

AMRFV

Training



IRELAND

24 JUNE 2025



Funded by
the European Union



Additional relevant legislation, provisions and/or guidelines to be considered by veterinarians & farmers (II) *Lecture 4*

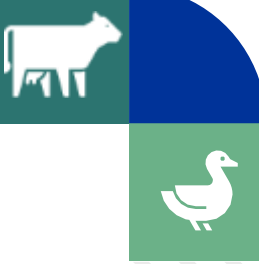
Hands-on Training for Farmers and Veterinarians: New measures to fight antimicrobial resistance

IRELAND, 24 JUNE 2025



Funded by
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EU legal framework on veterinary medicinal products/medicated feed



**Regulation (EU) 2019/6 on Veterinary
Medicinal Products**

**Regulation (EU) 2019/4 on
Medicated Feed**

+ Implementing and delegating Acts

CERTAIN ANTIMICROBIALS ARE PROHIBITED TO USE FOR ANIMAL TREATMENT



The human reserve list: antimicrobials which are reserved for treatment of certain infections in humans

The antimicrobials and group of antimicrobials listed in this Regulation **cannot be used in animals under any circumstances.**

This list will **be kept under continual review** in the light of new scientific evidence or emerging information

“reserve list”

L 191/58

EN

Official Journal of the European Union

20.7.2022

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

*Commission Implementing Regulation (EU)
2022/1255*

ANTIMICROBIALS ON THE HUMAN RESERVE LIST

“human reserve list”

Supporting prudent use and preserving efficacy

(1) Antibiotics

- (a) Carboxypenicillins
- (b) Ureidopenicillins
- (c) Ceftobiprole
- (d) Ceftaroline
- (e) Combinations of cephalosporins with beta-lactamase inhibitors
- (f) Siderophore cephalosporins
- (g) Carbapenems
- (h) Penems
- (i) Monobactams
- (j) Phosphonic acid derivatives
- (k) Glycopeptides
- (l) Lipopeptides
- (m) Oxazolidinones
- (n) Fidaxomicin
- (o) Plazomicin
- (p) Glycylcyclines
- (q) Eravacycline
- (r) Omadacycline

(2) Antivirals

- | | |
|----------------------------|--------------------|
| (a) Amantadine | (l) Peramivir |
| (b) Baloxavir marboxil | (m) Ribavirin |
| (c) Celgosivir | (n) Rimantadine |
| (d) Favipiravir | (o) Tizoxanide |
| (e) Galidesivir | (p) Triazavirin |
| (f) Lactimidomycin | (q) Umifenovir |
| (g) Laninamivir | (r) Zanamivir |
| (h) Methisazone/metisazone | |
| (i) Molnupiravir | (3) Antiprotozoals |
| (j) Nitazoxanide | (a) Nitazoxanide |
| (k) Oseltamivir | |



CERTAIN ANTIMICROBIALS ARE NOT ALLOWED OR CONDITIONALLY ALLOWED TO USE UNDER ART 112 & 113*

- Commission Implementing Regulation (EU) 2024/1973 lists antimicrobials which cannot be used in accordance with article 112 & 113* (outside the marketing authorisation) or can only be used subject to certain conditions.
- Some examples:
 - ✓ Third- and fourth-generation cephalosporins cannot be used in accordance with Article 113 in poultry
 - ✓ Polymyxins are allowed only after prior pathogen identification and susceptibility testing showing that they are likely to be effective and other preferable antimicrobials would not be effective.
 - ✓ Quinolones (including fluoroquinolones) cannot be used in accordance with Article 113 for salmonellosis in poultry or for metaphylaxis of salmonellosis in animals other than poultry

All details here: https://eur-lex.europa.eu/eli/reg_impl/2024/1973/oj

This Act will apply from 8 August 2026

Upcoming Delegated and Implementing Legal Acts

- List of substances authorised for use in food-producing terrestrial animal species or substances contained in a medicinal product for human use authorised in the Union, which may be used in **food-producing aquatic species** in accordance with Article 114(1) 
- **List of substances which are essential for the treatment of equine species**, or *which* bring added clinical benefit compared to other treatment options available for equine species and for which the withdrawal period for equine species shall be six months. 

More info on all delegated and implementing Acts:

https://food.ec.europa.eu/animals/animal-health/vet-meds-med-feed/implementation_en



List of antimicrobials that may be used for food-producing aquatic species

Article 114

The Commission will establish a list of substances used in veterinary medicinal products authorised in the Union for use in food-producing terrestrial animal species or substances contained in a medicinal product for human use authorised in the Union in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004, **which may be used in food-producing aquatic species in accordance with Article 114(1).**



'(a) risks to the environment if the food-producing aquatic species are treated with those substances;

(b) impact on animal and public health if the food-producing aquatic species affected cannot receive an antimicrobial listed in accordance with Article 107(6);

(c) availability or lack of availability of other medicinal products, treatments or measures for prevention or treatment of diseases or certain indications in food-producing aquatic species.'



List of antimicrobials for specific species (equine species)

The Commission published a list of substances essential for the treatment of Equidae (Commission Regulations (EC) No. 1950/2006 & No. 122/2013)

The VMP Regulation requires the Commission to establish a list of substances which are essential for the treatment of equine species, or which bring added clinical benefit compared to other treatment options available for equine species and for which the withdrawal period for equine species shall be six months to be established

In July 2024 EMA published its scientific advice regarding the list of substances which are essential for the treatment of equine species ([SA - Art115\(5\) - List of substances essential for equine species \(europa.eu\)](#))

The Commission is now working on the required implementing act.



It is crucial to report adverse events (pharmacovigilance)

Adverse events are:

Unintended, unfavourable reaction in animals to a veterinary or human medicine

Lack of efficacy of a veterinary medicine

Any **environmental** incidents after applying a veterinary medicine

Any noxious reaction to **humans**

Exceeding the MRL when withdrawal period was respected

Any suspected transmission of an infectious agent via the medicine

Do not forget to report adverse events including **lack of efficacy!**

Why report? To ensure safety, monitor efficacy, prevent harm, guide regulation and to inform research.

Disposal of Veterinary Medicines

How and where does pharmaceutical waste occur?

- ✓ Immediate packaging and the remains of medicines within after use.
- ✓ VMP or MF that are past their expiry date or that have not been stored in accordance with the instructions.
- ✓ Prescription of a quantity exceeding the required quantity or uncompleted course of treatment due to either administration difficulties, adverse reactions, change in treatment or because animals died during treatment.

Disposal of Veterinary Medicines

Best practices for disposal

[PharmaceuticalWasteDisposal.pdf \(epruma.eu\)](#)

- ✓ Everybody (prescribers and users) is responsible for minimising pharmaceutical waste.
- ✓ Disposal of pharmaceutical waste via waterways should be excluded.
- ✓ Pharmaceutical waste should be stored in a dedicated container, bin, or facility to ensure adequate protection to animal health, human health, feed, food and the environment and this must be separated from any stocks of veterinary medicines to ensure that the waste cannot be inadvertently used.
- ✓ Waste must be disposed of in accordance with the Summary of Product Characteristics (SPC) and the waste legislation and national systems developed in consultation with all parties for the collection, transport, and disposal of the waste.
- ✓ Member States shall ensure that appropriate collection or discard systems are in place for waste veterinary medicinal products (including medicated feed) and to ensure that the location of collection or discard points as well as other relevant information is made available to farmers, animal keepers, veterinarians, and other relevant persons.

Other considerations for prescriptions

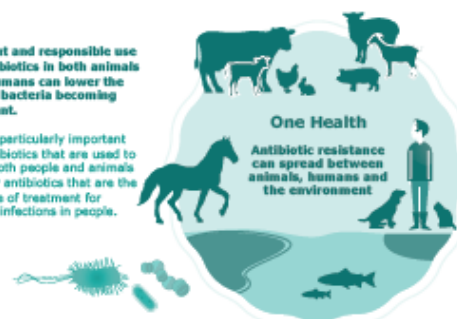


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Categorisation of antibiotics for use in animals for prudent and responsible use

Prudent and responsible use of antibiotics in both animals and humans can lower the risk of bacteria becoming resistant.

This is particularly important for antibiotics that are used to treat both people and animals and for antibiotics that are the last line of treatment for critical infections in people.



The Antimicrobial Advice Ad Hoc Expert Group (AMEG) has categorised antibiotics based on the potential consequences to public health of increased antimicrobial resistance when used in animals and the need for their use in veterinary medicine.

The categorisation is intended as a tool to support decision-making by veterinarians on which antibiotic to use.

Veterinarians are encouraged to check the AMEG categorisation before prescribing any antibiotic for animals in their care. The AMEG categorisation does not replace treatment guidelines, which also need to take account of other factors such as supporting information in the Summary of Product Characteristics for available medicines, constraints around use in food-producing species, regional variations in diseases and antibiotic resistance, and national prescribing policies.

Category A Avoid

- antibiotics in this category are not authorised as veterinary medicines in the EU
- should not be used in food-producing animals
- may be given to companion animals under exceptional circumstances

Category C Caution

- for antibiotics in this category there are alternatives in human medicine
- for some veterinary indications, there are no alternatives belonging to Category D
- should be considered only when there are no antibiotics in Category D that could be clinically effective

For antibiotics in all categories

- unnecessary use, overly long treatment periods, and under-dosing should be avoided
- group treatment should be restricted to situations where individual treatment is not feasible
- check out the European Commission's guideline on prudent use of antibiotics in animals: <https://bit.ly/2s7LUP2>

AMEG is the acronym for EMA's Antimicrobial Advice Ad Hoc Expert Group. It brings together experts from both human and veterinary medicine. They work together to provide guidance on the impact on public health of the use of antibiotics in animals.

Categorisation of antibiotic classes for veterinary use (with examples of substances authorised for human or veterinary use in the EU)

A	Antipseudomonas medicines pivmecillinam	Carbapenems meropenem doripenem	Drugs used solely to treat fungal or other mycobacterial diseases isavuconazole pyrazinamide ethambutol	Glycopeptides vancomycin	AVOID
	Ketolides telithromycin	Lipopeptides dalbavancin		Glycylicolones tigecycline	
B	Monobactams aztreonam	Oxazolidinones linezolid		Phosphonic acid derivatives fosfomycin	RESTRICT
	Fluoroquinolones (except rifabutin) moxifloxacin	Minocyclines doxycycline	Other cephalosporins and penicillins (ATC code J01DE), including combinations of 2nd generation cephalosporins with beta-lactamase inhibitors	Penamides ceftazidime	
C	Carbapenems and antipseudomonas, including combinations with beta- lactamase inhibitors piperacillin-tazobactam	Sulfonamides sulfamonomethoxime trimethoprim	Ceftazidime ceftiofur ceftiofur sodium	Substances newly authorised in human medicine following publication of the AMEG categorisation to be determined	CAUTION
D	Cephalosporins, 2nd- and 3rd-generation, with the exception of combinations with beta-lactamase inhibitors cefepime ceftriaxone cefuroxime cefazolin	Polymyxins colistin polymyxin B	Quinolones: fluoroquinolones and other quinolones ciprofloxacin enoxacin ofloxacin levofloxacin moxifloxacin		PRUDENCE
E	Antibacterials (except spectinomycin) amikacin netilmicin thiostrepton francimycin gentamicin kanamycin neomycin paromomycin streptomycin tetracycline	Antipseudomonas, in combination with beta- lactamase inhibitors aztreonam + clavulanic acid aztreonam + sulbactam	Amphotericins chlamphenicol fortified triazophenol	Macrolides erythromycin clarithromycin azithromycin rospirin telithromycin fusidic acid fusidate sodium	
F	Antipseudomonas, without beta-lactamase inhibitors amikacin aztreonam netilmicin	Antipseudomonas, without beta-lactamase inhibitors amikacin aztreonam netilmicin	Amphotericins chlamphenicol fortified triazophenol	Macrolides erythromycin clarithromycin azithromycin rospirin telithromycin fusidic acid fusidate sodium	
G	Tetracyclines doxycycline minocycline tetracycline	Antipseudomonas, without beta-lactamase inhibitors amikacin aztreonam netilmicin	Amphotericins chlamphenicol fortified triazophenol	Macrolides erythromycin clarithromycin azithromycin rospirin telithromycin fusidic acid fusidate sodium	
H	Natural, narrow-spectrum penicillins (beta- lactamase-sensitive penicillins) benzathine benzylpenicillin benzathine phenoxymethylpenicillin benzylpenicillin phenoxymethylpenicillin phenoxymethylpenicillin phenoxymethylpenicillin	Antipseudomonas, without beta-lactamase inhibitors amikacin aztreonam netilmicin	Amphotericins chlamphenicol fortified triazophenol	Macrolides erythromycin clarithromycin azithromycin rospirin telithromycin fusidic acid fusidate sodium	
I					

Other factors to consider

The route of administration should be taken into account alongside the categorisation when prescribing antibiotics. The list below suggests routes of administration and types of formulation ranked from the lowest to the highest estimated impact on antibiotic resistance.

- Local individual treatment (e.g. udder injector, eye or ear drops)
- Parenteral individual treatment (intravenously, intramuscularly, subcutaneously)
- Oral individual treatment (i.e. tablets, oral bolus)
- Injectable group medication (metaphylaxis), only if appropriately justified
- Oral group medication via drinking water/milk replacer (metaphylaxis), only if appropriately justified
- Oral group medication via feed or premixes (metaphylaxis), only if appropriately justified



Prudent Use Guidelines

Not legally binding as the previous acts/provisions!

Guideline for the prudent use of antimicrobials in veterinary medicine
2015/C 299/04

https://health.ec.europa.eu/system/files/2016-11/2015_prudent_use_guidelines_en_0.pdf

Best-practice framework for the use of antimicrobials in food-producing animals in the EU - Reaching for the next level.

<https://epruma.eu/home/best-practice-guides/best-practice-framework-for-the-use-of-antimicrobials-in-food-producing-animals-in-the-eu-reaching-for-the-next-level/>



Animal Health Law (Regulation (EU) 2016/429 on transmissible animal disease)

“Prevention is better than cure”

Preventive driven approach:

improvement of animal health and biosecurity measures, good farming practices

Clear **responsibility** for all players for animal health

- **Operators** → ensure a high level of animal health and welfare, and biosecurity
- **Vets** → raise awareness and help in the prevention and spread of pathogens
- **CA** → protect animal health, human health and environment

Prioritising EU intervention

- Regulatory tools/interventions for resistant pathogens: "disease agents"
- Disease preventive and control measures may apply (surveillance, eradication etc.)
- Legal basis monitoring AMR in animal pathogens

National provisions



provisions

National



Use of antibiotics

Legislation: S.I. 462/2024 Veterinary Medicinal Products Regulations 2024

Veterinary Records- a statement is required outlining the justification for a veterinary prescription if prescribing an antimicrobial, in particular for metaphylaxis and prophylaxis.

I have prescribed this antimicrobial medicinal product for prophylactic/metaphylactic purposes
in accordance with 2019/6 Article 107(3)/(4) ⓘ

- ☒ Not applicable
- ☐ Prophylactically
- ☐ Metaphylactically

Vet notes *(optional)*

e.g. diagnosis, justification, etc

National Measures



National Measures



IFA



Code of Good Practice Regarding the Responsible Prescribing and Use of Antibiotics in Farm Animals

These Guidelines have been developed
by Irish Farmers and Veterinary
Practitioners to guide good practice in
the responsible prescribing and use of
antibiotics in farm animals, in response
to the global societal challenge of
antimicrobial resistance



Riadas na hÉireann
Government of Ireland



Antimicrobial Prescribing Guidelines for Veterinary Practitioners



National Measures

Code of Good Practice Regarding the Responsible Use of Antimicrobials on Dairy Farms



These Guidelines have been developed by Irish Farmers and Veterinary Practitioners to guide good practice in the responsible prescribing and use of antibiotics in farm animals, in response to the global societal challenge of antimicrobial resistance



Code of Good Practice Regarding the Responsible Use of Antimicrobials on Pig Farms



These Guidelines have been developed by Irish Farmers and Veterinary Practitioners to guide good practice in the responsible prescribing and use of antibiotics in farm animals, in response to the global societal challenge of antimicrobial resistance



Code of Good Practice regarding responsible use of Antimicrobials on Suckler and Beef Farms



These Guidelines have been developed by Irish Farmers and Veterinary Practitioners to guide good practice in the responsible prescribing and use of antibiotics in farm animals, in response to the global societal challenge of antimicrobial resistance



Code of Good Practice Regarding the Responsible Use of Antimicrobials on Sheep Farms



These Guidelines have been developed by Irish Farmers and Veterinary Practitioners to guide good practice in the responsible prescribing and use of antibiotics in farm animals, in response to the global societal challenge of antimicrobial resistance



Code of Good Practice Regarding the Responsible use of Antimicrobials on Poultry Farms



These Guidelines have been developed by Irish Farmers and Veterinary Practitioners to guide good practice in the responsible prescribing and use of antibiotics in farm animals, in response to the global societal challenge of antimicrobial resistance



National Measures



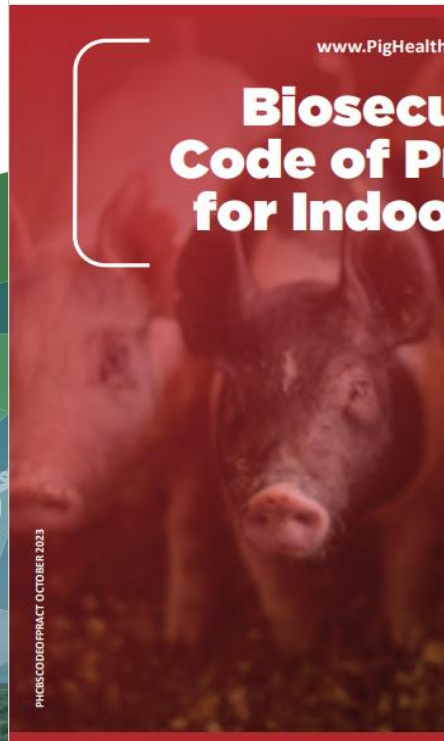
An Roinn Talmhaíochta,
Bia agus Mara
Department of Agriculture,
Food and the Marine

Keeping Animals Safe from Disease

A National Farmed Animal Biosecurity Strategy (2021-2024)



ANIMAL



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

Keeping Animals Safe from Disease:

Biosecurity Code of Practice for Dairy Cattle



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

Keeping Animals Safe from Disease:

Biosecurity Code of Practice for Poultry



Disposal of VMPs

The holder of a veterinary medicinal product marketing authorisation, or a person carrying out activities on his or her behalf, and a person who imports a veterinary medicinal product under a special import licence or special import notification,

Shall maintain a system designed to ensure, in accordance with Article 117 of the VMP Regulation, that a veterinary medicinal product including the immediate packaging supplied by him or her in the State, which is unused and unopened, expired or recalled, is disposed of.

- (a) a holder of a wholesale distribution authorisation
- (b) a veterinarian
- (c) a pharmacist
- (d) a holder of a VMP retailers's licence
- (e) a person registered as a companion animal medicines seller, to whom he or she supplies a VMP

shall have a system in place to receive medicines from those they supply to, a VMP that is unused, unopened, expired or recalled for return.

Disposal of VMPs

The owner or keeper of an animal shall ensure that:

- (i) unused and unopened, expired or recalled VMP or
- (ii) unused and unopened, expired or recalled medicated feed, or intermediate product,

Including its immediate packaging is disposed of in an appropriate manner and may return such products or feed to:

- (i) the person from whom the owner or keeper purchased that product or feed or
- (ii) a place designated by the Minister in respect of such owners and keepers specified by the Minister.

Records of return or disposal of unused and unopened, expired or recalled VMPs, medicated 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.

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