

FVE's perspective on new EU medicines legislation

Symposium

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Federation of
Veterinarians of Europe



Federation of veterinarians of Europe

48 national organisations
40 European countries

4 FVE Sections

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



The FVE Network

 Members  Observers





FVE's Strategy 2015-2020



Veterinarians: caring for
animals *and* people



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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.

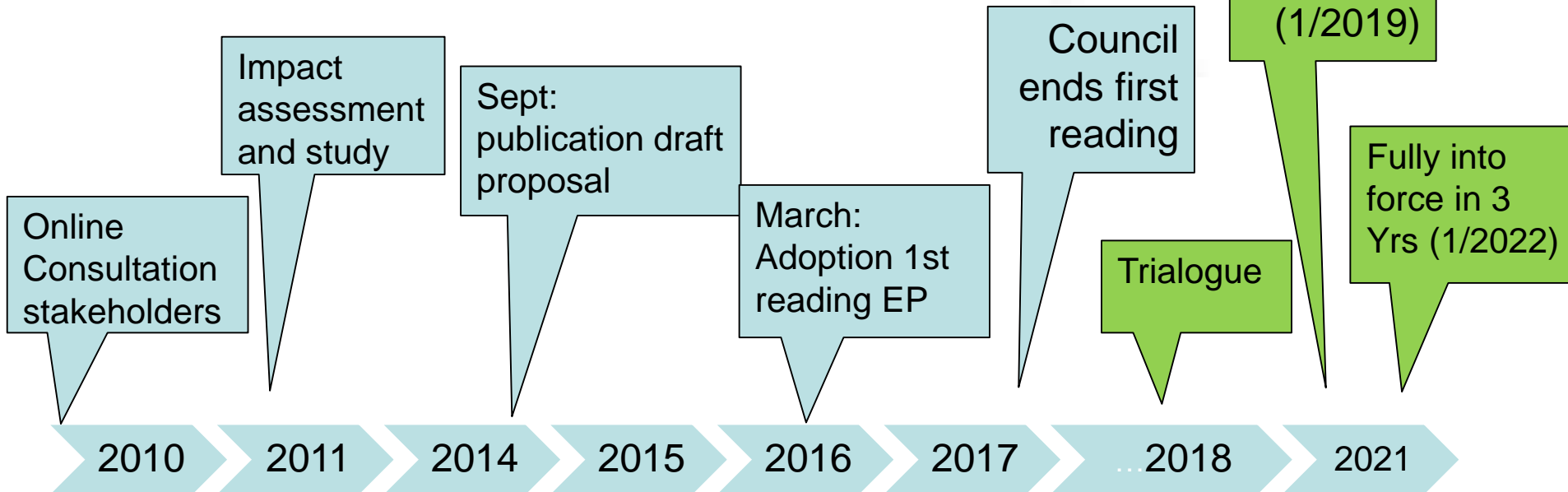
Together with its members, FVE aims to support veterinarians in delivering their professional responsibilities to the best possible standard, and that this expertise is recognized and valued by society.

FVE Affiliations & Liaison



And many more...

Timeline EU Medicines legislation revision: 2019/6



FVE and national delegations input!

All FVE position papers on www.fve.org

Main reasons to revise EU Veterinary medicines legislation



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- 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



What will change in veterinary practice?



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Reg. 1.179A-6 Art. 306



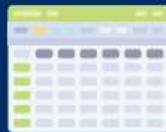
Aug. 2019/6 Am. 26, 100



Бог. ЦЕРКОВЬ. 112.



802, 2019/6/18 67, 138



Reg. DTPN's Art. 55, 56, 11



Reg. 2019-04; 135, 136, Reg. 2019-04, 1



Reg. 17794-01. 000



Revis. 2019/05-04: 118

* Regulation (EU) 2017/1 on veterinary medicinal products: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0001>; Regulation (EU) 2017/4 on medicinal products for human use: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0004>



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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

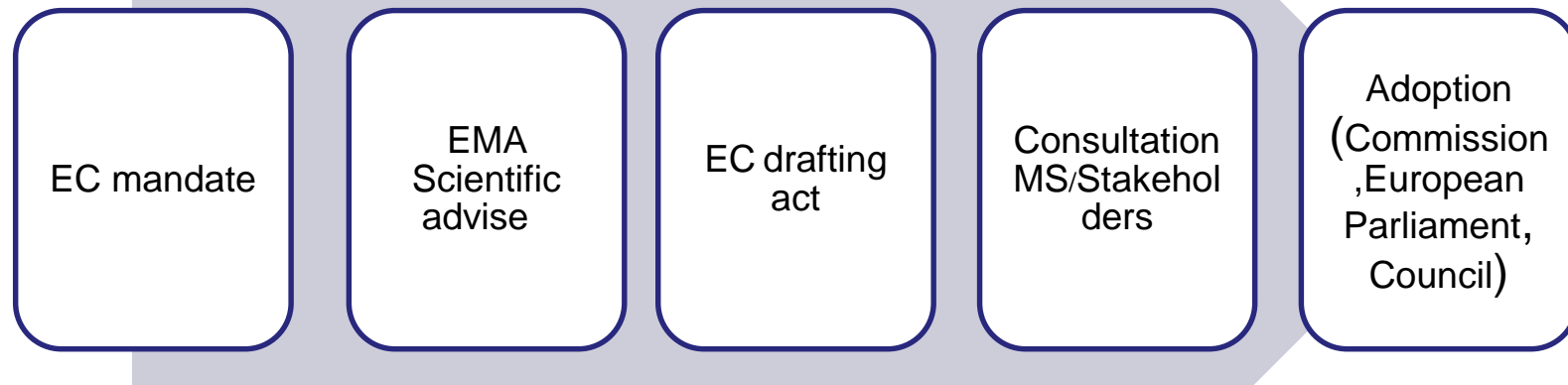
➤ National derogations possible

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

Working method tertiary legislation:



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Special EU website:

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:



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BLUE = New

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

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

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

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

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

e.org

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

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

Updated CIA listing

	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				 MONOBACTAMS				OIE
  TETRACYCLINES				 NITROFURANTOINS	For CA only			Veterinary critically important Antimicrobials (VCIA)
  AMINOCYCLOLIDS				 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 ACIDS				WHO
  AMPHENICOLS				 RIMINOFENAZINES				Critically important AB- Highest Priority
  ANSAMICINS				 SULFONES				Critically important AB- High Priority
  CEPHALOSPORINS (1 st and 2 nd Generation) + CEPHAMICINS				 OXAZOLIDINONES				Highly important antimicrobials
  LINCOSAMIDES				 DRUGS USED SOLELY TO TREAT TUBERCULOSIS OR OTHER MYCOBACTERIAL DISEASES				important antimicrobials
  PENICILLINS (anti-staphylococcal)				 RIFAMYCINS				No opinion
  PLEUROMUTILINS				 STEROID ANTIBACTERIALS (FUSIDIC ACID)	For CA only			
  STREPTOGRAMINS				 IONOPHOREN				
  SULFONAMIDES								
  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



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ESVAC report Oct 2019

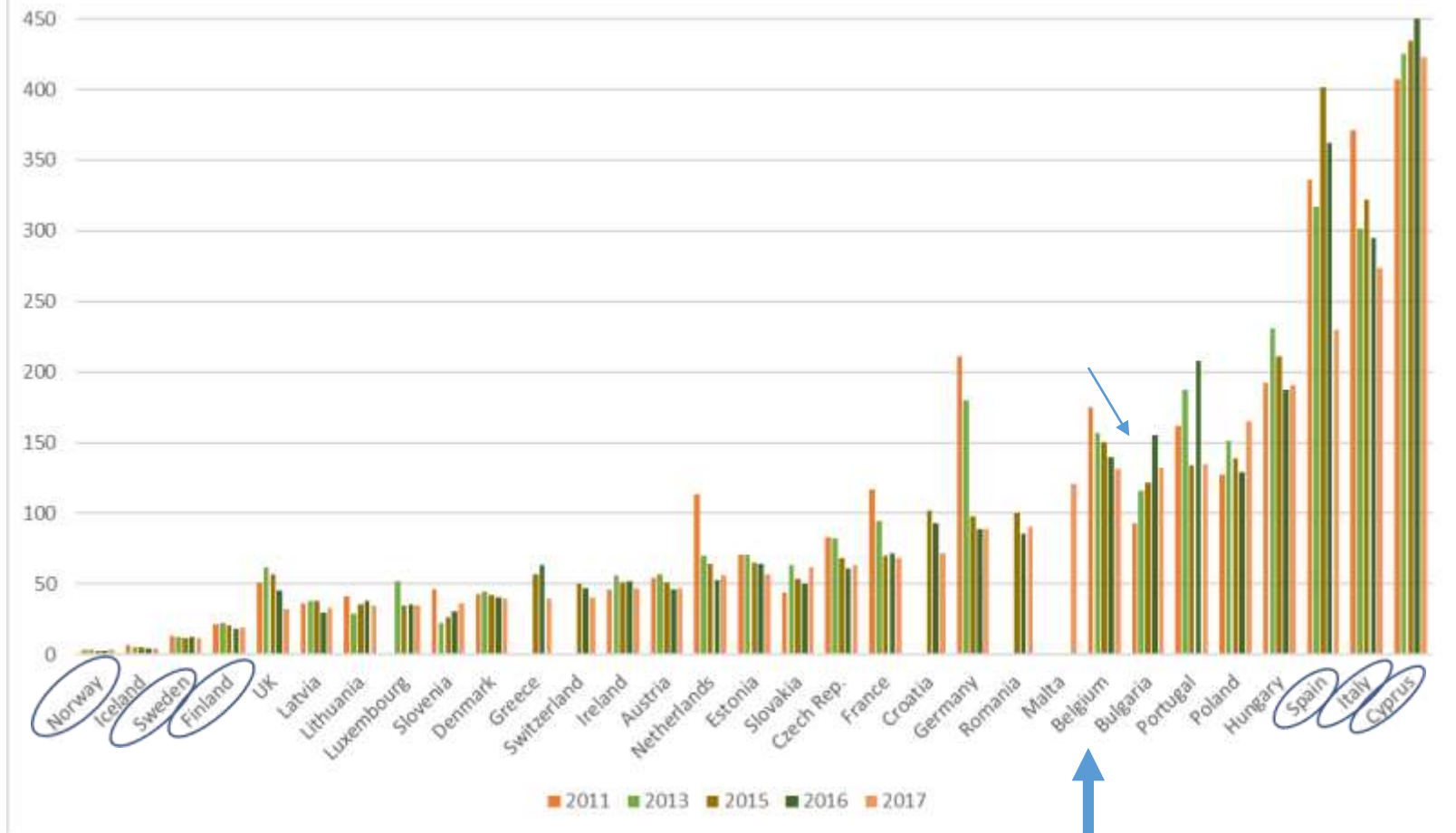


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- Data 2017 from 31 countries
- Total reduction of sales of veterinary antibiotics 2011 and 2017:
 - Overall sales -32.5%
 - Polymyxins (Colistin) -66.4%
 - 3th/4th gen. Cephalosporins -20.9%
 - Fluoroquinolones -10.3%



Antimicrobial sales in mg/PCU (2011-2017)



FVE believes in Global One Health Approach against AMR



- ✓ 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



Federation of
Veterinarians of Europe

***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



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



Main Conclusions



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- 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

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FVE UEVP MWG 2017-2020



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Thanks for your attention.
Questions?

