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SSVI

Department of Agriculture, Food & the Marine

Agriculture House

Kildare Street

Dublin 2

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**DAFM Stakeholder Consultation**

**EU Veterinary Medicinal Products Regulation 2019/6**

**Response by the Irish Co-operative Organisation Society (ICOS)**

**Introduction**

ICOS is pleased to respond to this important consultation. ICOS and its member co-operative businesses are major contributors to Ireland’s €14.5 bn agri-food exports, with dairy sector exports accounting for €4.4 bn and beef & other livestock at over €3.9 bn in 2019.

Currently Ireland has over 1,000 licenced merchants’ (LM) outlets approved by the Department of Agriculture Food and the Marine (DAFM), with a significant number owned and operated by ICOS members. This route to market along with private veterinary practices (PVP) ensures that the widest possible distribution network to enable farmers access to antimicrobial, anti-parasitic and anthelminthic products which after 28th January 2022 may become predominantly prescription only products (POM).

As food processors we have a much greater reliance than other stakeholders in ensuring food producing animals are cared for and treated with the best possible care and any products used to treat these animals must fully comply with legal requirements and best practice.

ICOS and its members fully recognise the significant threat to human and animal health posed by Antimicrobial Resistance (AMR). We are committed to playing our part in this regard as a decrease in Antimicrobial Usage (AMU) is to society’s benefit as a whole, but most of all to the benefit to our suppliers and required by our international customers. We as a sector have demonstrated leadership by prohibiting the sale of intramammary tubes containing Critically Important Antibiotics (CIA’s) in most co-op retail outlets, which has been positively recognised by the European Commission during the recent ECDC Country Visit.

ICOS also recognises the substantial risks posed by the development of Anthelmintic Resistance to food production in Ireland, which is primarily grass based and a key element of Ireland’s green and sustainable image promoted internationally by Bord Bia and directly by co-ops on international markets. It is vitally important that the efficacy of antiparasitic and anthelmintic products are protected for the benefit of farmers by implementing data driven decisions, development of best practice programmes and awareness building and education.

Reform of the current distribution network will need careful consideration as many LM’s, be that co-op branches or privately owned are in danger of closing, because they will be at an immediate disadvantage as veterinary practices will have the unfair competitive advantage as being the prescriber and dispenser. This is contrary to emerging veterinary best practice across several EU member states, such as Italy and Sweden whereby the prescriber cannot dispense, and indeed is contrary to the situation that exists regarding human health i.e. the prescriber cannot dispense. `

**Article 34 – Classification of veterinary medicinal products**

We note that the HPRA’s Advisory Committee for Veterinary Medicines has established a Task Force to review the available evidence and report on whether antiparasitic and anthelmintic products are compliant with the criteria contained in Article 34 (3) of Regulation 2019/6 and to consider the likely impact of any change of the method of distribution. The HPRA Task Force has concluded that there is evidence of resistance to anthelmintics in parasites of livestock in Ireland, and indeed across Europe. Risks have also been identified with regard to environmental safety with using these products.

Notably, the Task Force concluded that the availability of antiparasitic veterinary medicinal products through LM outlets does not present a particular risk to public health, as regards residues. The HPRA further concluded that the labelling of veterinary medicinal products is generally very comprehensive and includes information on warnings, contraindications, withdrawal periods and potential adverse reactions, and the reported incidences of adverse reactions is extremely rare. As such, the availability of antiparasitic veterinary medicinal products through LM outlets does not present a particular risk in that respect. The HPRA recommends that these products be upregulated to prescription only (POM). It further recommends that the use of parasitological diagnostic services to farmers, be the basis on which the veterinary prescriptions of antiparasitic medicines are generated.

ICOS reminds DAFM that one of the three main objectives of the new regulation is to increase the availability of veterinary medicinal products. ICOS contends that the maintenance of the current network of over 1,000 individual licenced merchants (LM) outlets should be a priority for DAFM. The current proposal from the HPRA to make antiparasitic and anthelmintic products POM will greatly undermine and render many of these outlets economically unviable, as farmers will now be forced to attend their local veterinary surgeon’s office to secure a prescription. They will be unlikely to then go to a LM when the VMPs in question will be available to them at the point of issue of the prescription. An unintended consequence of this recommendation will be a potential market distortion, which will result in less market competition and is contrary to the objective outlined above, which is to increase the availability of veterinary medicinal products, but especially preventative products such as vaccines.

**Article 57 – Collection of data on antimicrobial medicinal products used in animals**

ICOS contends that the only credible and reliable way to counteract the potential issue of market distortion, and to comply with Article 57 of Regulation 2019/6 related to data collection is for all prescriptions for food producing animals to be made available on the Animal Identification and Movements Database (AIM) or another equivalent national database. This also provides for DAFM’s obligation that Member States shall send collated data on the volume of sales and the use per animal species and per types of antimicrobial medicinal products used in animals to the EU, and this must be completed before 27th January 2027.

On a practical level, this will translate into a farmer’s PVP or consulting co-op vet issuing an electronic prescription held on the AIM database for legally and readily available products as authorised by the HPRA. These prescribed products can then be dispensed in a transparent and extremely competitive manner in the PVP’s office, pharmacy or LM premises.

This allows for full and fair competition and keeps open the widest range of availability of these products. Once the farmer has presented his herd number details to any of the above outlets, the products are dispensed by suitably qualified personnel as currently approved by DAFM, the prescription will then be deleted from the AIM system and therefore cannot be duplicated. This will ensure the integrity of prescriptions used only once will be adhered too with no scope for misuse. Whilst the prescription is electronically stored, it does not necessitate an ICT capability by the farmer as the PVP or consulting co-op vet is creating the prescription either on his handheld device or office-based devices for secure storage on the AIM database. The farmer merely presents him/herself with their herd number to access the product, within 5 days as per Regulation 2019/6. We emphasise that no ICT skills are required or internet access on behalf of the farmer.

**Article 103 – Retail of veterinary medicinal products and record keeping**

ICOS members, currently being LM outlets and authorised by DAFM retail a wide range of VMP’s. ICOS agrees that the proposals outlined under Article 103 are achievable and all our staff are suitably qualified personnel (SQP) under the LM regulations as enforced by DAFM. This further strengthens the integrity and traceability of VMP availability through the LM outlet. ICOS members have invested considerably in training their SQP’s so as to operate and comply with the current requirements under the LM regulation. They are an expertly qualified resource that were trained in the past to comply with the current requirements and consideration needs to be given by DAFM as to how we can utilise and integrate these trained individuals to effectively meet the new objectives of Regulation 2019/6. An important objective of Regulation 2019/6 is to reduce administrative burdens. We strongly encourage DAFM to ensure that record keeping where possible should be held electronically to reduce the administration burden on business.

**Article 105 – Veterinary Prescriptions**

In terms of ensuring that antimicrobials are used in accordance with the 5 R’s (Right advice, Right animal, Right antibiotic, Right dose and Right duration) we recognise the importance of the proposals under Article 105.

ICOS fully endorses the principle that all antibiotics prescribed to food producing animals should be by POM. However, this is not exclusively by a clinical visit and Regulation 2019/6 clearly provides for other proper assessment by a veterinarian, which in certain cases translates into data driven decisions being the more appropriate method to generate a prescription. Currently Schedule 8 of S.I. No.786 of 2007 enables certain antimicrobials (intramammary tubes) to be prescribed by a veterinarian employed by co-ops to farmers participating in an approved Mastitis Control Programme (MCP).

Additionally, dairy farmers must comply with Regulation 853/2004 whereby his/her PVP certifies the overall herd health on an annual basis.

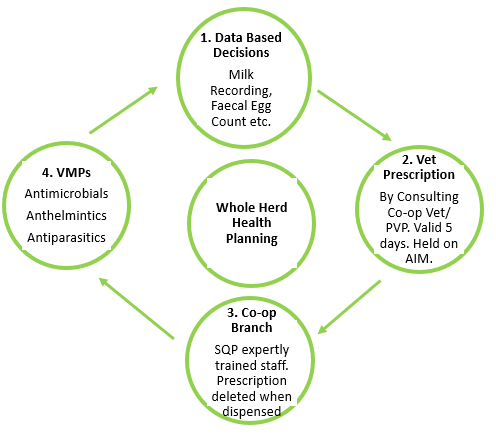
This involves a holistic approach to mastitis control incorporating co-op farm advisors, milking machine technicians, MCP co-op vets and co-op nutritionists, delivering a single message based on the AHI CellCheck Farmer Guidelines and MCP checklist.

As all VMPs including anthelmintics appear to require a prescription after 2022, ICOS wants to clearly state that these VMPs should be available under the similar criteria outlined under Schedule 8. Co-ops through their diligent administration of MCP’s operate a holistic approach to herd health management as outlined above.

This will now become an all-encompassing multi-faceted herd health programme combining the MCP, a PCP (parasite control programme) and IDPP (Infectious diseases prevention plan) supported by data-based decision making (milk recording, milk culturing & sensitivity testing, faecal egg count results, antibody detection tests as illustrated in figure 1. Additionally incorporating VMP implementation strategies and herd management protocols such as grazing management, biosecurity SOP’s, milking parlour servicing/maintenance plans to control the various animal health concerns listed in the herd health programme. This herd health plan will not be limited to the three programmes listed, but also include national disease eradication and control programmes and other aspects of on-farm animal health management.

As demonstrated above, the dairy co-op sector has a vested interest in ensuring full compliance with the prescribing and use of these products in food producing animals. Indeed, any changes to this current route of supply could possibly be detrimental to Ireland’s €14.5 billon agri-food exports by undermining the integrity of the food supply chain.

**Figure 1: Outline of a sustainable and responsible prescribing model proposed by ICOS**



**Article 107 – Use of antimicrobial medicinal products**

Article 107 stipulates that antibiotics must not be used for prophylaxis (preventive treatment to a healthy animal) except in very exceptional circumstances. Article 107 further states that antibiotics must not be used for metaphylaxis, (treatment of healthy cohort animals) except when the risk of spread of an infection or of an infectious disease in the group of animals is high and no other appropriate alternatives are available.

This stipulation that antibiotics must not be used for prophylaxis (preventive treatment to a healthy animal) except in very exceptional circumstances will have significant consequences for the existing practice of drying off lactating dairy animals in Ireland. The practice promoted and followed by Irish dairy farmers over many years has been to treat their animals with an antimicrobial intramammary tube before drying off. Irish dairy farmers have now been advised and encouraged through Animal Health Ireland, Teagasc and dairy co-op milk advisory teams to adopt Selective Dry Cow Therapy (SDCT) in view of AMR concerns. However, transitioning from the traditional approach of Blanket Dry Cow Therapy (BDCT) to SDCT will take time, education and significant financial resources, if the timeframe of January 2022 is to be achieved.

It is estimated that approximately 40% of dairy herds, representing 50% of the total dairy cow numbers are milk recorded. SDCT cannot be effectively implemented at farm level in the absence of milk recording data. It is estimated by the milk recording organisations, that an investment of circa €10 million will be required over the next two years to adequately scale up the milk recording capability to a situation whereby the national dairy herd can be milk recorded. There is significant investment needed to achieve this in such a short timeframe.

ICOS and our members believe that the widespread use of milk recording across the national dairy herd will be extremely positive and will complement a range of national objectives in the area of AMR, climate change, animal health and welfare (e.g. encouraging participation in the Irish Johne’s Control Programme) as well as supporting farm income.

For example, the objective to increase milk recording to 75% of the national dairy herd by 2025 is a specific action identified in the ‘Ag Climatise’ National Climate and Air Roadmap for the Agriculture Sector to 2030 and beyond published by DAFM in November 2019.

The purpose of the ‘Ag Climatise’ Roadmap is to implement the Teagasc Marginal Abatement Cost Curve, and its rollout is of strategic importance to the agriculture sector and the Irish economy as a whole. The ICOS recommendations contained in this paper encourages DAFM to ensure our national objectives in the area of AMR, animal health & welfare and the environment are fully aligned.

In recent years, collectively ICOS members through their on-farm milk advisory teams in conjunction with the AHI CellCheck Programme has delivered year on year reductions in Somatic Cell Count (SCC) across the national herd. The national SCC average is 183k in 2018, noticeably down from an national average SCC of 272k in 2009.

Many of the co-ops through their administration of Schedule 8 have documented evidence of significant reductions in the sale of antimicrobial intramammary tubes. There is a substantial risk of derailing and reversing these positive trends by making rash changes to the current method of prescription and distribution.

**Article 123 – Controls**

ICOS would like to draw DAFM’s attention to the fact that on the Island of Ireland we currently have two different models of prescribing VMP’s under EU law. After 2022, this issue may be exacerbated by the decision of the UK to exit the European Union and increased surveillance may be needed to protect the integrity of the Single Market.

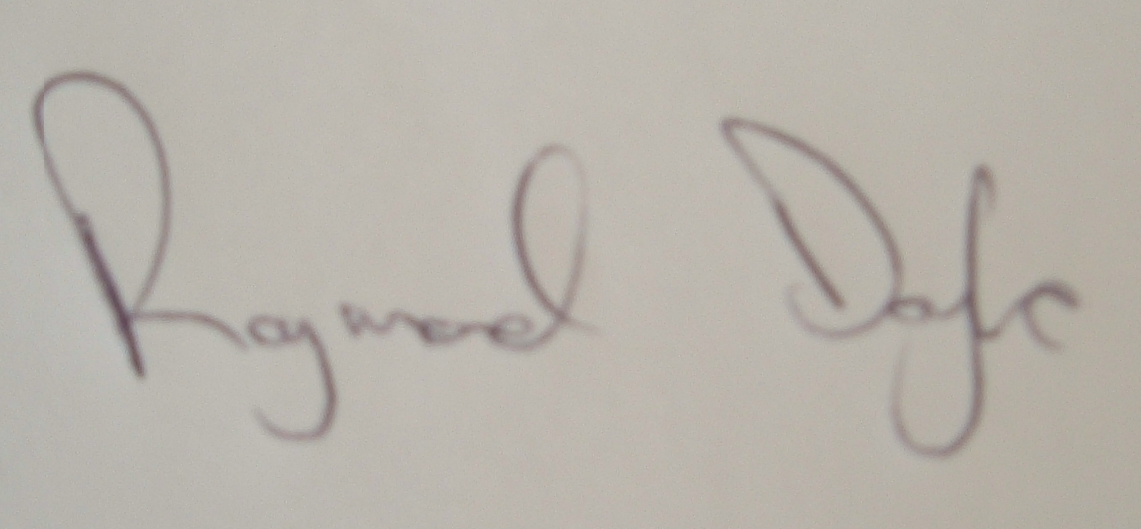
**Concluding Remarks**

ICOS and its members looks forward to constructively engaging with DAFM to ensure the timely and successful implementation of Regulation 2019/6.

We look forward to discussing the issues we have highlighted in this submission as some of our proposals will require significant investments by ICOS members and DAFM itself especially around IT, method of prescription generation and subsequent integrity of dispensing models.

In summary, ICOS is asking DAFM to consider the following:

1. Continuation of the existing LM network as a recognised route of supply, as expertly administered by suitably qualified personnel to ensure maximum and fair competition and availability for farmers.
2. Maintenance and strengthening of the holistic approach to herd health management as implemented by co-ops through multi-disciplinary teams and veterinary oversight.
3. Prescriptions available electronically on the AIM database.
4. Prescriptions can be generated on the basis of data driven decisions (milk recording, milk culturing & sensitivity testing, faecal egg count results, antibody detection tests) under the other assessment method, where appropriate.
5. Considered implementation of 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.
6. Recognition of the fact that the transition from BDCT to SDCT will result in a substantial investment at industry level to ensure compliance with the 2022 deadline.
7. Alignment of national objectives in the area of AMR, animal health and welfare and the environment.
8. The ICOS proposal facilitates the need for a national prescription, dispensing and usage database as per Regulation 2019/6. This will allow measurement & benchmarking, which is critical to identify & manage AMU.



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Ray Doyle

Livestock & Environmental Services Executive