

Review Veterinary Medicines European Legislation

State of play

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*FEEVA GA, Berlin
27 October 2016*



Federation of
Veterinarians of Europe

VMP Regulation



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Proposal for a Regulation on Veterinary Medicinal Products

EU/2014/0257

10 september 2014

Legislation before and today



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- 'Before' we made our own rules.
- Today, that's Europe (which also is us)
- Principle of Proportionality – EU should only act according to Treatate + 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)!





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Europa: 47 landen & 820×10^6 inwoners



EU: 28 landen & 508×10^6 inwoners





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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?



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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!



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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)

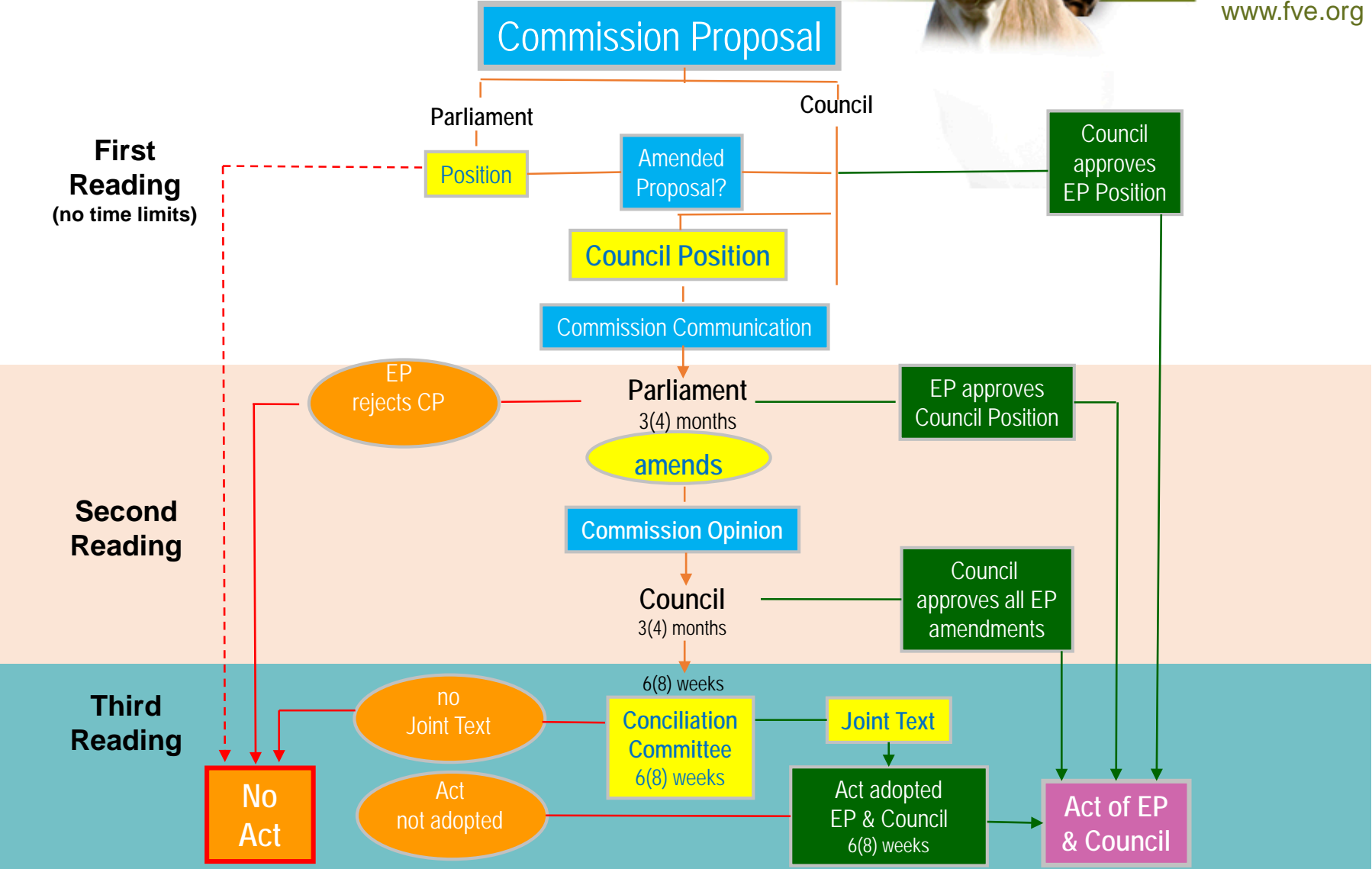
Implementing acts

- EC allowed to issue rules in order to standardise implementation of legislation in the MSs
- MSs need to approve

How Brussels decides



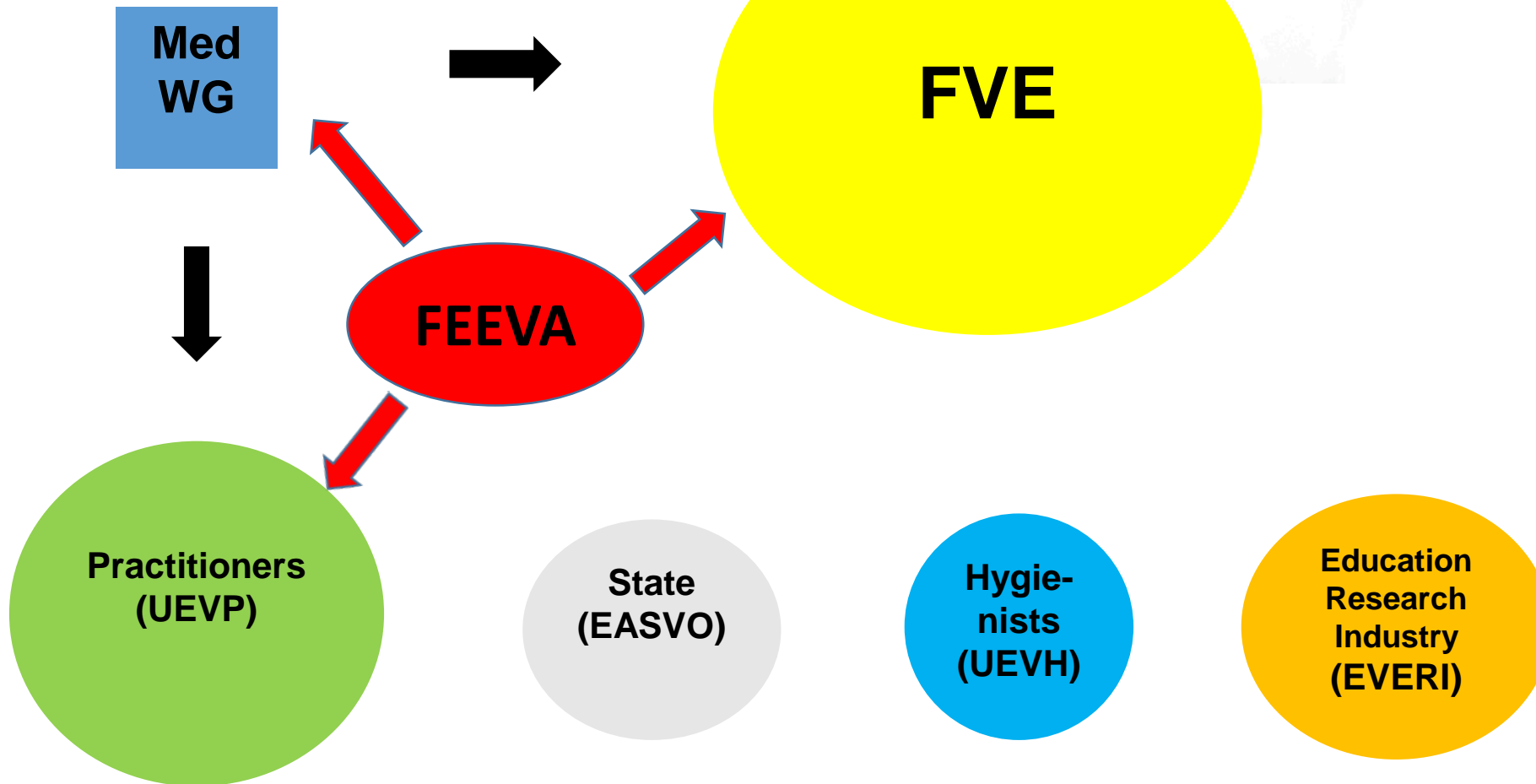
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How is the vet profession organised on a European level?



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Three levels of approach

- **European Commission** **Specialists/technocrats**
- **European Parliament** **Politicians**
- **Council of EU** **Experts from different countries / Politicians**



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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?**



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The Commission. Berlaymont building





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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



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European Parliament



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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 - 2Q2/ 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 - A5G-3
- 23-02-2015 15:00 Brussels : ASP - A5G-3
- 24-02-2015 09:00 Brussels : ASP - A5G-3/ 24-02-2015 15:00 Brussels : ASP - A5G-3
- 23-03-2015 15:00 Brussels : ASP - A5G-3
- 24-03-2015 09:00 Brussels : ASP - A5G-3/ 24-03-2015 15:00 Brussels : ASP - A5G-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 1 www.fve.org

- 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



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.....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)**



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Regarding horses

????

VMP regulation



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European Parliament: Responsible Committee: ENVI

Rapporteur:

Francoise Grossetête (EPP/FR)

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)

Opinion

Marit Paulsen (ALDE, SE)

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



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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**



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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

FVE | Federation of Veterinarians of Europe

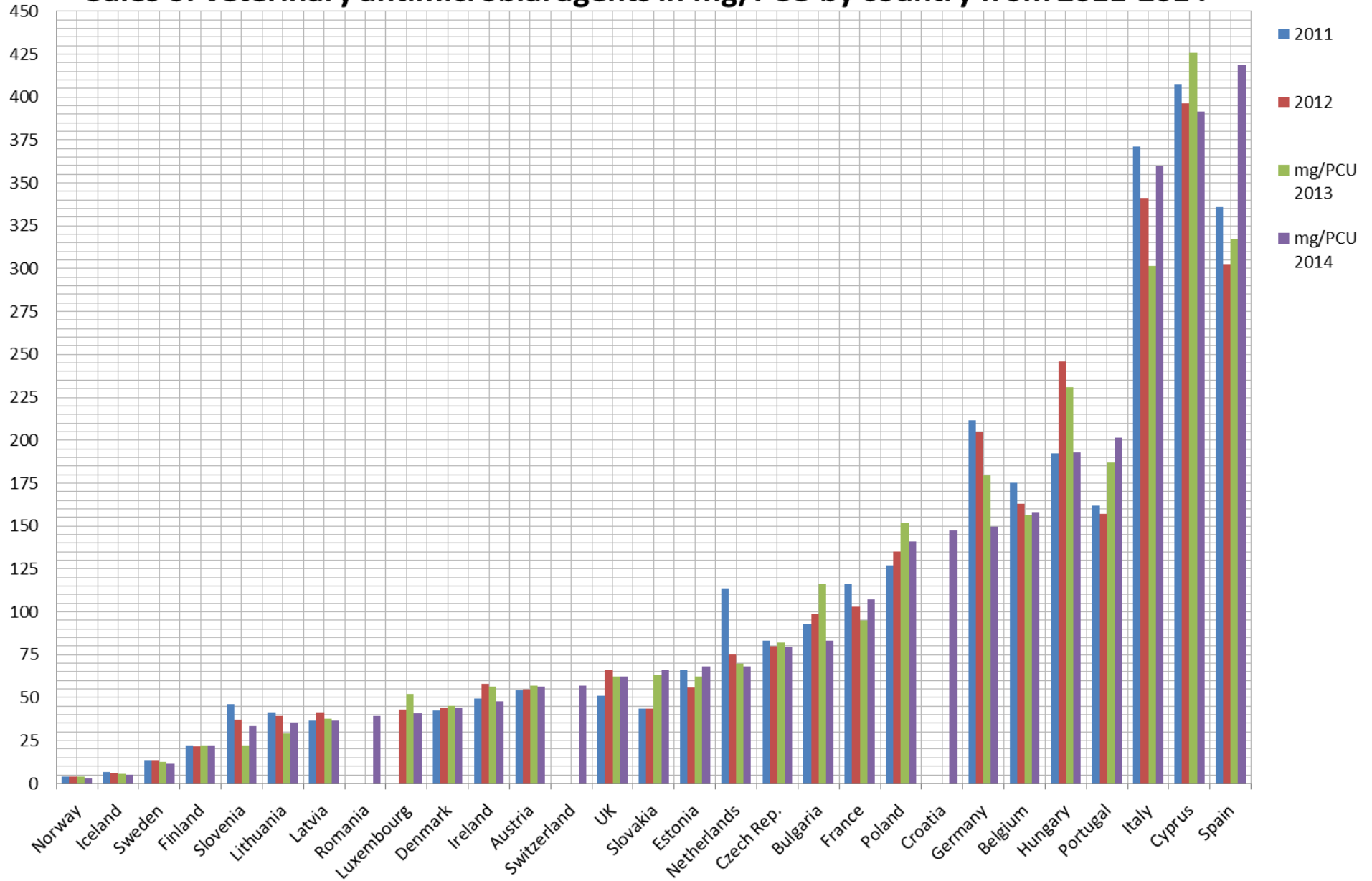
Antibiotic consumption and the veterinarian's right to dispense

MAIN FINDING: Antibiotics are not prescribed more if dispensed by vets

The graphic includes a map of Europe with various icons: a green cross in Sweden, Norway, Finland, and Denmark; and a red cross with a white circle in Estonia, Latvia, Lithuania, Poland, Germany, France, and others. The map is color-coded by region.

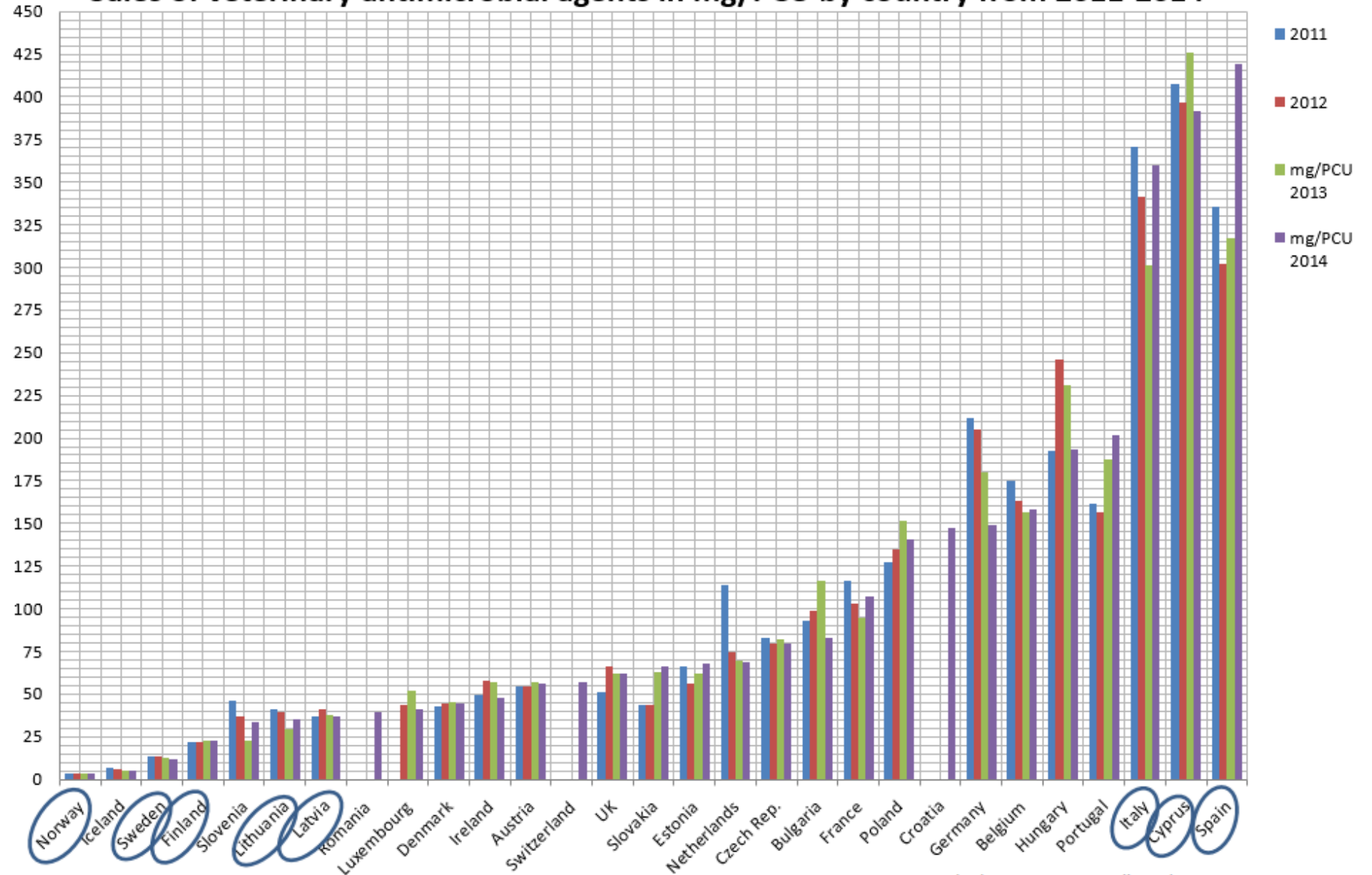
mg/PCU

Sales of veterinary antimicrobial agents in mg/PCU by country from 2011-2014



mg/PCU

Sales of veterinary antimicrobial agents in mg/PCU by country from 2011-2014



0 = countries in which vets can not sell medicines

European Parliament vote



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- ✓ **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, psychotropic, 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



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ANTIMICROBIAL USE IN FOOD-PRODUCING ANIMALS



29-Feb-16

Replies to EFSA/EMA questions on the use of antimicrobials in food-producing animals in EU and possible measures to reduce antimicrobial use.

**FVE Report finalised
Feb 2016**

**Input for EFSA/EMA
opinion**

**Thank you for
FEEVA to
coordination all
horse input**



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