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Representative of the Irish Pharmacy Union, who represent over 2000 pharmacies in Ireland of which over 300 of whom are committed to the supply of veterinary medicines.

Pharmacist from Crossmolina, Co Mayo.

Post Graduate Diploma in Agricultural and Veterinary Pharmacy (Now accorded a Masters Degree) in which my thesis focused on the implications of EU Directives 81/851 and 81/852 on the supply of Veterinary Medicinal Products (VMPs). This thesis was subsequently published and used as a reference document by the Veterinary Medicines Directorate in the UK in establishing their regulatory system for VMPs.

Opening Statement:

My professional role as a pharmacist is dispensing medicines and advice to patients, some of these medicines are prescribed by other healthcare professionals, some are counter prescribed by myself in response to the symptoms presented by the patient. Sometimes I refer the patient to another healthcare professionals and in the case of animals to the veterinarian where appropriate. At all times, my primary concern is for the welfare of the patient, making their health, wellbeing and safety my primary focus.

The supply of veterinary medicines to animal owners reflects the counter prescribing of medicines to our human patients. The pharmacy mnemonic of **WWHAM**, **Who** is the patient, **What** are the symptoms, **How** long have the symptoms been present, **Action** taken, **Medication** being taken, are supplemented with additional appropriate questions for VMPs including the species, cohort stage, previous treatments, climatic and local factors which are assessed before counter prescribing an appropriate VMP.

All VMPs are supplied with appropriate advice for 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. We 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 us 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.

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

Responsible Persons, provide a similar service in the stores of over 900 Licensed Merchants and Coops. They are trained to 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. The 2019 cohort of graduates were presented with their QQI Level 6 awards in September 2019 by none other than Minister Charlie McConologue. The awards and graduation ceremony over recent years have included contributions from DAFM officials, Pat Brangan (2017, 2018, 2019), Caroline Garvan (2019), Breda Meehan (2018), Denis Healy (2017) and Hazel Sheridan

(2016), who emphasised 'the critical role of the RP in the supply chain of VMPs'. The cost of training to this professional QQI Level 6 is €995 per student and over 100 hours of lectures, tutorials, study and assessments are required.

CVO, Martin Blake, in his letter (attached) to the European Commission confirms that 'there was no suggestion in the HPRA Report that the channel of sale or avenues of supply of antiparasitics were a causation factor in these exempting criteria not being met.' The exemption referred to under Directive 2006/130/EC allowed for the continued availability without prescription of antiparasitic VMPs. So NO professional involved in the supply of antiparasitic VMPs was required to issue a written prescription in this regard. Counter prescribing of these VMPs with corresponding documentation has been undertaken by multiple stakeholders, vets, pharmacists, qualified responsible persons.

Antiparasitic pharmaceuticals are precious commodities, many are unique molecules offering a therapeutic effect against parasites which infect animals and humans. We have a responsibility to safeguard their use while promoting animal health, welfare and productivity. This is a responsible role as we have to sustain the efficacy of these medicines for future generations.

Antiparasitic resistance differs from antimicrobial resistance.

Antiparasitic resistance is an aspect of evolution and not a new phenomenon. Fasinex (Triclabendazole) was launched to treat Liver Fluke in 1985. Reports pertaining resistance in sheep to this VMP in Glencar, Co Sligo were documented in 1995. However, this is a multifactorial problem with environmental, geographical, genetic aspects. Armed with results from diagnostic faecal egg count tests, a history of the treatment programme on the farm, prevailing climatic and environmental conditions, allows controlled use of this VMP to achieve excellent results. Responsible Persons and Veterinary Pharmacists have been counter prescribing and educating farmers on the use of this and other antiparasitic VMPs for decades in a manner which will sustain the viability of these VMPs.

The HPRA report of December 2019 recommended the upregulation of antiparasitic veterinary medicines to prescription only medicine (POM) status as they no longer can avail of the exemption from POM status for these medicines under Directive 2006/130/EC. The HPRA Task Force recommended a 'multi-actor' stakeholder approach to future regulation. The proposal by DAFM to exclude professionals other than veterinarians from issuing prescriptions is controversial. At present many animal owners are reluctant to pursue their present entitlement to obtain a prescription from their Veterinary Practitioner to source the relevant VMP elsewhere as they are afraid of jeopardising their relationship with their vet. Many vets ignore their statutory obligation under Regulation 43.3 of the current Animal Remedies Regulations 2007 where the prescriber of an animal remedy 'shall at that time, issue a veterinary prescription to the owner or person in charge of the animal'. This Regulation is intended to encourage competition and prevent a monopoly. It has not been enforced.

The Irish experience shows that the Prescription Only Medicine (POM) regulations have virtually excluded Veterinary Pharmacists from their dispensing function – to the extent that it is not economically viable for some marginal rural pharmacies to continue to practice Veterinary Pharmacy and the numbers involved in VMP provision has decreased substantially throughout the country. The absence of competition for the supply of antiparasitic VMPs will result in price inflation to the farmer

if a monopoly is permitted to develop. This will add further cost burden to Irish farmers reducing the viability of industry and making Irish food products less competitive on the world market.

If EU Regulation 2019/6 is applied as proposed then this will equally impact on Merchants, Co-ops and Rural pharmacies. Job losses in the 1000's will result. Jobs are a scarce commodity in rural Ireland. This will impact on many of your constituents, merchants, pharmacies, coops, their staff, their families, the farming communities. This is yet another hammer blow to rural Ireland, to those outside the M50.

A request of the DAFM through the forum of the Antiparasitic Resistance Stakeholder Group to conduct an economic impact assessment in advance of implementation of EU Regulation 2019/6 was refused. However it was confirmed that DAFM had established that a proposal to separate of the prescribing and dispensing of VMPs in Ireland would threaten the viability of some rural veterinary practices. No consideration has been given to the impact of this regulation on the viability the farmer or animal owner, on rural merchants, rural coops or rural pharmacies. It will add further cost to rural living.

Last Friday, a hill farmer visited our pharmacy in North Mayo seeking advice on treatment of a sick lamb. My response to the symptoms described was to refer the farmer to his vet for treatment. The farmer's response was that a vet consultation fee of €60 combined with the cost of treatment would exceed the value of the lamb. His decision was that he would allow nature to take its course. This situation will become widespread. Many hill sheep farmers, small holders and horse owners do not routinely engage with a vet. These animals are liable to neglect. Animal welfare will suffer. Farmers and animal owners care for their animals. Refusing to avail of the derogation available under Article 105.4 will have a seriously detrimental effect on farm life

There is an irony in that I as a pharmacist am deemed competent to supply and advise on the use of anthelmintics and ectoparasiticides for human use without requirement for prescription but from 2022, a veterinary prescription will be required to supply and advise on the veterinary equivalent. Veterinary Nurse prescribers, Pharmacist prescribers and 'Suitably Qualified Persons' prescribers are legislated for in the UK, having availed of the derogation in the Regulation.

Animal Health Ireland the All Island Animal Health and Welfare Strategy in 2018. This should include Animal Health Products. However with two different supply systems on one island without a border, this will inevitably result in importation of these products, reducing accountability and transparency. At present, certain VMPs are obtained by farmers across the border for reasons of cost and availability without a prescription. Many of these are unlicensed and unregulated in this state. A recent court case, reported in the 'Farmers Journal' involving the alleged importation of a VMP from NI was intercepted by a DAFM inspector, who stated in a Longford court that preventing illegal cross border transactions was becoming more difficult to detect due to Government cutbacks. Quoted from the Irish Farmer's Journal, "I think there is an absence of political will" he said. The cross border trade in VMPs will evolve from the present trickle to a torrent post January 2022 with no accountability and no transparency thereby undermining the quality assurance associated with Irish food products.

The western regions of Donegal, Mayo, Galway, Clare, Kerry and Cork have all been reported as having limited veterinary services. The Erris Region of Mayo, an area the size of Louth, has one vet based in that area. In these areas the service provided by the merchant,

coop and pharmacist in providing VMPs and advice is essential. Many of our island communities have no veterinary service. This Regulation will further challenge life on the west coast.

The **solution** available to the Minister that will maintain competition in the supply of these VMPs and prevent development of Antiparasitic Resistance is to:

Authoritise Pharmacists & Suitably Qualified Responsible Persons including Ag. Merchants & Co-ops to issue prescriptions for anti parasitic VMPs. They have been 'de facto' prescribing these VMPs at the time of entry into force of this Regulation. Precedence exists in this regard. The response from the European Commission (attached) confirms the availability of the derogation to the Minister under Article 105.4 of the Regulation. DAFM have agreed to seek the advice of the Attorney General in this regard.

CVO, Martin Blake, in the attached letter, expressed his view that changing the route of supply alone will not address the resistance or environmental concerns. DAFM stated that they plan to have a holistic and multi stakeholder approach but evidence to date shows otherwise.

Refusal to avail of the derogation afforded in Regulation 105.4 would be tantamount to **a legalised coup d'etat** of this already highly regulated sector. It will potentially eliminate Veterinary Pharmacists, Responsible Persons, Licenced Merchants and Cooperatives from the supply chain of VMPs in a system where some Veterinary Practitioners refuse to issue a veterinary prescription for antiparasitic VMPs to the animal owner.

We all have a part to play. This is going to require the political will of the Minister to avail of the derogation.