An Roinn Talmhaíochta,
Bia agus Mara
Department of Agriculture,
Food and the Marine

Department of Agriculture, Food and the Marine
Public Consultation on
EU Regulation on Veterinary Medicinal Products 2019/6

Public Consultation Introduction

The Department of Agriculture, Food and the Marine (DAFM) and the Health Products Regulatory Authority (HPRA) are the competent authorities for the purpose of this Regulation. The Regulation applies in the European Union on 28 January 2022 and sets out rules for the sale, manufacture, import, export, supply, distribution, advertisement, control and use of veterinary medicinal products, aiming to:

1. modernise legislation;
2. stimulate innovation in and increase the availability of veterinary medicinal products; and
3. strengthen the EU's campaign against antimicrobial resistance.

National discretion is allowed in a number of areas and these are listed later in this document. DAFM invites submissions from the public on the contents of the new Regulations.

The Regulation entered into force on 28 January 2019, following a 5 year period of negotiation and cannot now be changed. It applies directly on Member States from 28 January 2022. DAFM and the HPRA will use the intervening time to consult with stakeholders, develop a Regulatory Impact Assessment and draft complementary national legislation to give effect to various optional provisions of the Regulation.

Submissions

The email address for receipt of all submissions is vetmedregs@agriculture.gov.ie
They should be titled EU Regulation Public Consultation Submission.

The closing date for submissions is 17.00 on Wednesday 22nd July 2020.

All submissions received may be made available on the DAFM website after the closing date and are subject to the provisions of the Freedom of Information Acts.

Background

EU Regulation on Veterinary Medicinal Products 2019/6 entered into force in January 2019. However, it only applies from 28 January 2022 and is directly applicable and binding throughout the European Union (EU).

The main objectives of the new Regulation are to:

1. simplify the regulatory environment and reduce the administrative burden for pharmaceutical companies developing veterinary medicines, for example through streamlined pharmacovigilance rules;
2. stimulate the development of innovative veterinary medicines, including products for small markets (minor use and minor species);
3. improve the functioning of the internal market for veterinary medicines;
4. strengthen EU action to fight antimicrobial resistance through specific measures ensuring prudent and responsible use of antimicrobials in animals, including reserving certain antimicrobials for the treatment of infections in humans in line with a 'One Health' approach for the benefit of animal and public heath and every EU citizen.

Regulation (EU) 2019/6 repeals Directive 2001/82/EC and amends the provisions of Regulation (EU) 2004/726 relating to the authorisation and supervision of veterinary medicines, which currently governs the centralised marketing authorisation procedure for both human and veterinary medicines.

It should be noted that EU Regulations have binding legal force throughout every Member State while Directives lay down certain results that must be achieved but each Member State is free to decide how to transpose Directives into national laws. Therefore, in order to transpose EU Directives into Irish law detailed national secondary legislation is typically required specifying how the provisions of the Directive will be achieved. The provisions of Directive 2001/82/EC are largely captured in Statutory Instrument 786/2007 European Communities (Animal Remedies) (No.2) Regulations 2007.

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.

In considering aspects of 2019/6, the competent authorities in consultation with stakeholders will seek to be guided by the principles underpinning the new Regulation:

1. Increase the availability of veterinary medicinal products

2. Reduce administrative burden
3. Stimulate competitiveness and innovation
4. Improve the functioning of the internal market
5. Address the public health risk of antimicrobial resistance (AMR)

The aim is to respect these principles while also safeguarding public and animal health and the protection of the environment. For example, under Articles 10 and 11 Member States have discretion whether to provide for additional national labelling requirements. Providing for labelling requirements unique to Ireland may result in additional costs to industry in supplying the Irish market. This could result in a commercial decision not to supply the Irish market or to increase the product cost to the consumer. In these circumstances it may be in Ireland's best interests not to provide for additional national labelling requirements.

Antimicrobial Resistance (AMR)

A particular focus underpinning the drafting and implementation of Regulation 2019/6 is the growing understanding of the risks of AMR. The World Health Organisation (WHO) has defined AMR as "a catastrophe that must be managed with the utmost urgency". AMR is estimated to be responsible for 33,000 deaths per year in the EU alone and 700,000 deaths per year globally. Without effective antimicrobial cover, routine surgical procedures and cancer chemotherapy become high risk and infections that were once deemed relatively minor have the potential to kill. In animal health, antibiotics are vital 'tools' to protect animal health and welfare in both companion and food producing animals. The misuse and overuse of antibiotics accelerates the rate at which resistance develops. Reducing the use of antibiotics in both the human and animal health sectors is seen as a key intervention in tackling AMR.

It is clear that a multi-faceted approach with engagement from all sectors in the food supply chain is required to achieve long lasting behavioural change in the way we use antibiotics.
The new Regulation aims to reduce antimicrobial usage and includes the following important principles:

1. Antimicrobials must not be applied routinely; and must not be used to compensate for poor hygiene, inadequate animal husbandry, or poor farm management (article 107.1);
2. Antimicrobials must not be used for prophylaxis (preventive treatment to a healthy animal) except in very exceptional circumstances (article 107.3);
3. Antimicrobials 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 (article 107.4);
4. Restrictions apply regarding the use of certain types of antimicrobials (article 37.5);

5. All veterinary prescriptions should be based on a clinical examination or other proper assessment by a veterinarian (article 105.3);
6. Veterinary prescriptions for antimicrobials are only valid to be filled for 5 days; and are limited to the amount required for the treatment concerned (article 105.10). This means the prescription must be filled within 5 days, but the duration of treatment may be for longer than 5 days.

Antiparasitics

Separately, the route of sale of antiparasitic veterinary medicinal products is due to change following the December 2019 HPRA Task Force report. The HPRA's Advisory Committee for Veterinary Medicines established a Task Force to review all available evidence following substantial reporting of anthelmintic resistance in parasites found in Ireland and a global demonstration of resistance to all antiparasitic veterinary medicinal products.
The report conclusively determined that the scientific evidence now available shows that antiparasitic veterinary medicinal products do not comply with veterinary prescription exemption criteria in Directive 2006/130/EC which are also contained in Regulation 2019/6. Therefore, from 2022 all antiparasitics will be reclassified as prescription only medicines. This brings Ireland in line with other Member States. Ireland must now comply with this new classification.

While this reclassification is not as a direct result of the incoming EU Regulation it is an area recognised by DAFM as a significant change to the veterinary medicinal product industry in Ireland and as such DAFM would like to take this opportunity to seek comment on it. This area is addressed separately at the end of this consultation document.

Note also, that it is not open to Ireland to re-open the Regulation to allow for non-veterinarians to prescribe antiparasitic drugs; however 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 invites comments on Areas of National Discretion

There are a number of areas where Member States have national discretion, and these are listed below. The competent authorities are proposing that generally existing national legislation will pertain.

You are invited to comment on these areas.

Areas of particular focus for DAFM in considering implementation include:

1. Clarifying wholesaling standards – articles 99-101 detail new standards for the wholesale distribution of veterinary medicinal products. The requirement for a responsible person and adoption of good distribution practices will be a major change for the industry.
2. Addressing AMR challenges; collection of data on the volume of sales and use of antimicrobials .The Regulation will put in place the EU AMR database (article 57). Ireland is already collecting AMR information from certain areas of the industry. Providing rules on and encouraging prudent use of antimicrobials (article 107) all provide challenges to our stakeholders.
3. Strengthening and recognising the role of veterinary practitioners and prescriptions (article 105-107) in facilitating prudent use and effective regulation of veterinary medicinal products. There are significant challenges facing authorities in implementing this Regulation which will respect its principles while taking account of the impact on all stakeholders. There is a very substantial task in finding a balanced approach which also seeks to try and satisfy availability of medicinal products and reducing the administrative burden while safeguarding public and animal health and protection of the environment.
4. If the provision of distance selling of prescription only veterinary medicinal products (article 104) is appropriate or feasible. The Regulation allows Member States the opportunity to decide whether they wish to allow the internet sales of prescription only medicines. If allowed, Prescription Only Medicines may only be sold within a Member State, and there must be a national secure system in place to control this practice. DAFM would welcome feedback from stakeholders at to whether a secure national system is desirable and what format it might take.
5. Collection and disposal of waste of veterinary medicinal products (article 117).
6. Appropriate advertising of different categories of veterinary medicinal products (article 119-122). There is a new provision to allow immunological prescription only veterinary medicinal products to be advertised to professional keepers of animals, so long as it is accompanied by an invitation to the keeper to consult a veterinary practitioner. This

provision will assist with the recognised public health need for promotion of vaccines to professional keepers of animals.

7. Autogenous Vaccines (article 2.3). There is the need to put in place a national procedure to regulate autogenous vaccines and their use. Good manufacturing practice will need to be adhered to as well as other measures and this is a significant change for that sector of the industry.

The relevant legislative references, per Competent Authority, are set out in Tables 1 and 2 below.

As mentioned previously, DAFM and the HPRA are the competent authorities for the purposes of regulating the veterinary medicines market in Ireland. DAFM's role is primarily concerned with the supply, administration and use of veterinary medicinal products, in such areas as wholesaling, retail and special import licences of veterinary medicinal products. The HPRA is responsible for the authorisation of veterinary medicinal products and all activities associated with their manufacture, clinical trials, and regulating scientific use of animals.

Table 1: DAFM areas as competent authority

Article	Definition	Text	Reference to provision in Current Legislation
99	Wholesale distribution authorisations	4. Member States may decide that supplies of small quantities of veterinary medicinal products from one retailer to another in the same Member State shall not be subject to the requirement of holding a wholesale distribution authorisation.	Directive 2001/82: Article 65
103	Retail of veterinary medicinal products and record keeping	1. The rules on retail of veterinary medicinal products shall be determined by national law, unless otherwise provided in this Regulation.	SI 786/2007: Regulations 27-29, 31-36, 38. Schedule 6
		4. Where Member States consider it necessary, they may require retailers to keep detailed records of any transaction of veterinary medicinal products not subject to veterinary prescription.	SI 786/2007: Regulation 31 (5), 34

Article	Definition	Text	Reference to provision in Current Legislation
		6. Member States may impose conditions justified on grounds of protection of public and animal health or of the environment for the retail on their territory of veterinary medicinal products provided that such conditions comply with Union law, are proportionate and non-discriminatory.	**NEW**: DAFM envisage policy areas such as our national Antimicrobial Resistance Policy will inform DAFM decision.
104	Retail of veterinary medicinal products at a distance	2. By way of derogation from paragraph 1 of this Article, a Member State may allow persons permitted to supply veterinary medicinal products in accordance with Article 103(1) to offer veterinary medicinal products subject to a veterinary prescription pursuant to Article 34 by means of information society services, provided that the Member State has provided a secure system for such supplies. Such permission shall only be granted to persons established in their territory and supply shall only occur within the territory of that Member State.	**NEW**
		10. Members States may impose conditions, justified on grounds of public health protection, for the retail, on their territory, of veterinary medicinal products offered for sale at a distance by means of information society services.	**NEW**: DAFM envisage policy areas such as our national Antimicrobial Resistance Policy will inform DAFM decision.
105	Veterinary prescriptions	11. In addition to the requirements set out in this Article, Member States may lay down rules on record-keeping for veterinarians when issuing veterinary prescriptions.	SI 262/2012: Regulation 12 & SI 558/2017 Regulation 6
		12. Notwithstanding Article 34, a veterinary medicinal product classified as subject to veterinary prescription under that Article may be administered without a veterinary prescription by a veterinarian personally, unless otherwise provided for under applicable national law. The veterinarian shall keep records of such personal administration without prescription in accordance with applicable national law.	SI 786/2007: Regulation 28(6) & SI 558/2017: Regulation 3

Article	Definition	Text	Reference to provision in Current Legislation
106	Use of medicinal products	3. Member States may lay down any procedures they deem necessary for the implementation of Articles 110 to 114 and 116.	SI 786/2007: Regulation 16-18
		4. Member States may, if duly justified, decide that a veterinary medicinal product shall be administered only by a veterinarian.	SI 786/2007: Regulation 39
107	Use of antimicrobial medicinal products	7. A Member State may further restrict or prohibit the use of certain antimicrobials in animals on its territory if the administration of such antimicrobials to animals is contrary to the implementation of a national policy on prudent use of antimicrobials.	**NEW**: DAFM envisage policy areas such as our national Antimicrobial Resistance Policy will inform DAFM decision under this article.
108	Record-keeping by owners and keepers of food-producing animals	4. Member States may lay down additional requirements for record-keeping by owners and keepers of food-producing animals.	SI 786/2007: Regulation 42, Schedule 7
110	Use of immunological veterinary medicinal products	1. The competent authorities may, in accordance with the applicable national law, prohibit the manufacture, import, distribution, possession, sale, supply or use of immunological veterinary medicinal products on their territory or in a part of it if at least one of the following conditions is fulfilled: (a) the administration of the product to animals may interfere with the implementation of a national programme for the diagnosis, control or eradication of animal disease; (b) the administration of the product to animals may cause difficulties in certifying the absence of disease in live animals or contamination of foodstuffs or other products obtained from treated animals; (c) the strains of disease agents to which the product is intended to confer immunity is largely absent in terms of geographic spread from the territory concerned.	2001/82: Article 71; SI 193/2014: Control on Animal Vaccines Regulations

Article	Definition	Text	Reference to provision in Current Legislation
		2. By way of derogation from Article 106(1) of this Regulation, and in the absence of a veterinary medicinal product as referred to in Article 116 of this Regulation, in the event of an outbreak of a listed disease as referred to in Article 5 of Regulation (EU) 2016/429 or an emerging disease as referred to in Article 6 of that Regulation, a competent authority may allow the use of an immunological veterinary medicinal product not authorised within the Union.	SI 786/2007: Regulation 16
		3. By way of derogation from Article 106(1) of this Regulation, when an immunological veterinary medicinal product has been authorised but is no longer available within the Union for a disease which is not referred to in Article 5 or 6 of Regulation (EU) 2016/429 but which is already present in the Union, a competent authority may, in the interest of animal health and welfare and public health, allow the use of an immunological veterinary medicinal product not authorised within the Union on a case by case basis.	SI 786/2007: Regulation 16
		5. If an animal is to be exported to a third country and thereby subject to specific binding health rules in that third country, a competent authority may permit the use, solely for that animal concerned, of an immunological veterinary medicinal product that is not covered by a marketing authorisation in the relevant Member State but its use is allowed in the third country to where the animal is to be exported.	SI 786/2007: Regulation 16
117	Collection and disposal of waste of veterinary medicinal products	Member States shall ensure that appropriate systems are in place for the collection and disposal of waste of veterinary medicinal products.	SI 786/2007: Regulations 11(9), 30(5j), 42(4). This will be further informed by the iNAP working group on hazardous waste.

Article	Definition	Text	Reference to provision in Current Legislation
119	Advertising of veterinary medicinal products	1. Only veterinary medicinal products that are authorised or registered in a Member State may be advertised in that Member State, unless otherwise decided by the competent authority in accordance with applicable national law.	SI 786/2007: Regulation 37
120	Advertising of veterinary medicinal products subject to veterinary prescription	2. By way of derogation from paragraph 1 of this Article, advertising of veterinary medicinal products that are subject to veterinary prescription in accordance with Article 34 to professional keepers of animals may be permitted by the Member State provided the following conditions are met: (a) the advertising is limited to immunological veterinary medicinal products; (b) the advertising includes an express invitation to the professional keepers of animal to consult the veterinarian about the immunological veterinary medicinal product.	NEW: DAFM intend to allow this provision to assist with the recognised public health need for promotion of vaccines to professional keepers of animals.
122	Implementation of advertising provisions	Member States may lay down any procedures they deem necessary for the implementation of Articles 119, 120 and 121.	SI 786/2007: Regulation 37
131	Suspending or revoking a wholesale distribution authorisation	2. In the event of non-compliance with the requirements laid down in Article 101, other than paragraph 3 thereof, the competent authority may, without prejudice to any other appropriate measures under national law, take one or more of the following measures: (a) suspend the wholesale distribution authorisation; (b) suspend the wholesale distribution authorisation for one or more categories of veterinary medicinal products; (c) revoke the wholesale distribution authorisation for one or more categories of veterinary medicinal products.	SI 786/2007: Regulation 49(4B)

Table 2: HPRA areas as competent authority

Article	Definition	Text	Reference to provision in Current Legislation
5	Marketing authorisations	The HPRA is the competent authority for deciding whether a product falls under the scope of the Regulation and requires a marketing authorisation. The existing system needs updating to provide for developments in science as well as improved compliance. A system of registration of products deemed out of scope of the Regulation could provide a useful database and public register of such products. 6. In the case of veterinary medicinal products intended for animals which are exclusively kept as pets: aquarium or pond animals, ornamental fish, cage birds, homing pigeons, terrarium animals, small rodents, ferrets and rabbits, Member States may allow exemptions from this Article, provided that such veterinary medicinal products are not subject to a veterinary prescription and that all necessary measures are in place in the Member State to prevent unauthorised use of those veterinary medicinal products for other animals. If no exemptions are allowed, the products concerned will require marketing authorisations (as for conventional veterinary medicines). Alternatively, if exemptions are allowed, the products concerned must still meet certain provisions of Regulation 2019/6, meaning that a registration system is needed to give effect to the specified controls.	Directive 2001/82: Article 5.1, SI 786/2007: Regulation 3(3)(a)(i) Directive 2001/82: Article 4.2, SI 786/2007: Regulation 3(3)
9	Clinical Trials	Under existing legislation, the HPRA consults the DAFM in relation to applications for clinical trials. This system could be simplified and better formalised. It could be clarified that substances and products used for pre-clinical testing under Directive 2010/63/EC are outside the scope of this legislation.	SI 786/2007: Regulation 19 amended by SI 361/2014

Article	Definition	Text	Reference to provision in Current Legislation
10	Labelling of the immediate packaging of veterinary medicinal products	3. Notwithstanding paragraph 1, a Member State may decide that, on the immediate packaging of a veterinary medicinal product made available in its territory, an identification code shall be added to the information required under paragraph 1.	**NEW**: Authorities are not intending to provide for specific national labelling as this may negatively impact supply of veterinary medicinal products to Ireland.
11	Labelling of the outer packaging of veterinary medicinal products	2. A Member State may decide that, on the outer packaging of a veterinary medicinal product made available in its territory, an identification code shall be added to the information required under paragraph 1. Such a code may be used to replace the marketing authorisation number referred to in point (h) of paragraph 1.	**NEW**: Authorities are not intending to provide for specific national labelling as this may negatively impact supply of veterinary medicinal products to Ireland.
14	Package leaflet of veterinary medicinal products	3. Member States may decide that it shall be made available on paper or electronically, or both.	**NEW**
34	Classification of veterinary medicinal products	2. The competent authority or the Commission, as applicable, may, notwithstanding paragraph 1 of this Article, classify a veterinary medicinal product as subject to veterinary prescription if it is classified as a narcotic drug in accordance with national law or where special precautions are contained in the summary of product characteristics referred to in Article 35.	SI 786/2007: Schedule 1 Part 2(3a)
		3. By way of derogation from paragraph 1, the competent authority or the Commission, as applicable, may, except as regards veterinary medicinal products referred to in points (a), (c), (e) and (h) of paragraph 1, classify a veterinary medicinal product as not subject to veterinary prescription if all of the following conditions are fulfilled: (a) the administration of the veterinary	SI 786/2007: Schedule 1 Part 2(3a)

Article	Definition	Text	Reference to provision in Current Legislation
		medicinal product is restricted to pharmaceutical forms requiring no particular knowledge or skill in using the products; (b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal or animals treated or to other animals, to the person administering it or to the environment; (c) the summary of the product characteristics of the veterinary medicinal product does not contain any warnings of potential serious adverse events deriving from its correct use; (d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent adverse event reporting; (e) the summary of the product characteristics does not refer to contra-indications related to the use of the product concerned in combination with other veterinary medicinal products commonly used without prescription; (f) there is no risk for public health as regards residues in food obtained from treated animals even where the veterinary medicinal product is used incorrectly; (g) 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.	
79	Pharmacovigilance responsibilities of the competent authorities and the Agency	2. Competent authorities may impose specific requirements on veterinarians and other healthcare professionals in respect of the reporting of suspected adverse events. The Agency may organise meetings or a network for groups of veterinarians or other healthcare professionals, where there is a specific need for collecting, collating or analysing specific pharmacovigilance data.	SI 786/2007: Regulation 12(7a)
86	Registration of homeopathic veterinary medicinal products	2. Member States may lay down procedures for the registration of homeopathic veterinary medicinal products in addition to those laid down in this Chapter.	SI 786/2007: Regulation 7 as amended by SI 262/2012

Article	Definition	Text	Reference to provision in Current Legislation
88	Manufacturing authorisations	2. Notwithstanding paragraph 1 of this Article, Member States may decide that a manufacturing authorisation shall not be required for preparation, dividing up, changes in packaging or presentation of veterinary medicinal products, where those processes are carried out solely for retail directly to the public in accordance with Articles 103 and 104	SI 786/2007: Regulation 20 (3aii)
97	Qualified person responsible for manufacturing and batch release	5. The competent authority may lay down appropriate administrative procedures to verify that a qualified person referred to in paragraph 1 fulfils the conditions referred to in paragraphs 2 and 3.	SI 786/2007: Regulation 21 (2); Schedule 4
130	Suspending, revoking, or varying the terms, of marketing authorisations	5. Member States shall lay down procedures for application of paragraphs 1, 2 and 3.	SI 786/2007: Regulation 13

Reclassification of Antiparasitics as Prescription Only Medicines

Background

While the issue of the change in route of sale of antiparasitics is not as a result of the incoming EU Regulation it is an area recognised by DAFM as of significant change to the veterinary medicinal product industry in Ireland and as such DAFM would like to take this opportunity to seek comment on it.

In 2004 European legislation established a requirement that all veterinary medicinal products that are intended for use in food-producing animals should be subject to a veterinary prescription. However, a 2006 EU Directive allowed for the maintenance of non-prescription status for certain veterinary medicinal products which did not present a risk to human or animal health or to the environment, and which met the specified criteria for exemption from veterinary prescription. Ireland availed of the exemption in Directive 2006/130/EC at the time and antiparisitics were allowed to continue to be available without prescription.

There is a similar exemption available under the new EU Regulation 2019/6. So, in effect, European legislation in respect of dosing products has not changed as a result of EU Regulation 2019/6. However, since that time our knowledge and the scientific evidence regarding the impact of extensive use of antiparisitics has changed:

- Antiparasitic resistance has been widely reported in parasites of livestock species in Ireland.
- Globally, resistance is developing year-on-year and is now a significant animal health issue.

Antiparasitic Resistance

It is generally accepted that antiparasitic resistance is now a significant animal health issue. Resistance to antiparasitics has been confirmed and is now widespread in livestock and other species in Ireland. It has been widely reported in Ireland that resistance to all currently used antiparasitic veterinary medicinal products is developing year-on-year. Antiparasitics are an essential farm management tool but in order to preserve their efficacy we must strive to limit resistance.

In conjunction with the damaging effects on the environment by the overuse of antiparasitics, there are many costs to antiparasitic resistance including animal health and welfare and the actual economic cost of parasitic burden. Views from the HPRA's Task Force report included *"that*

resistance would ultimately lead to reduced production efficiency on Irish farms as well as reduced welfare standards and a decline in overall farm profitability."

The control of resistance is one of the objectives of Regulation 2019/6, including both AMR as well as antiparasitic resistance. Although there are a range of specific provisions directed to enhancing the available regulatory tools to control AMR, a number of measures have also been provided to address antiparasitic resistance, including:

a) Article 4: The assessment of the benefit-risk balance now specifically addresses '*any risk relating to the development of resistance'* in addition to the risks relating to the quality, safety and efficacy of the product,
b) Article 35: The Summary of Product Characteristics must contain information relating to '*special conditions for use, including restrictions on the use of antiparasitic veterinary medicinal products in order to limit the risk of development of resistance'*,
c) Article 37: An application for a marketing authorisation to the HPRA must be refused where *'the risk for antiparasitic resistance outweighs the benefits of the veterinary medicinal product to animal health'*,
d) Article 141: The Central European Committee for Medicinal Products for Veterinary Use (CVMP) has a task to '*provide scientific advice on the use of antiparasitics in animals in order to minimise the occurrence of resistance in the Union, and update that advice when needed'*.

The technical requirements for application dossiers, for marketing authorisations to the HPRA, have also been enhanced regarding testing to investigate resistance.

HPRA Task Force Report Findings

One of the tools to combat resistance is considered to be the effective use of antiparasitics. Key to addressing resistance is prescribing on foot of an accurate diagnosis. In 2019 the HPRA's Advisory Committee for Veterinary Medicines established a Task Force to review the method of supply of antiparasitic veterinary medicinal products that are intended for food-producing animals against the criteria set out in Regulation 2019/6. These are the same criteria as set out in Directive 2006/130/EC. A copy of the Report is available on the HPRA's website https://www.hpra.ie.

The Report states that the available scientific evidence shows that antiparasitic veterinary medicines that are intended for use in food-producing species do not comply with the criteria for derogation from veterinary prescription specified in EU Regulation 2019/6. It also states that a consequence of this determination is that any such products that are supplied without veterinary prescription will need to be up-regulated to supply under veterinary prescription. This brings

Ireland in line with other Member States. Ireland and all other Member States must now comply with this Regulation from January 2022. The decision to make antiparasitics prescription only medicines has now been made based on the scientific evidence contained within the HPRA taskforce report. There is no option to change this decision.

In accordance with existing national legislation, antiparasitic veterinary medicinal products for use in food-producing species that are supplied under prescription may be dispensed by veterinary practitioners, pharmacists and licensed merchants. This means that all current stakeholders that are already permitted to supply such products will be entitled to continue to stock them in the future; however, from January 2022 onwards a veterinary prescription will be needed to dispense them.

DAFM's Position on Antiparasitics

The Department's primary role is to regulate the responsible use of antiparasitics in the interests of animal health, animal welfare and supportive effective farm management. DAFM is focused on the acknowledged need to protect these products, recognising their importance in modern agriculture, and to ensure that they remain effective into the future. It is imperative to protect the antiparasitics we have available currently for this purpose as it is not envisaged that any new antiparasitics are imminent.

All stakeholders who can currently dispense antiparasitics (Licenced Merchants, Pharmacies and Veterinary Practitioners) will continue to be able to do so once they are presented with a veterinary prescription. EU Regulation 2019/6 does not permit Ireland to allow anyone other than a veterinary practitioner to prescribe veterinary medicines. This Regulation requires that a prescription shall only be issued after a veterinarian has conducted a clinical examination or another proper assessment of the health status of the animal or group of animals. DAFM acknowledges the challenges this brings in relation to the necessary use of antiparasitics and is working with its Regulatory partners to ensure compliance with these elements of the Regulation.

DAFM recognises the concerns and impacts of this change on the Licensed Merchants industry in particular and are engaging with stakeholders to seek workable solutions. However the solution cannot involve prescribing by non-vets as this matter is explicit in the Regulation 2019/6 and is not open to challenge at this point.

A further impact of antiparasitic veterinary medicinal products being reclassified will be the prohibition of these products from being advertised to the general public, as is the case for all prescription only medications. This will have a bearing on the farming media among others.

Principles to be adhered to in reducing Antiparasitic Resistance

- Promote economic benefits of a healthier herd
- Protect the efficacy of the drugs to sustain animal health and welfare
- Limit the development of resistance
- Promote the use of evidence based scientific tests to underpin the use of medicines
- Responsible prescribing
- Control access to antiparasitics
- Decrease use of antiparasitics
- Correct use of antiparasitics
- Protection of the environment

DAFM asks you to consider the following:

In order to promote the economic benefits of a healthier herd by protecting the efficacy of existing antiparasitics, how can Ireland provide for the necessary responsible use of antiparasitics given the principles to be adhered to in reducing antiparasitic resistance and respecting the legality and restrictions of the EU Regulation?

Submissions

The email address for receipt of all submissions is vetmedregs@agriculture.gov.ie
They should be titled EU Regulation Public Consultation Submission.

The closing date for submissions is 17.00 on Wednesday 22nd July 2020.

All submissions received may be made available on the DAFM website after the closing date and are subject to the provisions of the Freedom of Information Acts.

For information on data protection please see the following: https://www.agriculture.gov.ie/dataprotection/. The Data Protection Officer can be contacted at dataprotectionofficer@agriculture.gov.ie or, Data Protection Officer, Data Protection Unit, Department of Agriculture, Food and the Marine, Grattan Business Park, Dublin Road, Portlaoise, Co Laois R32 K857.