Department of Agriculture, Food and the Marine

Public Consultation on EU Regulation on Veterinary Medicinal Products 2019/6

Submission by the Irish Co-operative Organisation Society

Legislative Process & Consultation:

- On the 31st of January 2020, ICOS made a detailed submission to the Department of Agriculture, Food and the Marine's stakeholder consultation on the EU Veterinary Medicinal Products Regulation 2019/6. On the 28th of February 2020, ICOS made a further submission to the Health Products Regulatory Authority (HPRA) in response to its stakeholder consultation into the HPRA Task Force Report on the method of supply of antiparasitic veterinary medicinal products (VMPs) that are intended for food producing species.

- ICOS and other stakeholders subsequently participated in virtual meetings with DAFM and the HPRA to discuss the impact of the regulation. The holding of virtual meetings was necessary due to public health advice. However, these meetings cannot be used to replace formal stakeholder engagement due to the technical limitations associated with virtual meetings. We expect due to the importance of the regulation, that both competent authorities will engage in face to face meetings with stakeholders in the near future, subject to public health guidelines to ensure full and complete consultation.

- DAFM will develop a Regulatory Impact Assessment and draft complementary national legislation to give effect to Regulation 2019/6 into Irish law. The implementation of Regulation 2019/6 will have significant economic impacts on businesses and rural communities with potential competition implications. ICOS is calling on DAFM to ensure these economic and competition implications are fully and adequately assessed before the publication of the draft national legislation with all relevant agencies consulted including the Competition and Consumer Protection Commission.

- The consultation document states that as Regulation 2019/6 has direct effect with limited areas for national discretion, SI 786/2007 will be repealed and replaced by a new SI which provides for these limited areas of national discretion, as well as appropriate sanctions for non-compliances.

- However, in many aspects Regulation 2019/6 has similar provisions to SI 786/2007. For example, Regulation 2019/6 under Article 105 (3) states that 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 other proper assessment provision under Article 105 (3) enables the continuation of Schedule 8 of SI No 786/2007, whereby antimicrobial (AM) intramammary tubes can be prescribed by a veterinarian employed by a milk purchaser to farmers participating in an approved Mastitis Control Programme (MCP). ICOS is wiling to engage with DAFM on areas where Schedule 8 of SI No 786/2007 can be strengthened to ensure full compliance with all aspects of Article 107 of Regulation 2019/6. However, it would be completely unjustified and wrong to repeal and replace existing mechanisms such as Schedule 8 that have worked well and provide for prescribing on the basis of the "any other proper assessment" provision. This mechanism is already in national legislation and there is no reason why this provision shouldn't be continued. On the contrary, ICOS believes that this mechanism can provide a template for the prescribing of other veterinary medicines that may be upregulated to Prescription Only Medicines (POM) status such as antiparasitic VMP's.

Economic Role of Licenced Merchants:

- ICOS co-operative businesses are major contributors to Ireland's €14.5 billion agri-food exports, with dairy sector exports accounting for €4.4 billion and livestock exports worth €3.9 billion in 2019. ICOS members operate the majority of the over 1,000 licenced merchant (LM) outlets approved by the Department of Agriculture, Food and the Marine.

- This route to market for veterinary medicines alongside private LM outlets and private veterinary practices (PVP's) ensures the widest possible distribution network, which enables farmers access to antimicrobial, anti-parasitic and anthelminthic products, which after 28th January 2022 may become predominantly POM.

- ICOS is very concerned that without careful consideration by the competent authorities, the reform of the current distribution network may place many LM's (co-op and privately owned) in danger of closing.

- Veterinary medicines account for an important part of the annual sales generated by co-op agri-trading stores, creating vital footfall into stores that in many cases would not be viable without them. The network of agri-trading stores owned by ICOS members is geographically spread right throughout the rural economy.

- The upregulating of antiparasitic VMP's to POM will place LM outlets at an immediate disadvantage, as veterinary practices will have the unfair competitive advantage as being the prescriber and dispenser. This is contrary to best practice across several EU member states, such as Italy and Sweden whereby the prescriber cannot dispense and

indeed contrary to the situation that exists regarding human medicine i.e. the prescriber cannot dispense.

National Labelling:

- The consultation document notes that EU member states have discretion to provide for additional national labelling requirements under Article 10 and 11 of Regulation 2019/6. We agree with DAFM that providing labelling requirements unique to Ireland may result in additional costs to industry in supplying the Irish market. This could result in commercial decisions not to supply the Irish market and therefore it is not in Ireland's best interests to provide for additional labelling requirements. ICOS believes that greater awareness is needed in relation to products containing Critically Important Antibiotics for human medicine (HP-CIA's). We would support additional labelling on an EU wide basis only to better inform the public, as to whether a veterinary medicinal product contains HP-CIA's or not and in this regard Regulation 2019/6 is a missed opportunity.

Highest Priority Critically Important Antibiotics:

- ICOS fully supports and endorses DAFM's policy on the use of the highest priority critically important antimicrobials, which is a key action under Ireland's National Action Plan on Antimicrobial Resistance 2017-2020. ICOS members have demonstrated tangible leadership by destocking intramammary tubes containing HP-CIA's to mitigate the risk to public health. Our leadership was recognised positively by the European Commission during the ECDC Country Visit in 2019. This reflects our position as food processors and our greater reliance than other stakeholders to ensure food producing animals within the milk production supply chain 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.

Retention of the Holistic Approach to Mastitis Control:

- The consultation document rightly draws attention to the catastrophic risks posed by the development of AMR (Antimicrobial Resistance). Antibiotics are vital tools to protect animal health and welfare and we must ensure they are used prudently into the future.

- AM intramammary dry cow tubes account for an extremely small proportion of the total volume of antimicrobials sold in Ireland. In 2018, intramammary dry cow tubes represented 2.8% of total veterinary antimicrobial sales, while intramammary milking

tubes accounted for 0.6% of total sales. Of note, research presented to the iNAP Animal Health Implementation Committee in October 2019 by Dr Catherine McAloon demonstrated that the proportion of intramammary dry and in-lactation tubes sold through the Schedule 8 retail channel has fallen year on year since 2015. This is consistent with sales data from ICOS members demonstrating an increase in sales of teat sealants, in line with efforts by the dairy industry to promote the use of selective dry cow therapy. The evidence indicates that Ireland has seen a 33% reduction in the use of in-lactation intramammary treatments in the last decade, and a 25% reduction in the use of dry cow intramammary antibiotics in the last 5 years.

- Despite intramammary tubes representing a relevantly small proportion of the total antimicrobial sales, the new regulation will necessitate a significant change to the practice followed by dairy farmers, which has been to treat their cows with an AM intramammary tube before drying off. Article 107 (3) of Regulation 2019/6 states that antimicrobials must not be used for prophylaxis (preventative treatment to a healthy animal) except in very exceptional circumstances. The transition to selective dry cow therapy (SDCT), away from blank dry cow therapy (BDCT) will take considerable time, education and resources across the milk production supply chain. ICOS members through their on-farm milk advisory teams, alongside the AHI CellCheck Programme has delivered year on year reductions in the Somatic Cell Count (SCC) across the national herd. The national SCC average has fallen from an average of 272,000 cells/ml in 2009 to 183,000 cells/ml in 2018.

- ICOS is very concerned that the successful efforts to reduce SCC levels may be reversed with negative economic consequences at farm and processor level, given the extremely short timescale involved (less than 18 months before the implementation of the Regulation), and the lack of clarity provided by DAFM to date, as to what exactly Article 107 (3) will mean for dairy farmers.

- The transition to SDCT is a process not without risk and requires careful management with expert advice. AHI has offered a national dry cow consult through the CellCheck Programme with funding from the RDP TASAH programme and co-op milk advisory teams are actively helping suitable herds to make the transition. Additional supports and programmes will be needed to enable co-op milk advisors and farm advisors continue to assist milk suppliers with the transition from BDCT to SDCT.

- The carrying out of regular milk recording is an essential starting point to identify cows with a low SCC level, below 50,000 cells/ml and cows with no history of clinical cases. The level of milk recording is low in Ireland compared to international comparisons with 40% of dairy herds and 50% of total cow's milk recorded on an annual basis. Dairy co-ops have supported milk recording by offering incentives, which has encouraged the uptake of milk recording. However, an investment of over €10 million will be

required to increase milk recording capacity. This is a significant investment and highlights the scale of the challenge confronting industry.

- The greater use of milk recording will deliver important co-benefits, in terms of lower greenhouse gas emissions and improved animal health outcomes. ICOS is calling on DAFM to support milk recording through the Common Agricultural Policy by developing a milk recording eco-scheme for dairy farmers.

- The most effective approach to managing mastitis is through a holistic approach, incorporating co-op farm advisors, milking machine technicians, MCP co-op vets and local PVPs and co-op nutritionists. This involves the delivery of a single message based on the AHI CellCheck Farmer Guidelines and Co-op MCP checklist.

- ICOS is strongly calling on DAFM to legislate for the continuation of prescribing under Schedule 8 of SI 786/2007, which is legally possible under the provisions of Article 105 (3) of Regulation 2019/6. We recognise that Article 107 of Regulation 2019/6 includes important new principles, but there are no justifiable reasons why new provisions could not be included in the legislation, subject to adequate consultation that will strengthen and improve the prescribing of intramammary antimicrobials through this important route for farmers and their co-ops.

Anthelmintic Resistance /Antiparasitics:

- The consultation document states that from 2022, all antiparasitics will be reclassified as POM due to reporting of anthelmintic resistance in parasites in Ireland. The consultation document further states that it is not open to Ireland to re-open the Regulation to allow for non-veterinarians to prescribe antiparasitic drugs. However, the document notes that there are options for government relating to the prescribing of the products by veterinarians (e.g. period of validity of the prescription) as well as the dispensing of the products concerned, in conjunction with a valid prescription. DAFM recognises that the above is significant change and recognises the concerns and impacts of this change on the LM sector in particular.

- ICOS recognises that there is evidence of anthelmintic resistance in Ireland with resistance to benzimidazole (white wormer), levamisole (yellow wormer) and macrocyclic lactone (clear wormer) now identified on Irish cattle and sheep farms. Irish agriculture needs and requires anthelmintics now and in the future to be effective so as to maintain a sustainable agri-food sector.

- However, it is equally important to point out that in other EU Member States, there is evidence of Anthelmintic Resistance where anthelmintics have been POM for many years. There is clear evidence to suggest that inappropriate use and dosage of these

VMP's are the main drivers for resistance and not the route of supply or prescription method.

- The current route of supply and prescribing methods via Suitably Qualified Persons (SQP's) has not resulted in Ireland having a significant increase in resistance being detected.

- ICOS members have invested considerably in training their SQP's so as to operate and comply with the current requirements under the LM regulation. It is compulsory for all staff recruited to work as "responsible persons" for the purpose of selling or supplying veterinary medicines from a LM premises to complete a QQI level 6 course entitled "Retail Sale and Supply of Animal Remedies". 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.

- ICOS strongly emphasises that SQP's employed by co-ops are ideally positioned to advise and influence farmers decisions on the correct type and dosage of anti-parasitic treatments required by their livestock.

- ICOS understands that DAFM is in the process of seeking important clarifications from the European Commission as to whether Article 105 (4) of Regulation 2019/6 could apply in Ireland after the 22nd of January 2020, which we welcome.

- Article 105 (4) permits a Member State to 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 Regulation 2019/6. Given that antiparasitic VMP's were not POM before the entry into force of the Regulation in Ireland and these VMP's will not become POM until after the 22nd of January 2020, there are very strong grounds to argue that SQP's, as qualified professionals were dispensing these VMP's and that EU law recognises that current national practice before the entry into force of the regulation should be respected. ICOS is of the strong view that there should not be a change in the route of supply or the prescribing method.

- We reiterate that ICOS and its members fully 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 in international markets.

- ICOS has extensively engaged with DAFM and the HPRA on this matter over recent years. We have at all times, sought to bring solutions to the table that are practical and workable. Our proposal for a sustainable and responsible prescribing model has

been developed following detailed consultation with our members. In doing so, our proposal seeks to address three significant issues:

1. Introduction of an electronic prescription model to allow for full and free competition.
2. An electronic prescription model will also facilitate compliance with Article 57 of Regulation 2019/6 related to data collection.
3. A holistic approach based on herd health plans for antiparasitic control to facilitate prescribing under the other proper assessment by a veterinarian.

- 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 will facilitate 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 a SQP 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 to 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 for antimicrobial VMP's as per Article 105 (10) of Regulation 2019/6.

- Regulation 2019/6 specifically states under Article 105 (10) that "a veterinary prescription for antimicrobial medicinal products shall be valid for five days from the date of its issue." Regulation 2019/6 under Article 4 defines an antimicrobial as "a

substance with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals, antifungals and anti-protozoals". It is evident therefore that the 5-day stipulation in Regulation 2019/6 is specific to antimicrobials and that the validity of prescriptions for non-antimicrobials is not subject to binding restrictions. If the competent authorities proceed with the HPRA advice to upregulate antiparasitic veterinary medicines to POM, ICOS recommends that the prescription for these VMP's should be valid for at least one year from the date of issue. From a practical perspective, a farmer participating in an annual herd health plan requires the flexibility to administer these VMP in a practical and appropriate manner.

- 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. We believe that the co-op sector is ideally placed to deliver these outcomes in targeted manner that will mitigate against the development of resistance. ICOS contends that a considerable knowledge transfer focus is needed to ensure that the correct dosing technique is used and that the animals are treated according to the manufacturer's instructions and dose rates, with the involvement of Teagasc, AHI, Co-ops and VMP manufacturers.

- ICOS recommends the establishment of a sustainable and responsible prescribing model based on a multi-faceted herd health programme combining the MCP, a PCP (parasite control programme) and IDPP (Infectious diseases prevention plan) with veterinary oversight.

- 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.

- This multi-faceted approach will incorporate 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.

- We are calling on the competent authorities to facilitate this new prescribing model, which is a holistic and multi-faceted approach to herd health management implemented by co-ops through multi-disciplinary teams and veterinary oversight.

Distance Selling:

- We note that Article 104 of Regulation 2019/6 provides for distance selling of POM's but this is at the discretion of the EU member state and there must be a national secure system in place to control this practice. The competent authorities should consider how a system would work effectively in an Irish context and consult widely with stakeholders, providing the necessary controls to regulate a secure national system. A key provision must be that the medicine can only be dispensed to the farmer by a 'Responsible Person' at a LM retail premises such as a co-op branch, a PVP or pharmacy. The challenges associated with regulatory alignment on the Island of Ireland will have to be considered.

Regulatory Alignment on the Island of Ireland:

- The decision by the HPRA to recommend the upregulating of antiparasitic VMP's to POM will reinforce a divergence in regulatory standards on the Island of Ireland in relation to veterinary medicines. ICOS calls on the HPRA and DAFM to carefully consider this matter before proceeding with its decision, as after 2022 increased surveillance may be needed to protect the integrity of the Single Market.

- DAFM have assured ICOS that the surveillance and administration of potential usage of product prescribed in Northern Ireland but administered by ROI farmers on their livestock will not occur. This will be a challenge, considering the significant cross border trade along the 500km border on the Island of Ireland, and has the potential to cause a significant trade distortion to LM outlets operating in the border counties.

Advertising:

- We note and agree with the sentiment expressed in Regulation 2019/6 that the usage of POM products cannot be promoted by advertising except to veterinary practitioners. However, the provision of information regarding the correct usage of anthelmintics and antiparasitics in general must be promoted as part of educational programmes both within and outside herd health plans. The new national legislation should also allow for the advertising of POM immunological (vaccine) VMP's to the end user, as the use of preventive medicines play a vital role in reducing antibiotic usage.

Wider access to preventative medicines:

- A key objective of Regulation 2019/6 is to increase the availability of VMP's, but especially preventative products such as vaccines. Many of the new generation vaccines are categorised as POM or POM (E). This appears to be counter-intuitive to the overarching principle of the WHO that prevention is better than the cure. The HPRA needs to consider carefully the recategorisation of many new vaccines to ensure

their access and use is increased in order to have a positive downward pressure on antimicrobial usage.

Veterinary Medicines Supply Chain:

- Given our location on the periphery of Europe, and the impending challenges posed by Brexit, the competent authorities must ensure the maximum availability of veterinary medicines into the Irish market without extra costs or conditionality.

- We support the maintenance within the new national legislation to allow registered veterinary practitioners and licenced wholesalers under the cascade to import under DAFM licence, VMP's authorised in another Member State (or for pharmaceuticals from a third country which is provided in the new regulations).

- It should be noted that Ireland represents a small market, and access to the best veterinary medicine technology is vital to maintain our competitiveness as a global exporter of agri-food products. Under Article 99 (6), consideration should be given to differentiation between human and veterinary products with regard to good distribution practice.

- ICOS contends that the national legislation when interrupting Article 105 (11) should ensure that veterinary practices when dispensing a VMP are compliant with the appropriate record keeping procedures to prevent the bundling of professional services and sales of VMP's.

- The application of Article 121 (1) should apply to the person (s) to whom the medicine is being supplied.

Summary:

- Maintenance of the current distribution network for antiparasitic VMP's is essential for Irish farmers and their co-ops and must be the aim of DAFM in the implementation of Regulation 2019/6. The future upregulating of antiparasitic VMPs to POM will cause serious disruption to the current distribution model and will create significant market distortion. In the absence of solutions to this unintended outcome, the Irish Government should be in no doubt that it must adopt best practice in other Member States such as Italy and Sweden, whereby the prescriber cannot dispense thereby ensuring no anti-competitive consequence. ICOS in our submission has put forward a number of proposals that we believe will strengthen and improve animal health outcomes, whilst maintaining the wide availability of VMP's and the integrity of the POM system of prescribing for food producing animals.