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

VMP regulation:

Responsible Committee: ENVI
- Rapporteur Francoise 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

Medicated Feed regulation:

Responsible Committee:
- Rapporteur: AGRI - Clara Aguilera (S&D, ES)
- + Shadows: Buda D (PPE, RO), Girling J (CRE, UK), Federley F (ALDE, SE), Viegas (GUE, PT), Erikkson P (Greens, SE)

Opinion Committee:
- Rapporteur: ENVI - Norbert Lins (ALDE/SV)
- + Shadows: Szanyi (S&D, Hu), Huitema (ALDE, NL)

NOT RELEVANT FOR HORSES

May
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?

!! Regulation!!
Copy-paste in national legislation
Proceeding/Influencing

- 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 **Secretariat EP**

- FVE met/spoke with **Council members**: Latvia, France, Luxemburg, Belgium, Poland, ...

- Many **hearings and meetings** on the revision
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)

• 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

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?

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
We need your help to promote and defend the position of the equine veterinarians to your government & MEPs.
Antibiotic use animals - humans

Humans: 116.4 mg/kg (56.7–175.8)

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

Joint EFSA, ECDC, EMA report 2015