

# FVE's perspective on new EU medicines legislation

## Symposium

19 november 2019

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Federation of  
Veterinarians of Europe



# The FVE Network

 Members  Observers





## FVE's Strategy 2015-2020



Veterinarians: caring for  
animals *and* people



[www.fve.org](http://www.fve.org)

## FVE's mission

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

Together with its members, FVE aims to support veterinarians in delivering their professional responsibilities to the best possible standard, and that this expertise is recognized and valued by society.

# FVE Affiliations & Liaison

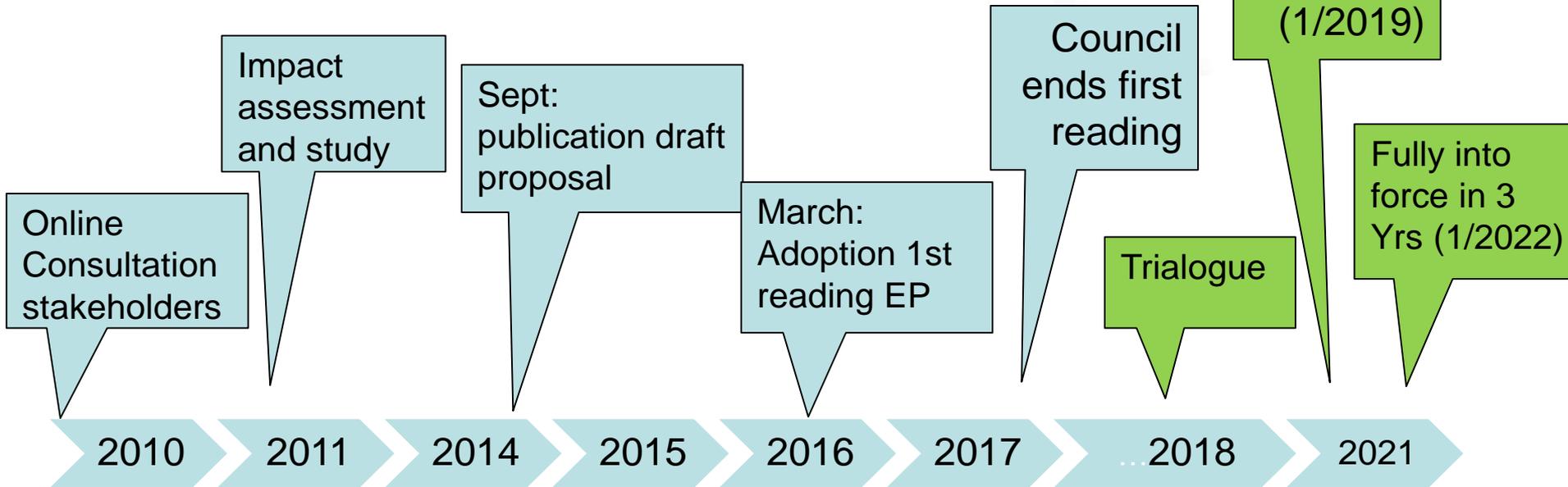


[www.fve.org](http://www.fve.org)



And many more...

# Timeline EU Medicines legislation revision: 2019/6



**FVE and national delegations input!**

All FVE position papers on [www.fve.org](http://www.fve.org)

# Main reasons to revise EU Veterinary medicines legislation



www.fve.org

- Increase availability
- Better rules to fight AMR and around the use of antimicrobials
- Improved pharmacovigilance
- Reduce administrative burden
- Promote innovation
- Facilitate single market

# Authorisation and use of veterinary medicines is regulated on EU level

- EU legislations dictates the conditions around authorisation and use of veterinary medicines
- Current EU legislation:
  - Directive 2001/82/EC re veterinary medicines
  - Directive 90/167/EEC re medicated feed
- Been revised, new rules will enter into force Jan 2022
  - Regulation (EU) 2019/6 re veterinary medicines
  - Regulation (EU) 2019/4 on medicated feed
- Despite EU rules, most medicines will remain **nationally authorised**

# New rules contain many improvements!



- European database of all medicines & Pharmacovigilance
- Cascade remains and improved
- Veterinary prescription only to be issued by vet
- No internet trade POMs
- Better rules to fight AMR
- No decoupling on a European level!  
Right to dispense maintained
- Centralised authorisation route opened -)  
more availability



# But still some worries!

- Ban of use of certain antibiotics for animals
- Will the new legislation really improve availability?
- How will the new pharmacovigilance system work?
- Medicated feed for pets. No thank you.
- Will administrative burden veterinarians increase e.g. recording antibiotic use?
- Will the union database be ready by 2022?
- Is it fit for the future? What about diagnostics, essential oils, phages, etc?
- Validity vet prescription EU wide vs no internet trade POMs





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# Now FVE is following the tertiary legislation...

## ➤ Many implementing & delegating acts

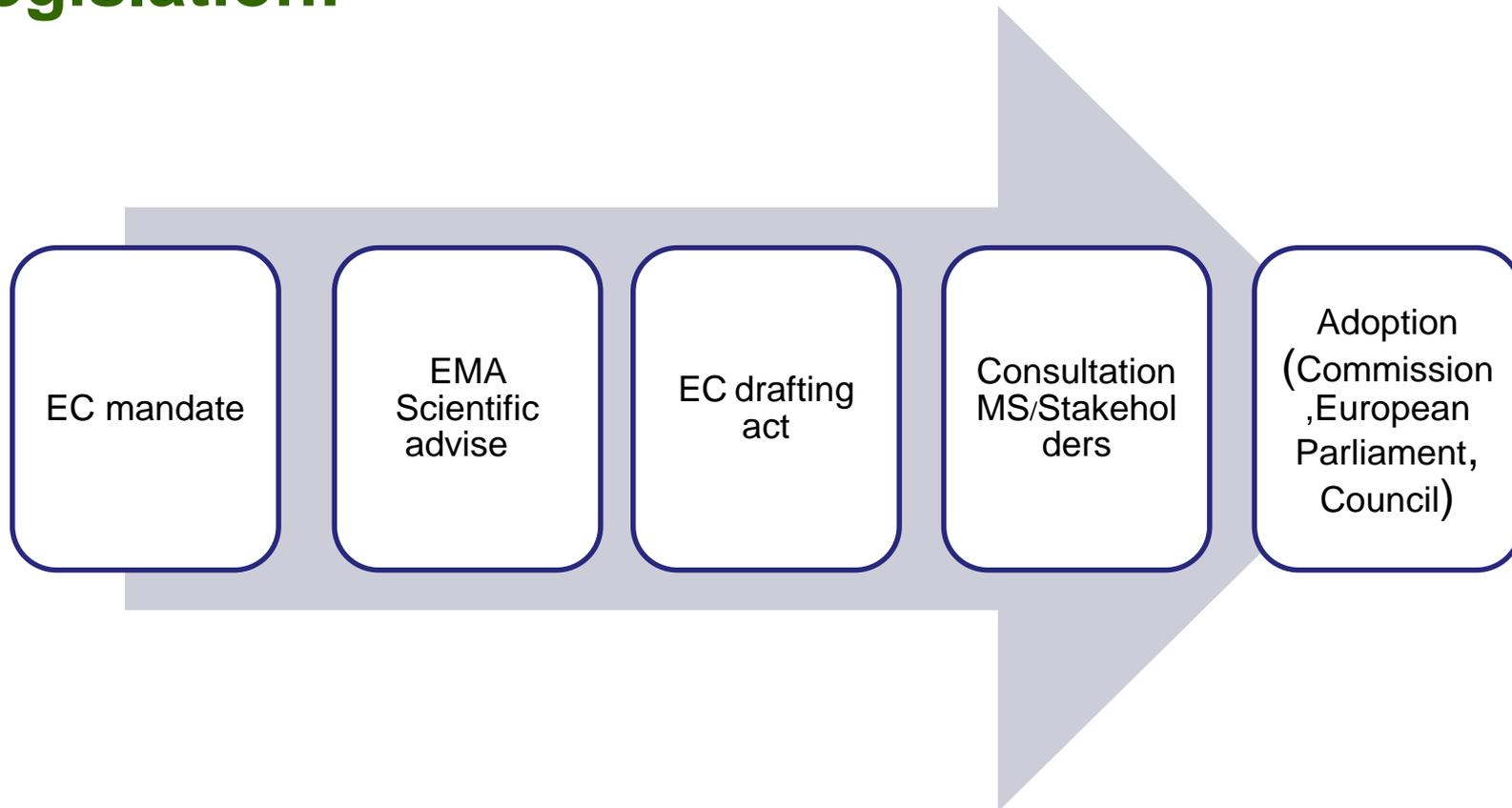
- DA&IA: Pharmacovigilance
- IA: on collection antibiotic use data per species
- IA: list of restricted antibiotics
- DA/IA: horse passport, essential list horses

## ➤ National derogations possible

- Restriction of antibiotics
- On internet sales
- On administration of products



## Working method tertiary legislation:



Special EU website:

[https://ec.europa.eu/food/animals/health/veterinary-medicines-and-medicated-feed/imp-regs-2019\\_en](https://ec.europa.eu/food/animals/health/veterinary-medicines-and-medicated-feed/imp-regs-2019_en)

# Mandates given & advice ready

1. Revision of Annex II of the Regulation (data requirements);
2. List of variations not requiring assessment;
3. Detailed rules on the methods of gathering data on the use of antimicrobials;
4. Preparatory work on Product Data Base

Purple – important ones for veterinary practitioners

# Mandates given, awaiting advice

- Criteria to establish antimicrobials reserved for treatment of certain infections in humans; (next week EMA advice ready)
- Good Pharmacovigilance practice;
- Pharmacovigilance system master file
- Oral medication rules; (task force started working)
- Format for the collection of data on antibiotics in animals
- Detailed rules on the methods of gathering data on the use of antimicrobials;
- List of antimicrobials reserved for use in humans (2020)
- GDP active substances
- GDP for VMPs

# FVE gave input in:

- Before EMA advice into '**Criteria to ban antibiotics**'
- Before and after EMA advice on '**Veterinary product and pharmacovigilance database**'
- After EMA advice on '**data collection future ESVAC system**'



POSITION PAPERS | Animal Health & Welfare / Medicines

## Designation of antimicrobials reserved for humans: FVE inputs

Regulation 2019/6 on veterinary medicinal products lays down that the Commission shall adopt tertiary legislation to set up criteria for the designation of antimicrobials reserved for treatment of certain infections in humans. FVE has sent its inputs to the EU Institutions and to the European Medicines Agency. Through its input paper FVE restates that banning is not a solution for animal health care nor the miracle to reduce the human antimicrobial burden.



To combat antimicrobial resistance (AMR), there is the need to continue working on Reduction, Replacement and the Re-thinking of the use of antimicrobials in animals and humans.

### POSITION PAPERS

Medicines

Internet sales of veterinary medicines: How to ensure a legitimate system in place



### POSITION PAPERS

Animal Health & Welfare

Charity work in the field of veterinary medicine: checklist for charities, veterinarians and veterinary students – DE



### BROCHURES / LEAFLETS / POSITION PAPERS

Veterinary Profession

Charter for liberal professions

# Future ESVAC proposed:



[www.fve.org](http://www.fve.org)

**BLUE** = New

Mandatory collection	Voluntary collection:
Sales and <b>use data</b> of all antibiotics now collected	<b>Sales data</b> for antiprotozoals (8), antifungals (7), antimycotics, antimycobacterials and antivirals (0)
<b>Sales of antibiotics</b> for skin, nose, eye, ear and anti-mycobacterials for intramammary use	<b>Use data of antibiotics</b> for skin, nose, eye, ear and anti-mycobacterials for intramammary use and ones above
	<b>R. Equi treatments</b>

2024	2027	2030
Cattle, pigs, poultry	All food animals: Sheep, Goats, Finfish, Horses, Rabbits	Dogs, cats, fur animals

# Critically Important Antibiotics





EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

1 4 February 2019  
2 EMA/CVMP/CHMP/682198/2017  
3 Committee for Medicinal Products for Veterinary use (CVMP)  
4 Committee for Medicinal Products for Human Use (CHMP)

5 Answer to the request from the European Commission for  
6 updating the scientific advice on the impact on public  
7 health and animal health of the use of antibiotics in  
8 animals - Categorisation of antimicrobials  
9 Draft

Agreed by the Antimicrobial Advice ad hoc Expert Group (AMEG)	29 October 2018
Adopted by the CVMP for release for consultation	24 January 2019
Adopted by the CHMP for release for consultation	31 January 2019
Start of public consultation	5 February 2019
End of consultation (deadline for comments)	30 April 2019

# EMA draft new categorization CIA's

Adoption foreseen in December

.org

Category	Details	Examples
Cat A ' <b>Avoid</b> '	not authorised in vet med, forbidden LA, exceptional CA	e.g. Carbapenems, glycopeptides, drugs used solely to treat tuberculosis
Cat B ' <b>Restrict</b> '	Only after AST, last resort	Quinolones, 3/4 Generation cephalosporins, polymixins
Cat C ' <b>Caution</b> '	Higher risk but < B	Aminoglycosides, macrolides, rifamycins
Cat D ' <b>Prudence</b>	All others	

**FVE support categorisation and plans to support EMA to communicate to practitioners**

# Updated CIA listing

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

→ Animal Use      → Human Use

N. De Bityne, 2019

# FVE approach to CIA listing



- FVE is pro-active, following all consultations on the CIA's very closely
- FVE underlines animals need antibiotics too and gives examples of animal conditions where certain antibiotics are essential
- FVE is against banning of authorized antibiotics for animals
- FVE underlines need for science-based '**One-Health**' **approach**, which we achieved in the legislation

# ESVAC report Oct 2019



[www.fve.org](http://www.fve.org)



Federation of Veterinarians of Europe

# ESVAC report Oct 2019

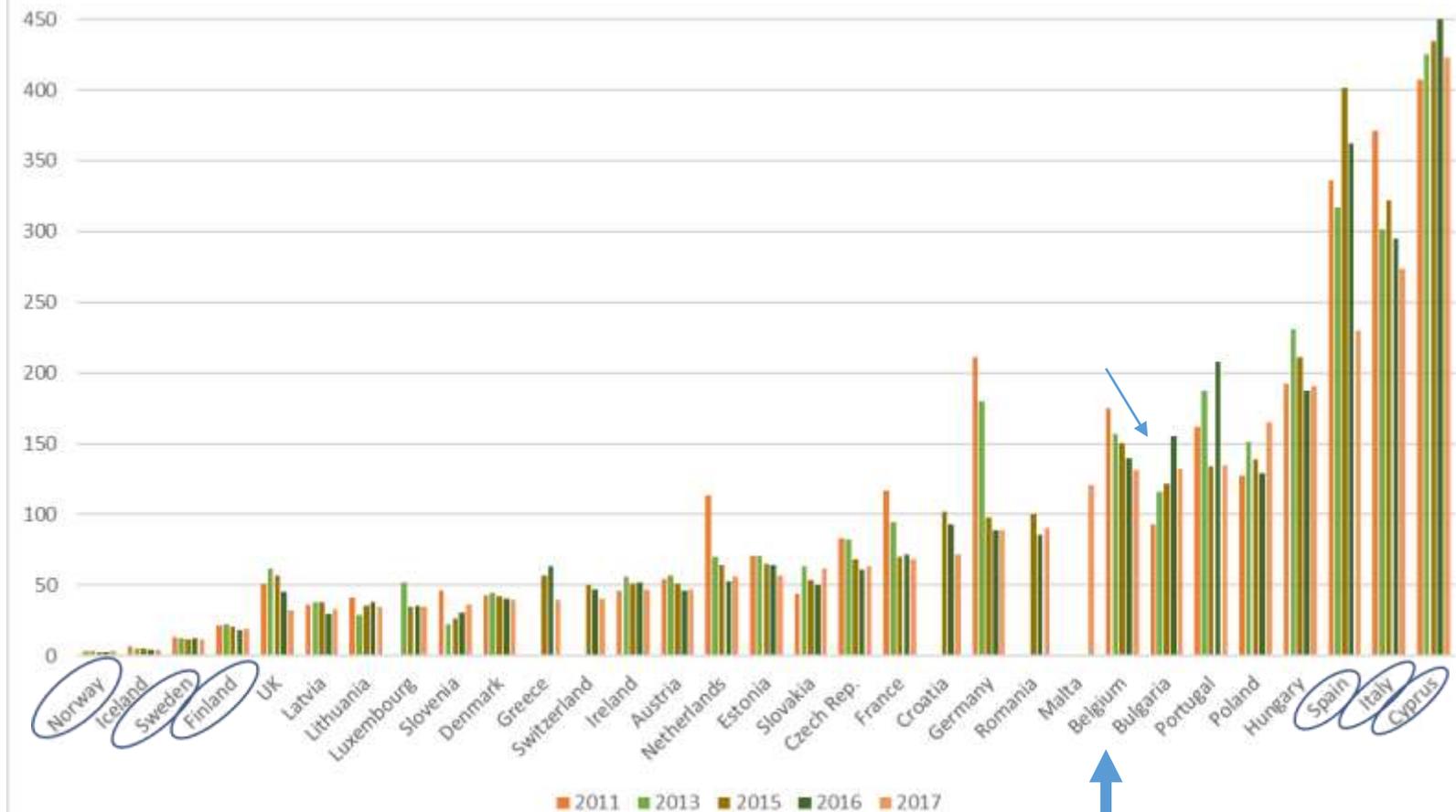


[www.fve.org](http://www.fve.org)

- Data 2017 from 31 countries
- Total reduction of sales of veterinary antibiotics 2011 and 2017:
  - Overall sales -32.5%
  - Polymyxins (Colistin) -66.4%
  - 3th/4th gen. Cephalosporins -20.9%
  - Fluoroquinolones -10.3%



## Antimicrobial sales in mg/PCU (2011-2017)



# FVE believes in Global One Health Approach against AMR



[www.fve.org](http://www.fve.org)

- ✓ FVE collaboration with medical doctors, dentists, etc ([link](#))
- ✓ FVE collaboration worldwide, via World Veterinary Association and with American and Canadian Veterinary Medical Association
- ✓ FVE founding member of [EPRUMA](#)
- ✓ FVE with 177 organisations active in human and animal health sent [open letter](#) to European Parliament to keep up fight on AMR
- ✓ FVE in EU-JIAMRAI



***American Veterinary Medical Association (AVMA) &  
Canadian Veterinary Medical Association (CVMA/ACMV) &  
Federation of Veterinarians of Europe (FVE)***

***Joint Statement on***

***RESPONSIBLE AND JUDICIOUS USE OF ANTIMICROBIALS***

(Approved by the AVMA Board of Directors on 23 August 2011, FVE Board of Directors on 30 August 2011 and the CVMA Council on 8 July 2014)

Responsible and judicious use of antimicrobials is in the best interests of both animal health and human health. Approaches to preserve antimicrobial efficacy must be well coordinated and encompass everyone involved in the use of antimicrobials, including physicians, veterinarians, individual patients, animal caretakers, and producers.

# FVE works on **practical** solutions to reduce antibiotic use



www.fve.org

- ✓ Many leaflets, folders
- ✓ [Position paper](#) to move away from routine dry-cow treatment
- ✓ FVE founding member of [EPRUMA](#)
- ✓ [HealthyLivestock Project](#)
- ✓ ....

**FECAVA/FVE RECOMMENDATIONS FOR APPROPRIATE ANTIMICROBIAL THERAPY**

FECAVA Recommendations for Appropriate Antimicrobial Therapy

DOWNLOAD NOW!

FECAVA  
Federation of European Colleges  
Animal Veterinary Associations

FVE

The image shows a poster for 'FECAVA/FVE Recommendations for Appropriate Antimicrobial Therapy'. The poster features a large table with columns for different animal species (indicated by icons of a cow, pig, dog, and cat) and rows for various antimicrobial classes. The table contains specific recommendations for each combination. At the bottom left of the poster is a yellow circular button that says 'DOWNLOAD NOW!'. At the bottom right is the FECAVA logo, which includes a stylized animal icon and the text 'FECAVA Federation of European Colleges Animal Veterinary Associations'. The FVE logo is also present in the top right corner of the poster.

# Main Conclusions



[www.fve.org](http://www.fve.org)

- Many important issues are going on in relation to the use of veterinary medicines for practitioners
- FVE believes the new medicines legislation has much potential
- However, much still depends on the implementing and delegating acts
- And... national implementation and restrictions
- Availability will remain a problem due to the small market
- Important for legislators to closely work together with practitioners and other stakeholders in order to make sure workable solutions are found.

# FVE/UEVP MEDICINES WORKING GROUP



[www.fve.org](http://www.fve.org)



*FVE UEVP MWG 2017-2020*



Federation of Veterinarians of Europe

Thanks for your attention.  
Questions?

