



**Veterinary Ireland  
Submission to the  
Joint Oireachtas Committee  
on Agriculture, Food and the Marine  
on Pre-legislative Scrutiny of Veterinary Medicinal Products,  
Medicated Feed and Fertilisers Regulation Bill 2022**

We would like to thank the Committee and the Chair for the opportunity to address this proposed Bill.

**Introduction**

Veterinary Ireland is the representative body for the veterinary profession in Ireland. There are approximately 1,000 Private Veterinary Practitioners (PVPs) engaged in farm animal veterinary practice who play a key role in the Irish agri-food industry.

Veterinary practitioners are the gatekeepers of animal health and animal welfare and more pertinently act as the gatekeepers in the supply of prescription only medicines (POMs). This is an important role in ensuring that medicines, and in particular antimicrobial medicines, get to the right animal with the right diagnosis and for the right duration. The prudent prescribing of antimicrobials is essential to ensure that we achieve our goals and commitments to address the growing human health threat that is antimicrobial resistance.

While it is clear that a mindset change was needed and has commenced with regard to the usage of antimicrobial medicines especially in the areas of

- Prophylactic use
- Metaphylactic use
- Use of Highest Priority Critically Important Antibiotics (HPCIAAs)

it is evident from the available data that veterinary practitioners in working with farmers, DAFM, AHI and other stakeholders have already delivered real improvements in this area. This reduction in use benefits farmers, the agri-food industry and trade and human health. This development is very encouraging and should be welcomed by all stakeholders.

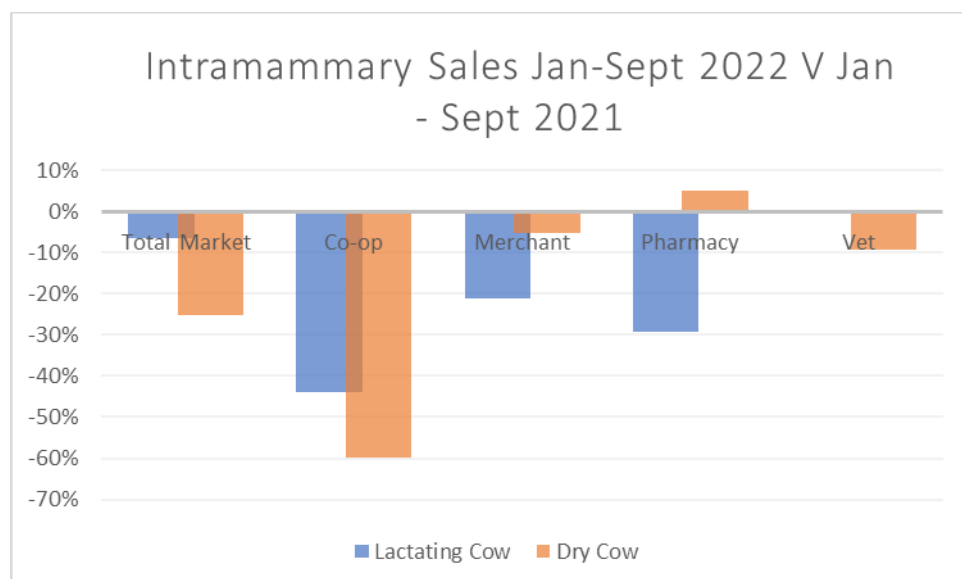
**Sales Data from 2022**

This Committee has heard sales of antimicrobial intramammary products through co-ops, merchants and pharmacies have fallen by a catastrophic 90% since January 2022 as a result of the cessation of Schedule 8 of the Animal Remedies Act 2007 which has been repealed. Veterinary Ireland has access to the distribution data and would like to correct the record and indeed outline the benefit that has been realised to primary farmers but also to human health.

Schedule 8 was inserted in the Animal Remedies legislation in 2007 as a last-minute intervention by the then Minister to appease the co-ops and farm organisations regarding the prescription of intramammary antimicrobial products. It exempted vets working on behalf of co-ops from having the burden of knowledge that would be expected from a PVP prescribing the same medication. Since 2007 Veterinary Ireland has highlighted to DAFM that this was not alone entirely anticompetitive but would also lead to less prudent prescribing. In some isolated instances, PVPs have been prosecuted, fined, received suspended prison sentences, and been struck off the veterinary register for prescribing for animals not under their care – an offence to which a vet prescribing under Schedule 8 was granted immunity.

The removal of Schedule 8 will have had no effect whatsoever on the supply of prescribed intramammary antibiotics from merchants and pharmacies – they always were dependent on a prescription from a PVP. Since January 2022, the prescribing of intramammary antimicrobials has reduced by 25.3% and the prescribing of lactating cow intramammary antimicrobials has reduced by 6.5%.<sup>1</sup> The overall market for intramammary antibiotic products has reduced by 19.7%. This not only represents a prudent reduction in antibiotics but represents a saving to Irish farmers of approximately €3.4M in the first nine months of 2022. Furthermore, contrary to the assertions, vets have not seen a 90% increase in supply through the veterinary channel. A decrease of 9.4% is seen in dry cow intramammary antibiotics whilst a modest increase of 0.3% in lactating cow antibiotics is demonstrated in the figures. With regard to dry cow antibiotics the figures demonstrate the only channel to increase is a 5.2% increase through the pharmacist channel. The removal of Schedule 8 has therefore benefited Merchants and Pharmacy as these actors have established relationships developed with some PVPs who do not wish to carry stock over many years. The real benefactor however has been farmers, animals, and human health.

Fig 1: Intramammary antibiotic sales Jan-Sep 2022 versus Jan-Sep 2021



Through prudent prescribing and the activity of PVPs working with their farmers to implement selective dry cow therapy using the AHI TASA Dry Cow Consults, the intramammary market has reduced considerably and less antibiotics are being used in animals. The assertion that vets have grabbed 90% of the market is therefore incorrect and any extrapolation of a similar outcome with antiparasitic medicinal products is also based on incorrect figures and assumptions.

The sales of intramammary antibiotics containing HPCIs (critically important antibiotics) have reduced massively. Cephaguard DC is down 73%, Cobactan LC is down 77%. The sales of critically important antibiotics in injectable form (e.g., Marbocyl) have also seen a collapse in sales anecdotally but the exact percentage was not available at time of writing.

<sup>1</sup> Kynetec VetTrak Sales Data Sept 2022

## **Antiparasitic Medicinal Products**

Antiparasitic medicinal products have been designated as POM all over Europe since 2007. Ireland availed of a derogation from 2007 to 2019 to allow these products to be sold as Licensed Merchant (LM) over the counter. The dispensing of these products is done by Responsible Persons (RPs) that are required to take a short level 6 course in handling, storage and dispensing of these products. This category of product has never been prescribed in Ireland. Any farmer or animal owner can purchase his/her product of choice over the counter in a store, pharmacy, or indeed online shop. There are frequently special offers available for example 1L free with 5L of product, a free dispensing gun if you buy two cans of product etc. This is perfectly legal at present.

## **Antiparasitic Resistance**

The issue of antiparasitic resistance is a worldwide phenomenon and is both a public health issue as well as being a serious issue for the agri-food industry here in Ireland. The ability to farm livestock on grazing systems is only possible where parasitic disease can be managed effectively. A study by DAFM in 2016 outlined that 56% of worming interventions in sheep were not effective<sup>2</sup>. Kelleher et al.<sup>3</sup> in 2017 found extremely high levels of resistance to all groups of wormers in cattle. The Veterinary Record recently published a case of high mortality on a dairy farm in Wales where adult cows died due to inability to treat lungworm infections due to resistance<sup>4</sup>. It is without doubt that the entire agri-food industry must address this issue before it is too late to do so. Crucially a Teagasc study found that 20% of all antiparasitic medication was used incorrectly and wasted<sup>5</sup>. This represents a loss to farmers in product purchased of approximately €6 million. Clinical disease from parasites is increasing year on year as referenced in the All-Island Veterinary Laboratory Annual Reports. We know that the most significant loss from parasites is actually subclinical through lack of performance and therefore the losses to Irish farmers are extremely significant.

To address the issue of resistance we must ensure that the right product is given to the right animals at the right time, that refugia is maintained through selective, targeted treatments and that parasite control becomes a planned farm-specific procedure. The gateway to this outcome is through proper, scientific, farm-specific veterinary advice from the farmers' vet where a Client Practice Patient Relationship (CPPR) is in existence. This advice must be ongoing and monitored, take account of farm specific issues such as epidemiology, pharmacology, the clinical picture, stocking densities, buying policy and local factors. The PVP then issues a prescription to the farmer as appropriate ensuring that the farmer's animals are treated correctly. This mindset change on how we sustainably control parasitic disease and use antiparasitic products has already begun in 2022 with the introduction of the Parasite TASAHS (Targeted Advisory Service on Animal Health) and it is imperative that this programme is continued to affect the change that is required in the agri-food industry. It is no longer good enough to use these chemicals as we wish as long as withdrawal periods are observed.

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<sup>2</sup> Keane et al., High level of treatment failure with commonly used anthelmintics on Irish sheep farms. *Ir Vet J* **67**, 16 (2014)

<sup>3</sup> Kelleher et al., Anthelmintic resistance among gastrointestinal nematodes of cattle on dairy calf to beef farms in Ireland. *Ir Vet J* **73**, 12 (2020)

<sup>4</sup> Lungworm in dairy cows with suspected failure of previous pour-on anthelmintic treatment. *Vet Record* (2022)

<sup>5</sup> Sayers, R., Use of anthelmintics on farms in Ireland. Teagasc research

## **Dispensing**

Once the farmer has a prescription on when to treat, what animals to treat and with what active ingredient the farmer can then fill the prescription from any legitimate channel – either in Ireland or across the EU. DAFM have proposed the National Veterinary Prescription System (NVPS) one of the aims of which is to make it as easy as possible for farmers to fill their prescriptions at their outlet of choice. Veterinary Ireland believes that this development increases competition rather than diminishes it. The removal of Schedule 8 has not resulted in increased revenues going through the veterinary channel with intramammary antibiotics and we will likely see a similar trend happening when the Regulation is finally implemented in Ireland. Less product will be sold, therefore as with the intramammary antibiotics the main benefactors are farmers and the agri-food industry.

## **The Right to Prescribe**

Veterinary Medicine is a restricted profession governed by the Veterinary Practice Act 2005. Only a Registered Veterinary Practitioner can perform acts of veterinary medicine and it is illegal for others to do so. This is not anti-competitive – it is the law. Acts of veterinary medicine are very few in reality and include

- Diagnosis of disease and advising on disease control
- Prescribing veterinary medicinal products
- Performing surgery on animals (with certain named exemptions)
- Veterinary Certification

The downside of being in this seemingly privileged position is that PVPs must adhere to the rules of the Veterinary Council of Ireland (VCI) and their Code of Professional Conduct. Failure to do so may result in a Fitness to Practice Investigation which is the equivalent of High Court proceedings. To defend oneself in a Fitness to Practice Investigation is particularly onerous both mentally and financially with very few having the resources to avail of their Constitutional right to appeal as it is through the High Court. As a result, the vast majority of PVPs are extremely careful to abide at all times to the Code of Professional Conduct through fear of Fitness to Practice Investigation as well as the desire to practise ethical Veterinary medicine.

As detailed previously, Schedule 8 of the Animal Remedies Act 2007 exempted vets working for co-ops from the same requirements as all other PVPs in the Code of Professional Conduct. This is the essence of anti-competitive behaviour. PVPs are obliged to provide 24-hour care to animals under their care – irrespective of not the animals owners declare they do not want such care, the obligation is there. The provision of 24-hour care is a significant burden on veterinary practices as it

- Is expensive to provide and loss making
- Interferes with work life balance of vets and their families
- Places vets in potential contravention of the Working Time Directive
- Makes recruitment and retention of vets in large animal practice more difficult

PVPs accept their obligations under the Code but it is absolutely imperative that any vet allowed to perform acts of veterinary practice are not exempted from their obligations by virtue of who their employer is. It is also essential that the Code is upheld to avoid imprudent distance prescribing, cherry picking of daytime work or any anti-competitive actions that undermine the veterinary profession in Ireland from providing the excellent service that farmers have become accustomed to or that leads to loose/improper prescribing of precious compounds that need to be controlled for the good of the industry and public health.

The proposal that non-vets should be allowed to prescribe is wholeheartedly disputed by the veterinary profession. A level 8 degree in Veterinary Medicine, registration with VCI, being registered with a Certificate of Suitability, an ongoing obligation to continuous professional development, an obligation to have professional indemnity insurance in place, adherence to the Code of Professional Conduct and the obligation to provide 24-hour veterinary care is in no way comparable to a 3–5-day level 6 Responsible Persons course.

### **Regulation of prescribing**

Only vets are subject to VCI rules. Any other actors in the field cannot be held to account by VCI. The thrust of this legislation is that all the responsibility rests with the prescribing vet. The majority of antiparasitic medicinal products were classified as LM and therefore have never been prescribed in Ireland. Penalties for vets under this legislation are ultimately Fitness to Practise Investigations which are High Court proceedings. For other actors in the system the majority of penalties are Class A fines. The spirit of the regulation is to reduce the incidence of antiparasitic resistance through proper parasite control planning and targeted and sustainable use of veterinary medicinal products. Veterinary Ireland believes that failure to implement this Regulation would be a catastrophic action to take in a country with such an important agri-food industry and a country that exports 90% of its food produce. We would be complete outliers in the EU and the reputational damage to Irish food would be significant.

### **Summary**

PVPs are the gatekeepers of Animal Health & Welfare and as such act as the gatekeepers of the use of prescription only medicines in order to ensure they are used prudently and sustainably and that only as much as necessary is used in food producing animals. PVPs have demonstrated their ability when given a level playing field in prescribing to significantly reduce the quantities of product used in farm animals. This is good for the farmer, for food exports and the entire agri-food industry.

Antiparasitic medicinal products have been reclassified as POM as a result of the HPRA taskforce report and the responsibility now falls on PVPs to engage with their farmer clients to plan parasite control so that product is used in a targeted scientific way to minimise the development of further resistance to these precious resources. This is an essential intervention to safeguard the future of livestock production from grazing systems. PVPs with cooperation from all the other stakeholders and support from DAFM in the form of TASA will affect positive change in this area as we have in other fields. We simply cannot proceed as we have heretofore.

The sale of antiparasitic medicinal products will continue through all the channels as currently. The Responsible Persons will still have a role in dispensing prescriptions as will the 450-500 Responsible Persons employed by veterinary practices. A prescription will be valid throughout the EU so additional competition is envisaged by Veterinary Ireland not less competition. The key fact is however that every stakeholder will supply less product as this is the aim of the regulation. The ultimate winners will be farmers and the agri-food industry.

### **National Veterinary Prescription System (NVPS)**

The NVPS was born out of a desire to fulfil two requirements of DAFM namely

- To comply with the obligation under Article 57 on Member States to collect data on the usage of antimicrobial products per species

- To satisfy co-ops, merchants, and pharmacists that veterinary prescriptions would be readily available to allow seamless dispensing to farmers and essentially level the playing field for dispensing

The NVPS as proposed brings many more significant benefits to DAFM

- Evidence availability for improving National animal health/welfare policies
- Maintain competitive VMP dispensing market
- Provides Digital Capability for Distance Selling (Art 104(2))
- Improved Regulatory oversight of VMP Usage and Supply
- Increases International confidence in Irish Food Production

The NVPS will have data down to individual animal level, individual farm level and individual vet level. It will be used to monitor prescribing practices and usage levels on farm. This data will form the basis for further investigations by DAFM on farmers and VCI on PVPs. The data is a very powerful tool which will facilitate regulation from a desk be you a farmer or a vet. It will allow the categorisation of farms and vets as low or high users of medicines and allow for reduction targets to be set by DAFM without the benefit of on farm knowledge and other mitigating factors.

PVPs have experience of such databases controlled by DAFM namely the Animal Health Computer System (AHCS). When introduced in 2003/2004 the ER4 was an instruction document from DAFM on how to TB test cattle correctly. It eventually expanded to a 78-page legal contract that had to be accepted and signed each year without any negotiation with Veterinary Ireland in order for a PVP to be allowed to test cattle. Ongoing supports promised to PVPs to run AHCS were unilaterally withdrawn by DAFM. The fact that NVPS is part of this Bill and in primary legislation means that a large animal vet in Ireland must now

1. Have a Level 8 Veterinary Degree which is approved by VCI
2. Register with VCI
3. Obtain a Certificate of Suitability for a premises from VCI
4. Obtain Professional Indemnity Insurance
5. Undertake 20 hours of further education annually
6. Adhere to the Code of Professional Conduct
7. Adopt the NVPS

There is no requirement to write prescriptions electronically in Regulation 2019/6 or Regulation 2019/4. The obligation is on the Member State to collect macro sales data and usage data (i.e., at farm level). DAFM by way of derogation have unilaterally decided without agreement to collect prescription data as a proxy for usage data. They have decided to put the NVPS into primary legislation to force PVPs to either use it or retire from practice as opposed to the normal method of consultation and agreement with Veterinary Ireland, to ensure the system was fit for use and to ensure unwarranted collection of data was not placing an undue burden on already stretched PVPs. PVPs also need assurances on how this data will be used, who might be able to access this data and that further additional requirements are not thrust upon PVPs annually as was the case with AHCS.

There is no mention in this Bill of collection of data of gross sales which is in contravention of Article 57(1) of the Regulation. This is required to cross check usage data and is collected from market authorisation holders. It is only in terms of cross-checking and completing the data to ensure that it is accurate that other data providers, such as vets, should be utilised to provide data on the volume of sales (Art. 11(11) of Regulation 2021/578). The Bill is accordingly entirely deficient in relation to the collection of this first data stream by placing the data collection obligation solely on private practicing vets.

The Bill seeks to place an entirely disproportionate burden on PVPs in two respects. Not only has the Bill placed a disproportionate and non-compliant burden on PVPs in respect of antimicrobial medicinal products used in animals, it seeks to expand this burden even further to include all prescriptions issued by PVPs. In this way, the NVPS operates as a Trojan horse to expand the reach and scale of data collection well beyond what is required and in an entirely discriminatory manner.

In Regulation 2021/578, this obligation to collect data at a farm level is also carried through. Article 13(1) states that data on use is to be collected by Member States “from the following data providers, as appropriate: veterinarians, retailers, pharmacies, feed-mills and end-users, including farmers or breeders”. This is not a list of data providers from which Member States are permitted to select one type of data provider to undertake all the data collection and inputting. The use of the word “and” makes it clear that data is to be collected from each of these data providers, as appropriate to the particular circumstances of the use, e.g., feed mills might not be always involved in the particular use. It is not permissible for the General Scheme to place the entire burden of data collection onto one data provider, PVPs, as it seeks to do, and such an approach is not in line with either Regulation.

By placing the entire burden of gathering and transmitting data on PVPs, the Bill places a disproportionate and discriminatory obligation on veterinarians to their disbenefit and to the benefit of other market operators and actors, leading to market distortions as well as interfering in a material manner with the ability of veterinarians to exercise their constitutional right to earn a livelihood. Veterinary Ireland has no doubt that older PVPs will retire rather than engage with NVPS and as such put the veterinary service farmers value under more strain than it is currently. Veterinary graduates when choosing the field in which to practice currently have a myriad of opportunities both in Ireland between the many disciplines of veterinary medicine and also abroad as our Veterinary degree is accepted in all major destinations. The additional requirement now foisted upon farm animal vets without adequate consultation and without any agreement in this Bill will make recruitment and retention of farm animal vets significantly more difficult.

### **Practical Issues with NVPS**

Following initial meetings with DAFM it became clear that negotiation on the implementation of this system was less favoured than putting the obligation on PVPs to use NVPS into primary legislation. Despite this stance of non-engagement, twenty PVP practices agreed to run testing on NVPS on a pilot basis to help DAFM improve the system.

Vets have a number of issues with the system as proposed

- Time. The time taken to input data on to NVPS on a standard clinical call is 3 minutes and 17 seconds. This equates for an average PVP into 6.8 working weeks annually of extra time they must find to use NVPS. This time is not there and even if it was who will pay for this time? There has been no discussion around this.
- Some PVP practices (approximately 15%) already have electronic prescribing systems which collect the same data and billing/ financial/ accounting data but in a fraction of the time that the NVPS app takes. These commercially available systems are much slicker than NVPS as they were created to ease the burden on PVPs. It is the undoubted opinion of Veterinary Ireland that to comply with NVPS, PVPs will have no option but to engage these private entities to interact with NVPS. The commercial outlay for these systems is substantial and ongoing.
- DAFM has an obligation to collect data of antimicrobial usage at species level. This could be a monthly report from practice computer software for example. The creation of NVPS has put a disproportionate burden on PVPs to facilitate competition with other

stakeholders in the supply chain in derogation so that the data does not have to be collected at farm level. This is disproportionate and diminishes the ability of PVPs from earning a livelihood. This would not be accepted by any other sector. When a PVP is treating a cow at 3am on a Saturday morning there will be no available pharmacy or store open until the following Monday. The extra time taken to comply with NVPS is significant to overworked and sleep deprived PVPs.

- Extra PVPs will be needed to replace those that leave as a result of NVPS yet there is no business case to hire extra vets as costs will be significantly higher and sales significantly lower.
- PVPs are skilled professionals and must have the latitude to use their professional judgement and clinical experience to treat seriously ill animals with what is required to affect a successful outcome within the law and ethical veterinary practise. The extra 3 minutes and 17 seconds will pale to insignificance if PVPs end up explaining their rationale for treatment to DAFM afterwards.
- The market supplying PVPs with software is small in Ireland. Ultimately the commercial software that will be required to engage with NVPS in a practical manner will be consolidated over time and ultimately could end up being acquired by a commercial interest with a conflict of interest. Who can predict in the future if this software is not acquired by a drug manufacturer, a corporate veterinary entity or other competing interest? PVPs have seen this exact scenario occur in relation to software that interacts with AHCS. The data contained on these systems is commercially sensitive and must be only shared with the express written permission of PVPs.
- The GDPR is all about data minimisation. NVPS as proposed is a glaring example of data maximisation. It will contain personal data of PVPs and personal data of end users to which we have a responsibility. The data collected is far in excess of what the Regulations require. The sharing of this data to third parties will ultimately mean this data at PVP level and at farm level will be available to a wide-reaching audience. Assurances are required regarding data sharing and usage.

When AHCS was introduced, it was negotiated and agreed with Veterinary Ireland. We delivered a 95% compliance rate in year one as a result. The attempt to push through an unfinished system, not fit for purpose without the requirement for third party commercial software with undetermined terms and conditions on an already stretched veterinary profession is not the way to conduct business.

Veterinary Ireland and the veterinary profession are proud of the key role PVPs play in the agri-food industry. Veterinary Ireland believes that PVPs will rise to the challenges posed to us in the implementation of the Regulation in order to protect human health, animal health and welfare, the efficacy of veterinary medicinal products and the reputation of the Irish agri-food industry. Veterinary Ireland would ask this Committee to ensure DAFM engages with Veterinary Ireland to ensure a smooth and agreed integration of NVPS into veterinary practices that minimises the impact on the running of veterinary practices, enable PVPs to provide the clinical services required by the agri-food industry and reduce the use of veterinary medicinal products prudently in compliance with the Regulation.