Frequently Asked Questions

on the EU Regulation on Veterinary Medicinal Products EU 2019/6

The Regulation applies in the European Union on 28 January 2022 and sets out rules for the sale, manufacture, import, export, supply, distribution, advertising, control and use of veterinary medicinal products.
The main aims of the Regulation are to increase the availability of veterinary medicinal products; to strengthen the EU's campaign against antimicrobial resistance; to safeguard public and animal health and protection of the environment; there is also a strong focus on responsible prescribing and use of veterinary medicines.

Prescribing

Q. Who can prescribe in Ireland?

A. The only person allowed to prescribe veterinary medicinal products (VMPs) in Ireland is a registered veterinary practitioner (VP). Under legislation before a VP can prescribe medicines for animals, those animals must be 'under their care' - this means, among other criteria, that the VP has been consulted by the owner and given responsibility for the professional care of the animal, herd or flock and be available for follow-up consultation/treatment.

Q. The Regulation mentions a derogation which allows someone other than a Veterinary Practitioner to prescribe – does this apply to Ireland?

A. No, Article 105(4) of EU Regulation 2019/6 states that: "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."

This Regulation entered into force in January 2019 and at that time Ireland's national legislation **did not allow** for a veterinary prescription to be issued by anyone, other than a VP. Therefore, it is **not an option open to Ireland**, or any other EU member state, to now apply for this derogation.

Q. A Suitably Qualified Person (SQP) can prescribe antiparasitics for food-producing animals in Northern Ireland; can Ireland not assign the same status to the Licensed Merchant's Responsible Person (RP) in the Republic?

A No, Article 105(4) of EU Regulation 2019/6 states that:

"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." The SQP in the UK was permitted to prescribe when this Regulation entered into force in 2019.

At that time Ireland's national legislation **did not allow** for a veterinary prescription to be issued by anyone, other than a VP.

Therefore, it is **not an option open to Ireland**, or any other EU member state, to now apply for this derogation to allow non-VP prescribing unless it was already in place in national legislation prior to January 2019.

Q. Can I buy antiparasitics for food-producing animals from a Suitably Qualified Person (SQP) in Northern Ireland and use them on my animals in the Republic?

A. No, article 105 states that any prescriptions written by anyone other than a VP, i.e. an SQP, shall be valid only in that Member State and shall exclude prescriptions of antimicrobial medicinal products and any other VMPs where a diagnosis by a VP is necessary. Doing so would be illegal and would be considered an illegal treatment and you would be subject to the sanctions associated with the offence.

Q. How long will a prescription for antimicrobials be valid?

A. A prescription for antimicrobials is valid for 5 days from date of issue. (Article 105.10) This means a prescription must be filled within 5 days. This only applies to antimicrobials. The length of validity of a prescription for all other VMPs has yet to be set by DAFM following consultation with stakeholders.

Q. How long will a prescription for antiparasitics for food-producing animals be valid?

A. Under the new Regulation, from 2022, your VP will need to write you a prescription in order for you to get antiparasitics for food-producing animals. The length of validity of a prescription for these products has yet to be set by DAFM following consultation with stakeholders.

Digital Prescribing

Q	**Can I get a digital prescription from my veterinary practitioner?**
A	There is provision to allow for this in the Regulation. Consideration is being given to this by DAFM but the details have not yet been decided upon by DAFM. There will need to be a secure system put in place to allow this.

Prophylactic/Metaphylactic Prescribing/Use of Antimicrobials

Q.	**How will the new Regulations impact the prophylactic (preventive treatment) use of antimicrobials?**
A	Post January 2022 antimicrobials are only allowed for prophylaxis in "exceptional cases" for administration to an individual animal or restricted number of animals when the risk of infection is very high and consequences are likely to be severe. In the event of an antibiotic being used in "exceptional" cases for prophylaxis it shall be limited in quantity and duration to the treatment to cover the risk of an individual animal.

Q.	**How will the new Regulations impact the metaphylactic (control treatment) use of antimicrobials?**
A	Post January 2022 a prescription for antimicrobials for metaphylaxis may only to be issued after diagnosis of infection, when the risk of spread of an infection is high and when no other appropriate alternatives are available.

Special Import Licences

Q.	**Are there provisions for the Cascade in the new Regulation?**
A.	Yes, there are similar provisions allowed to import VMPs under the Cascade in the new Regulation. DAFM is responsible for issuing special import licences and will provide guidance on these nearer the date of implementation of this Regulation.

Q.	**Are there provisions to allow the import of veterinary medicinal products from a 3rd country in the new Regulation?**
A.	Yes, there are provisions to allow the import of VMPs from a 3rd country. DAFM is responsible for issuing special import licences and will provide guidance on these nearer the date of implementation of this Regulation.

Q. Are there provisions to allow the import of vaccines in exceptional circumstances in the new Regulation?

A. Yes, there are provisions to allow the import of vaccines in exceptional circumstances. DAFM is responsible for issuing special import licences and will provide guidance on these nearer the date of implementation of this Regulation.

Q. How do I apply for special import licences?

A. DAFM is responsible for issuing special import licences please see: https://www.agriculture.gov.ie/animalhealthwelfare/veterinarymedicinesresidues/veterinarymedicines/veterinarymedicinesforms/

Veterinary Medicinal Products - Sale

Q. Routes of Sale – What are they? Who decides?

A. The route of sale or method of supply determines where you can obtain a VMP. DAFM defines in legislation what a route of sale means and The Health Products Regulatory Authority (HPRA) is responsible for assigning a route of sale to VMPs. There are currently 7 routes of sale: Prescription Only; Licensed Merchant; Companion Animal; Pharmacy Only; Prescription Only (Exempt); Veterinary Practitioner Only (VPO & VPO-1) Full details can be found here.

Q. Prescription Only Medicines – where can I buy them?

A. From your VP, Pharmacist and in the case of certain VMPs from a Licensed Merchants premises.

Q. What is a Responsible Person (RP)?

A. A person responsible for the retail sale or supply of VMPs, and who is not a VP, a pharmacist or a registered nurse, must undergo adequate training in the proper and safe handling and storage of animal remedies. They must complete the Retail Sale and Supply of Animal Remedies Course. This course is accredited to QQI Level 6. A RP is employed by a Licensed Merchant. It is a legislative requirement for a Licensed Merchant to ensure that animal remedies are not sold from their premises other than by a Responsible Person.

Q. Can a Responsible Person prescribe veterinary medicinal products?

A. No. This is not provided for in national legislation.

Q. Will antiparasitics for food-producing animals require a prescription from 2022?

A. Yes, in line with Regulation 2019/6 and the conclusions of the HPRA Task Force Report, all antiparasitic VMPs for food-producing animals will require a veterinary prescription from 2022. In 2019, the HPRA Task Force reported that both resistance to antiparasitics and the damaging environmental impacts of use of antiparasitics was conclusively proven in Ireland. Therefore, under Regulation 2019/6 these products must be upregulated and require a prescription to be obtained. This will be implemented from January 2022.

Q. Where can I get antiparasitics for food-producing animals from January 2022?

A. You can purchase antiparasitics for food -producing animals from a VP, a pharmacist, or a RP in a Licensed Merchant's premises, upon presentation of a valid prescription.

Internet Sales

Q. Can I buy veterinary medicinal products on the internet?

A. Currently yes, you can buy certain types of VMPs on the internet. You can only buy non-prescription VMPs. They should have a route of sale of Licensed Merchant or Companion Animals only. You can buy from websites anywhere within the EU so long as the product being purchased is licenced and authorised for the Irish market. If not, it will be seized upon entry into the country and you may be liable for fines. Under the new Regulation this situation will remain unchanged.

Q. How do I know I am buying from an official source?

A. DAFM licence companies to provide internet sales of VMPs. Any company with a licence should have that number displayed on their website. You can confirm the validity of a site by contacting the veterinary medicines section of DAFM. Details can be found here: https://www.agriculture.gov.ie/animalhealthwelfare/veterinarymedicinesresidues/veterinarymedicines/

Q. Are Prescription Only Medicines allowed be sold on the internet?

A. Currently this is not allowed. However, under the new Regulation there is a provision for Member States to allow the sale of prescription only medicines on the internet within a member state. DAFM has not made any decision on whether this will be allowed after the new Regulation comes into effect in January 2022. This question has

been posed in the public consultation launched by DAFM on implementation of the Regulation.

Advertising

Q. What veterinary medicinal products can be advertised to the public?

A. When the Regulation comes into effect only VMPs that are not subject to a prescription will be allowed be advertised to the general public. Vaccines, subject to a prescription will be allowed to be advertised to professional keepers of animals.

Q Will I be allowed advertise antiparasitics for food-producing animals?

A. Antiparasitics for food-producing animals will require a prescription from January 2022. Therefore, they can no longer be advertised to the general public. However, as with other VMPs that are subject to a veterinary prescription, they may be advertised only when made exclusively to VPs and other persons permitted to supply VMPs.

Wholesaling

Q. What is wholesale distribution?

A. Wholesale distribution means all activities consisting of procuring, holding, supplying or exporting outside of the EU VMPs whether for profit or not, apart from retail supply of VMPs to the public.

Q. How can I find an approved wholesale distributor?

A. Currently DAFM have a list of approved wholesale distributors on their website at: https://www.agriculture.gov.ie/animalhealthwelfare/veterinarymedicinesresidues/veterinarymedicines/informationnotes/

When the regulation is implemented there will be an EU-wide database that can be accessed to locate an approved wholesale distributor.

Q. Good Distribution Practice - What does it mean?

A. All wholesale distributors will need to comply with Good Distribution Practices (GDP). The aim of GDP is to guarantee that VMPs are appropriately procured, stored, transported and handled as well as to ensure control of the distribution chain and consequently maintain the quality and the integrity of VMPs while preventing falsified medicines from entering the legal supply chain. The EU Commission has not yet provided details on what this will entail, but advice is expected in Q3 2020.

Autogenous Vaccines

Q. What are autogenous vaccines?

A. Autogenous vaccines are inactivated immunological VMPs which are manufactured from pathogens and antigens obtained from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the same epidemiological unit or for the treatment of an animal or animals in a unit having a confirmed epidemiological link.

Q. Are autogenous vaccines covered in the Regulation?

A. They are outside the scope of most of this Regulation but certain areas do apply to them, such as articles 94, 105, 108, 117, 120, 123 and 134 - which include areas such as Good Manufacturing Practice, veterinary prescriptions, record keeping by owners of food producing animals, disposal of veterinary medicines and advertising.

Q. When can I use an autogenous vaccine?

A. Autogenous vaccines are only to be used in exceptional circumstances with a veterinary prescription and if there is no authorised vaccine for the species and indication.