Proposal for a Regulation on Veterinary Medicinal Products

EU/2014/0257

10 september 2014
Legislation before and today

• ‘Before’ we made our own rules.

• Today, that’s Europe (which also is us)

• Principle of Proportionality – EU should only act according to Treate + procedure of implementation is as much as possible up to the MSs

• Principle of Subsidiarity – decision is made as ‘low as possible’. Brussels only decides on topics which can’t be decided on, on a national level

• Where it comes to agriculture / farmers / veterinarians / animals / medicines / animal diseases, ‘Brussels’ decides (to allow trade)!
Europa: 47 landen & 820 X 10^6 inwoners

EU: 28 landen & 508 X 10^6 inwoners
TREATY on the EUROPEAN UNION
Lays down the mandate
Member States have given to EU

It describes:
• EU goals,
• its competences and the areas wherein it can be active,
• role of the institutions,
• procedures,
• etc.

Everything EU does, is based on a provision in the Treaty
What instrument to use?

PRIMARY LEGISLATION

Regulations
• binding legislative act.
• It must be applied in its entirety across the EU.

Directives
• sets out a goal that all EU countries must achieve. However, it is up to the individual countries to decide how.

Decisions
• binding on those to whom it is addressed (e.g. an EU country or an individual company) and is directly applicable.

Recommendations
• not binding.
And than refining!

Delegated acts
• EC allowed unilaterally to add / fill in / change as long as it does not touch the essence of the legislation
• EP and Council have the authority to block
• E.g. Adaptation to technical development (Rabies vaccination and crossing borders)

Implementing acts
• EC allowed to issue rules in order to standardise implementation of legislation in the MSs
• MSs need to approve
How Brussels decides

Commission Proposal

First Reading (no time limits)

Parliament

Amended Proposal?

Council

Council Position

Commission Communication

Second Reading

Parliament

3(4) months

amends

Commission Opinion

Council

3(4) months

approves all EP amendments

Third Reading

EP rejects CP

no Joint Text

Act not adopted

Conciliation Committee

6(8) weeks

Joint Text

Act adopted EP & Council

6(8) weeks

Act of EP & Council

Council approves EP Position

EP approves Council Position

Council approves all EP amendments

EP approves Council Position

6(8) weeks

Act not adopted

Act of EP & Council
How is the vet profession organised on a European level?

FVE

FEEVA

Practitioners (UEVP)

State (EASVO)

Hygienists (UEVH)

Education Research Industry (EVERI)

Med WG
Three levels of approach

- European Commission: Specialists/technocrats
- European Parliament: Politicians
- Council of EU: Experts from different countries / Politicians
How to start? Lobby!

- Lobby. Choose your topics (interest / opportunities for success)
- Which moment of the decision process to interfere?
- Which institutions to lobby?
- Which persons to approach?
- Also in the MS?
- When?
- Who to act?
- How to deal with other stakeholders?
- Can we do ourselves or do we need external, professional support?
- Can we make alliances?
- Did we make friends during peace time which can support us now?
The Commission. Berlaymont building
The Commission

High ranking persons you shake hands with for the picture opportunity.

But .............................

even today, the power is in the hand of the writer!
European Parliament Brussels
Europe is transparent. Enough information!

Committee on the Environment, Public Health and Food Safety
- 21-01-2015 09:00 Brussels: JAN - 2Q2 / 21-01-2015 15:00 Brussels: JAN - 2Q2
- 22-01-2015 09:00 Brussels: JAN - 2Q2
- 29-01-2015 09:00 Brussels: JAN - 2Q2 / 29-01-2015 15:00 Brussels: JAN - 2Q2
- Extraordinary meeting 09-02-2015 19:00 Strasbourg: LOW - N1.3
- 23-02-2015 15:00 Brussels: JAN - 4Q2
- 24-02-2015 09:00 Brussels: JAN - 4Q2 / 24-02-2015 15:00 Brussels: JAN - 4Q2
- 18-03-2015 09:00 Brussels: JAN - 4Q2 / 18-03-2015 15:00 Brussels: JAN - 4Q2
- 19-03-2015 09:00 Brussels: JAN - 4Q2
- 26-03-2015 09:00 Brussels: JAN - 4Q2 / 26-03-2015 15:00 Brussels: JAN - 2Q2
- 30-03-2015 15:00 Brussels: JAN - 4Q2
- 31-03-2015 09:00 Brussels: JAN - 4Q2 / 31-03-2015 15:00 Brussels: JAN - 4Q2
- 13-04-2015 15:00 Brussels: JAN - 4Q2
- 14-04-2015 09:00 Brussels: JAN - 4Q2 / 14-04-2015 15:00 Brussels: JAN - 4Q2

Committee on Agriculture and Rural Development
- 21-01-2015 09:00 Brussels: JAN - 4Q1 / 21-01-2015 15:00 Brussels: JAN - 4Q1
- 22-01-2015 09:00 Brussels: JAN - 4Q1
- Extraordinary meeting + PUBLIC HEARING: 27-01-2015 15:00 Brussels: ASP - ASG-3
- 23-02-2015 15:00 Brussels: ASP - ASG-3
- 24-02-2015 09:00 Brussels: ASP - ASG-3 / 24-02-2015 15:00 Brussels: ASP - ASG-3
- 23-03-2015 15:00 Brussels: ASP - ASG-3
- 24-03-2015 09:00 Brussels: ASP - ASG-3 / 24-03-2015 15:00 Brussels: ASP - ASG-3
- 16-04-2015 09:00 Brussels: JAN - 6Q2 / 16-04-2015 15:00 Brussels: JAN - 6Q2
European Parliament

Responsible Committee
Advice Committee

VMP
- Responsible C - ENVI
- Advice C – AGRI

MF
- Responsible C – AGRI
- Advice C - ENVI
Focus points in the VMP Regulation

- Economic incentives prescriber antibiotics forbidden!!!
- Single market: availability
- Cascade’ allowed when ‘veterinary need’, instead of emergency
- ‘Cascade’ human antibiotics only after approval competent authority!
- Off-label possibility should continue
- Definition ‘veterinary prescription’? ‘Language confusion.
- Only the vet to prescribe (veterinary act)
- How to define “under his care”?
- Prescription valid European wide
and in VMP Regulation 2

- Strict rules/ban Internet trade vmp
- Pharmacovigilance
- Promoting use of veterinary diagnostics lacking
- Ban/restriction prophylactic use antibiotics
- Definitions meta/prophylactic
- Antimicrobials ≠ antibiotics

- Lots of MEPs have a ‘blind focus’ on antibiotic resistance (25,000 deaths annually in EU)
Regarding horses
VMP regulation

European Parliament: Responsible Committee: ENVI

Rapporteur: Francoise Grossetête (EPP/FR)

Opinion: Marit Paulsen (ALDE, SE)

Shadows:
- TĂNĂSESCU Claudiu Ciprian (S&D, RO)
- PIECHA Bolesław G. (ECR, PL)
- KYLLÖNEN Merja (GUE/NGL, FI)
- HÄUSLING Martin (Verts/ALE, DE)
- PEDICINI Piernicola (EFD, IT)

1117 AMENDMENTS -) Voted & adopted in Plenary Feb 2016

Council of the European Union: Technical discussions

- First reading has not been completed yet
- Discussions go very slow
Council of the EU

- Consists of Ministers and highest civil servants.

- In this case:
  - Ministers of Agriculture / Public Health
  - Chief Veterinary Officers
  - Other experts

- Closer to home. This is a national lobby!

- Action of national veterinary bodies with ‘some help’ of the FVE from Brussels
Actions against decoupling

• Prepared special paper
  • Against decoupling
  • Promoting farm visitation
  • Systems & monitoring
  • (based on article E. Vandaële and K.de Lange)

• Talked to many MEPs and other decision makers
European Parliament vote

- No decoupling!
- All antibiotics under vet prescription following clinical examination and diagnosis
- Preventative use of antimicrobials only in individual animals with exceptional indications, metaphylactic use following requirements
- Possibility to ban/restrict use of certain highly critical antibiotics for human health (FVE raised concern)
- Internet trade ban for antimicrobials, psychotropics, biological or immunological medicines + MS can go further
- Prohibits veterinarians to have any interest in companies retailing veterinary medicines.
- Increased importance of diagnostic testing
- FVE’s raised concerns that limited availability will remain
FVE Medicines legislation review

State of play:

→ European Parliament vote done 10 March 2016
→ Council discussions moving very slowly

● The first 67 articles have been discussed, most of them being on the basis of a second draft. SK Presidency makes effort to find agreement.
● However still very slow progress, very little sense of political urgency

→ After Council manages to get an agreement, institutional agreement between Council and Parliament and Commission needs to be reached. Adoption 2017?

FVE remains in regular contacts with all European Institutions
FVE Report finalised
Feb 2016

Input for EFSA/EMA opinion

Thank you for FEEVA to coordination all horse input
YOU OK?

I SHOULD HAVE LET YOU KNOW I WAS STOPPING.