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

Information for Veterinary Practitioners

New provisions in EU Regulation 2019/6 on Veterinary Medicinal Products (VMP) and EU Regulation 2019/4 on Medicated Feed

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Introduction

Regulation (EU) 2019/6 on veterinary medicinal products sets out rules for the sale, manufacture, import, export, supply, distribution, advertisement, control and use of veterinary medicinal products, aiming to:

1. harmonise and enhance the internal market for veterinary medicinal products
2. modernise legislation;
3. stimulate innovation in and increase the availability of veterinary medicinal products; and
4. strengthen the EU's campaign against antimicrobial resistance (AMR).

Regulation (EU) 2019/4 on the manufacture, placing on the market and use of medicated feed aims to harmonise at a high safety level the manufacture, marketing and use of medicated feed and intermediate products in the EU and to reflect technical progress in this field.

The previous legal framework for medicated feed dates back to 1990, before the creation of the internal market, creating no uniformity in its implementation across EU Member States.

Both EU Regulations came into force across the EU on 28 January 2022. Together they are a cornerstone to support the achievement of the objectives set in the European One Health Action Plan and in the Farm to Fork Strategy against antimicrobial resistance (AMR). The legislation also consolidates the EU's leading role on the global stage to act against AMR.

The Regulation is central to achieve the Farm to Fork Strategy target to reduce overall EU sales of antimicrobials by 50% for farmed animals and in aquaculture by 2030, through very concrete measures such as banning the preventive use of antibiotics in groups of animals.

In January 2022 Ireland revoked some of its previous secondary legislation on veterinary medicines and medicated feed S.I. 786/2007 (as amended) and S.I. 176/1994. The new legislation implementing the Regulations in Ireland is Statutory Instrument No 36/2022.

Veterinary Practitioners have a recognised key role as gatekeepers and in ensuring prudent use of antimicrobials and as such there are changes that the Regulations brought in that affect the practice of veterinary medicine and these are detailed in the following document.

Contents

General Prescribing

Changes to the rules around the prescribing of veterinary medicinal products (VMPs) include:

- A prescription shall be issued only after clinical examination or "proper assessment".
- Quantity prescribed shall be limited to amount required for treatment.
- Prescriptions must contain all current details as required in accordance with SI 182 of 2009 and the following additional information – (EU Reg 2019/6 Article 105(5) - See Annex 1)
    - The Veterinary Council of Ireland (VCI) registration number
    - The active substances of the veterinary medicinal product (VMP)
    - Pharmaceutical form and strength
    - If a VMP is prescribed for use outside of the terms of the marketing authorisation (formerly known as the Cascade) a statement to that effect
    - If the VMP prescribed is an antimicrobial (AM) and is prescribed for prophylaxis/metaphylaxis a statement to that effect, including any warnings necessary to ensure proper and prudent use.
- Please note that the National Veterinary Prescription System (NVPS[1]) has a fully compliant prescription flow in its free of charge prescription app. The app only currently provides functionality for food producing species and all horses. It is expected to be updated by 2027 to include companion animals.
- When new prescription legislation is enacted in the near future and it becomes **mandatory** to submit all prescriptions for VMPs and medicated feed to the NVPS, vets will be required to record all administered and dispensed medicines also. NVPS has functionality which will cater for this requirement.
- Prescriptions shall be recognised across the EU.
- The EU Commission have indicated they may introduce a model format for prescriptions but there is no information on their intention to do so at the current time.

[1] Information on NVPS is available at www.gov.ie/nvps. Queries relating to NVPS can be submitted to nvps@agriculture.gov.ie

- Record keeping requirements are to be set by national law and will be provided for in the Veterinary Medicinal Products, Medicated Feed and Fertiliser Regulations Bill.

Antimicrobial Prescribing & Use

- Prescriptions for Antimicrobials (AMs), including antibiotics; antivirals; antifungals and antiprotozoals shall be valid for 5 days from date of issue. That means the prescription must be filled within 5 days of being written.
- Prescriptions for AMs for metaphylaxis are only to be issued after diagnosis of infection.
- A Veterinary Practitioner (VP) must provide "justification" for prescribing of AMs, especially for metaphylaxis/prophylaxis.
- AMs are only permitted for metaphylaxis when the risk of spread of an infection or of an infectious disease is high and no other appropriate alternative is available.
- If AMs are prescribed for prophylaxis/metaphylaxis it must be for only a limited duration to cover the period of risk. The European Medicines Agencies Committee for Medicinal Products for Veterinary Use (CVMP) will set down criteria for prophylaxis use of AMs at a future date.
- AMs are not permitted for prophylaxis use unless, in exceptional cases when the risk of infection is very high and consequences of infection likely to be severe and, in the case of **antibiotics** are limited to the individual animal only.
- AMs are not permitted for routine use nor to compensate for poor hygiene, inadequate animal husbandry or to compensate for poor farm management.
- AMs are not permitted for growth promotion, nor to increase yield.
- There are certain AMs reserved for human use only. These are listed in Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022 designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council
- DAFM may restrict/prohibit use of AMs in Ireland on foot of national AMR policy.

The VCI Code of Professional Conduct for Veterinary Practitioners provides guidance on such matters and should be consulted in conjunction with the new regulations.

Dry Cow Therapy

- Dry Cow Therapy (DCT) may be prescribed provided the VP adopts a **selective** approach to DCT.
- A selective approach to DCT is holistic in the responsible use of antimicrobials. It endeavors to reduce the use of antimicrobials by identifying as many suitable cows as possible to receive an internal teat sealant only and no antimicrobial treatment at drying off.

  An assessment of the risk factors associated with the farm, the risk of infection of the individual cows and in some cases the individual quarter will allow for the remainder of the cows to receive both an antimicrobial treatment and an internal teat sealant.
- A blanket approach to DCT is **not legally permissible** and must be avoided. A blanket approach to DCT is the administration of antibiotics to all animals based on herd-level risk factors alone, irrespective of the health status of an individual animal or related risk factors. This use of antibiotics in a blanket approach to DCT is systematic and is not legally permissible. The new legislation requires that you adopt a selective approach when prescribing for the dry period.
- A VP must be able to provide justification for **prophylactic** prescribing of dry cow antibiotics. Prophylaxis is legally permissible in a selective approach to DCT. In contrast prophylaxis is not legally permissible in a blanket approach to DCT.

Animal Health Ireland issued guidelines for VPs on prudent prescribing of dry cow and in lactation antibiotics. These are available at the following link https://animalhealthireland.ie/assets/uploads/2022/01/CellCheck-Prudent-Prescribing-2022-FINAL.pdf?dl=1

Further guidance is available from the Veterinary Council of Ireland Code of Professional Conduct https://www.vci.ie/Publications/Code-of-Professional-Conduct

Use of medicinal products outside the terms of the marketing authorisation (Formerly known as "Cascade")

- The underlying principle that a VP can treat an animal with an unauthorised medicine, exceptionally, to avoid causing unacceptable suffering to an animal remains and is detailed in Articles 112, 113 and 114.
- In the case of non-food-producing animal species, if there is no authorised medicine to treat a condition, a VP may administer to an animal:

    - (a) A VMP authorised in Ireland or another EU Member State[2] for use in the same species or in another species;
    - (b) If there is no authorised medicine available under (a), a medicine authorised for human use in the European Union;
    - (c) If there is no authorised medicine available under (a) or (b), a VMP that is prepared extemporaneously in accordance with a veterinary prescription.
    - If there is no authorised medicine available under (a) or (b) and no product available under (c), a VP may use a VMP authorised in a third country (e.g., UK) for the same species and same indication. This last provision does not apply to immunological products.

- In the case of food-producing terrestrial species if there is no authorised medicine to treat a condition, a VP may administer to an animal:

    - (a) A VMP authorised in Ireland or another EU Member State for use in the same species or in another food-producing species;
    - (b) If there is no authorised medicine available under (a), a VMP authorised in Ireland for use in a non-food animal species for the same indication;
    - (c) If there is no authorised medicine available under (a) or (b), a medicine authorised for human use in the European Union;
    - (d) If there is no authorised medicine available under (a), (b) or (c), a VMP that is prepared extemporaneously in accordance with a veterinary prescription;

[2] A central EU database (Universal Product Database) of all authorised veterinary medicines has been set up and is easily accessible by all veterinary practitioners.

- (e) If there is no authorised medicine available under (a), (b) or (c) and no product available under (d), a veterinary medicine authorised in a third country (e.g., UK) for the same species and same indication. This provision does not apply to immunological products.

- In all the above cases, the substances used in the medicine must comply with the legislation on maximum residue levels (Regulation 470/2009). However, the essential substances list for horses can continue to be used in the same way as under previous legislation, with a withdrawal period of six months; the list will be updated by 28 January 2027.

- There are significant changes to the **withdrawal periods needed for medicines used off-label**.
  - The withdrawal for meat and offal will be not less than:
    (i) The longest withdrawal period given for meat and offal for any species multiplied by a factor of 1.5;
    (ii) 28 days, if the medicine is not authorised for food-producing animals;
    (iii) One day, if the medicine has a zero-withdrawal period for another target species.

  - The withdrawal period for milk shall be not less than:
    (i) The longest withdrawal period given for milk multiplied by a factor of 1.5;
    (ii) Seven days, if the medicine is not authorised for milk producing animals;
    (iii) One day, if the medicine has a zero-withdrawal period.

- For further information relating to withdrawal periods refer **Article 115 of Regulation EU 2019/6.**

Changes to anti-parasitic medicines for food-producing animals

- The Health Products Regulatory Authority (HPRA) completed the changing of the legal route of supply for antiparasitic veterinary medicinal products for food-producing animals from licensed merchant (LM) to prescription only medicines (POM) at the end of July 2021. This change will come into force in 2023.

- After this deadline, a digital veterinary prescription will be required for anti-parasitic treatments for food producing animals.

Online Retail

- Online retail sales are only allowed for medicines not requiring a veterinary prescription.
- Legal online retailers and pharmacies must be monitored and certified with a common EU logo, in Ireland DAFM is responsible for regulating this.

Advertising

- Advertising prescription only medicines to the public is not permitted, although Member States can allow vaccine advertising to professional keepers of animals. Ireland intends to do this.

Medicated Feed

- Data collection to help combat antimicrobial resistance (AMR) & pharmacovigilance obligations apply to Medicated Feed (MF).
- Homogeneity: The Feed Business Operator must ensure that the premix (VMP) is homogeneously dispersed in the MF or intermediate product. The Commission will at some point establish criteria for the homogeneity in future regulations - No indication of a timeline for this.
- Anticipated production is permitted but a prescription must be presented for supply to the animal keeper.
- Advertising:
    - Advertising of MF is not allowed to end users; it is allowed to VPs.
    - Samples of MF are not allowed if they contain AMs.
- Veterinary Prescriptions:
    - Veterinary Written Direction will no longer be used – Veterinary Prescription is the document required.
    - A veterinary prescription is required to acquire MF, or to manufacture in the case of an on-farm mixer.

- 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 VP and for a diagnosed disease (MF containing immunologicals or antiparasitics without antimicrobial effects may be issued in the absence of a diagnosed disease).
- The prescribed feed shall only be used for those animals described on the prescription and MF shall not be used for more than one treatment under the same prescription.
- Treatment must comply with the SPC unless Art 112 113 or 114 of EU 2019/6 'formerly the cascade' is being used. Duration of treatment must comply with the SPC if it is not specified in SPC the duration of treatment shall not exceed 1 month **or 2 weeks if antibiotics are contained within feed.**
- Prescriptions for food producing animals shall be valid for 3 weeks; in the case of MF containing AMs the maximum validity shall be 5 days.
- The prescribing VP must be able to provide justification for the prescription.
- It is not permitted to prescribe MF with more than one VMP (premix) containing AM's.
- Veterinary prescription for medicated feed shall contain the information set out in Annex 2 of this document. **It is important to read this as the prescription requirements have changed.**
- If a prescription is being issued for metaphylaxis or for use under the Cascade, then a statement to that affect must be contained on the prescription.
- The EU Commission may introduce a model format for prescriptions but there is no information on their intention to do so at the current time.
- Please note that the NVPS has a fully compliant MF prescription flow in its free of charge prescription app.
- When new prescription legislation is enacted in the near future it will become **mandatory** to submit all prescriptions for medicated feed to the NVPS.
- There is no longer the provision for trade details, and this will be required to be kept in a separate record.
- Prescriptions shall be recognised across the EU.

- Use of MF:
    - Only animals identified on the prescription should be administered with the MF.
    - The MF can only be used in accordance with the prescription including only those animals identified on the prescription.
    - Antimicrobial MF
        - shall not be applied routinely nor to compensate for inadequate animal husbandry lack of care or poor farm management
        - for the purposes of promoting growth or increasing yield
        - shall not be used for prophylaxis
        - shall be used for metaphylaxis only when clinical disease has been diagnosed, the risk of spread of infection is high, for animals in close contact and at risk, and where no appropriate alternatives are available
    - The keeper must take measures to avoid cross contamination.
- Disposal of Waste MF: A national system is to be put in place for collection and disposal of waste MF.

These Regulations have been implemented in Ireland by
Statutory Instrument No 36/2022.

Annex 1: Information to be included in a veterinary prescription

EU Regulation 2019/6 – Article 105(5)

A veterinary prescription shall contain at least the following elements:

(a) identification of the animal or groups of animals to be treated;

(b) full name and contact details of the animal owner or keeper;

(c) issue date;

(d) full name and contact details of the veterinarian including, if available, the professional number;

(e) signature or an equivalent electronic form of identification of the veterinarian;

(f) name of the prescribed medicinal product, including its active substances;

(g) pharmaceutical form and strength;

(h) quantity prescribed, or the number of packs, including pack size;

(i) dosage regimen;

(j) for food-producing animal species, withdrawal period even if such period is zero;

(k) any warnings necessary to ensure the proper use including, where relevant, to ensure prudent use of antimicrobials;

(l) if a medicinal product is prescribed in accordance with Articles 112, 113 and 114, a statement to that effect;

(m) if a medicinal product is prescribed in accordance with Article 107(3) and (4), a statement to that effect.

Annex 2: Information to be included in the veterinary prescription for MF

Annex V – EU Regs 2019/4

1. Full name and contact details of the veterinarian including, if available, the professional number.

2. Issue date, unique number of prescription, expiry date of prescription (if the validity is shorter than that referred to in Article 16(8)) and signature or an equivalent electronic form of identification of the veterinarian.

3. Full name and contact details of the animal keeper, and identification number of the establishment, if existing.

4. Identification (including category, species and age) and number of animals or, where appropriate, the weight of the animals.

5. Diagnosed disease to be treated. In the case of immunological veterinary medicinal products or antiparasitics without antimicrobial effects, disease to be prevented.

6. Designation (name and marketing authorisation number) of the veterinary medicinal product or products, including the name of the active substance or substances.

7. If the veterinary medicinal product is prescribed under Article 107(4), Article 112, Article 113 or Article 114, of Regulation (EU) 2019/6, a statement to that effect.

8. Inclusion rate of the veterinary medicinal product or products and active substance or substances (quantity per weight unit of Medicated Feed).

9. Quantity of Medicated Feed.

10. Instructions for use for the animal keeper, including the duration of the treatment.

11. Percentage of Medicated Feed in the daily ration or quantity of Medicated Feed per animal and day.

12. For food-producing animals, withdrawal period, even if such period is zero.

13. Any warnings necessary to ensure the proper use including, where relevant, to ensure prudent use of antimicrobials.

14. For food-producing animals and fur animals, the mention ‘This prescription shall not be re-used’.

15. The following mentions to be completed by the supplier of the Medicated Feed or the on-farm mixer, as appropriate:

    — name or business name and address,

    — date of delivery or of on-farm mixing,

    — batch number of Medicated Feed delivered under the veterinary prescription for Medicated Feed, except for on- farm mixers.

16. Signature of supplier to the animal keeper or of on-farm mixer.