

#### **IRELAND**









Lecture 3

Hands-on Training for Farmers and Veterinarians: New measures to fight antimicrobial resistance

IRELAND, 24 JUNE 2025

















## EU legal framework on veterinary medicinal products/medicated feed



Regulation (EU) 2019/6 on Veterinary Medicinal Products

Regulation (EU) 2019/4 on Medicated Feed

## Common rules – Veterinary prescription



#### MEDICATION VIA FEED OR WATER

#### Medicated Feed

(feed mixed with medicines in feed mill or mobile mixer or via special equipped vehicle by feed business operator) Reg. (EU) 2019/4 (MF)

Different rules apply for

#### **Oral Medication**

(on-farm mixing in feed or water by the animal keeper)

Via Feed

Via Water

Reg. (EU) 2019/6 (VMP) & Commission Delegated Reg. (EU) 2024/1159

#### Use of Antimicrobial Veterinary Medicinal Products



## EU legislative framework: Regulation (EU) 2019/4 on MEDICATED FEED (MF)

#### Principles for the use of medicated feed

- Ban on the use of MF with antimicrobials for prophylaxis.
- Requirement for diagnosis of disease prior to the mandatory prescription for MF.
- Limitation on the duration of a treatment and validity of prescription.
- Reduce any potential synergy between feed medication carryover residues and occurrence of antimicrobial resistance.
- Measures to increase the quality of medicated feed production (more precise dosage) to avoid subtherapeutic exposure.
- Maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed.

## Common rules – Veterinary prescription



## Veterinary prescriptions in relation to medicated feed (1/2)

Reg.(EU) 2019/4

#### **Article 16**

Medicated feed (animal feed mixed with medicines by feed business operator) requires:

- a veterinary prescription
- can only be issued after clinical examination or any other proper assessment of the health status of the animals
- only for diagnosed diseases (except for vaccines and parasitics)



■ Watch out for interactions with other medications!

## Common rules – Veterinary prescription



## Veterinary prescriptions in relation to medicated feed (2/2)

Reg.(EU) 2019/4

#### **Article 16**

- Record keeping: Veterinary prescriptions should be kept by feed mill and the veterinarian prescribing & animal keeper for 5 years
- 1 prescription = 1 veterinary treatment
- Maximum duration of treatment: 2 weeks for antibiotics, 1 month for other medicines
- Validity prescription: max 5 days for feed with antimicrobial, max 3 weeks for other medicines for food-producing animals, rest 6 months



## **Delegated Regulation (EU) 2024/1159 on Oral Administration**

Lays down rules to ensure the effective and safe use of VMPs authorised and prescribed for oral administration via routes other than medicated feed and administered by the animal keeper to food-producing animal

- ✓ To avoid reduction of effectiveness, resistance development, contamination
- ✓ Covers VMPs in drinking water or mixed in or spread on feed **by the animal owner**. Does not cover medicated feed (also not if mixed by mobile mixer by feed operator on farm).
- ✓ Important role for veterinarians they should evaluate equipment, species, situation on the farm, etc before prescribing. They should also advise the owner on how to dose correctly and on correct disposal.
- ✓ Important role for animal keeper: needs to properly store, prepare, have suitable equipment to administer and dispose of the leftovers. Ensure the feed/water is suitable. Ensure no contamination.

## Delegated Regulation (EU) 2024/1159 on Oral Administration

Lays down rules to ensure the effective and safe use of VMPs authorised and prescribed for oral administration via routes other than medicated feed and administered by the animal keeper to food-producing animal

- ✓ The mixing of antibiotics or antiparasitics in solid feed should only be done for animals fed individually or for a small group of animals. MS may restrict those uses only to animals individually fed (if not harming animal health or welfare). Administration via drinking water for groups of animals is allowed.
- ✓ EXCEPT If medicated feed is not available, or waiting for delivery, it is allowed for aquatic animals to mix antimicrobials and antiparasitics in feed for group treatment
- ✓ It is not allowed to administer several antimicrobials at the same time
- ✓ Only on veterinary prescription based on a diagnosis and indicating the target species and the number of animals to be treated.
- ✓ Be careful with biocides, feed additives or other substances used simultaneously, they can interact

## **Delegated Regulation (EU) 2024/1159 on Oral Administration**

Lays down rules to ensure the effective and safe use of VMPs authorised and prescribed for oral administration via routes other than medicated feed and administered by the animal keeper to food-producing animal

- ✓ MS may develop further national guidelines to facilitate the application of that Regulation.
- ✓ Shall apply from 9 November 2025.





# National provisions

National provisions



## **National Legislation**

The implementation at National Level of the provisions of Regulation(EU) 2019/6 for Veterinary Medicinal Products and of Regulation (EU) 2019/4 for Medicated Feed is through:

Veterinary Medicinal Products, Medicated Feed and Fertilisers Act 2023

S.I. 462/2024- Veterinary Medicinal Products Regulations 2024

#### **National legislation**

#### Main provisions on VMPs:

- 1. The rules of issuing and dispensing a veterinary prescription:
- Veterinary prescriptions have to be issued and dispensed using the electronic national database (the National Veterinary Prescription System (NVPS)) for all food producing animals, including equines.
- A medicinal product prescribed under Article 105 of the VMP Regulation or Article 16 of the Medicated Feed Regulation shall not be supplied unless the prescription has been issued electroncially.
- 2. The maximum validity period of a prescription for non-antimicrobial VMP is 6 months from the date of its issue.

## **National legislation**

- 3. In addition to the requirements of Article 105(5) of the VMP Regulation, a veterinary prescription shall contain the following:
  - a prescription identifier
  - the VCI Registration Number of the prescribing veterinarian
  - where applicable, the marketing authorisation number relating to the product being prescribed.

#### **National Legislation**

If there is a reason for a veterinary prescription to be issued and dispensed other than using the NVPS, for instance in relation to a VMP or medicated feed prescried for a non-food producing species, it shall be required to be issued in triplicate with the original and one copy given to the owner or keeper of the animal to be treated and a copy retained by the veterinarian.

#### **National Legislation- Record Keeping**

#### **Record keeping for veterinarians:**

- A veterinarian shall keep copies of veterinary prescriptions issued by themselves, including those for medicated feed, at his or her premises, that are not held on the NVPS for a period of at least 5 years.

A veterinarian shall maintain, at his or her premises, records which shall be made available to an authorised officer on request, in relation to each client containing at least the following:

- the date of each visit to the premises on which the animal or group of animals was seen or the date they were properly assessed,
  - -The identification of the animals clinically examined, or the subject of a proper assessment,
  - the clinical condition diagnosed or disease to be prevented,
- -details of treatment, including details of all medicinal products, for each clinical condition diagnosed or disease to be prevented,
- a cross-reference to any relevant results of laboratory tests, or any other test results undertaken, or records evaluated for the purposes of diagnosis or proper assessment and

#### National Legislation- Record Keeping

#### Record keeping for owners and keepers of food producing animals

The record of all medicinal products to be kept in accordance with Article 108 and 109 of the VMP regulation by the owner or keeper of a food producing animal shall also include medicinal products not subject to a prescription.

In addition, the following must be kept by the owner or keeper of a food producing animal, namely-

- (a) the name of the person who administered a medicinal product to such an animal,
- (b) date of expiry of the withdrawal period,
- (c) the quantities of expired or waste medicinal products and unused, expired or waste medicated feed and intermediate products,
- (d) the method of disposal of that referred to in subparagraph (c)

Records referred to in this Regulation, including copies of veterinary prescriptions, shall be kept by the owner or keeper of a food producing animal for a period of at least 5 years and those records shall be made available on request to an authorised officer.

#### **National Legislation- Disposal**

#### Disposal of unused and unopened, expired or recalled medicated feed

- Manufacturers of medicated feed or intermediate products must have in place systems to receive
  from those they supply to, unused and unopened, expired or recalled medicated feed and
  intermediate products, ensure they are disposed of safely, having regard to the environment, public
  health and otehr guildeines.
- Reords of return or disposal of ununsed and unopened, expired or recalled veterinary medincal
  products, unused and unopened, expired or recalled mediated feed or intermediate products shall be
  kept for a period of at least 5 years and be made available on request to an authorised officer.







