investment at industry level to ensure compliance with the 2022 deadline.

UCD School of Veterinary Medicine & Animal Health Ireland

Professor Simon More and Dr Catherine McAloon from UCD School of Veterinary Medicine and Ms Finola McCoy from Animal Health Ireland appeared before the Committee on 23 March 2021.

Position on the Regulation:

- According to the witnesses, it is critical that implementation of the regulation in Ireland is in line both with scientific evidence and international best practice. There is a need for the highest standards in antibiotic stewardship in food animal production.
- **Antimicrobial resistance** - There is an urgent need to limit antibiotic resistance which is a problem that is primarily being driven by the volume and nature of antibiotics that are being used in people and animals. According to the witnesses, if we are not successful, we will face a future without effective antibiotics.
- **Antibiotic stewardship** – This refers to the efforts made to ensure that antibiotics are used only when necessary and appropriate. In food animal production, antibiotic stewardship refers to efforts:
    - to limit inappropriate usage, and
    - to optimise the choice, dose rate, route and duration of therapy to maximise clinical cures.

Witnesses informed the Committee that the CellCheck Technical Working Group has outlined detailed recommendations for improved stewardship of intramammary antibiotics in a submission to the Veterinary Council of Ireland.

Veterinary Ireland

Veterinary Ireland appeared before the Committee on 23 March 2021. Veterinary Ireland's role as a trade organisation is to represent veterinary surgeons and to facilitate the veterinary profession in its commitment to improving the health and

welfare of the animals under its care and protecting public health. There are approximately 1,000 vets employed in food animal practice.

Role:

Veterinary Ireland stated that the role of the veterinary practitioner needs to be recognised as a vital tool in the reduction of antibiotic usage and reduction in antibiotic resistance. Veterinary practitioners have developed stores of clinical data for the farms that they are attending and are aware of management shortfalls that need to be addressed to reduce reliance on antibiotics. According to Veterinary Ireland, distance prescribing by others often takes a blanket approach and rarely has follow-up on usage and success of treatment.

Position on the Regulation:

- **Antimicrobial & Antiparasitic resistance** - Ireland needs to use anti-parasitic medicinal products and antimicrobials properly to safeguard the viability of pasture-based farming, animal health and welfare and human health in a sustainable agricultural model. Overuse and inappropriate use of antimicrobials are the greatest drivers of resistance. There is a need to address issues that lead to inappropriate use of antibiotics and veterinary intervention results in reduced antibiotic usage.
- **Prescription Only Medicine (POM)** - Veterinary Ireland welcomes the decision by HPRA expert taskforce to recommend that antiparasitic veterinary medicinal products be reclassified as Prescription Only Medicines (POM) based on scientific advice.
- According to Veterinary Ireland, the changes brought by commencing this regulation will standardise the approach to medicine use on farm, enable farmers to maximise the value they get from inputs, reduce the use of precious resources, and improve overall herd/flock health management and welfare. This can only benefit farmers and the agri-food industry.

As a country that exports over 90% of our agricultural produce, Ireland needs to be a leader in the changes that are required and embrace these to the benefit of farmers and the public. Veterinary Ireland believes these changes will bring added value to agricultural output while enhancing the sustainability of the industry.

Health Products Regulatory Authority (HPRA)

The Health Products Regulatory Authority (HPRA) appeared before the Committee on 27 April 2021.

Role:

HPRA's role is to ensure that veterinary medicines are of good quality, and that they are safe and effective. HPRA fulfils its role by reviewing applications for marketing authorisation and ensuring that the medicines comply with the regulatory standards in place, as well as relevant European and national legislation. Following the launch of medicines to the marketplace, HPRA reviews the benefit/risk balance of products on an ongoing basis by means of pharmacovigilance monitoring. The DAFM regulate downstream activities relating to the wholesale, retail and use of veterinary medicines. DAFM also legislates nationally in respect of the conditions that must be fulfilled for the prescribing, dispensing, use and disposal of veterinary medicines nationally. The role of HPRA extends to evaluating applications for veterinary medicines and vaccines and setting the parameters for their use by issuing marketing authorisations.

Position on the Regulation:

- The new regulation aims to reduce the administrative burden for the animal health industry and thereby improve availability of medicines. The following will assist in achieving this aim:
  - **Packaging** - Simplification of packaging and labelling textual information on medicines and replacing text with pictograms and abbreviations that are standardised across the Union. Comprehensive instructions for use will instead be placed within the package leaflet, which may be in several Community languages, thereby facilitating the creation of common EU packaging rather than individual national package requirements. The package leaflet may be made available in paper or electronically, or both, being the choice of the Member States.
  - **EU database** - The creation of a European Union database of authorised veterinary medicines from every EU Member State. This database, which is being developed currently and which will contain

information on over 30,000 individual authorised medicines, is to go live on 28 January 2022. This milestone is expected to facilitate the identification of effective medicines from other Member States that will be available to treat animal diseases in this country. An EU database of suspected adverse reactions for all veterinary medicines that are authorised within the Community will also be created. This development, which will in time replace current databases held by each competent authority, is expected to improve detection of suspected adverse events and facilitate work-sharing between competent authorities throughout the EU.

- **Resistance** - The new regulation places significant emphasis on addressing resistance, both antimicrobial resistance as well as antiparasitic resistance. HPRA confirmed that the emergence of resistance was not the fault of the existing distribution network.
- **Innovation** - The regulation offers new possibilities for innovation and for improving availability of veterinary medicines throughout the EU, while safeguarding animal health, consumer health and environmental safety.

Veterinary Council of Ireland (VCI)

Veterinary Council of Ireland (VCI) appeared before the Committee on 27 April 2021. VCI is the independent statutory body responsible for the regulation and management of the veterinary professions, including the regulation of prescribing of veterinary medicines in Ireland. The functions of VCI include protection of the public through the regulation of veterinary education, the maintenance of the Register of veterinary practitioners and veterinary nurses, the registration of veterinary premises, and through disciplinary action in cases of professional misconduct.

Role:

VCI, in its public interest role as regulator of the veterinary professions was requested by the DAFM to consider offering definitions of the terms contained in the EU Regulation (2019/6). VCI considered the scope and spirit of the of the Regulation

and provided definitions to the terms contained in the Regulation. These definitions and their implications for prescribing veterinary practitioners will be published in the Council's Code of Professional Conduct, which is currently undergoing review and is due for publication later this year.

Position on the regulation:

The definitions offered by VCI aim to serve animal health and welfare and public health by reserving use of high-quality medicines to prevent the spread of disease in animals and help to mitigate against the growing threat of antimicrobial resistance (AMR). VCI will continue to:

- play their part in the public interest of animal health and welfare and public health, as Ireland navigates the implementation of EU Regulation 2019/6,
- foster best professional practice, in the interests of animal welfare and public interest; and
- work to ensure that the high standards expected in the veterinary professions are upheld and that quality of veterinary care is continuously improving into the future.

Recommendations, observations and conclusions

1. The Committee recommends that the Department of Agriculture, Food and the Marine ensures the continuation of the existing network, which includes Licensed Merchants and Veterinary Pharmacists, as a recognised route of supply of antiparasitic medicines. This will provide fair competition and access to farmers and products are expertly administered by trained Responsible Persons.

2. The Committee recognises the importance of services that Licensed Merchants and Veterinary Pharmacists provide to rural communities and the farming sector which are performed to a high standard. These services add to the rural economy by contributing to employment in these areas and maintain fair competition of products as farmers have an alternative choice of where to purchase products as well as the choice of different brands.

3. The prioritisation of the Department's legal advice request on Article 105(4) of EU Regulation 2019/6 with the Attorney General's office needs to be expedited as the commencement date of the Regulation is approaching. For transparency and fairness, this advice should be shared with all stakeholders impacted. The uncertainty caused by the derogation in Article 105(4) needs to be clarified. If it is not possible to avail of this derogation the Department needs to explore further a possible adoption of a mechanism to allow Responsible Persons in Licensed Merchants or pharmacists to play a role alongside veterinary practitioners in the prescribing and dispensing of antiparasitic veterinary medicines.

4. The Committee recognises the commitment of Ireland's veterinary practitioners to their role and the provision of excellent services. However, the Committee is concerned with the number and location of vets across the country and the number involved in livestock veterinary practices. In order to look after the health of their livestock, farmers need to have the right of prompt access to prescriptions With the introduction of this Regulation there

could be an issue of receiving prescriptions in a timely manner as the demand of access to veterinary surgeons will increase.

5. The trend of corporate bodies purchasing several veterinary practises in one area is disconcerting as this can cause a monopoly of services and perhaps, as a result of the anticipated change, a monopoly of veterinary products brands. Both issues will carry a significant cost to farmers as there will be a lack of competition of services and products in their local area. The Committee requests that the Department explores this matter to ensure fairness in competition and that farmers have the same access to veterinary services across the country.

6. The Committee heard that this Regulation could be anti-competitive and may result in increased costs for farmers. The Committee recommends that Veterinary Practitioners should not list their preferred branded medicine in their prescriptions to clients. This would allow farmers the choice of purchasing a generic version of the medication at a lower cost and, depending on the product, purchase the product with a Licensed Merchant or Veterinary Pharmacist if they prefer. The Committee is concerned that one stop shops at veterinary practices may be anti-competitive and unfair to clients, especially as corporate bodies appear to be purchasing several practices in one geographic area. This issue needs to be examined urgently by the Department ahead of the enactment of the Regulation.

7. Public awareness is required in relation to antimicrobial and antiparasitic resistances and the difference between the two needs to be highlighted. Antimicrobial resistance is the resistance of antibiotics. The use of antibiotics in animals is a potentially important risk factor for the selection and dissemination of resistant microorganisms and determinants from animals to humans. This risk arises via the consumption of produce from treated animals, but also with contact with treated animals themselves. Antiparasitic resistance may be defined as the ability of a parasite, e.g. gut worms/liver fluke, to survive a dose of an antiparasitic drug that would normally be

expected to kill them. Antiparasitic resistance doesn't affect the consumer in the food chain whereas antimicrobial resistance could impact the consumer. Thus, different strategies and approaches are required to deal with each kind of resistance.

8. The Committee recognises the roles of Veterinary Practitioners, Veterinary Pharmacists and Licensed Merchants in the provision of advice and animal healthcare products. From the series of Committee meetings, the shared commitment of all stakeholders in providing excellent services and looking after the health of animals is commendable.

9. Separation of prescribing and dispensing as advocated by ICOS, ILMA, IPU has been a proven success. ICOS recommend that if an appropriate legal solution cannot be found, the option of breaking the link between the dispenser and prescriber needs to be actively considered by the Department as an alternative but practical, fair and transparent solution to this issue. Other EU Member States such as Denmark, Sweden and Italy have implemented this option.

10. The qualifications, employments and livelihoods of suitably qualified Responsible Persons will be put in jeopardy by the failure of the Department to facilitate their continued role in the prescribing of antiparasitic veterinary medicines. The potential monopoly by veterinarians on the prescribing and dispensing of veterinary medicines will threaten the viability, livelihoods and right to earn a living of these people whose qualification was endorsed as fit for purpose by DAFM and their awards previously presented by no less than Minister McConalogue. These people are now deemed unsuitable, no longer fit for purpose and potentially redundant.

Appendix 1: Extract - Article 105 EU Regulation 2019/6

Artcle 105

Veterinary prescriptions

1. A veterinary prescription for an antimicrobial medicinal product for metaphylaxis shall only be issued after a diagnosis of the infectious disease by a veterinarian.

2. The veterinarian shall be able to provide justification for a veterinary prescription of antimicrobial medicinal products, in particular for metaphylaxis and for prophylaxis.

3. A veterinary prescription shall be issued only after a clinical examination or any other proper assessment of the health status of the animal or group of animals by a veterinarian.

4. By way of derogation from point (33) of Article 4 and paragraph 3 of this Article, a Member State may allow a veterinary prescription to be issued by a professional, other than a veterinarian, who is qualified to do so in accordance with applicable national law at the time of entry into force of this Regulation. Such prescriptions shall be valid only in that Member State and shall exclude prescriptions of antimicrobial medicinal products and any other veterinary medicinal products where a diagnosis by a veterinarian is necessary.

   Veterinary prescriptions issued by a professional, other than a veterinarian shall be, mutatis mutandis, subject to paragraphs 5, 6, 8, 9 and 11 of this Article.

5. A veterinary prescription shall contain at least the following elements:

   (a) identification of the animal or groups of animals to be treated;

   (b) full name and contact details of the animal owner or keeper;

   (c) issue date;

   (d) full name and contact details of the veterinarian including, if available, the professional number;

   (e) signature or an equivalent electronic form of identification of the veterinarian;

   (f) name of the prescribed medicinal product, including its active substances;

   (g) pharmaceutical form and strength;

   (h) quantity prescribed, or the number of packs, including pack size;

   (i) dosage regimen;

   (j) for food-producing animal species, withdrawal period even if such period is zero;

(k) any warnings necessary to ensure the proper use including, where relevant, to ensure prudent use of antimicrobials;

(l) if a medicinal product is prescribed in accordance with Articles 112, 113 and 114, a statement to that effect;

(m) if a medicinal product is prescribed in accordance with Article 107(3) and (4), a statement to that effect.

6. The quantity of the medicinal products prescribed shall be limited to the amount required for the treatment or therapy concerned. As regards antimicrobial medicinal products for metaphylaxis or prophylaxis, they shall be prescribed only for a limited duration to cover the period of risk.

7. Veterinary prescriptions issued in accordance with paragraph 3 shall be recognised throughout the Union.

8. The Commission may, by means of implementing acts, set a model format for the requirements set in paragraph 5 of this Article. That model format shall also be made available in electronic version. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

9. The medicinal product prescribed shall be supplied in accordance with applicable national law.

10. A veterinary prescription for antimicrobial medicinal products shall be valid for five days from the date of its issue.

11. In addition to the requirements set out in this Article, Member States may lay down rules on record-keeping for veterinarians when issuing veterinary prescriptions.

12. Notwithstanding Article 34, a veterinary medicinal product classified as subject to veterinary prescription under that Article may be administered without a veterinary prescription by a veterinarian personally, unless otherwise provided for under applicable national law. The veterinarian shall keep records of such personal administration without prescription in accordance with applicable national law.

Appendix 2: Terms of Reference

Scope and context of activities of Select Committees (DSO 94 and SSO 70)

DSO 94

(1) The Dáil may appoint a Select Committee to consider and, if so permitted, to take evidence upon any Bill, Estimate or matter, and to report its opinion for the information and assistance of the Dáil. Such motion shall specifically state the orders of reference of the Committee, define the powers devolved upon it, fix the number of members to serve on it, state the quorum, and may appoint a date upon which the Committee shall report back to the Dáil.

(2) It shall be an instruction to each Select Committee that—

(a) it may only consider such matters, engage in such activities, exercise such powers and discharge such functions as are specifically authorised under its orders of reference and under Standing Orders;

(b) such matters, activities, powers and functions shall be relevant to, and shall arise only in the context of, the preparation of a report to the Dáil;

(c) it shall not consider any matter which is being considered, or of which notice has been given of a proposal to consider, by the Joint Committee on Public Petitions in the exercise of its functions under Standing Order 125(1) [1]; and

(d) it shall refrain from inquiring into in public session or publishing confidential information regarding any matter if so requested, for stated reasons given in writing, by—

(i) a member of the Government or a Minister of State, or

(ii) the principal office-holder of a State body within the responsibility of a Government Department or

(iii) the principal office-holder of a non-State body which is partly funded by the State,

Provided that the Committee may appeal any such request made to the Ceann Comhairle, whose decision shall be final.

(3) It shall be an instruction to all Select Committees to which Bills are referred that they shall ensure that not more than two Select Committees shall meet to consider a Bill on any given day, unless the Dáil, after due notice to the Business Committee by a Chairman of one of the Select Committees concerned, waives this instruction.

[1] Retained pending review of the Joint Committee on Public Petitions.

SSO 70

(1) The Seanad may appoint a Select Committee to consider any Bill or matter and to report its opinion for the information and assistance of the Seanad and, in the case of a Bill, whether or not it has amended the Bill. Such motion shall specifically state the orders of reference of the Committee, define the powers devolved upon it, fix the number of members to serve on it, state the quorum thereof, and may appoint a date upon which the Committee shall report back to the Seanad.

(2) It shall be an instruction to each Select Committee that—

(a) it may only consider such matters, engage in such activities, exercise such powers and discharge such functions as are specifically authorised under its orders of reference and under Standing Orders;

(b) such matters, activities, powers and functions shall be relevant to, and shall arise only in the context of, the preparation of a report to the Seanad;

(c) it shall not consider any matter which is being considered, or of which notice has been given of a proposal to consider, by the Joint Committee on Public Petitions in the exercise of its functions under Standing Order 108 (1) [1]; and

(d) it shall refrain from inquiring into in public session or publishing confidential information regarding any matter if so requested, for stated reasons given in writing, by—

(i) a member of the Government or a Minister of State, or

(ii) the principal office-holder of a State body within the responsibility of a Government Department, or

(iii) the principal office-holder of a non-State body which is partly funded by the State,

Provided that the Committee may appeal any such request made to the Cathaoirleach, whose decision shall be final.

[1] Retained pending review of the Joint Committee on Public Petitions

Functions of Departmental Select Committees (DSO 95 and SSO 71)

DSO 95

(1) The Dáil may appoint a Departmental Select Committee to consider and, unless otherwise provided for in these Standing Orders or by order, to report to the Dáil on any matter relating to—

(a) legislation, policy, governance, expenditure and administration of—

(i) a Government Department, and
(ii) State bodies within the responsibility of such Department, and

(b) the performance of a non-State body in relation to an agreement for the provision of services that it has entered into with any such Government Department or State body.

(2) A Select Committee appointed pursuant to this Standing Order shall also consider such other matters which—

(a) stand referred to the Committee by virtue of these Standing Orders or statute law, or
(b) shall be referred to the Committee by order of the Dáil.

(3) The principal purpose of Committee consideration of matters of policy, governance, expenditure and administration under paragraph (1) shall be—

(a) for the accountability of the relevant Minister or Minister of State, and
(b) to assess the performance of the relevant Government Department or of a State body within the responsibility of the relevant Department, in delivering public services while achieving intended outcomes, including value for money.

(4) A Select Committee appointed pursuant to this Standing Order shall not consider any matter relating to accounts audited by, or reports of, the Comptroller and Auditor General unless the Committee of Public Accounts—

(a) consents to such consideration, or
(b) has reported on such accounts or reports.

(5) A Select Committee appointed pursuant to this Standing Order may be joined with a Select Committee appointed by Seanad Éireann to be and act as a Joint Committee for the purposes of paragraph (1) and such other purposes as may be specified in these Standing Orders or by order of the Dáil: provided that the Joint Committee shall not consider—

(a) the Committee Stage of a Bill,
(b) Estimates for Public Services, or

(c) a proposal contained in a motion for the approval of an international agreement involving a charge upon public funds referred to the Committee by order of the Dáil.

(6) Any report that the Joint Committee proposes to make shall, on adoption by the Joint Committee, be made to both Houses of the Oireachtas.

(7) The Chairman of the Select Committee appointed pursuant to this Standing Order shall also be Chairman of the Joint Committee.

(8) Where a Select Committee proposes to consider—

(a) EU draft legislative acts standing referred to the Select Committee under Standing Order 133, including the compliance of such acts with the principle of subsidiarity,
(b) other proposals for EU legislation and related policy issues, including programmes and guidelines prepared by the European Commission as a basis of possible legislative action,
(c) non-legislative documents published by any EU institution in relation to EU policy matters, or
(d) matters listed for consideration on the agenda for meetings of the relevant Council (of Ministers) of the European Union and the outcome of such meetings,

the following may be notified accordingly and shall have the right to attend and take part in such consideration without having a right to move motions or amendments or the right to vote:

(i) members of the European Parliament elected from constituencies in Ireland,
(ii) members of the Irish delegation to the Parliamentary Assembly of the Council of Europe, and
(iii) at the invitation of the Committee, other members of the European Parliament.

(9) A Select Committee appointed pursuant to this Standing Order may, in respect of any Ombudsman charged with oversight of public services within the policy remit of the relevant Department consider—

(a) such motions relating to the appointment of an Ombudsman as may be referred to the Committee, and
(b) such Ombudsman reports laid before either or both Houses of the Oireachtas as the Committee may select: Provided that the provisions of Standing Order 130 apply where the Select Committee has not considered the Ombudsman report, or a portion or portions thereof, within two months (excluding Christmas, Easter or summer recess periods) of the report being laid before either or both Houses of the Oireachtas.[2]

[2] Retained pending review of the Joint Committee on Public Petitions.

SSO 71

(1) The Seanad may appoint a Departmental Select Committee to consider and, unless otherwise provided for in these Standing Orders or by order, to report to the Seanad on any matter relating to—

(a) legislation, policy, governance, expenditure and administration of-

(i) a Government Department, and

(ii) State bodies within the responsibility of such Department, and

(b) the performance of a non-State body in relation to an agreement for the provision of services that it has entered into with any such Government Department or State body.

(2) A Select Committee appointed pursuant to this Standing Order shall also consider such other matters which –

(a) stand referred to the Committee by virtue of these Standing Orders or statute law, or
(b) shall be referred to the Committee by order of the Seanad.

(3) The principal purpose of Committee consideration of matters of policy, governance expenditure and administration under paragraph (1) shall be—

(a) for the accountability of the relevant Minister or Minister of State, and

(b) to assess the performance of the relevant Government Department or a State body within the responsibility of the relevant Department, in delivering public services while achieving intended outcomes, including value for money.

(4) A Select Committee appointed pursuant to this Standing Order shall not consider any matter relating to accounts audited by, or reports of, the Comptroller and Auditor General unless the Committee of Public Accounts–

(a) consents to such consideration, or

(b) has reported on such accounts or reports.

(5) A Select Committee appointed pursuant to this Standing Order may be joined with a Select Committee appointed by Dáil Éireann to be and act as a Joint Committee for the purposes of paragraph (1) and such other purposes as may be specified in these Standing Orders or by order of the Seanad: provided that the Joint Committee shall not consider-

(a) the Committee Stage of a Bill,

(b) Estimates for Public Services, or

(c) a proposal contained in a motion for the approval of an international agreement involving a charge upon public funds referred to the Committee by order of the Dáil.

(6) Any report that the Joint Committee proposes to make shall, on adoption by the Joint Committee, be made to both Houses of the Oireachtas.

(7) The Chairman of a Joint Committee appointed pursuant to this Standing Order shall be a member of Dáil Éireann.

(8) Where a Select Committee proposes to consider–

(a) EU draft legislative acts standing referred to the Select Committee under Standing Order 116, including the compliance of such acts with the principle of subsidiarity,
(b) other proposals for EU legislation and related policy issues, including programmes and guidelines prepared by the European Commission as a basis of possible legislative action,
(c) non-legislative documents published by any EU institution in relation to EU policy matters, or
(d) matters listed for consideration on the agenda for meetings of the relevant EC Council (of Ministers) of the European Union and the outcome of such meetings,

the following may be notified accordingly and shall have the right to attend and take part in such consideration without having a right to move motions or amendments or the right to vote:

(i) members of the European Parliament elected from constituencies in Ireland,

(ii) members of the Irish delegation to the Parliamentary Assembly of the Council of Europe, and

(iii) at the invitation of the Committee, other members of the European Parliament.

(9) A Select Committee appointed pursuant to this Standing Order may, in respect of any Ombudsman charged with oversight of public services within the policy remit of the relevant Department consider—

(a) such motions relating to the appointment of an Ombudsman as may be referred to the Committee, and

(b) such Ombudsman reports laid before either or both Houses of the Oireachtas as the Committee may select: Provided that the provisions of Standing Order 113 apply where the Select Committee has not considered the Ombudsman report, or a portion or portions thereof, within two months (excluding Christmas, Easter or summer recess periods) of the report being laid before either or both Houses of the Oireachtas.[2]

[2] Retained pending review of the Joint Committee on Public Petitions.

Powers of Select Committees (DSO 96 and SSO 72)

DSO 96

Unless the Dáil shall otherwise order, a Committee appointed pursuant to these Standing Orders shall have the following powers:

(1) power to invite and receive oral and written evidence and to print and publish from time to time—

(a) minutes of such evidence as was heard in public, and
(b) such evidence in writing as the Committee thinks fit;

(2) power to appoint sub-Committees and to refer to such sub-Committees any matter comprehended by its orders of reference and to delegate any of its powers to such sub-Committees, including power to report directly to the Dáil;

(3) power to draft recommendations for legislative change and for new legislation;

(4) in relation to any statutory instrument, including those laid or laid in draft before either or both Houses of the Oireachtas, power to—

(a) require any Government Department or other instrument-making authority concerned to—

(i) submit a memorandum to the Select Committee explaining the statutory instrument, or

(ii) attend a meeting of the Select Committee to explain any such statutory instrument: Provided that the authority concerned may decline to attend for reasons given in writing to the Select Committee, which may report thereon to the Dáil, and

(b) recommend, where it considers that such action is warranted, that the instrument should be annulled or amended;

(5) power to require that a member of the Government or Minister of State shall attend before the Select Committee to discuss—

(a) policy, or
(b) proposed primary or secondary legislation (prior to such legislation being published),

for which he or she is officially responsible: Provided that a member of the Government or Minister of State may decline to attend for stated reasons given in writing to the Select Committee, which may report thereon to the Dáil: and provided further that a member of the Government or Minister of State may request to attend a meeting of the Select Committee to enable him or her to discuss such policy or proposed legislation;

(6) power to require that a member of the Government or Minister of State shall attend before the Select Committee and provide, in private session if so requested by the attendee, oral briefings in advance of meetings of the relevant EC Council (of Ministers) of the European Union to enable the Select Committee to make known its views: Provided that the Committee may also require such attendance following such meetings;

(7) power to require that the Chairperson designate of a body or agency under the aegis of a Department shall, prior to his or her appointment, attend before the Select Committee to discuss his or her strategic priorities for the role;

(8) power to require that a member of the Government or Minister of State who is officially responsible for the implementation of an Act shall attend before a Select Committee in relation to the consideration of a report under Standing Order 197;

(9) subject to any constraints otherwise prescribed by law, power to require that principal officeholders of a—

(a) State body within the responsibility of a Government Department or
(b) non-State body which is partly funded by the State,

shall attend meetings of the Select Committee, as appropriate, to discuss issues for which they are officially responsible: Provided that such an office-holder may decline to attend for stated reasons given in writing to the Select Committee, which may report thereon to the Dáil; and

(10) power to—

(a) engage the services of persons with specialist or technical knowledge, to assist it or any of its sub-Committees in considering particular matters; and
(b) undertake travel;

Provided that the powers under this paragraph are subject to such recommendations as may be made by the Working Group of Committee Chairmen under Standing Order 120(4)(*a*).

SSO 72

Unless the Seanad shall otherwise order, a Committee appointed pursuant to these Standing Orders shall have the following powers:

(1) power to invite and receive oral and written evidence and to print and publish from time to time –

(a) minutes of such evidence as was heard in public, and
(b) such evidence in writing as the Committee thinks fit;

(2) power to appoint sub-Committees and to refer to such sub-Committees any matter comprehended by its orders of reference and to delegate any of its powers to such sub-Committees, including power to report directly to the Seanad;

(3) power to draft recommendations for legislative change and for new legislation;

(4) in relation to any statutory instrument, including those laid or laid in draft before either or both Houses of the Oireachtas, power to –

(a) require any Government Department or other instrument making authority concerned to –

(i) submit a memorandum to the Select Committee explaining the statutory instrument, or
(ii) attend a meeting of the Select Committee to explain any such statutory instrument: provided that the authority concerned may decline to attend for reasons given in writing to the Select Committee, which may report thereon to the Seanad, and

(b) recommend, where it considers that such action is warranted, that the instrument should be annulled or amended;

(5) power to require that a member of the Government or Minister of State shall attend before the Select Committee to discuss–

(a) policy, or
(b) proposed primary or secondary legislation (prior to such legislation being published),

for which he or she is officially responsible: provided that a member of the Government or Minister of State may decline to attend for stated reasons given in writing to the Select Committee, which may report thereon to the Seanad: and provided further that a member of the Government or Minister of State may request to attend a meeting of the Select Committee to enable him or her to discuss such policy or proposed legislation;

(6) power to require that a member of the Government or Minister of State shall attend before the Select Committee and provide, in private session if so requested by the attendee, oral briefings in advance of meetings of the relevant EC Council (of Ministers) of the European Union to enable the Select Committee to make known its views: Provided that the Committee may also require such attendance following such meetings;

(7) power to require that the Chairperson designate of a body or agency under the aegis of a Department shall, prior to his or her appointment, attend before the Select Committee to discuss his or her strategic priorities for the role;

(8) power to require that a member of the Government or Minister of State who is officially responsible for the implementation of an Act shall attend before a Select Committee in relation to the consideration of a report under Standing Order 168;

(9) subject to any constraints otherwise prescribed by law, power to require that principal office-holders of a –

(a) State body within the responsibility of a Government Department, or
(b) non-State body which is partly funded by the State,

shall attend meetings of the Select Committee, as appropriate, to discuss issues for which they are officially responsible: Provided that such an office-holder may decline to attend for stated reasons given in writing to the Select Committee, which may report thereon to the Seanad; and

(10) power to-

(a) engage the services of persons with specialist or technical knowledge, to assist it or any of its sub-Committees in considering particular matters; and
(b) undertake travel;

Provided that the powers under this paragraph are subject to such recommendations as may be made by the Working Group of Committee Chairmen under Standing Order 107(4)(a).

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