

FVE General Assembly Update Medicines

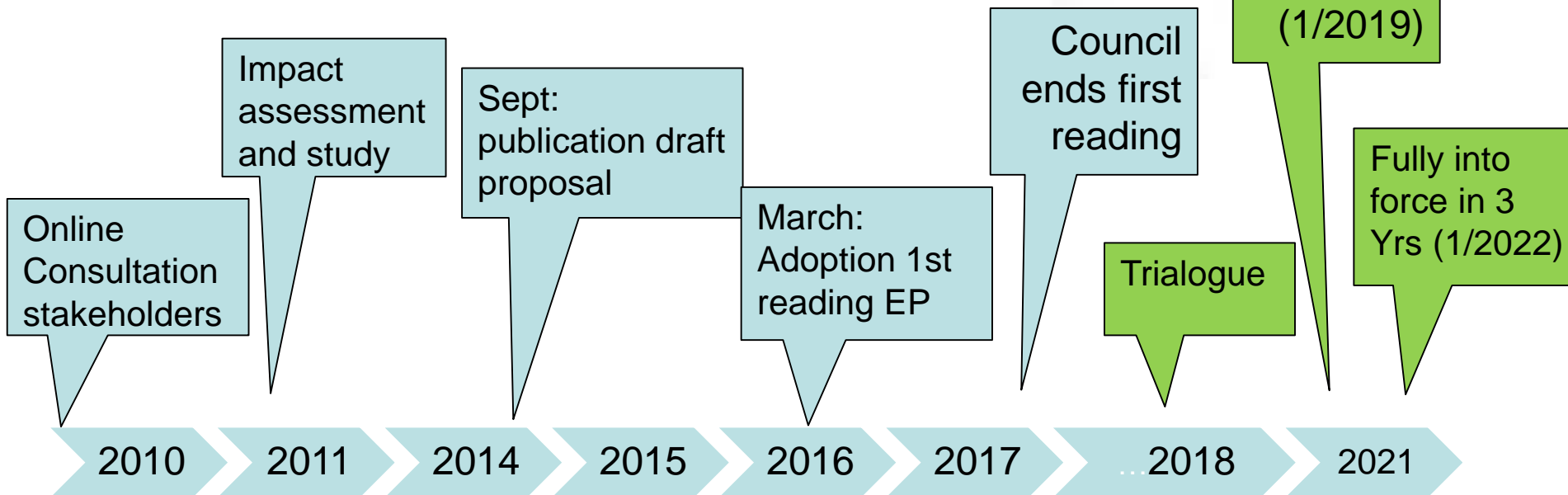
FEEVA GA
Birmingham
11 september 2019

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FVE Vice-president



Federation of
Veterinarians of Europe

Timeline EU Medicines legislation revision: 2019/6



FVE and national delegations input!

All FVE position papers on www.fve.org

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**



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Successes!

- No decoupling on a European level!
Right to dispense maintained
- Cascade remains and improved (availability VMPs)
- European database of all VMPs & Pharmacovigilance
- Veterinary prescription only to be issued by a vet
- No internet trade POMs
- Metaphylactic use of abs allowed (preventive use not)

But still some worries:

- Validity vet prescription EU wide vs no internet trade POMs

FVE infographic: explaining the new Regulation



European law on veterinary medicines: what's new?



The EU has officially adopted new legislation on veterinary medicines*. It will be applicable in all EU countries from 28 January 2022.

FVE has actively contributed to the drafting of the Regulations, allowing the new legislation to strengthen the position of the veterinarian.

The rules are more transparent and easier to implement, helping the profession in safeguarding animal health, animal welfare and public health, including combating antimicrobial resistance.

What will change in veterinary practice?



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. 2019/61, 10

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

Reg. 2019/61, 10, 107

The **prescription cascade** will become more flexible. Importing veterinary medicines from another EU country will become easier. Third country medicines can also be used under certain conditions. Restrictions may apply to antibiotics.

Reg. 2019/61, 115, 116

On-farm monitoring systems of antibiotic use and national surveillance of antibiotic use become mandatory. **Advertising** veterinary prescription medicines in the lay press will be forbidden, although Member States can allow vaccine adverts for farmers.

Reg. 2019/61, 17, 108

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

Reg. 2019/61, 65, 66, 71

Medicated feeds require a veterinary prescription, can only be prescribed for two weeks and cannot contain more than one antimicrobial substance. Preventive antibiotic use is not allowed, metaphylactic use only under certain conditions.

Reg. 2019/61, 105, 109, Reg. 2019/61, 15

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

Reg. 2019/61, 104

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

Reg. 2019/61, 118



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Almost finished but not completely...

➤ 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

**Important to follow
this in all countries!
Please keep us
informed.**



**Note: WHO
published 6th
CIA revision**

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 proposed new categorization CIA's



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- Cat A '**Avoid**': not authorised in vet med, forbidden LA, exceptional CA
- Cat B '**Restrict**': only after AST, last resort (fq,3th/4th CP, colistin)
- Cat C '**Caution**': higher risk but lower than B (AG, AP + BL, ML, etc)
- Cat D '**Prudence**': all others

FVE gave input, thanks to members who contributed!

FVE approach to CIA listing



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


FVE and FEEVA celebrated together World Vaccination Day



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World Animal Vaccination Day 2019

DON'T WAIT UNTIL THE SYMPTOMS APPEAR

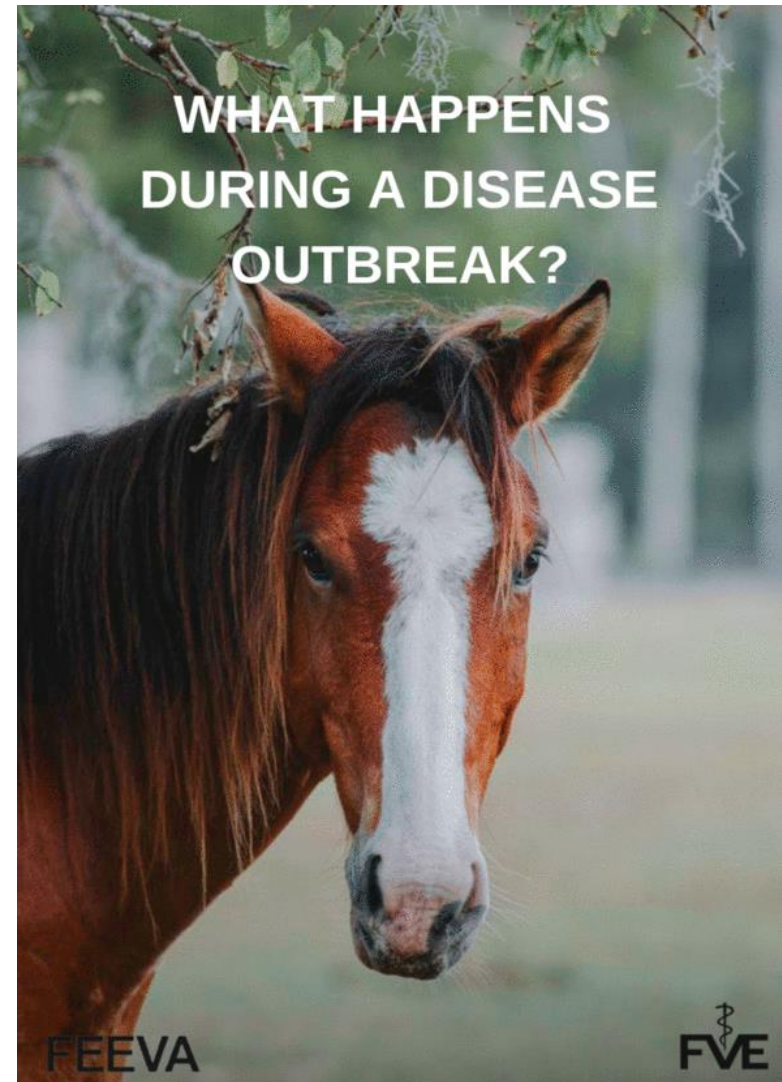


VACCINATE AGAINST EQUINE INFLUENZA!




FEEVA

**WHAT HAPPENS
DURING A DISEASE
OUTBREAK?**



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FVE/UEVP MEDICINES WORKING GROUP



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Last meeting
7 February

Next meeting:
1 October



FVE UEVP MWG 2017-2020

Thanks for your attention.
Questions?

