

Update revision medicines legislation

Lisbon, 15 May 2015



Federation of
Veterinarians of Europe



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Proposal for a **regulation on veterinary medicinal products**

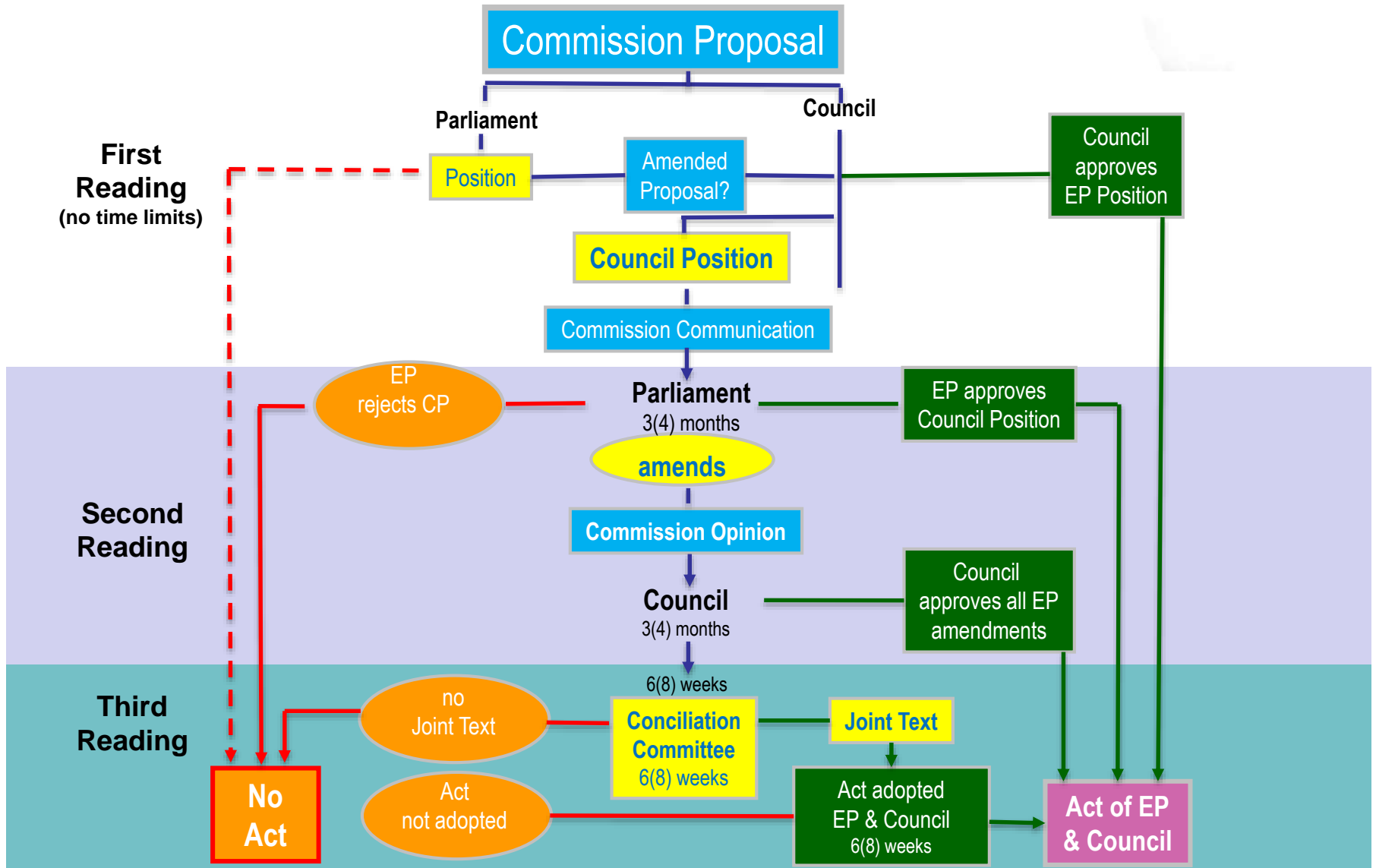
- EU/2014/0257 -

~~Proposal for a regulation on the manufacture,
placing on the market and use of **medicated feed**~~

~~- EU/2014/0255 -~~

~~(10 September 2014)~~

How Brussels decides



EP Committees and key MEPs



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VMP regulation:

Responsible Committee: ENVI

- Rapporteur Françoise Grossetête (EPP/FR) **REPORT READY**
- Schaduw rapporteur Claudiu Ciprian Tănăsescu (S&D/RO)
- Schaduw rapporteur Marit Paulsen (ALDE/SV)

Opinion Committee : AGRI

- Rapporteur Marit Paulsen (ALDE/SV) **REPORT READY**

Previous consultation:

- Economic and Social Committee

EP Committees and key MEPs



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Medicated Feed regulation:

**NOT
RELEVANT
FOR
HORSES**

Responsible for

- Rapporteur
- + Shadows
- Viegas (G)

May

(K), Federley F (ALDE, SE),

Opinion Co

- Rapport
- + Sha

RT READY

ALDE, NL)



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Many important aspects are regulated in this Regulation

- Single market; availability
- Conditions to use medicines off-label
- Conditions surrounding the veterinary prescription (when can you write, who can write, how long is a prescription valid)
- Conditions around the prescription of antibiotics
 - Will it still be allowed to use antibiotics preventively?
 - What about prescription of CIA's?
- Sale of veterinary medicines via internet
- Will vets still be allowed to dispense medicines?

Proceeding/Influencing



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- Negotiations European Parliament
- Negotiations European Council
- (later) Trialogues between European Parliament, European Council and European Commission
- European Council votes?
- European Parliament votes?

Final: Q1-2 2016 during Dutch Presidency

Meetings held...



- FVE met with **most key MEPs** : Paulsen M., Tanasescu C., Lins N., Huitema J., Grossetete F., Liese P., Dantin M., Aguilera C.E., Hausling M., Szanyi T., Dess A., Eriksson P., Andrieu , Liese P., Schaldemose C., Macedo G, Caputo N., Girling J., Schreijer-Meijer A. , ...
- FVE met with **Secretariat EP**
- FVE met/spoke with **Council members**: Latvia, France, Luxemburg, Belgium, Poland, ...
- Many **hearings and meetings** on the revision



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Identified topics (VMP)

For many MEPs, the only focus is AMR!

FVE draws their attention to

- Single market; availability
- Animals need right treatment when sick
- Vet. prescription is a vet act
- Internet sales
- Vet diagnostics not in the scope
- Pharmacovigilance
- Off label and use of CIA's use should remain

Topics after rapporteur (VMP)



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- Vet prescription is written by a vet
- Person to prescribe should be the vet
- *Under his/her care* should be specified
- ‘Cascade’ allowed when *veterinary need*
- Dispensed max amount & validity prescription vmp align with Medicated Feed proposal
- Economic incentives?
- Ban/restriction prophylactic use of antibiotics
- Antimicrobials ≠ antibiotics

Provisional schedule



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VMP Regulation (ENVI leading)

Consideration of the draft report → 6 May 2015

Deadline tabling amendments → 15 June 2015

Consideration of amendments → 15 July 2015

Vote in ENVI Committee. → 22 September 2015

Vote in plenary session. → November 2015 (tbc)

What's happening in the Council?



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The Council had already several expert meeting on the Medicated Feed and Medicines Legislation.

Medicated Feed → discussions seem to proceed well

VMP → discussions goes slow

They expect only to adopt the Council first reading **early 2016** under the NL Presidency



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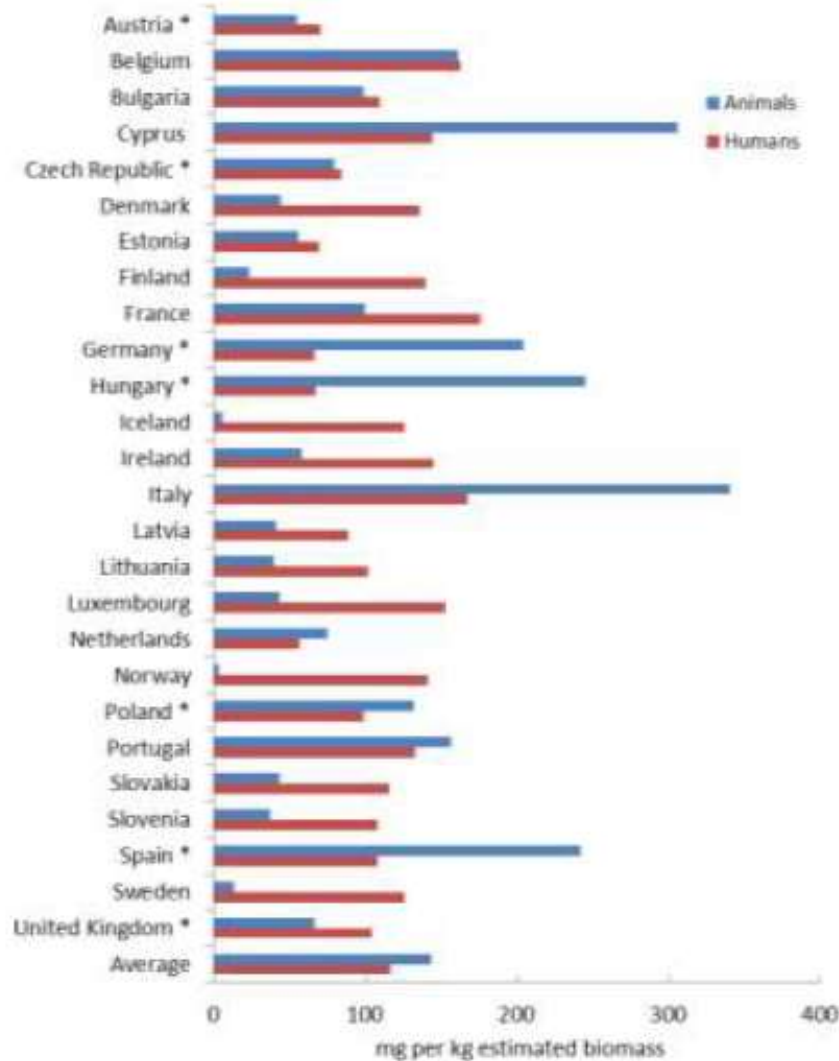
**We need your help
to promote and defend the
position of the equine
veterinarians
to your government & MEPs.**



Antibiotic use animals - humans



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Humans: 116.4 mg/kg
(56.7–175.8)

Animals: 144.0 mg/kg
(3.8–396.5 mg/kg)