

Categorisation of antimicrobials and its impact for veterinary practice

2nd EMA/FVE webinar, 23rd June 2021
Piotr Kwiecinski



Federation of
Veterinarians of Europe



Federation of veterinarians of Europe

47 national associations

39 European countries

4 Sections

- UEVP (*Practitioners*)
- UEVH (*Hygienists – Public Health Officers*)
- EASVO (*Veterinary State Officers*)
- EVERI (*Education, Research, Industry*)

FVE's mission

The European veterinary profession, embodied by FVE, **enhances animal health, animal welfare, public health and protect the environment** by promoting the veterinary profession.

Together with its members, FVE supports veterinarians in delivering their professional responsibilities to the best possible standards and ensures that veterinary expertise is recognised and valued by society.

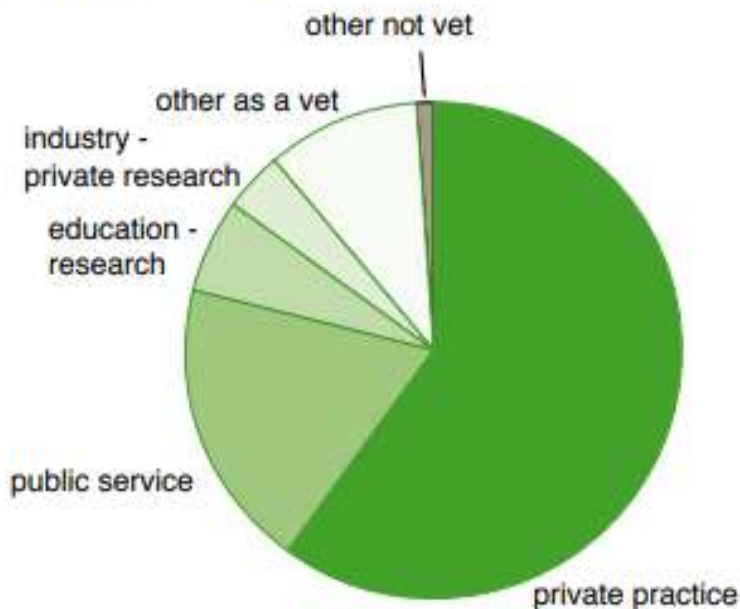


Federation of Veterinarians of Europe

UEVP is an independent organization with international statutes. Today UEVP represents 29 member countries and 5 European federations, **all representing European practitioners.**

- one European voice for practitioners
- setting standards across borders through education, influencing legislation, giving veterinary opinion and prudent use of medicines, including fighting AMR
- create professional environment for veterinary practitioners

Field of employment - Europe



- EPRUITA partners:**

Animal Health Europe
 The network of animal medicines regulatory authorities

COPA-COGECA
 European Farmers' and Agri-Organisations

EGGVP
 European Group for Veterinary General Practice

EDRA
 European Veterinary Association

EFCA
 European Federation of Animal Science

FEFSS
 European Federation of Veterinary Schools and Associations

FEV
 European Federation of Veterinary Associations

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European Platform for the Responsible Use of Medicines in Animals



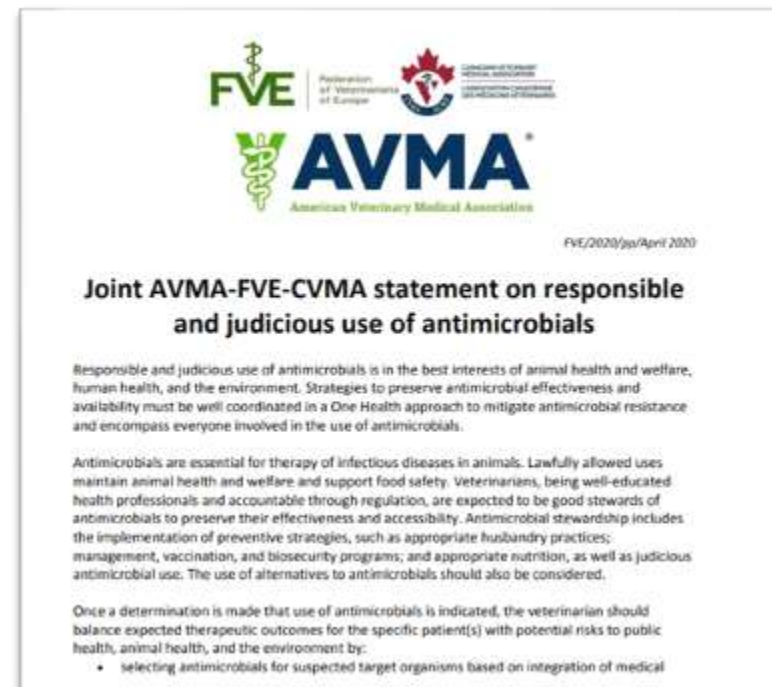
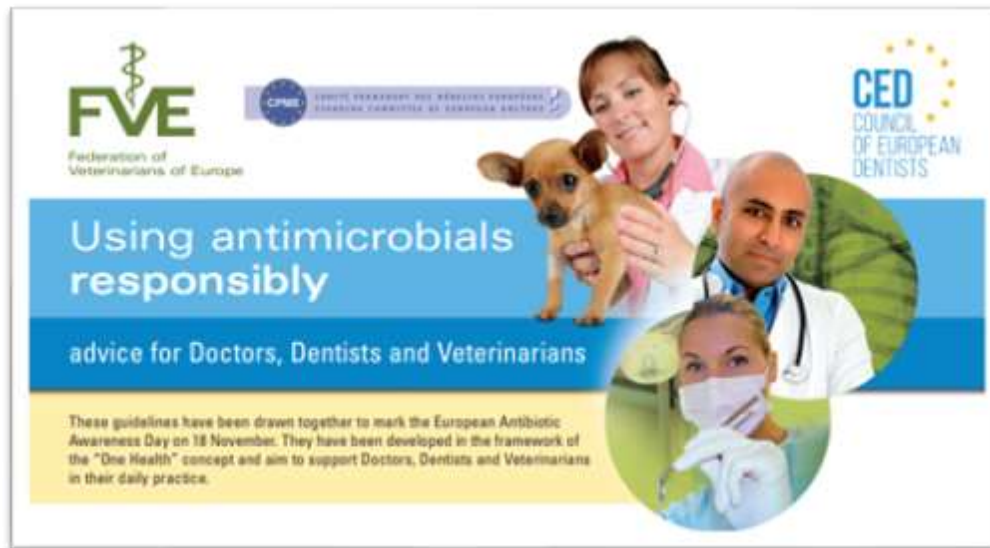


Need for **Global One Health Approach** against AMR



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- ✓ FVE works with medical doctors and dentists
- ✓ FVE has worldwide alliances
 - American and Canadian Veterinary Medical Association
 - World Veterinary Association



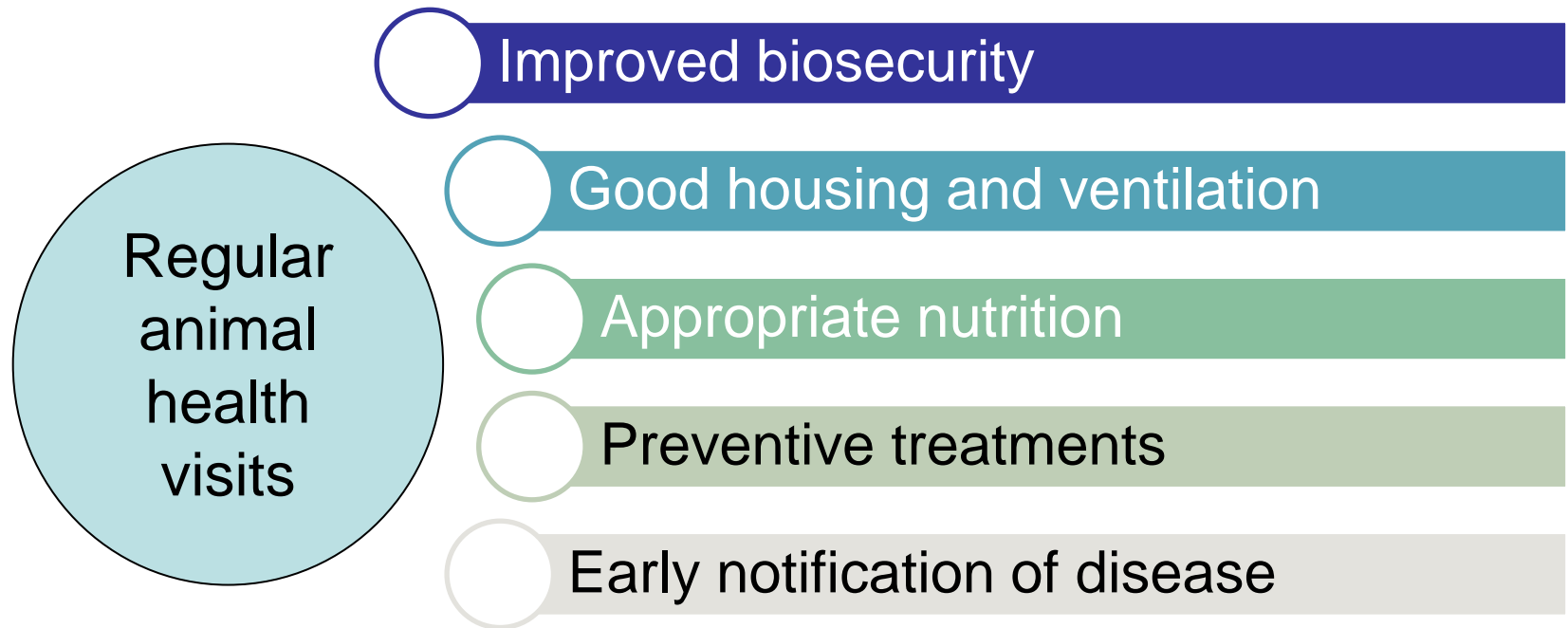
FVE promotes prudent and responsible use



The overall aim is to reduce **antimicrobial resistance** and not ONLY the antibiotic use

- Sick animals deserve treatment
- Against banning of certain antibiotics for all animals
- The treatment of bacterial infections is simultaneously essential to safeguard animal health and welfare, as well as public health concerning zoonotic diseases
- Focus on prevention: primary disease causes have to be eliminated (AHL)

Prevention is better than cure!



→ Reduction of antimicrobial use needs holistic approach

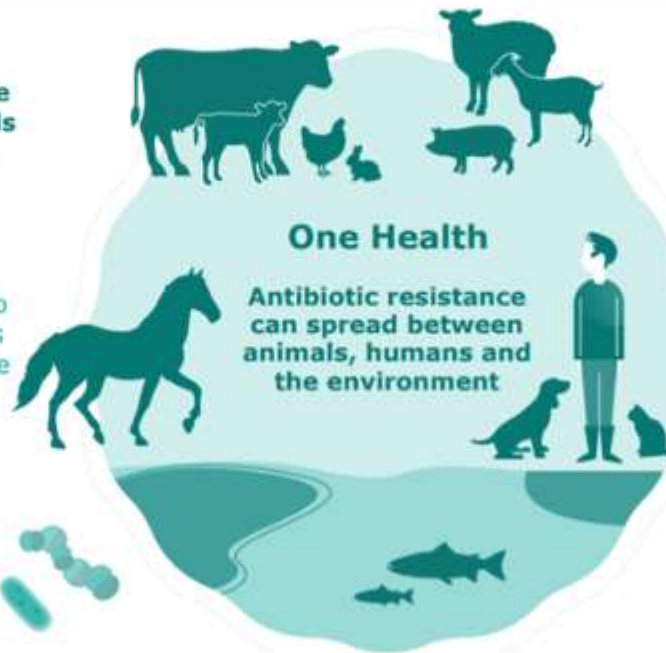
Categorisation of antimicrobials is an essential tool for veterinarians

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.

AMEG Categorisation is most important one for EU practitioners

	AMEG	OIE	WHO		AMEG	OIE	WHO	
 	AMINOGLYCOSIDES				AMIDINOPENICILLINS			AMEG
 	CEPHALOSPORINS				CARBAPENEMS			Category A ("Avoid") "prohibited"
 	MACROLIDES AND KETOLIDES			 	GLYCOPEPTIDES			Category B ("Restrict")
 	PENICILLINS				GLYCYLCYCLINES			Category C ("Caution")
 	POLYMYXINS				LIPOPEPTIDES			Category D ("Prudence")
 	QUINOLONES	1st	2nd		MONOBACTAMS			OIE
 	TETRACYCLINES				NITROFURANTOINS	For CA only		Veterinary critically Important Antimicrobials (VCIA)
 	AMINOCYCLOLITOLS				NITROIMIDAZOLES	For CA only		Veterinary Highly Important Antimicrobials (VHIA)
 	AMINOPENICILLINS (with β -lactamase inhibitors)				PHOSPHONIC ACID DERIVATIVES			Veterinary Important Antimicrobials (VIA)
 	AMINOPENICILLINS (without β -lactamase inhibitors)				PSEUDOMONIC ACID			WHO
 	AMPHENICOLS				RIMINOZENAZINES			Critically important AB-Highest Priority
 	ANSAMYCINS/RIFAMYCINS				SULFONES			Critically important AB-High Priority
 	CEPHALOSPORINS (1st and 2nd Generation) + CEPHAMYCINS			 	OXAZOLIDINONES			Highly important antimicrobials
 	LINCOSAMIDES				DRUGS USED SOLELY TO TREAT TUBERCULOSIS OR OTHER MYCOBACTERIAL DISEASES			Important antimicrobials
 	PENICILLINS (anti-staphylococcal)			 	STEROID ANTIBACTERIALS (FUSIDIC ACID)	For CA only		No opinion
 	PLEUROMUTILINS				IONOPHOREN			
 	STREPTOGRAMINS							
 	SULFONAMIDES							
 → Animal Use		 → Human Use						

Cat A: 'Avoid'

- Not authorised in Vet Med
- Forbidden for LA, except CA
- E.g. carbapenems, rifampicin, ...

Cat B: 'Restrict'

- Only after AST
- Last resort
- E.g. quinolones, 3-4th gen cephalosporins, colistin, ...

Cat C: 'Caution'

- Higher risk than D
- E.g. aminoglycosides, macrolides, amox + clav, ...

Cat D: 'Prudence'

- All others
- E.g. tetracyclines, penicillins, sulfonamides, ...



Cat A: 'Avoid'	Cat B: 'Restrict'	Cat C: 'Caution'	Cat D: 'Prudence'
• Not authorised in Vet Med • Forbidden for LA, except CA • E.g. carbapenems, rifampicin, ...	• Only after AST • Last resort • E.g. quinolones, 3-4 th gen cephalosporins, colistin, ...	• Higher risk than D • E.g. aminoglycosides, macrolides, amox + clav, ...	• All others • E.g. tetracyclines, penicillins, sulfonamides, ...

Veterinarians have open questions!



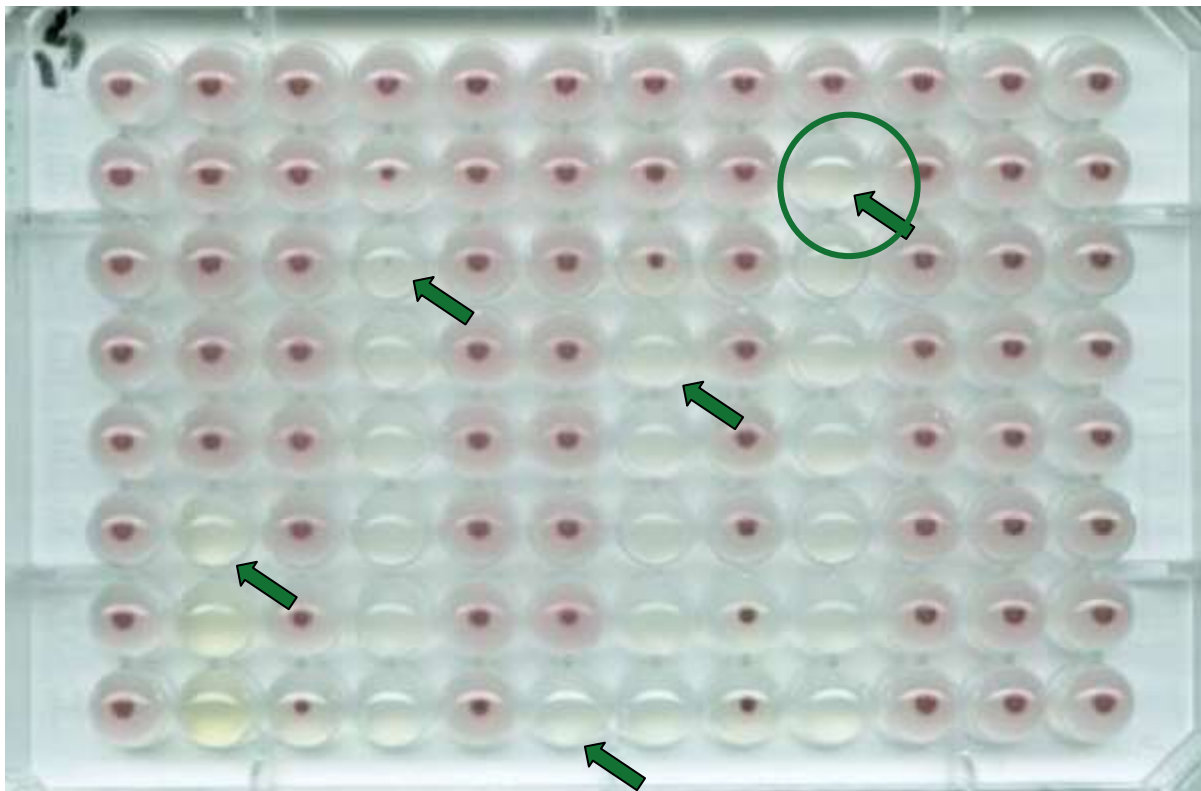
- What to do if national guidelines differ from AMEG guidelines?
- What if you only have a Category B antibiotic licensed for a certain indication/species in your country, while you could use off-label an antibiotic of Cat C or D?
- What if you have a shortage?

Diagnostic testing to improve rational prescribing



- ✓ Rapid identification of the etiological bacteria
- ✓ Use of antimicrobial susceptibility testing before administration of antimicrobials
- Standardization of currently available tests and clinical breakpoints for veterinary pathogens
- Need for novel rapid diagnostic testing methods
- Better guidance and surveillance

Diagnostic testing to improve rational prescribing



Allow veterinarians to **use their professionalism**



- Veterinarians are experts in animal health
- Use as less as possible - as much as necessary
- FVE underlines need for science-based

One Health approach

CA-Food producing animals

methods of administration

FVE approach to AMEG listing



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- FVE is against banning of authorized antibiotics for animals
 - Animals need antibiotics, too!
- FVE provides concrete examples of conditions, in which certain antibiotics are essential
 - Fluoroquinolones for small mammals
- The list of antibiotics to reserve for humans is still under development (implementing act still under development)

Main Conclusions



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- Globalisation accelerates AMR into an international One Health issue
- Need for collaboration between human health, animal health and environmental and agricultural sectors
- Legislators must closely work together with practitioners and other stakeholders in order to make sure **practical, workable solutions** are found:
 - Implementing and delegating acts
 - Harmonised regulatory frameworks
 - Availability will remain a problem due to the small market

Outlook



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- Changes ahead in agriculture and veterinary medicines
- Focus on prevention of diseases, rather than treatment
- As little as possible - as much as necessary
 - amount, timings, animals
- Need to continue to boost animal health & welfare to reduce need for antibiotic use
- Need to follow categorization and avoid, as much as possible, group treatment
- Let's continue to work together!

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Thu, 06 Aug 2020

POSITION PAPERS | Medicines

FVE inputs to consultations around new veterinary medicines legislation and AMR

The new Veterinary Medicine legislation (on veterinary medicine and medicated feed) will come into force on 28 January 2022. The main Regulations will be supplemented with several delegating and implementing acts.

European law on veterinary medicines: what's new?



Veterinary prescriptions can only be issued by veterinary surgeons (exceptions apply). The prescription will be valid throughout the EU. The quantity prescribed should be limited to the treatment.

Reg. 2019/631 16

All prescriptions require justification, such as a clinical diagnosis or proven knowledge of the animal.



<https://fve.org/publications/fve-inputs-id-acts-nvr/>



European law on veterinary medicines: what's new?



New legislation on veterinary medicines has been officially adopted by the EU*.

It will enter into force in less than three years - on 28 January 2022 - in all EU countries.

The new legislation will strengthen veterinary oversight and will further promote the responsible use of antibiotics.

The FVE has actively contributed to the drafting of the Regulations to make the rules more transparent and easier to implement and to help combat antimicrobial resistance while safeguarding public health, animal health and animal welfare.

What will change in veterinary practice?



Veterinary prescriptions can only be issued by veterinary surgeons (exceptions apply) and will be valid throughout the EU. Antibiotics can only be prescribed for 5 days. Extension of treatment using a new prescription is only allowed if justified (diagnostic testing).



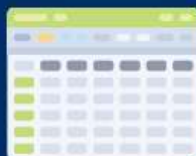
To combat **antimicrobial resistance**, use of certain **critically important antibiotics** can be prohibited in animals. The European Commission is expected to draw up a list. Preventive use of antibiotics is only permitted in exceptional circumstances. Restrictions also apply to metaphylactic use.



The **prescription cascade** will become more flexible and importing drugs from another EU country will become easier. Third country medicines can also be used under certain conditions. The cascade also applies to medicated feeds. Restrictions may apply to antibiotics.



On-farm **monitoring** systems of antibiotic use and national surveillance of antibiotic use become mandatory. **Advertising** veterinary prescription medicines in the farming press will be forbidden, although Member states can exempt vaccines.



A central **EU database** of all authorised veterinary medicines will be set up, easily accessible by all veterinarians. **Pharmacovigilance** data will become accessible to all veterinarians and reporting adverse events more user-friendly.



Medicated feeds require a veterinary prescription. The presence of more than one antimicrobial substance is prohibited. Preventive antibiotic use is not allowed, metaphylactic use only under certain conditions.



Online sales are only allowed for medicines not requiring a veterinary prescription. Individual Member states can overrule this, but only on their territory. Legal online pharmacies must be monitored and certified with a common EU logo.



Imported animals and products from outside the EU need to apply the ban on growth-promoting antimicrobials and on antibiotics reserved for human use.



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* New Regulation on veterinary medicines: <https://eur-lex.europa.eu/eli/reg/2022/69/01> - New Regulation on medicated feed: <https://eur-lex.europa.eu/eli/reg/2022/69/01>

THANK YOU FOR YOUR ATTENTION

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