Opening Statement,
Independent Licensed Merchants Association (ILMA),
12-11-20

Opening Statement Joint Committee Agriculture and Marine from Independent Licensed Merchants Association (ILMA) Presented by Ian Scott, consultant for ILMA

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INTRODUCTION. Ian Scott, working as Secretary General for the Animal Health Distributors Association (UK) Ltd, was the lead negotiator for UK to defend the rights of the Specially Qualified Professional (SQP) during the 4 years of discussions on EU regulation 2019/6. This involved many high-level meetings in Brussels with MEP's, Commissioners, Permanent Representatives, member state Counsellors, policy officers, Veterinary attaches and working with EU Committees. Ian wrote the text of Article 105(4) and with full support from UK government succeeded in securing the UK SQP system in the final stages of the Regulation discussions. As a result, the UK system, which is to all intent and purposes the same as for Responsible Persons (RP) in Ireland, works well and engages all stakeholders in the key issue of addressing Anti Parasitic Resistance (APR)

BACKGROUND The basic process in Brussels to write, discuss and approve Regulation 2019/6 involved 4 main stages: approval by MEP committees, approval by Veterinary experts from each member state, approval by Permanent Representatives from each member state and Trilogue agreement ahead of a full parliament vote. The Regulation entered the statue book on 27th January 2019 (called entry into force) and becomes enforceable by EU on the date of accessibility 27th January 2022. This interim time is to enable member states to alter National legislation to ensure compliance.

The role of DAFM During the course of the 4 years the UK reached out to Ireland for support specifically with Article 105 as both Nations have similar distribution systems. The original draft from the Commission stipulated that member states presided over their own distribution systems. The Irish MEP's were supportive and voted to retaining the status quo, the DAFM veterinary experts then supported a change to make these medicines to require a veterinary prescription, without informing any stakeholders in what appears to be a unilateral decision. DAFM made it quite clear to UK that they wanted to go it alone, assured Irish Farmers Association representatives and the UK that this ruling did not affect Ireland and that they wished to keep their system 'under the radar'. DAFM specifically insisted that the UK should not refer to the Irish system in any future discussions. However, the Irish Permanent Representative did vote finally to support 105 (4).

What is 105(4) all about? Article 105 states that all medicines for food producing animals including horses are subject to a veterinary prescription. ILMA accept that this cannot be changed. Currently LM medicines have an exemption from a veterinary prescription. However, Article 105(4) was included to allow professional persons other than vets to issue veterinary prescriptions. ILMA and IPU now find themselves at loggerheads with DAFM who are refusing to adopt the specially written derogation in 105 (4). By refusing to accept the derogation DAFM seem intent on dismantling the very system that they formulated, regulate and approve.

105 (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.''

Irish National Law (S.I. No. 786/2007) at time of entry into force enables a RP the option to dispense Licensed Merchant (LM) medicines without a prescription. A Licenced Merchant is a retail premises licenced by DAFM to retail veterinary medicinal products. It is subject to regulation, inspection and control by DAFM. There are over 900 Licensed Merchants premises and over 300 veterinary pharmacists' premises in Ireland

DAFM contend that only a vet can write a prescription. The first few words in 105 (4) contradict this assertion ''By way of derogation from point (33) of Article 4 and paragraph 3 of this Article'', The reference to Article 4 point 33 is the definition of a vet prescription. 105(4) is a derogation meaning this definition of a veterinary prescription no longer applies and clears the way so that a member state professional can also write a prescription. Any disagreement on this statement queries why the derogation was even inserted in the first place. Our evidence has therefore to address 2 key points; 1. that the Responsible Person (RP) is a professional and 2. that the RP is qualified to prescribe.

Key Point 1. The Responsible Person (RP) has a professional qualification, the QQI Level 6 retail sale and supply of animal remedies. Taking this exam costs 995 euros and this cost has been entirely self-funded. This qualification is recognised and approved by DAFM thus clearly establishing the RP as a professional.

Key Point 2. In order to dispense a LM Medicine, RP's and Veterinary Pharmacists (VP) currently follow a comprehensive prescribing protocol, including 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 and so on. This process is the normal procedure required when issuing a prescription. The RPs are accordingly, in layman's terms, both professional (the QQI level 6) and qualified to prescribe by virtue of their current advisory capacity.

Thus, in every sense of the word, 105 (4) enables the RP and VP to prescribe and dispense LM medicines whilst leaving Ireland compliant with 2019/6.

ILMA have offered solutions to enable DAFM to avail themselves of 105(4). Forming a Regulatory body for the RP with a Code of Practise 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 Anti Parasitic Resistance (APR) and include a disciplinary process. Additionally, to work with DAFM to form a specific prescription classification just for LM medicines that does not clash with a full veterinary prescription.

To put it simply

1. Irish National Law enabled an RP to dispense LM medicines without prescription
2. EU Regulation now says these medicines need a veterinary prescription
3. 105(4) allows Ireland to enable RP's to issue a prescription
4. DAFM need to accept this and work with ILMA and IPU to formulate a prescription classification for the RP to use when dispensing LM medicines

Anti-Competitive This committee will be quick to grasp another complication should the DAFM continue to refuse to adopt 105(4), that this move will be anti-competitive. DAFM argue that there is no change to the current system just that the livestock farmers and horse owners will first have to go to a vet to get a prescription and then can go to their favoured merchant to purchase the medicine. This is only partially true. Firstly, by visiting the vet premises the vet has an immediate unfair advantage to prescribe and dispense the medicine in a one stop shop scenario. This will inevitably result in sales of these products being largely undertaken by vets. Secondly, there are identical generic LM medicines licensed so that only a vet can dispense, the prescription has to specify a branded medicine and it would not be unfair to assume vets would want to prescribe brands only available from themselves. For example, where a cattle farmer would normally buy Ivermectin such as Ivomec from his local merchant, the vets would prescribe Enovex, available only from vets. The same applies to Eprinomectin and Closamectin generic brands. DAFM are actively encouraging manufacturers to register generic brands as POM vet only. In this way the LM is by-passed and prevented from dispensing product.
In a letter written by Mr. Martin Blake, Chief Veterinary Officer (CVO) of the DAFM, to the EU, there is a clear recognition that competition issues arise and that the current competitive environment would be significantly weakened. This committee should expect answers from DAFM to questions such as: is the purpose of the legislation in fact to, in effect, preclude RPs from dispensing product? Was it to create a situation whereby vets would, in effect, be placed in a dominant position in relation to prescribing and supplying LM veterinary medicines? Currently the LM and VP dispenses a substantial share of all LM medicines. DAFM's intended actions will reduce competition, narrow choice and restrict access. 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 cartel that will damage livestock and equine industries

SUMMARY The Committee will now be aware that DAFM acted against the wishes of Irish MEP's, the EU Commissioners original draft and against the Irish LM medicines distribution system that they themselves set up and regulate. They failed to notify stakeholders of their intentions, failed to put matters right in the year between approving this change and entry into force, failing to take responsibility for the actions of their predecessors and failing to avail themselves of a feasible solution. DAFM are in grave danger of contravening anti-competition law which could result in costly litigation to resolve matters.

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