Opening Statement,
Irish Cooperative Organisation Society (ICOS),
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Submission to the Joint Oireachtas Committee on Agriculture by ICOS

EU Veterinary Medicines Regulation 2019/6

February 2021

Introduction:

The Irish dairy industry is Ireland's largest indigenous industry and exports over €5 billion worth of Irish food to over 120 countries worldwide. It is extremely focussed on food safety, the consumer, and its reputation as a trusted supplier of safe and traceable food.

Over the past decade, it has invested over a billion euros in new processing capacity, routes to market, and in people and systems to ensure compliance and food safety. The Co-operative nature of the industry has ensured that it has developed a significant degree of vertical integration with its farmer members, and surrounds and supports them with the systems and expertise to deliver on safe and sustainable milk production. Included in this support is a huge investment in milk quality, built on animal health including lowering SCC levels and antibiotic usage. This reflects on the strategic importance of the dairy co-op sector as a key partner of government in delivering on shared objectives for the public good in; in animal health and welfare, food safety, climate change & water quality among others.

It is in this context that we raise some very significant concerns in relation to the implementation of the new EU Veterinary Medicines Regulation.

The Backdrop:

EU Regulation 2019/6 aims to strengthen the EU's response to antimicrobial resistance (AMR). Antibiotics protect human and animal health outcomes. However, the increasing evidence of resistance due to the improper usage of antibiotics in both human and animal medicine, combined with a lack of new antibiotic innovation may, in the future, render routine surgical procedures and cancer chemotherapy treatments very high risk. Even today, the WHO has estimated that AMR is responsible for 33,000 deaths in the EU and 700,000 deaths globally each year. The new regulation also aims to promote greater availability of veterinary medicines especially preventative medicines and to create a fit for purpose legal framework for animal medicines traded in the EU Single Market.

The legal situation:

EU Regulation 2019/6 will be applicable under Irish law from the 28th of January 2022 – in 12 months' time. EU Regulations are legally binding throughout each EU Member State, with national governments having very limited areas of discretion or flexibility in relation to their implementation. This compares to an EU Directive, where national governments will have greater discretion and flexibility[1]. The current legislation on animal remedies contained in Irish legislation under SI 786/2007 will expire in January 2022. SI 786/2007 will be repealed and replaced by a new Statutory Instrument (SI) reflecting the provisions of Regulation 2019/6.

[1] The legal basis of the existing animal remedies legislation is a directive. The provisions of the existing EU Directive 2001/82 EC on animal remedies are contained in Irish legislation under SI 786/2007.

Summary of the Key Provisions in Regulation 2019/6:

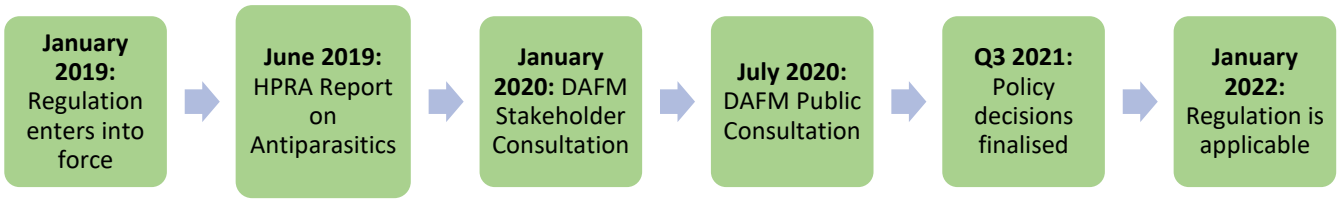
Article	Legal Provision	ICOS Commentary
Article 34 (3)	By way of derogation to a veterinary medicinal product being subject to a veterinary prescription if "there is no risk to public or animal health as regards the development of resistance to substances even where the veterinary medicinal product containing those substances is used incorrectly."	The HPRA has issued a recommendation that Ireland is no longer able to avail of the derogation exempting antiparasitics from the requirement of a prescription due to new evidence of resistance to these products on Irish cattle and sheep farms.
Article 105 (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."	The term "any other proper assessment" leaves open the option to DAFM to provide for an evolved Co-op Mastitis Control Programme and Co-op Herd Health Plans for Antiparasitics based on data supported prescribing in the new SI.
Article 105 (4)	"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."	Regulation 2019/6 entered into force in January 2019. Therefore, we have been advised by DAFM & the European Commission that Ireland would have needed national legislation in place on or before January 2019 to allow professionals other than a vet to prescribe antiparasitics. Antimicrobials in contrast have always been prescribed by a vet. The UK does allow its "Suitably Qualified Persons" (SQP) to issue prescriptions for a limited range of POM products but Ireland did not choose this route in 2007 when the current directive became law but instead relied on the derogation to Art 34 (3) relating to evidence of resistance. The Independent LMs have obtained legal opinions arguing that the Responsible Persons (Ireland's equivalent to the UK's SQP) in charge of dispensing antiparasitics in LMs and Co-ops were de-facto prescribing these products. DAFM have referred the matter to the Attorney General and we await this final decision. ICOS contends that the maintenance of the current network of over 1,000 individual LM outlets should be an absolute priority for DAFM. The current proposal from the HPRA to make antiparasitic 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 medicines in question will be available to them at the point of issue of the prescription. ICOS has always sought in its discussions with DAFM that the Responsible Persons should continue to be permitted to prescribe antiparasitics within the confines of a strictly regulated voluntary herd health programme, if a legal solution can be found.
Article 105 (10)	"A veterinary prescription for antimicrobial medicinal products shall be valid for five days from the date of its issue."	The new regulation will limit the validity of prescriptions for antimicrobial veterinary medicines to 5 days from the date of issue. This means the prescription must be filled within 5 days, but the duration of treatment may be longer than 5 days. For other veterinary medicines, such as antiparasitics, the period of validity is not specified and can be longer, possibly up to 6-9 months.
Article 107 (3)	"Antimicrobial medicinal products shall not be used for prophylaxis other than in exceptional cases".	Prophylaxis use of antimicrobials refers to the preventative use of antibiotics. Blanket Dry Cow Therapy (BDCT) is considered to be an example of prophylaxis use. After January 2022, Irish milk suppliers will have to adopt Selective Dry Cow Therapy and transition away from BDCT.
Article 107 (5)	"Medicinal products which contain the designated antimicrobials referred to in Article 37(5) (Critically Important Antibiotics for Human Medicine) shall not be used in accordance with Articles 112, 113 and 114."	The Irish dairy sector has demonstrated significant leadership by prohibiting the sale of intramammary tubes containing High Priority Critically Important Antibiotics (HP-CIA's) in most Co-op retail outlets, which has been positively recognised by the European Commission during an ECDC Country Visit in 2019.

The Process To-date & Timeline:

Jan 2019:	EU Regulation 2019/6 was agreed by the Council of Ministers and the European Parliament and entered into force in January 2019. A transition period started and will end in January 2022 when the Regulation becomes applicable.
June 2019:	The Health Products Regulatory Authority (HPRA) published a report recommending that Antiparasitic Veterinary Medicinal Products (VMP) be upregulated to the status of Prescription Only Medicines (POM). Ireland has availed of a derogation exempting antiparasitics from prescription requirements but based on latest research by Teagasc, evidence of resistance has been established on Irish cattle and sheep farms.
Jan 2020:	DAFM held a stakeholder consultation process in January 2020
July 2020:	A formal public consultation process took place July 2020.
Q1-Q3 2021:	The next steps will involve the carrying out of a regulatory impact assessment (RIA) and the drafting of the new SI. We envisage that the SI and RIA will be simultaneous processes that will be completed by Q3 2021 when policy decisions must be finalised.
Jan 2022:	Regulation 2019/6 becomes applicable under Irish law.

Figure 1: Regulation 2019/6 – Timeline & Process:



What are our major issues?

ICOS has identified two major issues of concern:

1. **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).**
2. **The HPRA Report recommending the upregulating of antiparasitics to POM.**

The Future Status of Co-op Mastitis Control Programmes (MCPs):

- Intramammary dry and lactation tubes can be prescribed by a Co-op vet employed by a milk purchaser to milk suppliers participating in an approved Mastitis Control Programme under Schedule 8 of SI 786/2007.
- Co-op MCP's includes advice related to correct milking machine function, milking hygiene, environmental mastitis management, summer mastitis prevention, correct nutritional supplementation, appropriate culling decisions, effective dry cow management, appropriate antibiotic use and record keeping.
- AHI have been examining the sales data and they are reporting a very significant drop in sales of mastitis tubes by approx. 43% comparing 2015 vs 2019 through the Schedule 8 channel, with the number of milk suppliers in an MCP only dropping by 5%. This illustrates the dairy sector's commitment to reducing Antimicrobial Resistance and Usage and highlights that Co-op MCP's are the correct vehicle to prescribe intramammary tubes.
- The influence of Co-ops in reducing the usage of Critically Important Antibiotics for Human Medicine and intramammary tubes in general will be undermined, and milk quality, traceability and AMR control may suffer, if DAFM fails to legislate for an evolved Co-op MCP.
- 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.
- The good news is that Regulation 2019/6 does provide a legal basis for the continuation of Co-op MCPs, as a prescription can be generated on the basis of "any other proper assessment" and not exclusively on the basis of a clinical visit by a vet.
- We acknowledge that extra conditionality will be required to address new requirements. For example, individual cow information to enable SDCT. It is clear from discussions with DAFM that bulk tank SCC data alone will not meet the new legislative requirements.
- The new regulation will mean a change to the existing practice followed by dairy farmers at drying off. Dairy farmers have traditionally treated their cows with an antibiotic intramammary tube before drying off their herd, as a preventative approach to avoid mastitis infection. The new regulation now states that antimicrobials must not be used for the preventative treatment of a healthy animal, except in very exceptional circumstances.
- Given the implied requirement for dairy farmers to move towards 100% milk recording in order to facilitate SDCT, it will be vital that the entire sector receives absolute clarity regarding this requirement, and the time in which to make the necessary investments in equipment, systems, people, and infrastructure.

Opposition to Co-op MCP's: There is a significant lobby opposed to the continuation of a Schedule 8 type arrangement in the new SI by the veterinary representative bodies. The Veterinary Council of Ireland - the Statutory Body that oversees the veterinary sector have published ethical guidelines for animals under the care of a vet, which is under review. The current VCI guidelines recommends that attending veterinarian practitioners should not exceed a maximum of 30 days between clinical contact and the prescribing of antimicrobials and a maximum of 90 days for other situations (will apply to the prescribing of antiparasitics). In direct, ICOS / VCI discussions they have strongly opposed the remote and data assisted prescribing option provided for under the "any other proper assessment" criteria. DAFM has asked the VCI to provide several definitions for its consideration for inclusion in the new SI including what constitutes the "any other proper assessment". The draft VCI document seen by ICOS provides for remote assessment but only in the context of the current "client patient practice relationship". This draft definition is totally unacceptable. The draft VCI definition needs to be widened to provide for data assisted prescribing by Co-op vets.

The HPRA Report recommending the upregulating of antiparasitics to POM.

- Antiparasitics (worm, lice treatments etc) are essential farm management tools and it is important to preserve their efficacy, especially with grass-based systems.
- There is clear evidence to suggest that inappropriate use and dosage of these VMP's are the main drivers of resistance and not the route of supply or prescription method.
- The current route of supply and prescribing methods via Responsible Persons has not resulted in Ireland having a significant increase in resistance being detected, compared to other EU Member States where these products have been POM for several years. Therefore, in the first instance, ICOS recommends that there should not be a change in the route of supply or the prescribing method for antiparasitics.
- ICOS is recommending that farmers should participate in annual herd health plans where strategies to manage antiparasitic resistance involving a combination of grazing management and rational use of anthelmintics/antiparasitics will be included as a central component. This is a more holistic approach rather than merely restricting these VMPs to POM, which will add unnecessary cost and burden at farm level.
- Each LM outlet has 'Responsible Persons' fully trained to dispense veterinary medicines. DAFM has stated that the solution to the upregulating of antiparasitics to prescription-only cannot involve prescribing by non-vets and that this point is not open to challenge.
- As all VMPs including anthelmintics/antiparasitics appear to require a prescription after 2022, ICOS wants to clearly state that these VMPs should be available under similar criteria to Co-op MCP's with the prescription issued by a Co-op vet assisted by data or through the Responsible Person for antiparasitics, if a legal accommodation can be found.
- Co-ops through their diligent administration of MCP's operate a holistic approach to herd health management as outlined above.
- This will now become a multi-faceted herd health programme combining the MCP, a PCP (parasite control programme) and IDPP (Infectious diseases prevention plan) assisted by data assisted decision making (milk recording, milk culturing & sensitivity testing, faecal egg count results, antibody detection tests) as illustrated in Figure 2.
- ICOS believes that Dairy Co-ops are ideally positioned to run comprehensive Herd Health programmes, given the detailed information and data available to them via their milk supply

agreements and associated conditions, advisory programmes, milk quality and herd health data, joint advisory programmes, and integration with AHI, Teagasc and other programmes.

Figure 2: ICOS Proposal for a Sustainable & Responsible Prescribing Model Assisted by Data

E-Prescribing: ICOS has supported an electronic prescription model to allow for full and fair competition. On a practical level, this will translate into a farmer's PVP or Co-op vet issuing an electronic prescription held on a secure database. The PVP or Co-op vet can create a prescription on his handheld or office-based device. Veterinary medicines can then be dispensed in a transparent manner. Once the veterinary product is dispensed to the farmer, the prescription will be deleted to ensure the integrity of the prescription is only used once with no scope for misuse. Such a system does not require an ICT capability by the farmer. An electronic prescription model will also enable DAFM to comply with the provisions on data collection contained in the new regulation.

Summary:

ICOS is concerned that the implementation of the new regulation will have the following implications:

- Negatively impact national milk quality standards, if the requirement to move from Blanket Dry Cow Therapy (BDCT) to Selective Dry Cow Therapy (SDCT) is rushed. 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.
- 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, Pharmacists and Independent Licenced Merchants (LMs). It will narrow the distribution channel and reduce choice. In turn, increase the costs of medicines, as Co-ops and LMs will be disadvantaged in the marketplace.
- This will undermine the sustainability of Co-op store networks, as a key pillar of their offering will be weakened, and footfall will be diminished. Therefore, 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.

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

1. 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.
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 or other national database.
4. 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.
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 environmental sustainability.
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.

ENDS