animalhealth europe | THE VOICE OF THE ANIMAL MEDICINES INDUSTRY

New Veterinary Legislation – Medicines Availability

The journey, the ambition and measuring the outcome

High level meeting - Veterinary Medicinal Products

20 June 2022

Roxane Feller
Secretary General AnimalhealthEurope

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Who we are

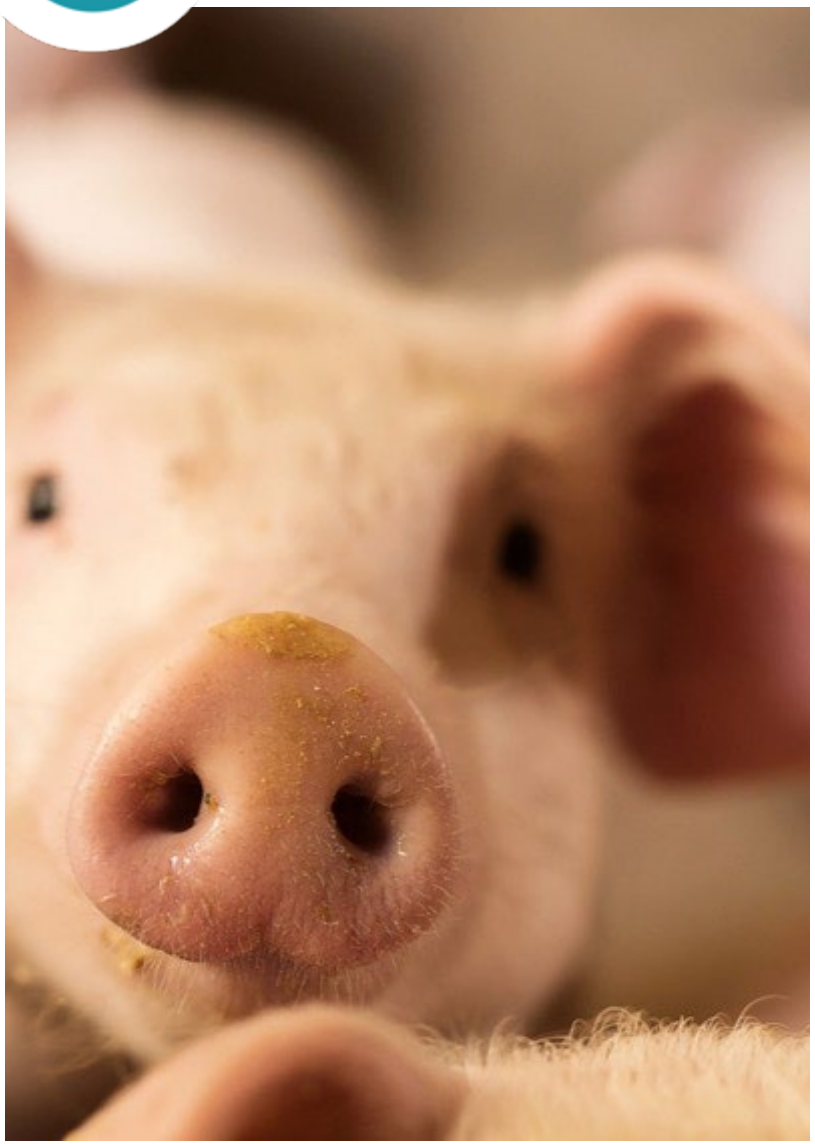
12 companies

Boehringer Ingelheim
ceva
Dopharma
Elanco
HUVEPHARMA
MSD Animal Health
Norbrook
ORION
syva
vetoquinol ACHIEVE MORE TOGETHER
Virbac
zoetis

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**

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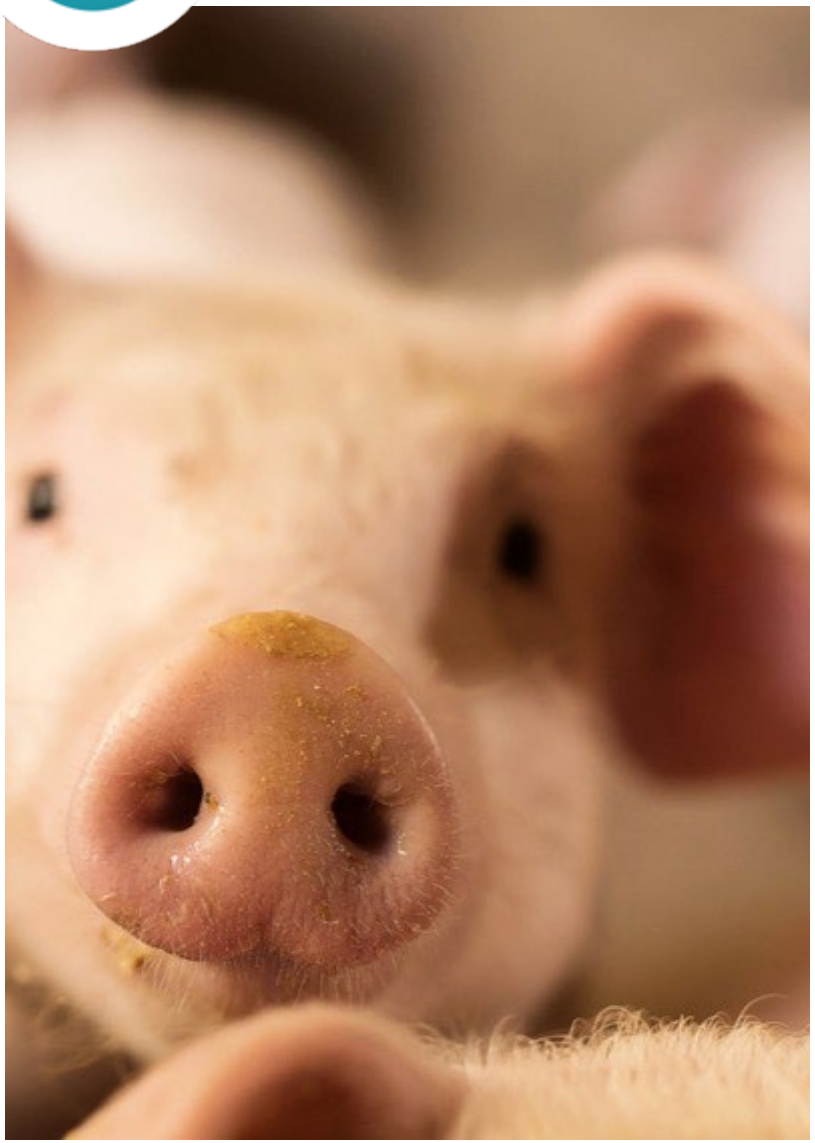
Tremendous achievement

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

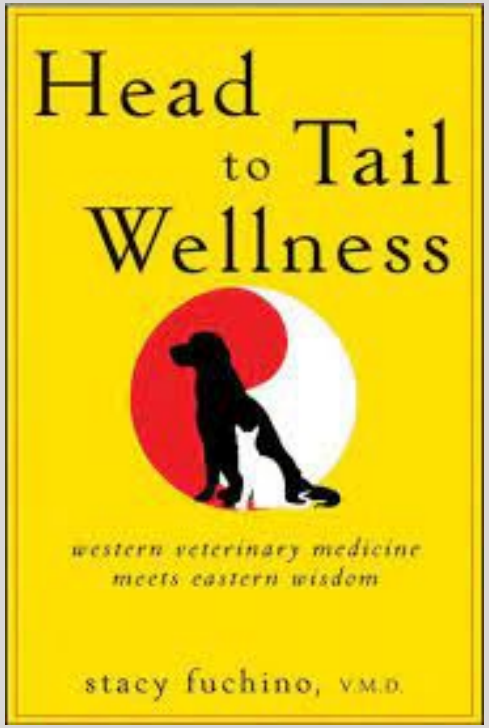
1. **Reduce administrative burden**
2. **Stimulate competitiveness and innovation**
3. **Improve the functioning of the internal market**

II. Address the public health risk of AMR

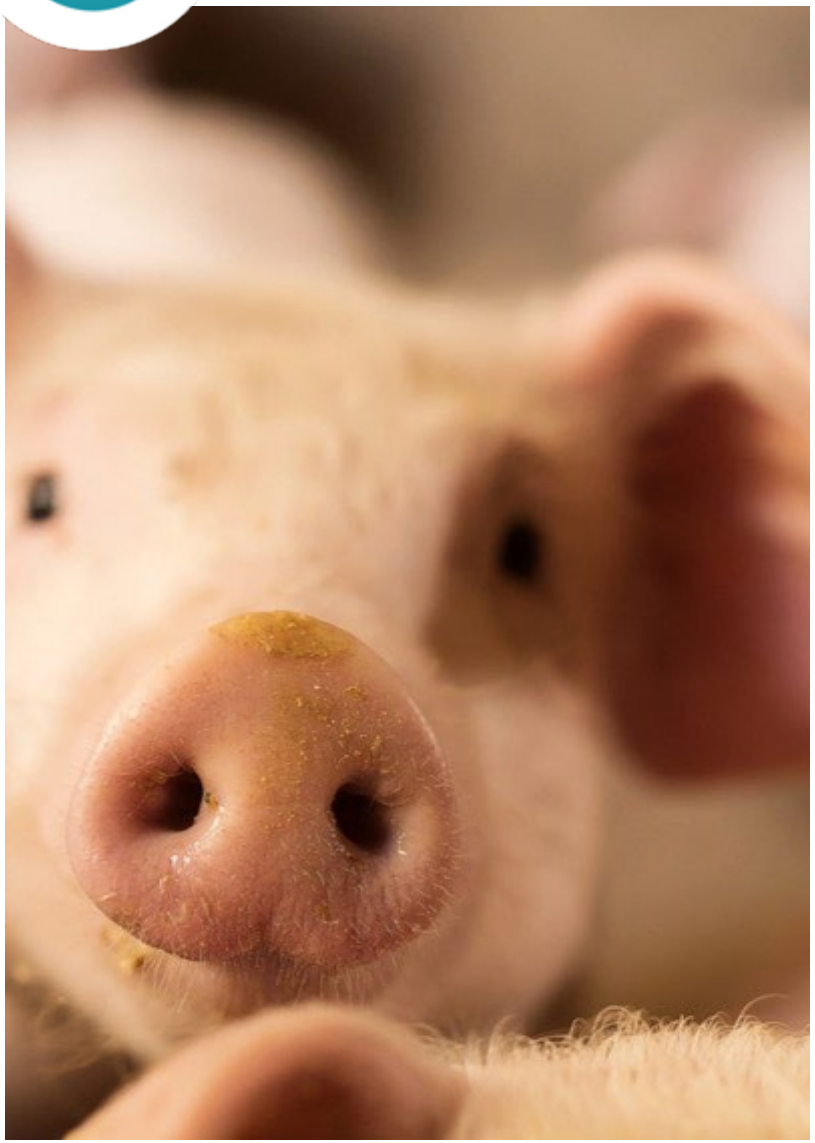
Increase availability

Increase **range** of veterinary medicinal products

Therapeutic gaps



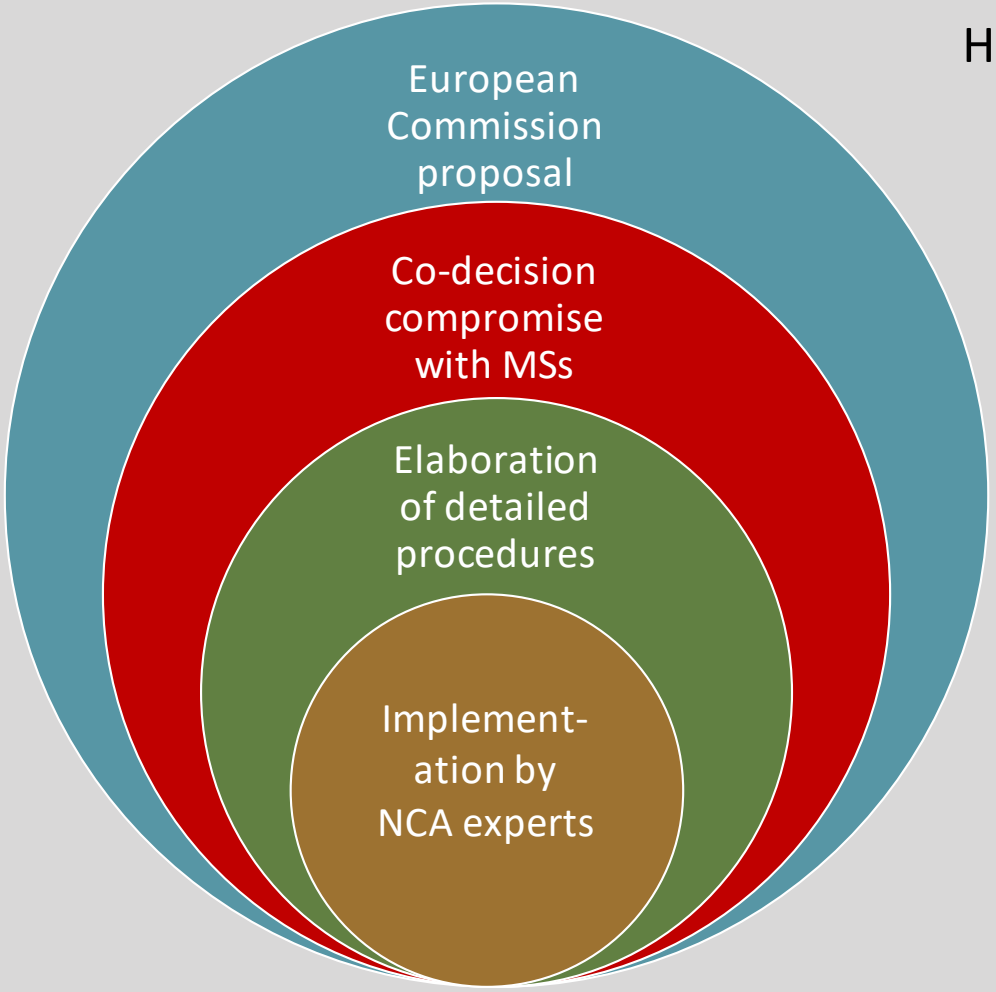
Novel therapies



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

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Thanks for listening