FEEVA AGM Basel
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Update on review veterinary medicines legislation

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Timeline EU Medicines legislation revision:

- **2010**: Online Consultation stakeholders
- **2011**: Impact assessment and study
- **2014**: Sept: publication draft proposal
- **2015**: March: Adoption 1st reading EP
- **2016**: Council ends first reading?
- **2017**: Fully into force in MSs (2022?)
- **2018**: Full adoption (2018?)
- ???

**Stakeholders Input**

All FVE position papers on www.fve.org
Revision medicines legislation (EU/2014/0257)

Takes a long time!
Reasons for revising the old Directive

1. Increase **availability** of veterinary medicinal products & improve functioning of **internal market**;
2. Address public health risk **antimicrobial resistance**.
3. Reduce administrative burden;
4. Stimulate competitiveness and innovation;

**Will the new legislation deliver this?**
Federación de Veterinarios de Europa

Medicines legislation review

State of play:

→ European Parliament vote done March 2016

→ Council managed to reach an agreement end 2017

→ Institutional triologue between European Commission, Council and European Parliament is now ongoing, led by Bulgarian Presidency

→ Aim is to get a principle agreement by summer, to get full adoption by end 2018

FVE is closely following the triologue deliberations and remains in close contact

Federación de Veterinarios de Europa
Will availability increase?

- No real single market
- Facilitates use of products from other EU countries or even abroad
- Introduces incentives to authorise new products and extend products (e.g. higher data protection, limited markets, etc)
- ‘Union product database’
Fighting AMR

- FVE supports strengthening veterinary prescription by vets & monitoring antibiotic sales/use

- FVE promotes science-based ‘Global One Health’ approach, focusing on measures to decrease AMR levels

- FVE objects vet prescription by non-vet & unregulated sales of antiparasitics/anti-inflammatory in supermarkets
OTHER KEY POINTS

- Internet trade ONLY for non-POMs
  - Need harmonisation POM-nonPOM
  - Need strict controls

- Veterinarians and animals NEED the Cascade!

- Pharmacovigilance: need simple reporting and efficient feed-back system such as through ‘EU Pharmacovigilance Database’

- Retail rules: keep national rules (object EP amendments)

Are you satisfied with the feedback received on your pharmacovigilance reports?
CASCADE NON-FOOD
(incl horses declared as not for human consumption in single lifetime identification document)

- Product non-food producing animal (same or other MS, same or other indication)
- Human product
- Extemporaneously product
- Third country VMP same indication/species
CASCADE FOOD

Product food producing animal (same or other MS, same or other indication) → Product non-food producing animal in MS for same indication → Human product → Extemporaneously product → Third country VMP same indication/species

Plus essentials list/added clinical benefit list is kept
Specific Equine articles: Record keeping obligations for equine animals

- **Record keeping** ‘The Commission shall adopt delegated acts concerning the content and format of the information necessary to apply with the cascade to be contained in the single lifetime identification document’

- **Exclusion food chain**: No later than three years after the date of application of this Regulation, the Commission shall present a report as regards the treatment of horses with medicines and their exclusion from the food chain, in particular re imports of horses from third countries, []

- **Equine Influenza**: adapting vaccines with new strains becomes easier
Antimicrobial sales in mg/PCU (2011-2015)
Critically important antibiotics

- EC can draw up list of antibiotics restricted to humans
- New veterinary antibiotics shall only be authorised after careful scientific benefit-risk analysis

- Prevention is better than cure
- Antibiotics will remain essential to cure animals.
- FVE does not support any ban, but promotes restricted use, e.g. following antibiotic guidelines, and CIA’s only be prescribed after sensitivity testing & as a last resort.
- Any restrictions should be science-based, end goal is reducing AMR.
TO CONCLUDE

- FVE supports the new Regulation and believes it will be a good step forward

- However, lack of availability especially for minor species (including horses) and limited markets will remain and should be monitored

- Will follow closely the final negotiations and need to also follow at national level as can be stricter
More details?

See our FVE website www.fve.org

Or follow us on Facebook or Twitter.
Thank you for your attention!