



New Veterinary Legislation - Medicines Availability

*The journey, the ambition and
measuring the outcome*

**High level meeting - Veterinary
Medicinal Products**

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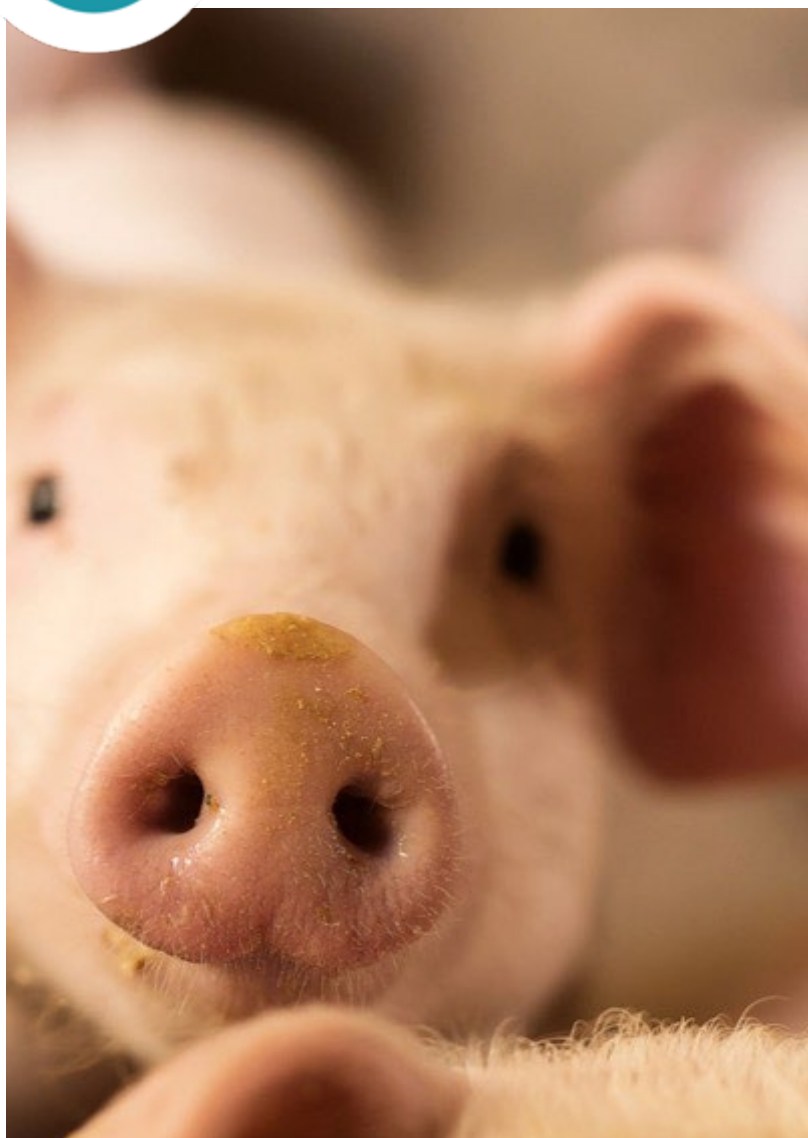
12 companies



16 associations in 20 countries

- Belgium
- Czech Republic
- Denmark
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Netherlands
- Norway
- Poland
- Portugal
- Slovakia
- Spain
- Sweden
- Switzerland
- Ukraine
- United Kingdom

Working to ensure a ready availability of
a wide range of animal health products throughout Europe



History - it has been a long road

- From an approximation of the laws - Directive 81/851/EEC
- Council Regulation (EEC) No 2309/93 (EMA!)
- Codification - Directive 2001/82/EC
- Directive 2004/28/EC & Regulation (EC) No 726/2004
 - Penalties EC Regulation (EC) No 658/2007
 - Variation EC Regulation 1234/2008
 - Annex on requirements EC Directive 2009/9/EC
 - MRLs Regulation (EC) No 470/2009
- To harmonised laws in an EU Regulation



Era of Better Regulation

- **Review 2001**

- Consultants report & drafting proposal - 2 years (2000-2001)
- Co-decision procedure - 2 years & 5 months
 - EC COM proposal published - November 2001
 - New legislation published - April 2004
- **Total time - 4.5 years**

- **Review 2014**

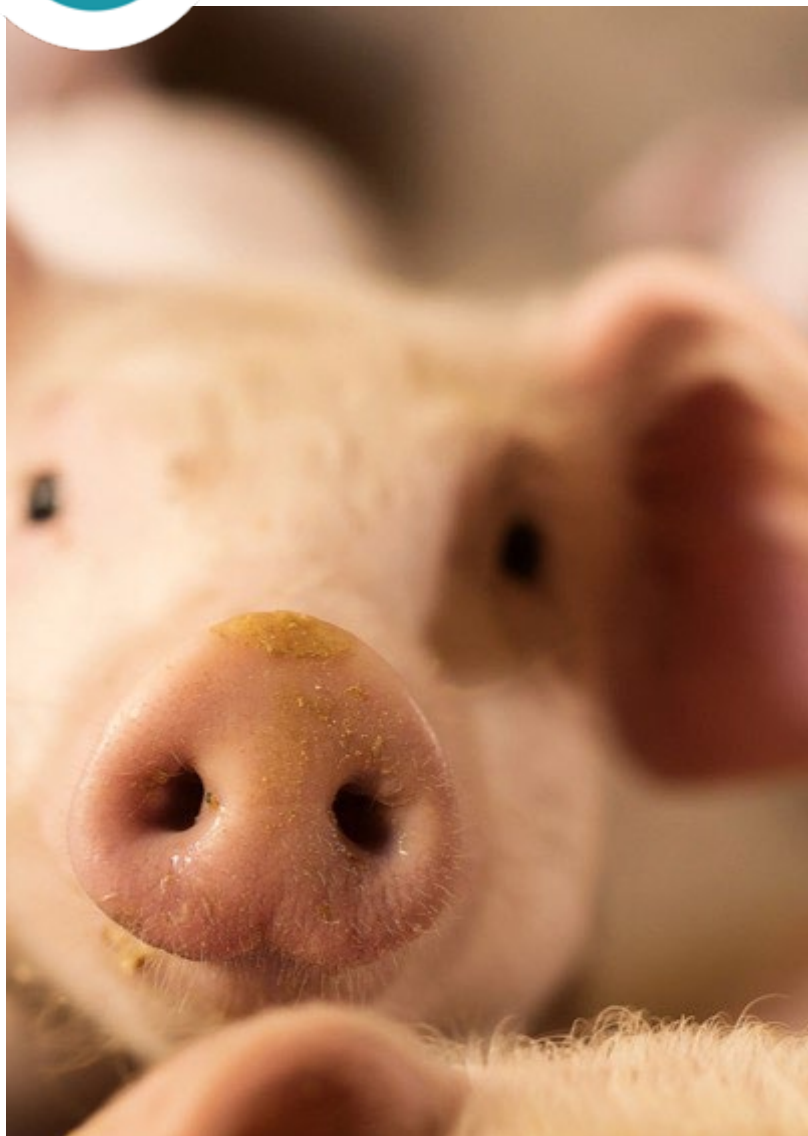
- Preparatory/consultation/Impact assess. time - 5 years
- Legislative procedure time - 4 years & 3 months
 - EC COM proposal published - September 2014
 - New legislation published - January 2019
- **Total time - 9.25 years**



Tremendous achievement

All involved must be congratulated

Thank you!



What's next?

- **Still much “implementation” work to do**
 - Secondary legislation
 - CVMP/CMDv guidelines and adapted procedures
 - New things and new ways of doing things
 - Databases, teething problems and making the systems work
 - Learning by doing
- **Did we meet the original objectives?**
 - Was it all worthwhile?
 - How do we measure progress against the objectives
 - Setting up the right metrics
 - Annual reports of progress

The initial objectives

I. Increase availability of veterinary medicinal products

- 1. Reduce administrative burden**
- 2. Stimulate competitiveness and innovation**
- 3. Improve the functioning of the internal market**

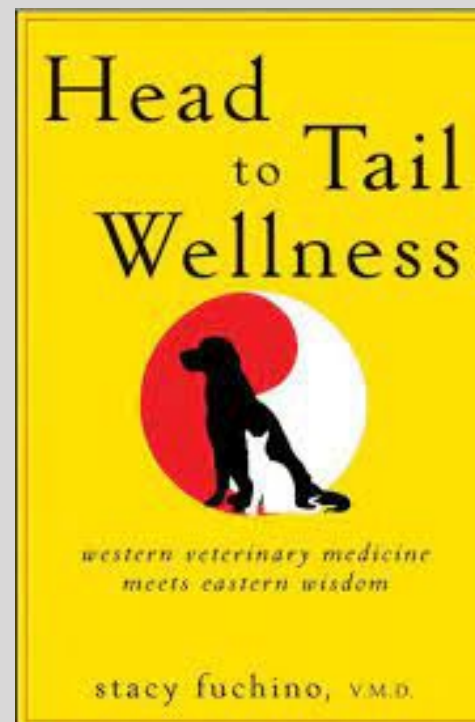
II. Address the public health risk of AMR



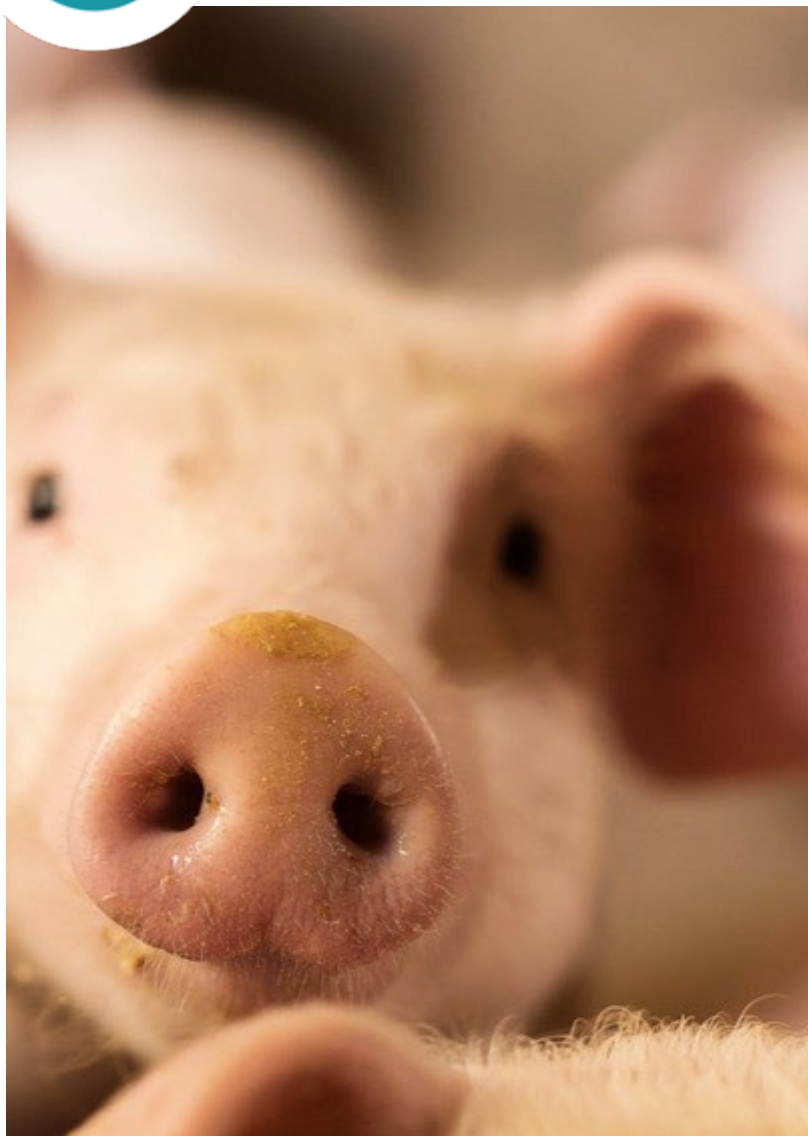
Increase availability

Increase **range** of veterinary medicinal products

Therapeutic gaps



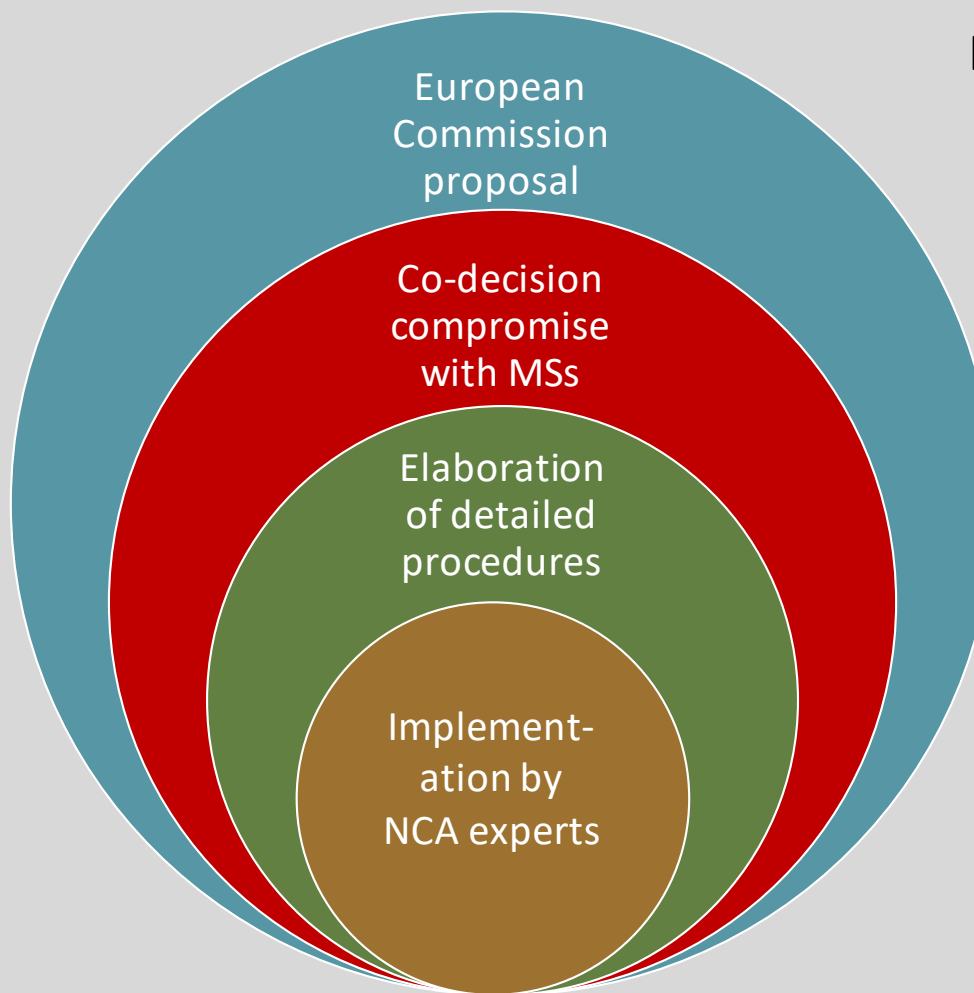
Novel therapies



Important challenges

- **Reducing admin burden**
 - Remember the original impact assessment - VMPs had double the admin burden experienced in human medicines sector
 - Initially admin burden has increased significantly
 - Need to deliver enhanced functionalities and learn by experience to deliver more efficient systems and procedures
- **Stimulation innovation**
- **Improve functioning of the internal market**

Reduce administrative burden



High ambition, radical



Gradual erosion at each step



Vestigial benefits



Thanks for listening