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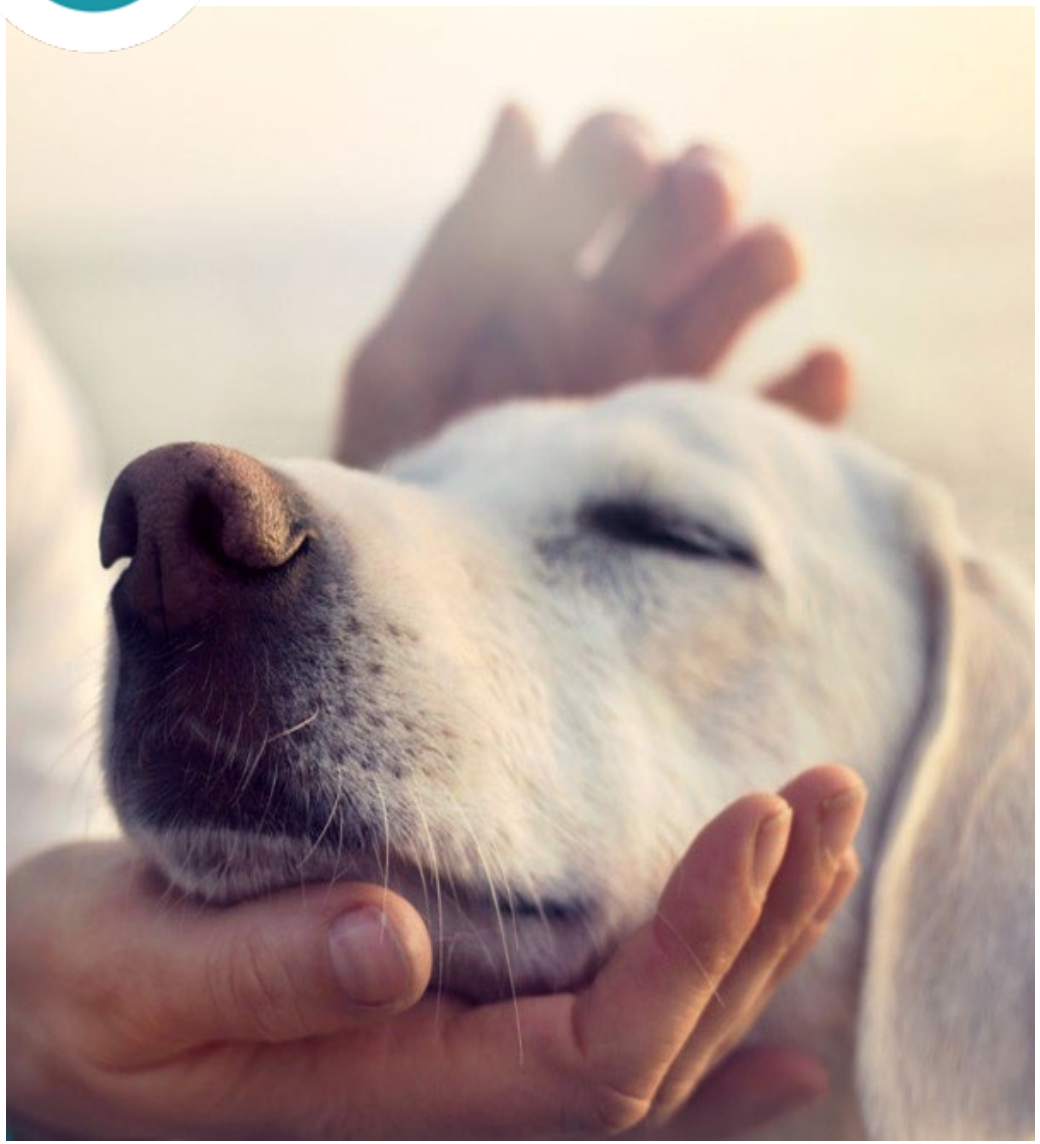

Contribution of EMA and the EU network to veterinary medicines science and regulation

Perspective of the manufacturers of veterinary medicines

Frederik Schutte (FIDIN and AnimalhealthEurope)

EMA Veterinary Awareness Day
12-13 September 2023
European Medicines Agency, Amsterdam

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Topics covered

- Introduction: Animal medicines industry
- What we need from the regulatory system
- Importance of the Regulation for the animal health industry
- Regulatory science
- Challenges and opportunities

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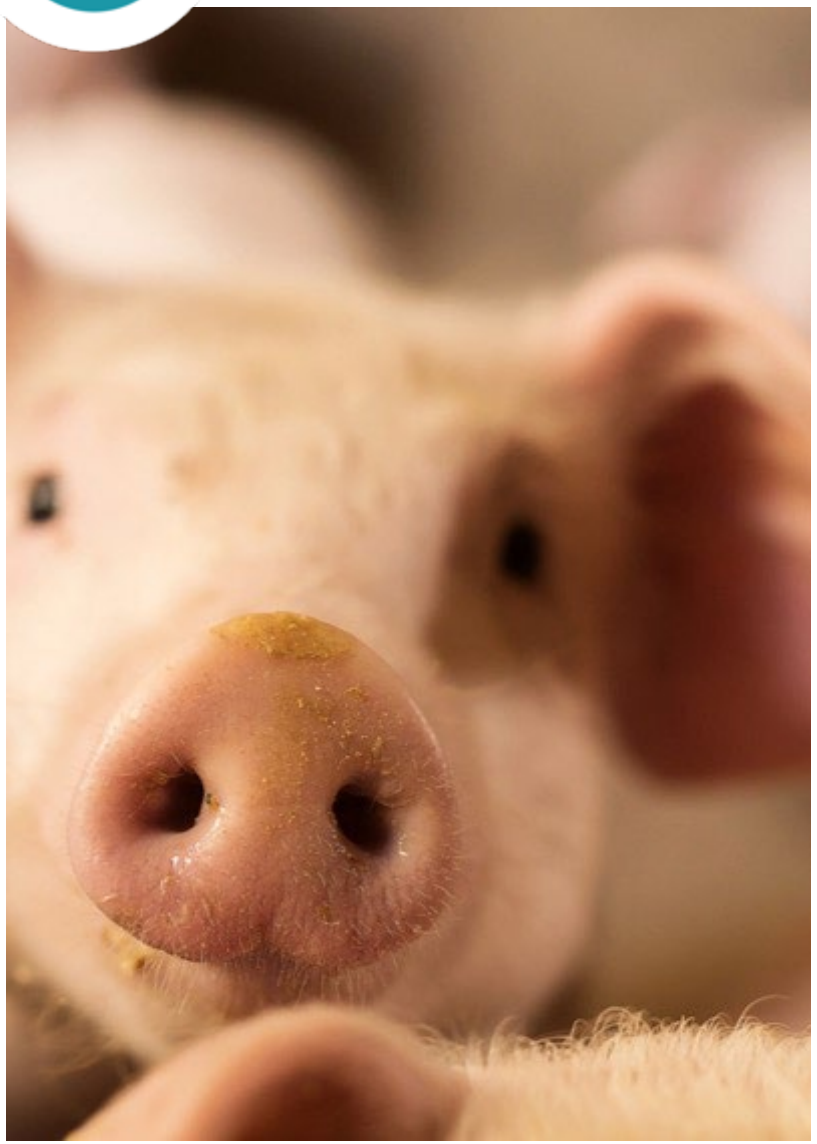
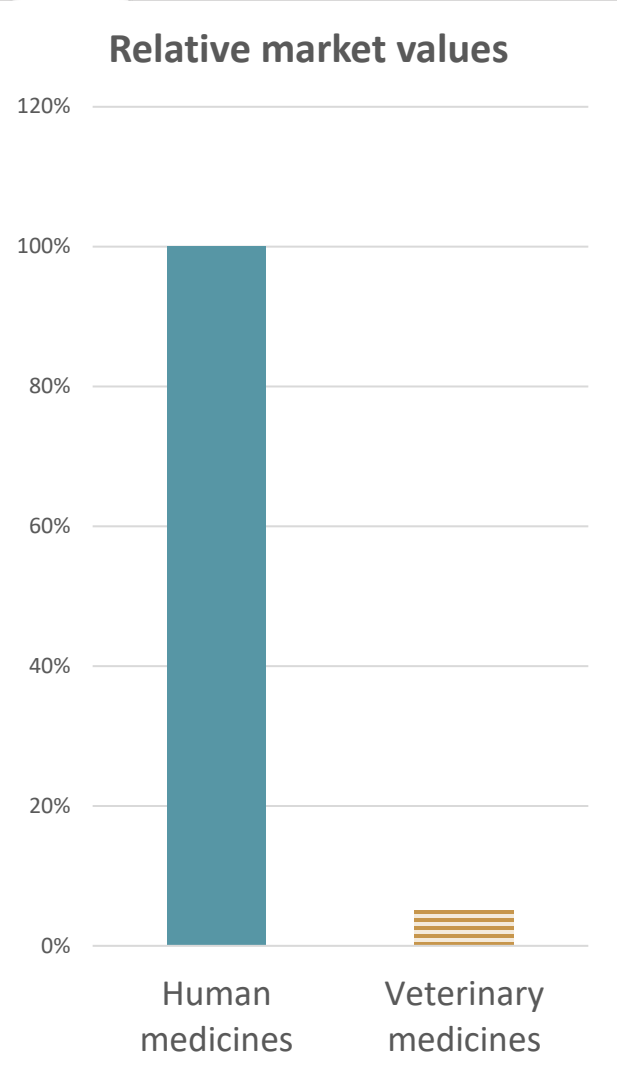
Introduction: Animal medicines industry



Introduction: Animal medicines industry

Providing solutions for animal health

- Research and product development
- Solutions to prevent, manage and treat disease
- Animals, just like people, get sick and require medicines
- Defence against new and emerging diseases (AMR, zoonoses)



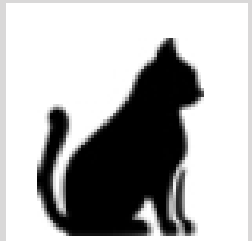
Introduction: Animal medicines industry

Market characteristics

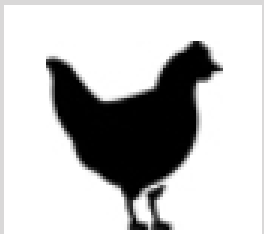
- At 27%, EU is 2nd largest animal medicines market in the world.
- Turnover in Europe: € 7.9 billion, in comparison to human pharmaceutical industry just 3%
- Small market and highly fragmented (multiple species)
- About 52,000 jobs (300,000 veterinarians, 3,000,000 livestock farms)
- Over 260 companies (of which over 110 SMES)
- On average companies re-invest 8% of turnover in R&D to develop new solutions for animal health

Introduction: Animal medicines industry

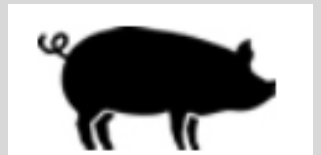
Animal populations in Europe > 1 billion


127 million


29 million


380 million


94 million


134 million


104 million


22 million


745 million


75 million

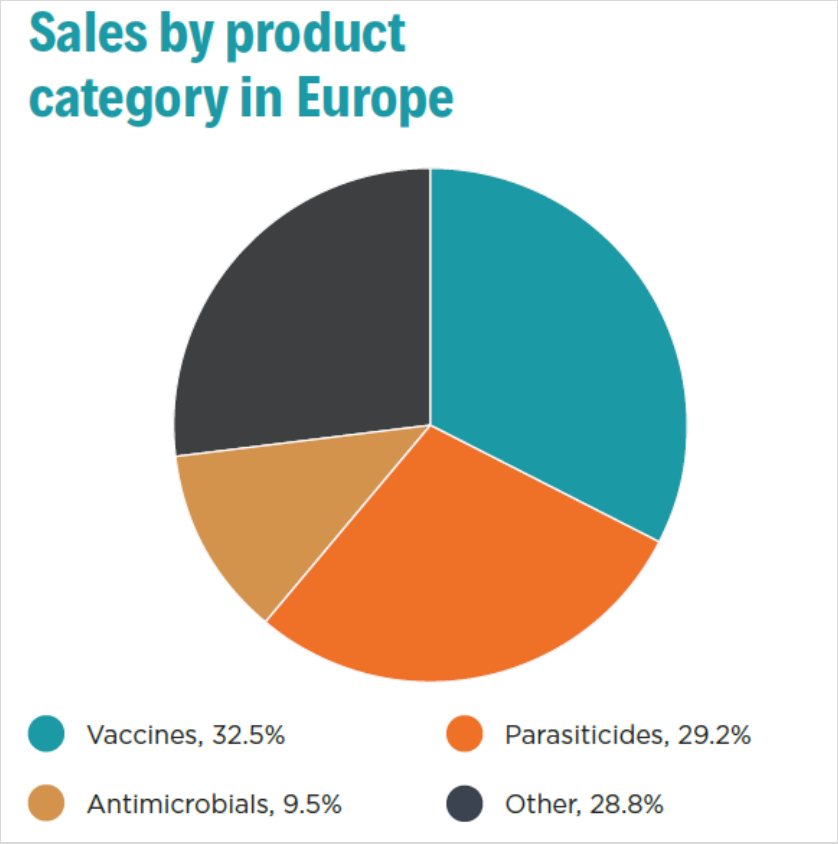

60 million


53 million


11 million

Sources: Eurostat

Introduction: Animal medicines industry



Constant evolution, investment in science

- Animal health care is constantly evolving

  to develop solutions that go beyond the traditional medicines.
- Shifting to disease prevention and animal resilience as well as earlier diagnosis.
  - Vaccines is now the biggest product category
- Investing in digital applications to monitor animal health and diagnostic tools to identify disease more rapidly.
- Animal health industry is highly innovative, based on scientific research and development

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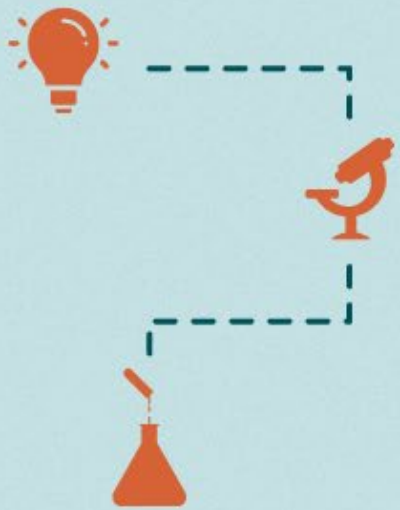
Developing new Veterinary medicines

New medicines and vaccines require extensive research and testing

2–4 years → 3 years → 2–4 years (seasons) → 1–2 years → = 8–13 years*

Discovery

- Hypothesis development and early research



Pre-clinical lab development

- Early testing in labs
- Safety and quality including environmental safety

Clinical development

- The approval process includes assessments for ***animal safety, user and consumer safety and environmental safety***
- The EU regulatory process for licensing animal medicines is designed to assess ***safety***, ***efficacy*** and ***quality***

Registration

- Product approval
- Evaluation and assessment by regulatory authority

Manufacture and delivery

- Getting approved products to people or veterinarians to enable them to care for their animals

*Some types of products may require more time.

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Regulation

Regulation of veterinary medicines

- A new Regulation (2019) intended to create a modern, flexible legal framework – fit for the future
- Broaden the scope of the central procedure
- Reward innovation – regulatory data protection periods
- Aims to reduce administrative burden and promote harmonization
- Provide transparency and predictability
- Define requirements for innovative biologicals and novel therapies
- Reduced documentation for limited markets

Importance of the Regulation for the animal health industry

- Well defined, transparent and predictable route to the market, based on science
- Well defined product development timeline
- Scientific guidelines for predictable route to the market
- Transparency for the public when veterinary medicines can be approved
- Address public health risks: AMR
  - methods to gather sales and use information (ESVAC)
  - criteria for antimicrobial substances restricted to human medicines
  - rules for imports of foodstuffs from third countries

Contribution of EMA and EU network

- Important role in the implementation of the Regulation
- Emphasis on scientific advice from EMA and member states' competent authorities and experts
- Possibility to provide input in public consultations
- Gatekeeper of the execution of the Regulation
  - Scientific evaluation of marketing authorisations (scope central procedure broadened)
  - Guarantee of transparent, predictable and consistent route to market
  - Pharmacovigilance and signal detection (security after market access)
  - Upholding the objectives of protecting public health and animal health

Contribution of EMA and EU network

- **EMA fosters scientific excellence**
  - Facilitating and promoting innovation
  - Access to novel medicinal products
  - Reliability of the evaluations towards the public (EPAR)

- **Support for innovation**
  - Scientific advice
  - Support for SMEs
  - ADVENT (Ad Hoc Expert Group on Veterinary Novel Therapies) / Novel Therapies and Technologies Working Party

Regulatory science

- Support for 3R's
  - replace, reduce and refine animal use for the development, manufacturing and testing of veterinary medicines
- Big data strategy
  - initiative to help EU medicines regulatory network move towards a more data-driven culture (make use of new digital technologies), e.g. in:
    - UPD
    - Pharmacovigilance (signal detection)
    - ESVAC
    - Environmental risk assessment
    - Regulatory submission and evaluation
    - Innovative use of digital technologies
- Artificial intelligence and machine learning

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Challenges and Opportunities

Challenges

- Socio-economic and political aspects
  - AMR, animal production and welfare, social media, environment, climate change
- Emerging diseases
  - require rapid responses – non-proportionate regulatory restraints
- Public attitudes towards new technologies
  - Distrust of new science; risk aversion – threat of regulatory uncertainty for new technologies
- Transparency paradox:
  - the more information you provide, the more questions it raises and the more suspicion it may create

Opportunities

- **High regulatory standards**
  - should be maintained – tied to the reality of market size
  - ensure science prevails over politics
- **Utilize high EMA reputation and international profile**
- **Expert networking**
  - EMA, national competent authorities, global
  - Sharing information with international partners
  - Global regulatory convergence, joint assessments
- **Dialogue between the authorities and industry**
  - Maintain strong stakeholder engagement
  - Particularly on new technologies and novel therapies