AMRFV Training

IRELAND

24 JUNE 2025

Funded by the European Union

AMRFV Training

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 the European Union

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

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 derivates
- (k) Glycopeptides
- (l) Lipopeptides
- (m) Oxazolidinones
- (n) Fidaxomicin
- (o) Plazomicin
- (p) Glycylcyclines
- (q) Eravacycline
- (r) Omadacycline

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

(3) Antiprotozoals
- (a) Nitazoxanide

Commission Implementing Regulation (EU) 2022/1255

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 b*ring 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.

FACTSHEET_PharmaceuticalWasteDisposal.pdf (epruma.eu)

Disposal of Veterinary Medicines

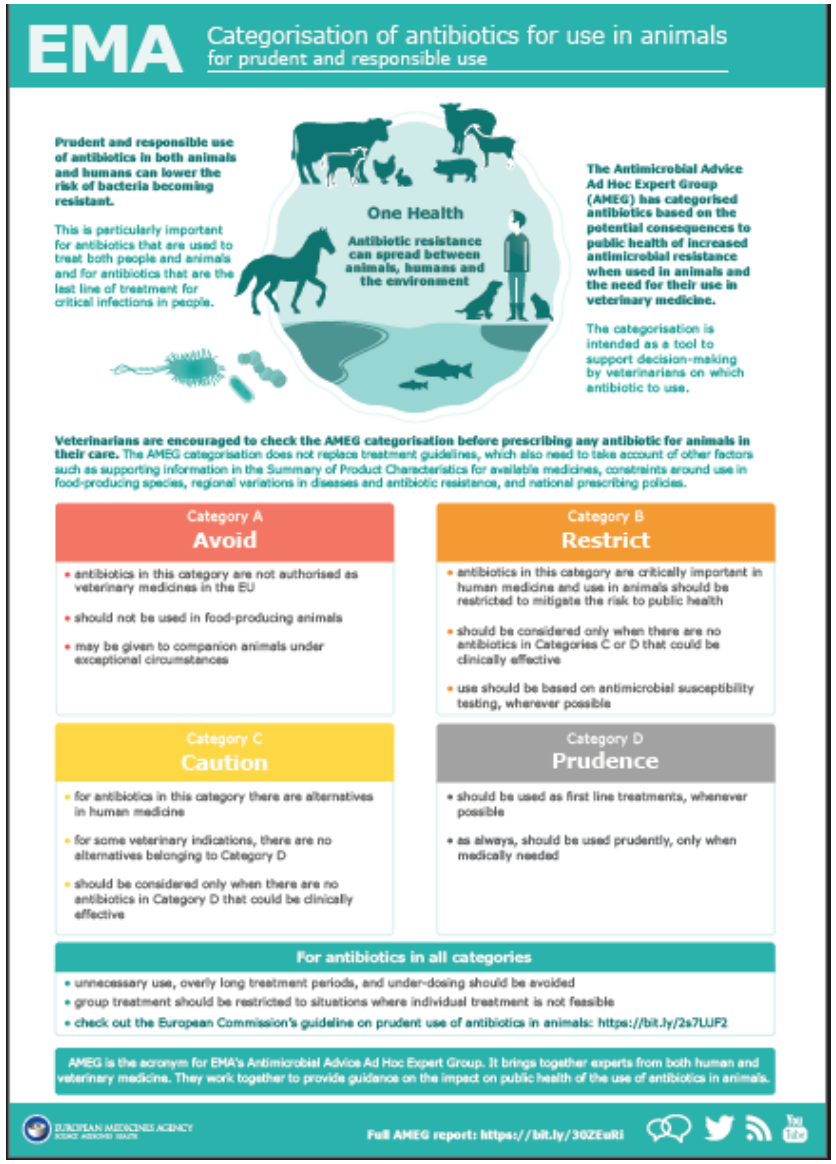
Best practices for disposal

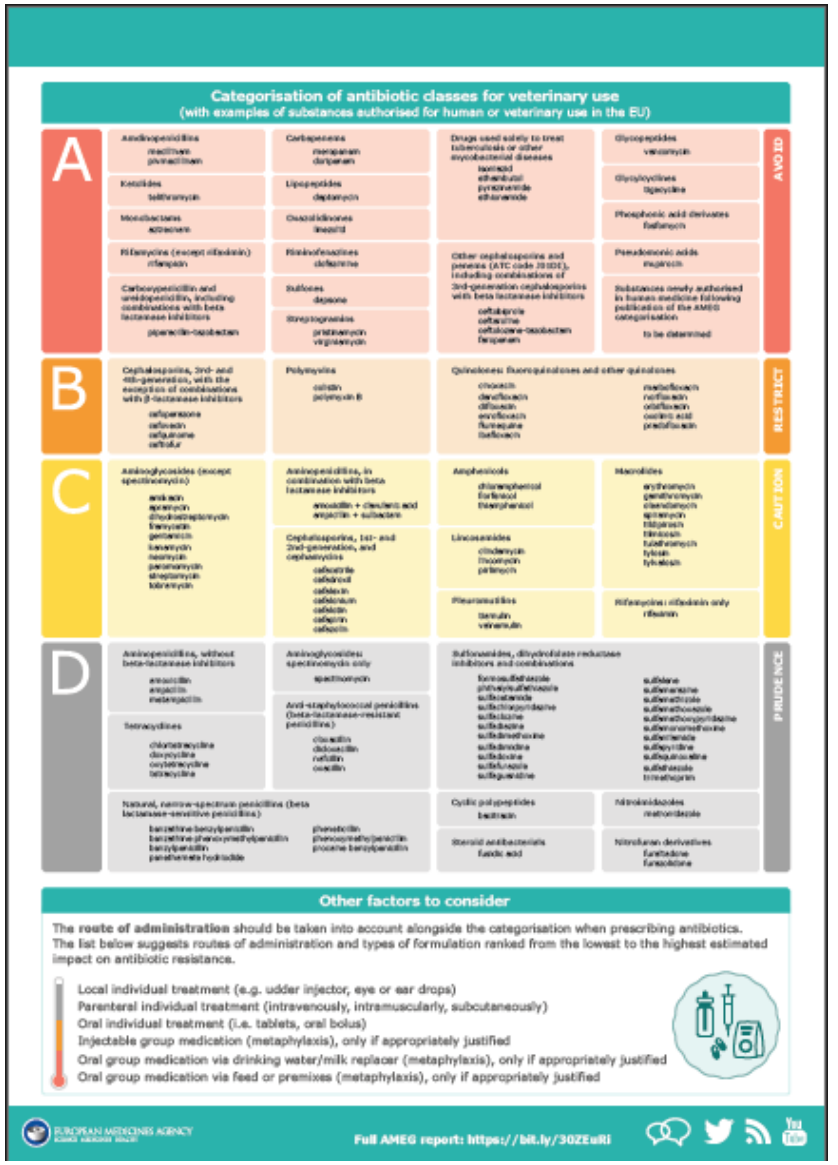
PharmaceuticalWasteDisposal.pdf (epruma.eu)

- ✓ 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





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

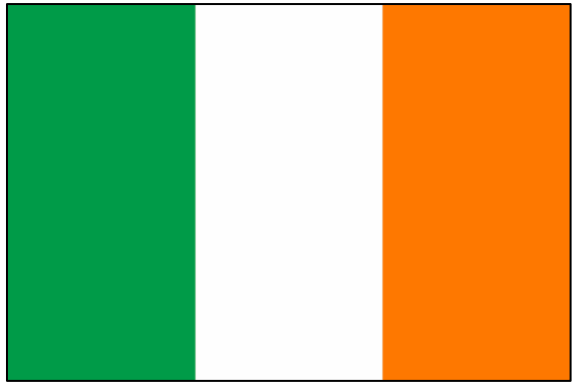
Clear **responsibility** for all players for animal health

- **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

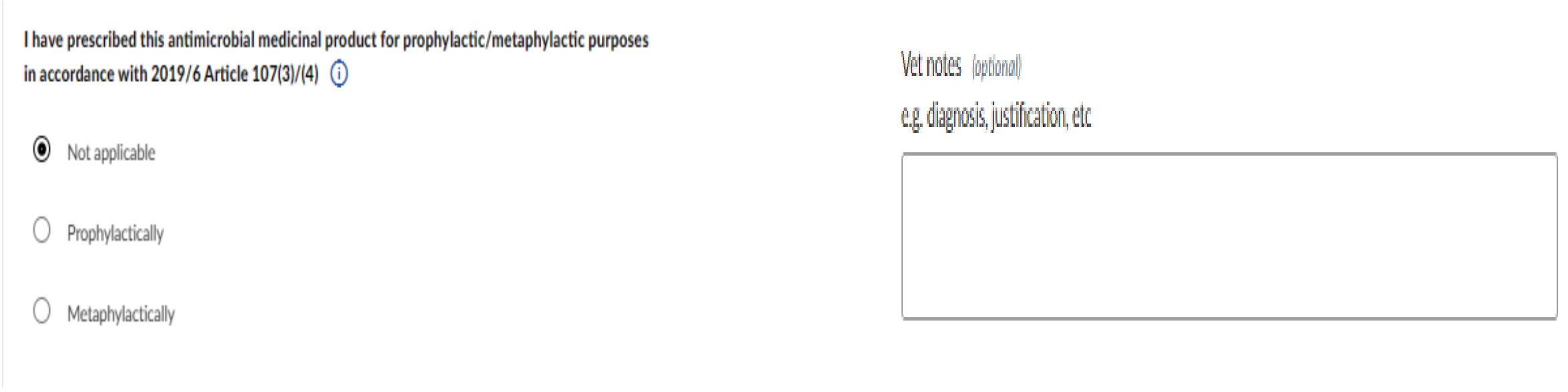
National provisions



Use of antibiotics

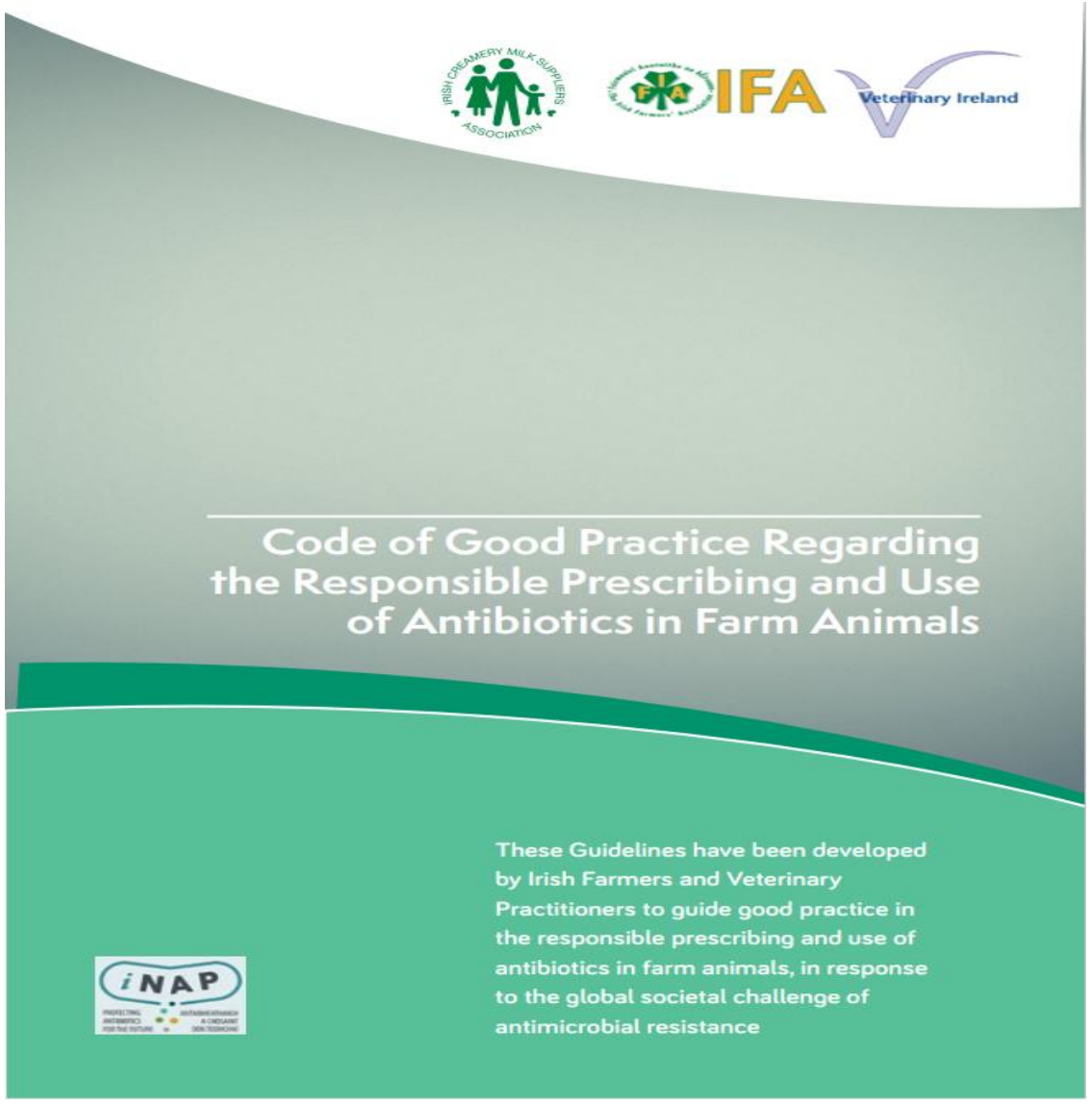
Legislation: S.I. 462/2024 Veterinary Medicinal Products Regulations 2024

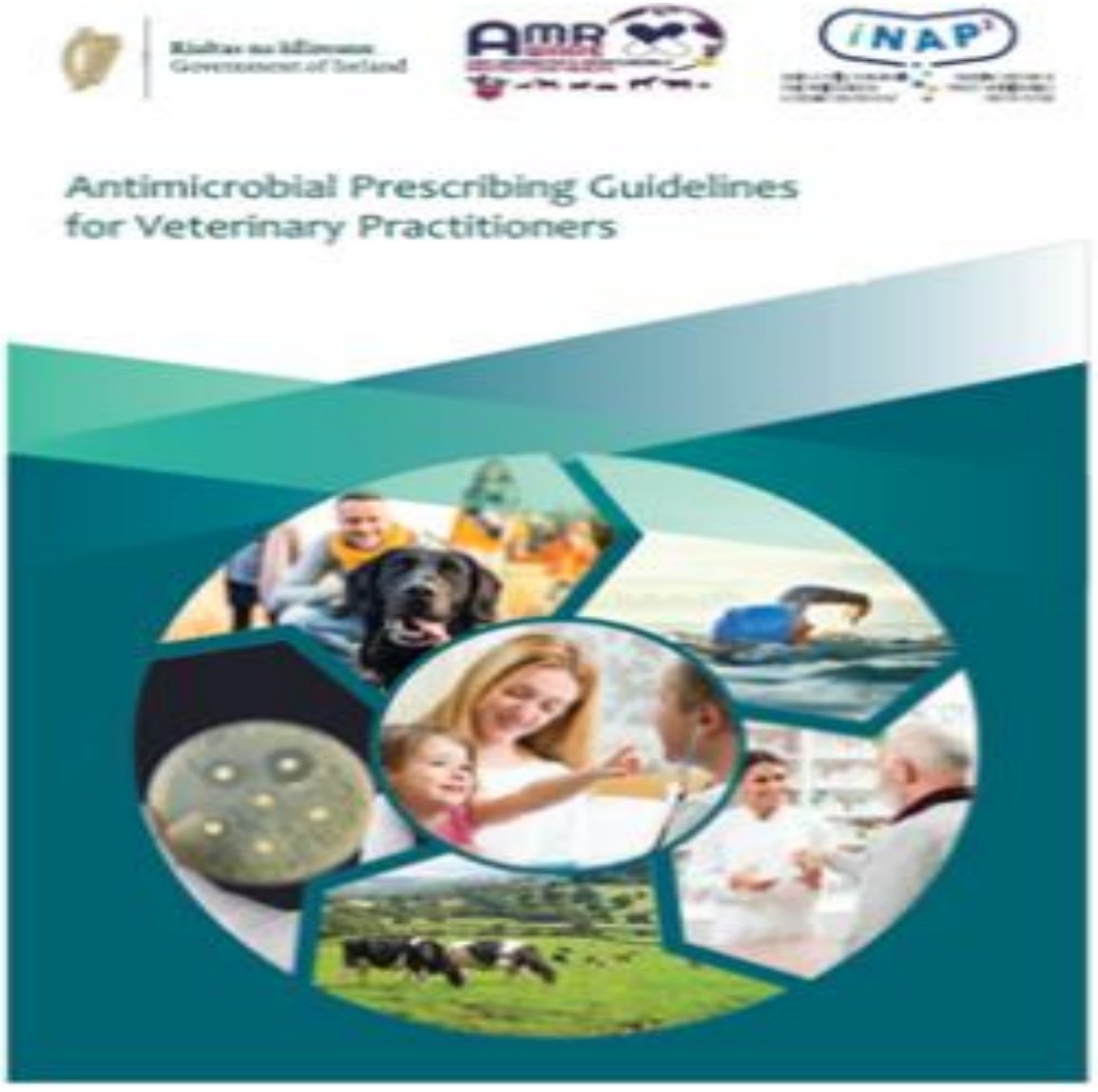
Veterinary Records- a statement is required outlining the justification for a veterinary prescription if prescribing an antimicrobial, in particular for metaphylaxis and prophylaxis.



National Measures

National Measures





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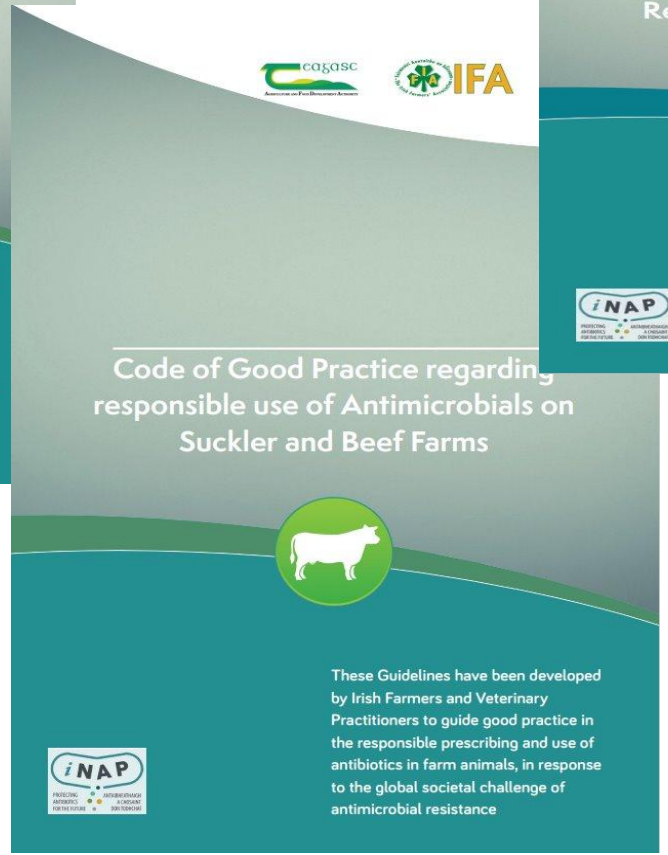

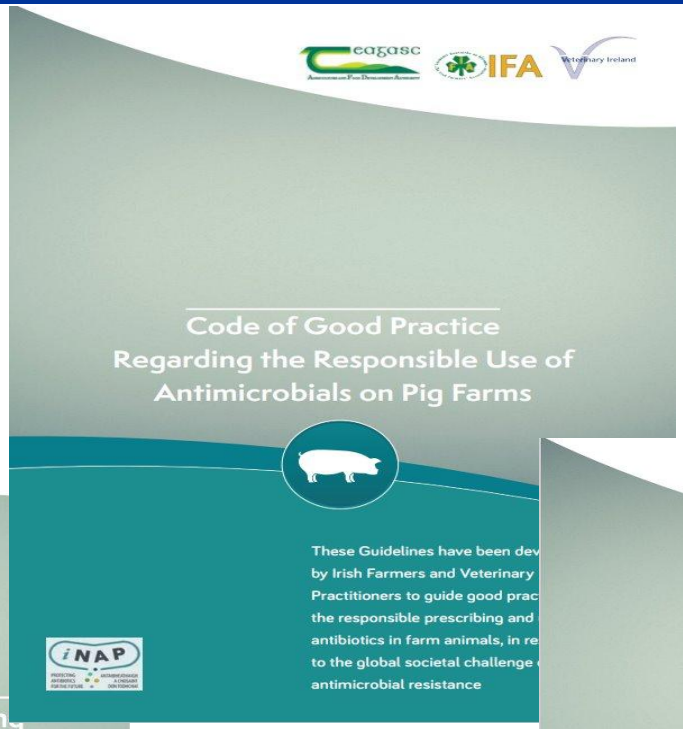

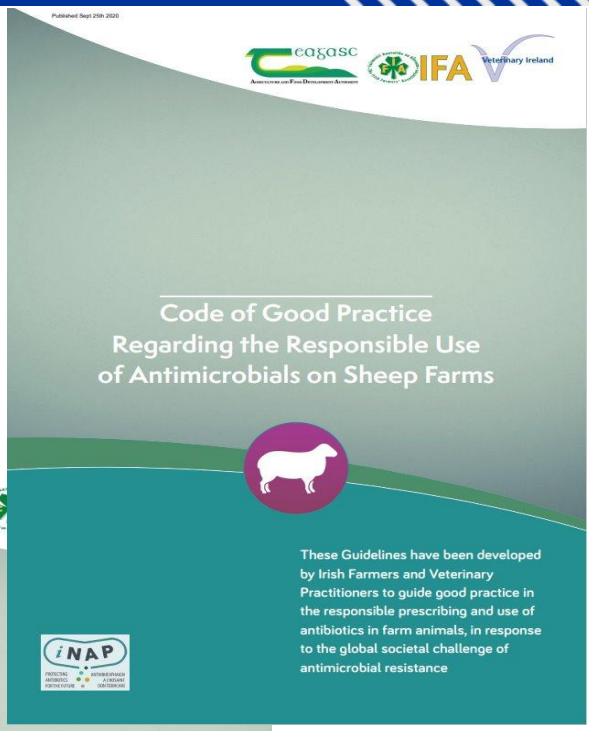

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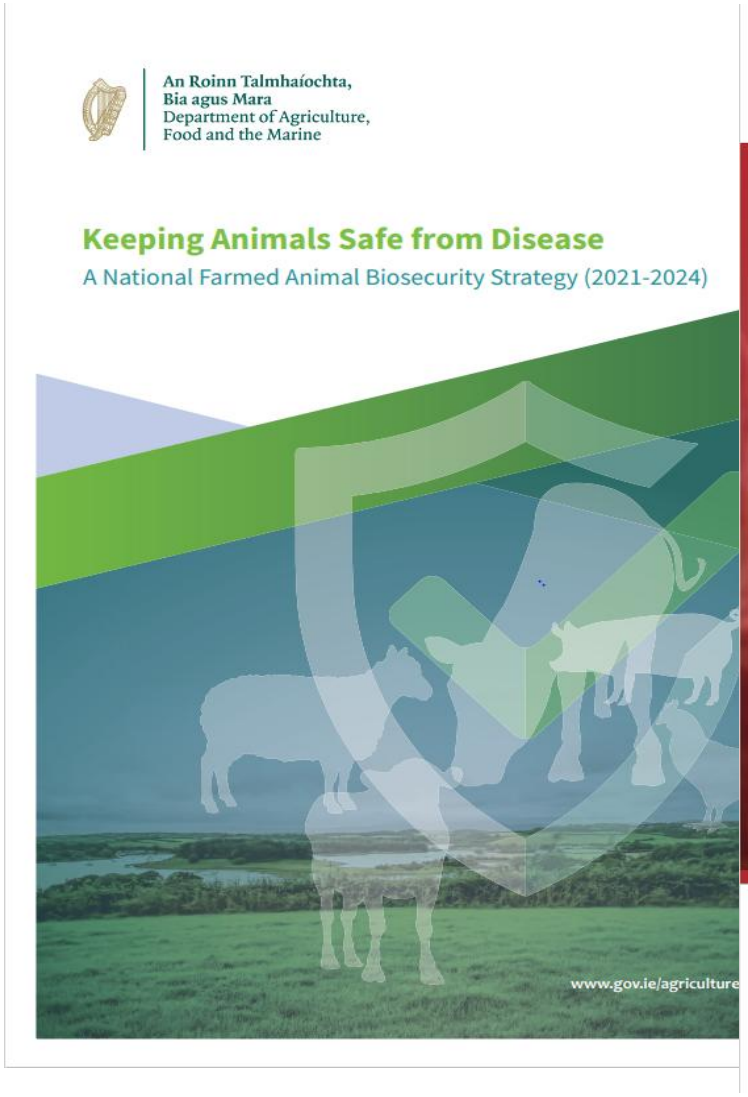

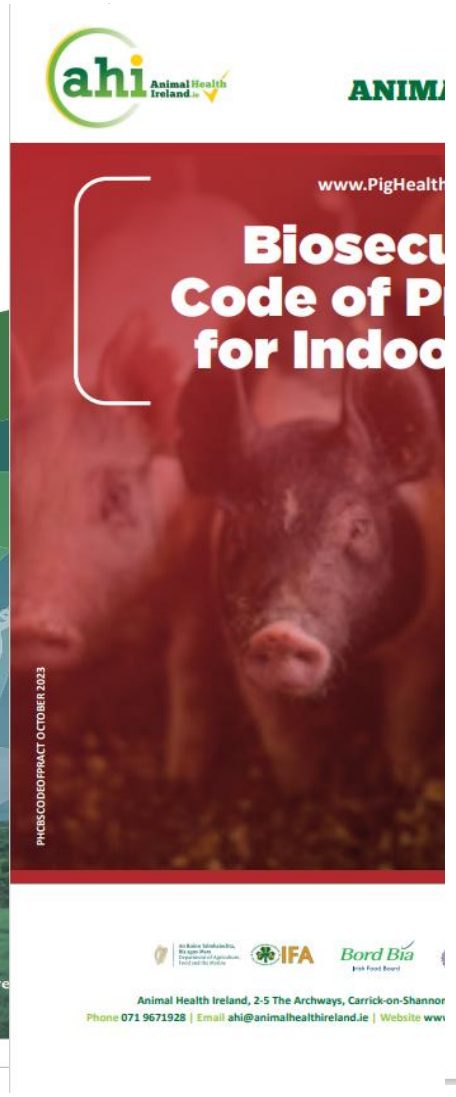

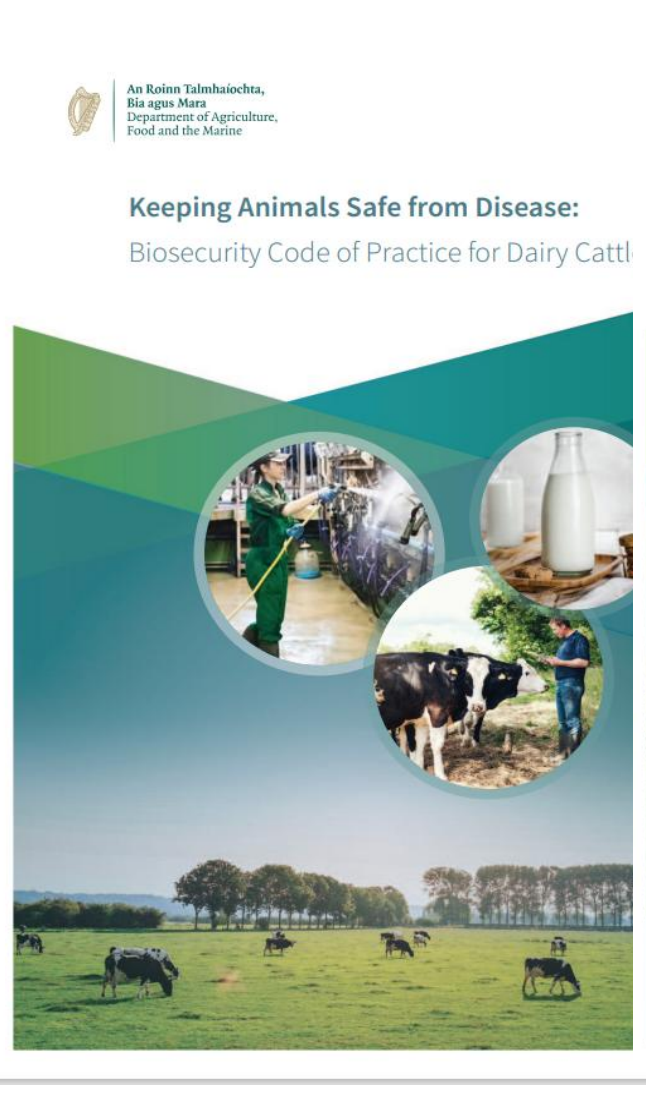

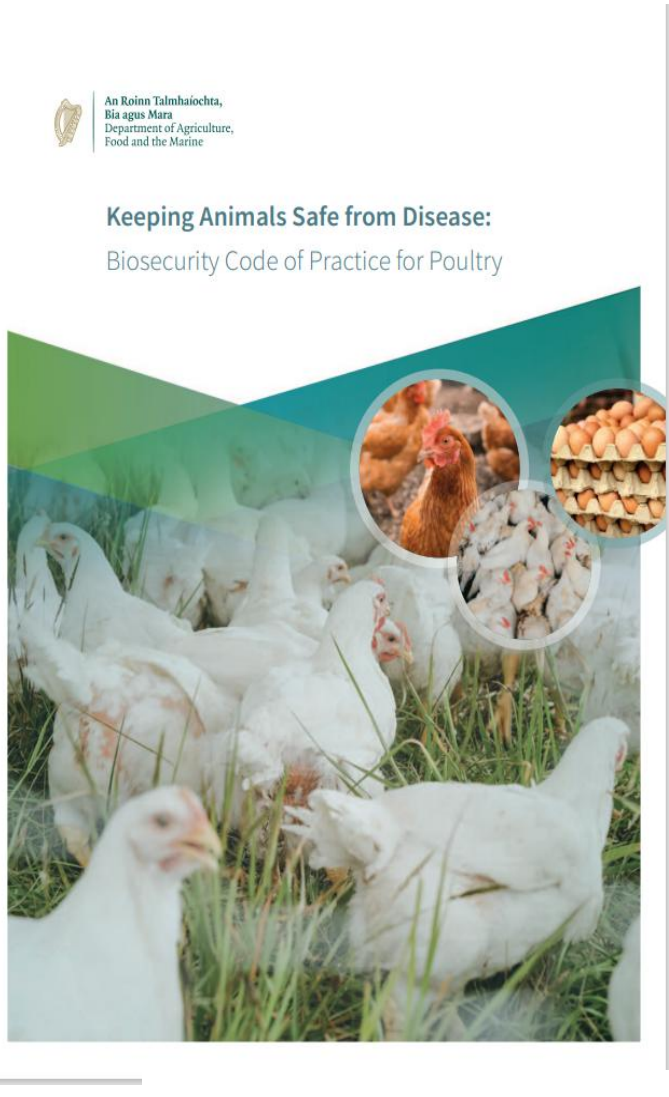

Disposal of VMPs

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 Minster 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 producs 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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