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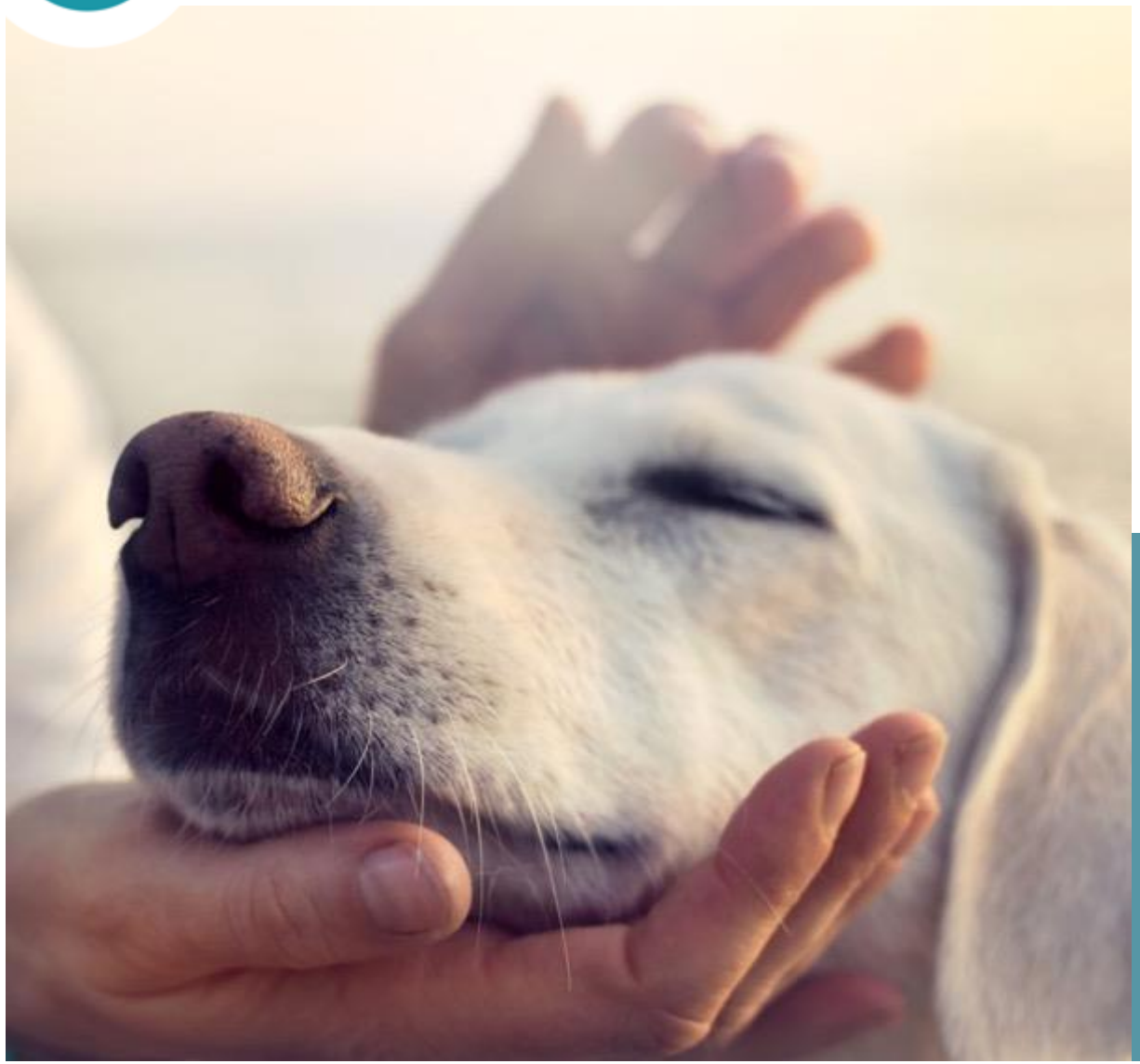

The new EU rules on veterinary medicines - *Quo vadis*?

CDG Animal Products – pig meat sector
Brussels, 28th May 2019

Rick Clayton
Technical Director
AnimalhealthEurope

AnimalhealthEurope members

12 corporate members

17 national associations in 19 countries

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

Representing over 300 companies both originators and generics - 135 of which are small and medium sized enterprises (SMEs)

90% of European sales

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Background

The pathway to new Veterinary medicines

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Developing new medicines and vaccines requires extensive research and testing

2 years | 3 years | 2–3 years (seasons) | 1–2 years | = 8–10 years

DISCOVERY

Hypothesis development and early research

PRE-CLINICAL LAB DEVELOPMENT

Early testing in labs

Safety and quality including environmental safety

CLINICAL FIELD TRIALS

Testing safety and efficacy in animal patients

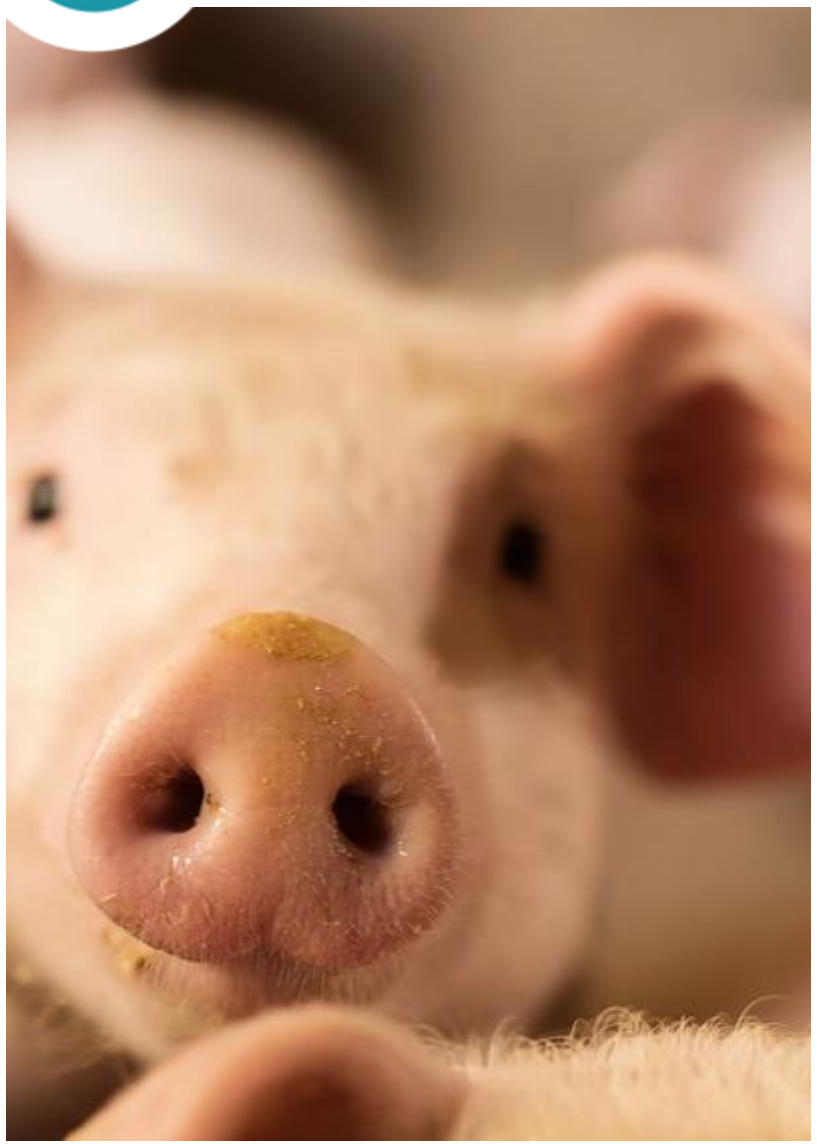
REGISTRATION

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



Market entry

Marketing authorisation - data requirements

Quality data

manufacturing

Safety data

In addition for VMPs:

Consumer safety (maximum residue limits)

Environmental safety

Clinical data,

field trials

Registration procedures

1. Centralised procedure

- European Medicines Agency

12 products p.a.
Innovative and biotech products

2. De-centralised / mutual recognition procedures

- National agencies cooperating

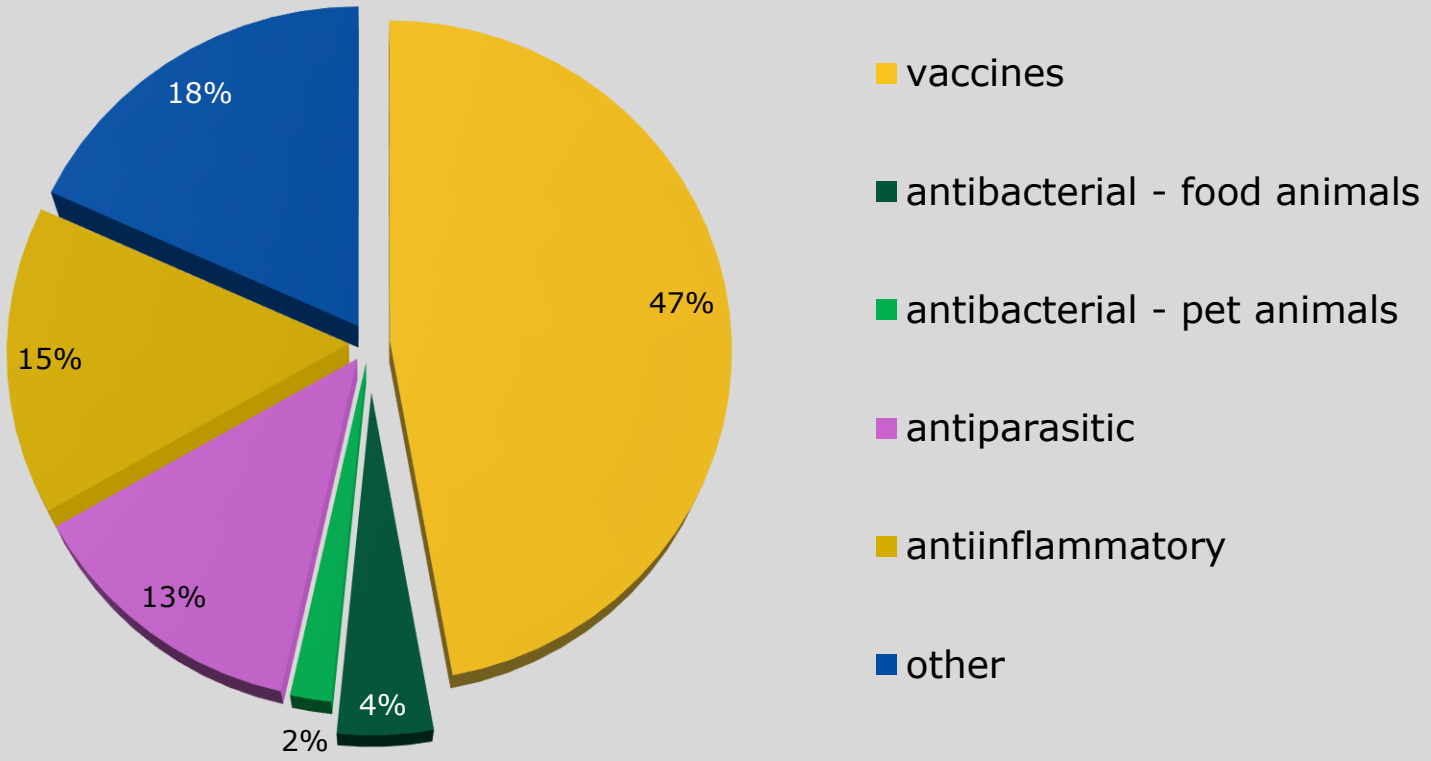
220 products p.a.
88% generic products

3. National procedure

- National agency/authority

few? products p.a.

Centrally authorised products



Our legislation

2004

- Human medicinal products Directive
- Veterinary medicinal products Directive
- Joint Regulation on European Medicines Agency and centralised procedure

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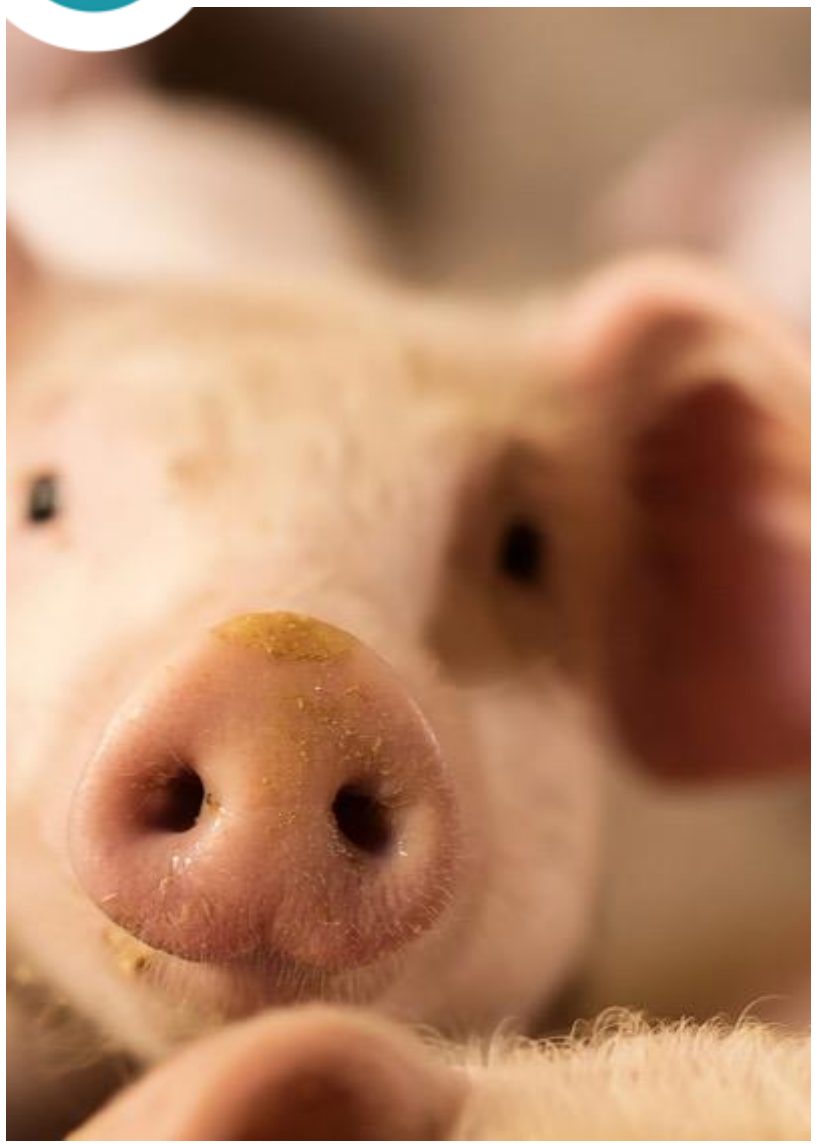
Review and update of the legislation

Problem definition



Review of the VMP legislation

- Prior Impact Assessment 2011
- COM proposal 2014

  - Objectives
    - Increase availability of veterinary medicinal products
    - Improve the functioning of the internal market
    - Stimulate competitiveness and innovation
    - Reduce administrative burden
    - Address the public health risk of AMR

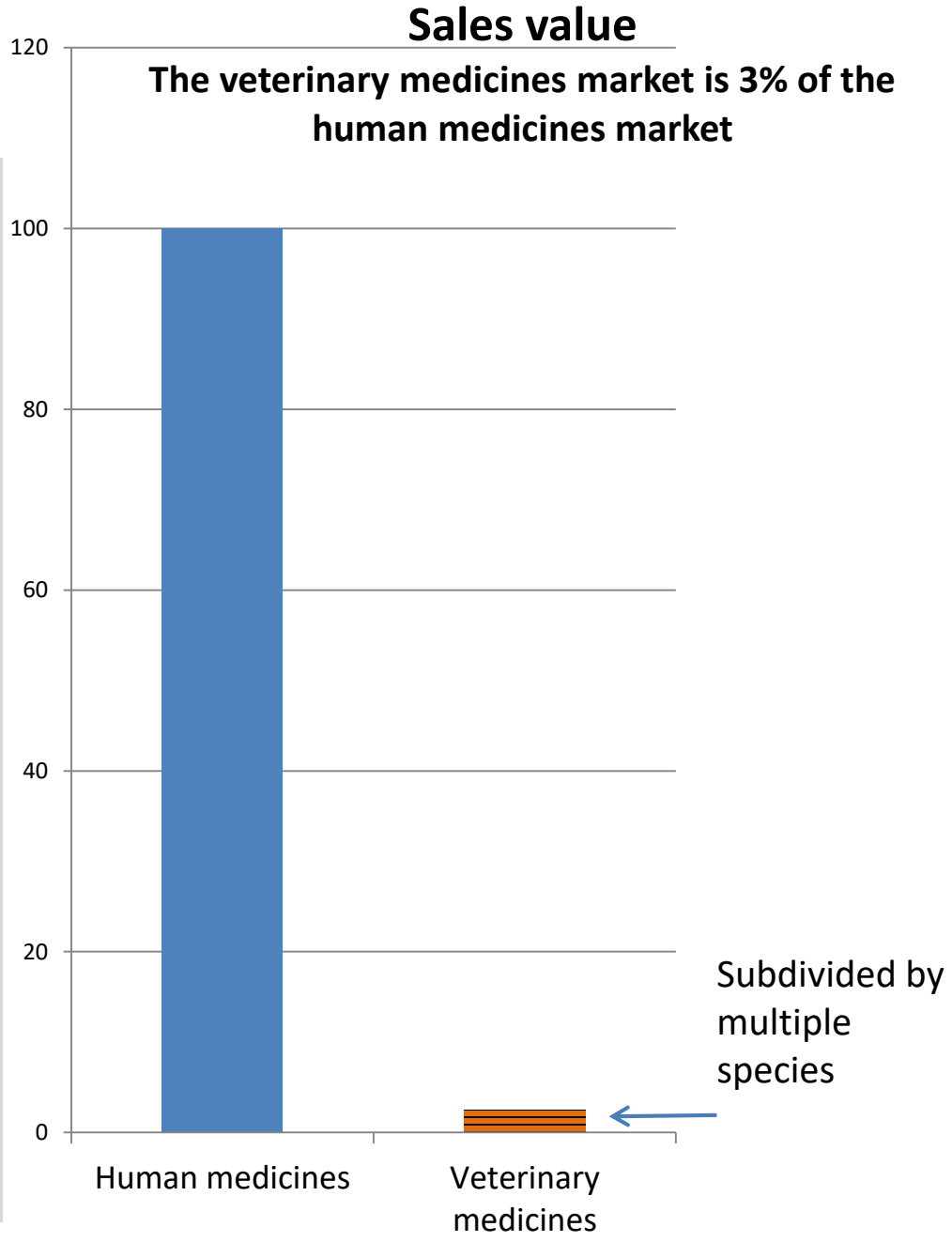
- Co-decision procedure: COM proposal 2104, EP/Council
- New Regulation published 7th January 2019

VMP sector market place

Market size

Small fraction of the human medicines market

Further fragmented by multiple species

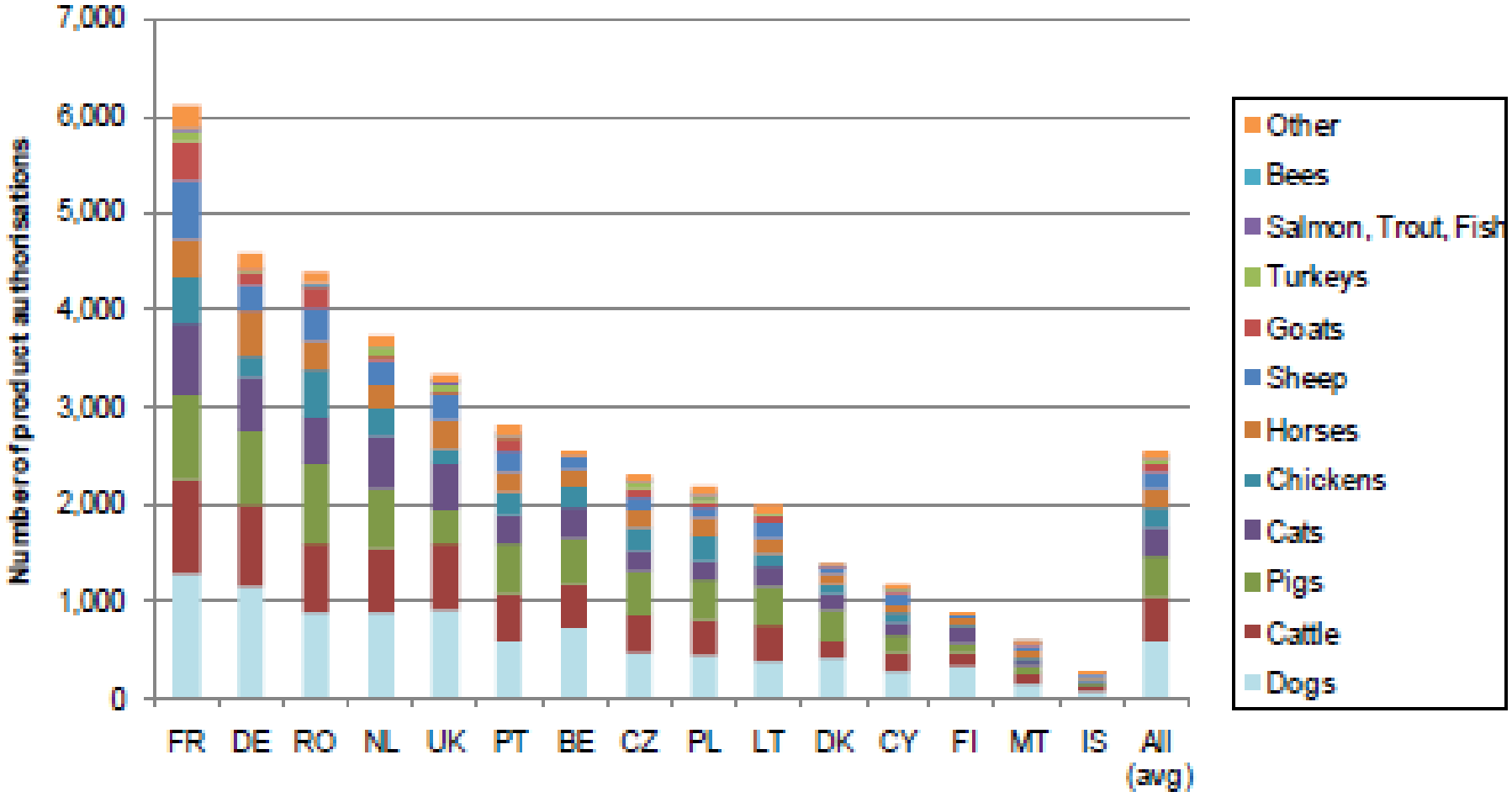


Objective: Improved availability & internal market

Background

Major variance in availabilty - countries / species

Few products for 'minor' species



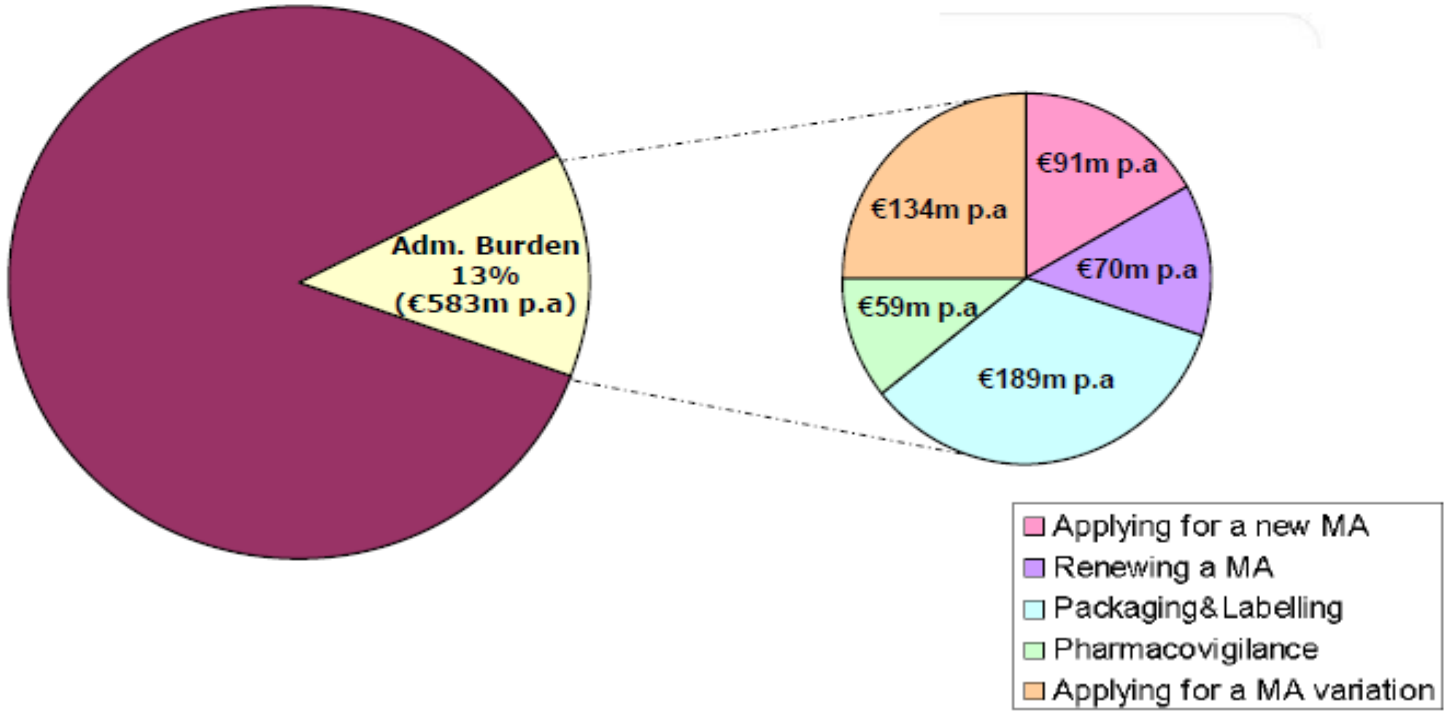
Source: Impact Assessment for the review of the legislation, 2011

Objective: reduce administrative burden

Directorate-General for Health & Consumers

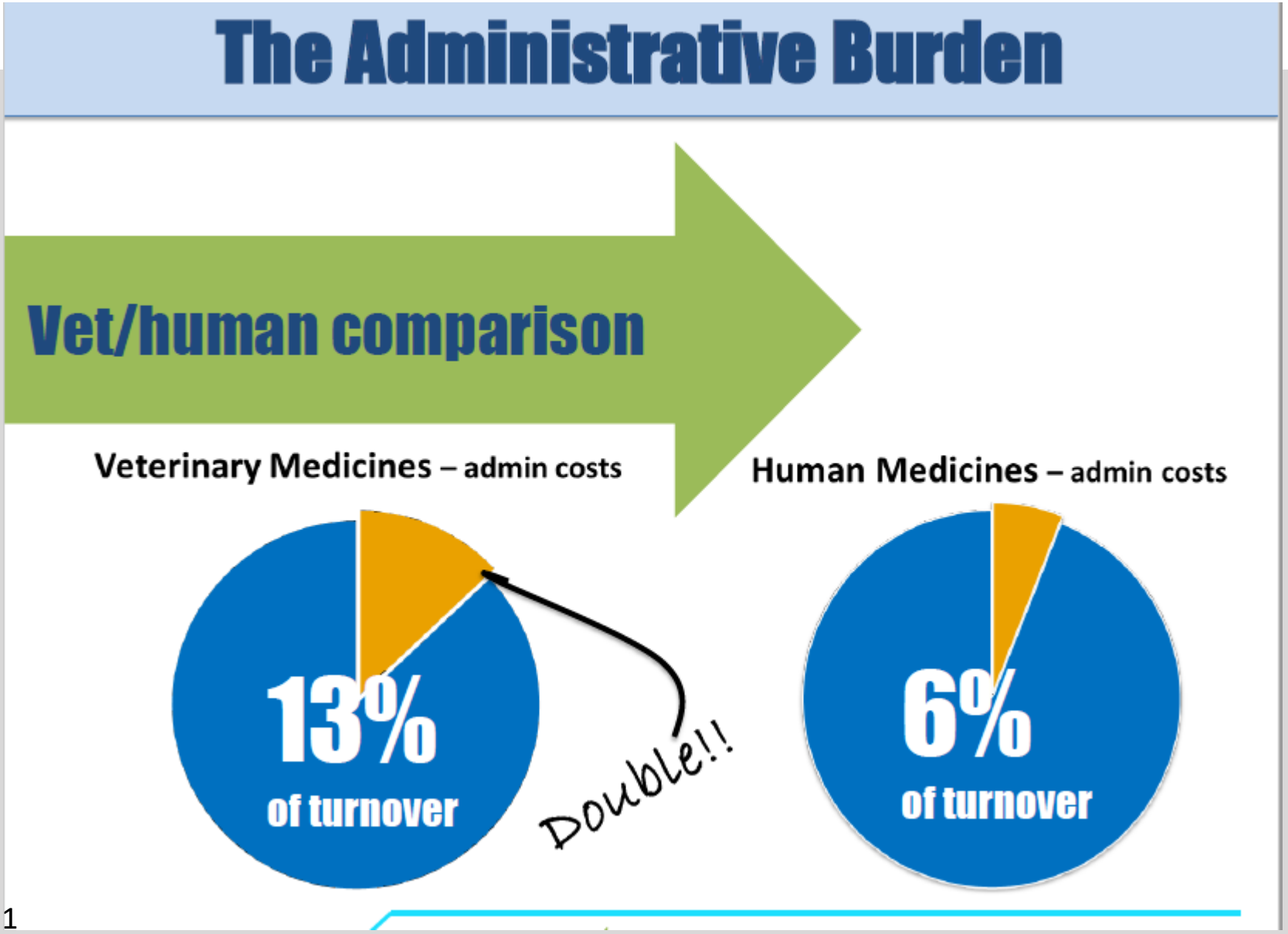
Problem definition: *administrative burden*

Sector's Annual Turnover



Background

Very high for veterinary medicines



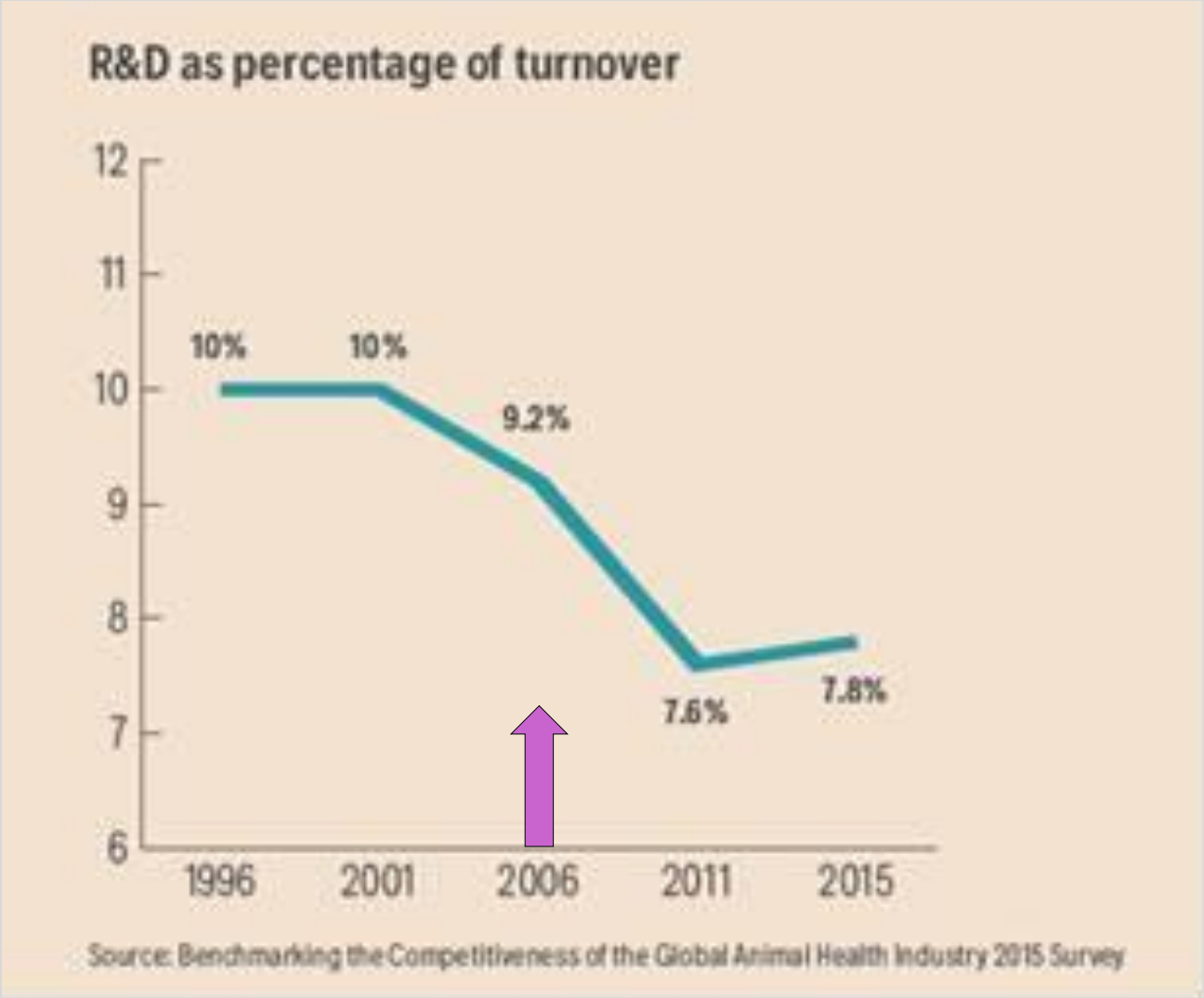
Source: Impact Assessment for the review of the legislation 2011

Obj.: Stimulate competitiveness and innovation

Background

Global Benchmarking Survey 2015

Decline in investment in regulated veterinary medicines



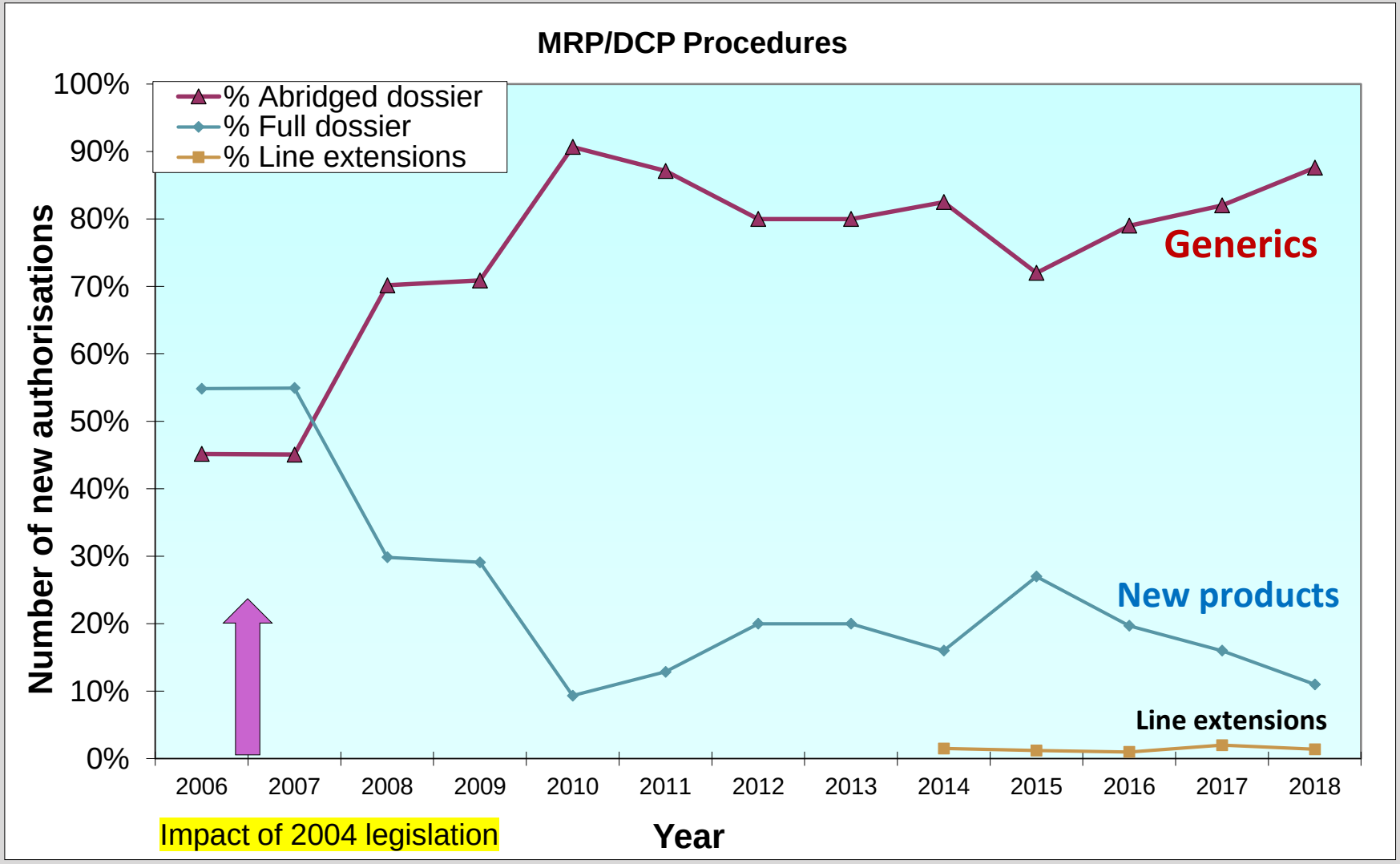
Stimulate competitiveness and innovation

Background

The switch to generics

Decline in investment

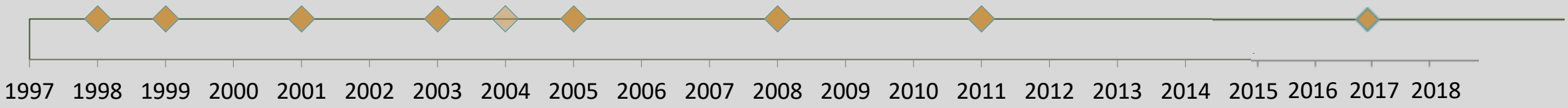
Unintended consequences?



Obj.: Stimulate competitiveness and innovation

Background

- **Decline in innovation in new veterinary antibiotics**
  - Increase in data requirements, decrease in market size, political uncertainty
- **Centralised procedure – for innovative products**
  - 9 livestock antibiotics are registered (22 years - 1996 to 2018):



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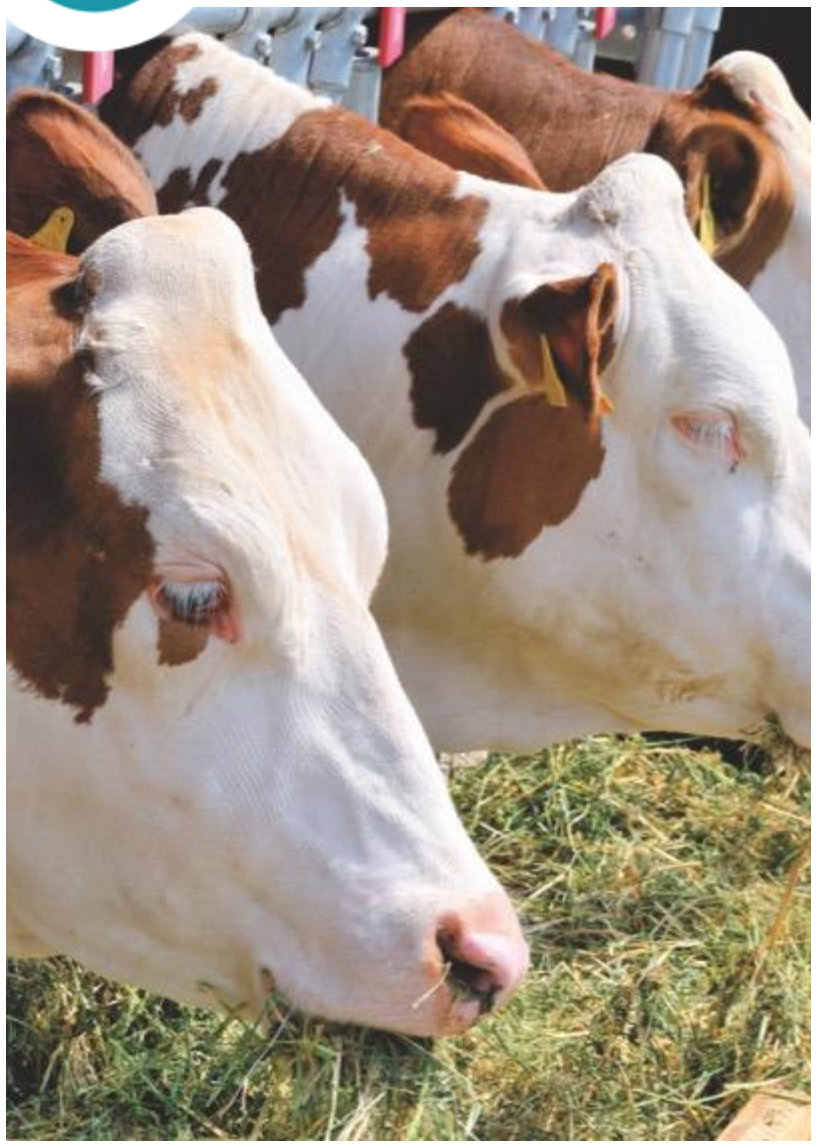
Review and update of the VMP legislation

Main outcomes



VMP legislation covers:

1. Scope and definition
2. Data requirements to obtain a marketing authorisation
3. Regulatory procedures to obtain a MA
4. Keeping up-to-date - post-authorisation regulatory work
5. Pharmacovigilance - in market safety surveillance
6. Manufacturing controls
7. Use, distribution, retail
8. Inspections, controls and penalties

New VMP Regulation - outcome summary

- Separate Regulation for the VMP sector
- Published January 2019 – becomes applicable Jan. 2022
- Good progress towards the objectives
- Overall impact on manufacturers is uncertain
- More focus on controlling antimicrobial resistance and on environmental protection

Impact - largely unpredictable

- Depends how the legislation is implemented
- 25 implementing measures on the details
  - 17 Implementing Acts
  - 8 Delegated Acts
  - 15 to be adopted in next 3 years (January 2022)
- Major new systems
  - **Pharmacovigilance**
  - A completely new chapter (harmonisation of product summaries)
  - **IT infrastructure** – databases, electronic submission, single e-submission portal, data management systems (SPOR)
  - **Major impact! - b**ut positive or negative on admin burden depends on how it is implemented

vs Objectives

Improved availability / single market?

Encouraging,
Many small but significant changes

- Stimulating investment in new products?
  - Novel therapies – clear regulatory route encourages innovation
  - Improved protection of (incremental) innovation
  - AMs: more restrictions on use and reasons to refuse authorisation
- Centralised procedure opened up – more EU wide products?
- Packaging and labelling – more multi-lingual packaging?
- No renewals & sunset clause ⬇ admin burden / product losses
- More harmonisation (SmPC) – annual prioritised list of products

vs Objectives

Improved availability / single market ?

- **Distribution & retail**
  - Wholesale/distribution licence valid throughout the Union
    - *Implementing Acts on 'Good Distribution Practice*
  - Vet prescriptions valid throughout the Union
  - On-line sales permitted (only for non-prescription products)
  - Parallel trade better defined

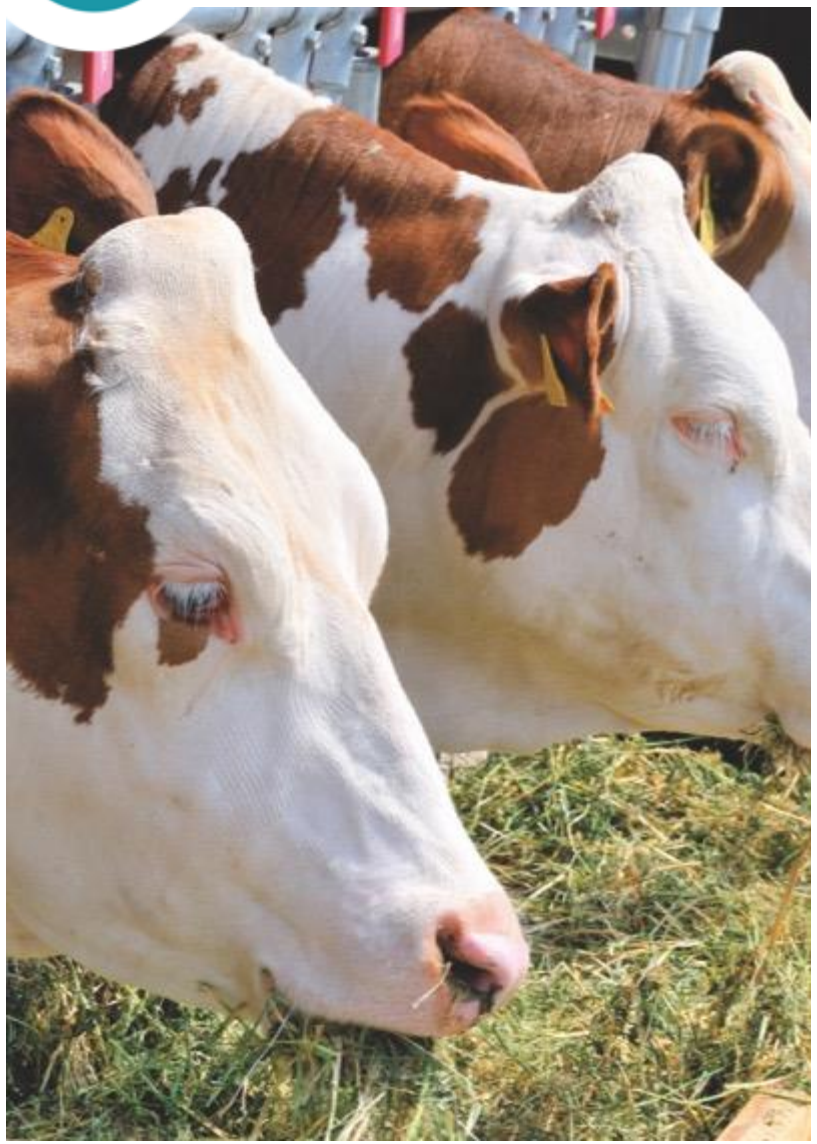
vs Objectives

Support for innovation

Encouraging, but not overly ambitious
Good for minor species

- Global MA concept still remains ☹
- Stimulus for minor species
- No stimulus for line extensions for major species
- Some stimulus for new antibiotics
- Some stimulus for some innovation on existing products
- Reduced requirements for exceptional circumstances, limited markets
- Improved route to market for novel therapies

vs Objectives

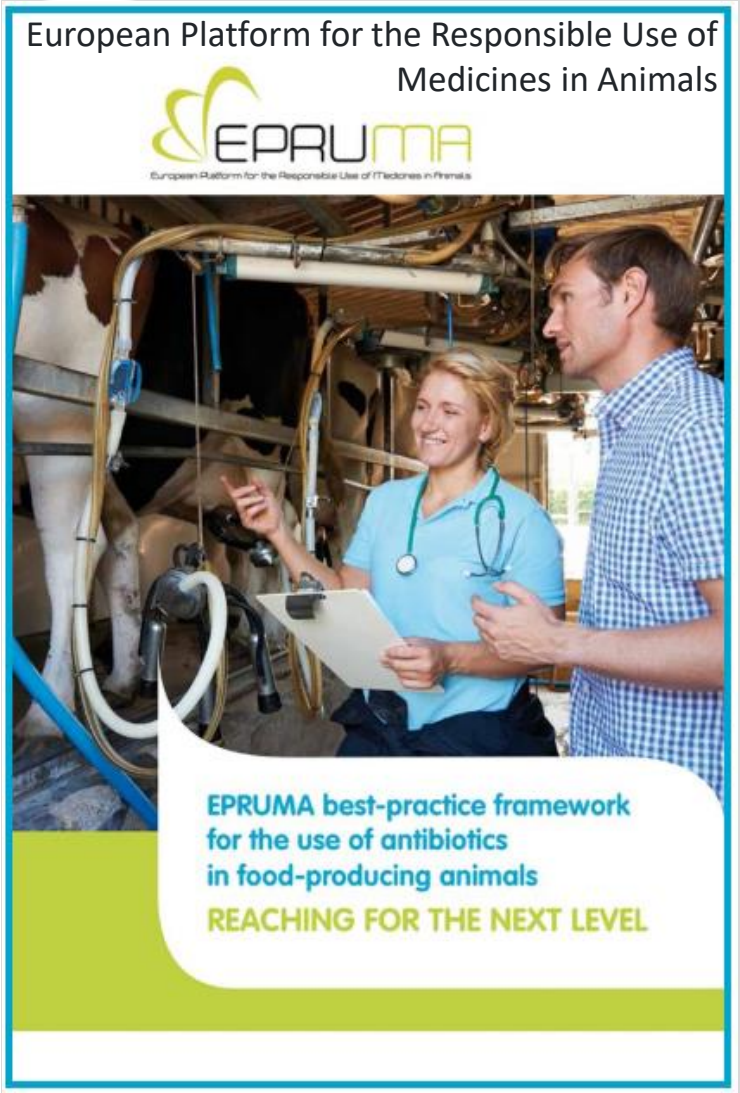


Administrative burden

Mixed bag – depends on good implementation

- No renewals - reduction in administrative burden ✓
- No sunset clause - but marketing status into product database ✓
- E-submission mandatory - all procedures, 1 common template ✓
- Labelling – clearer rules, less discussion on wording? ✓?
- DCP + MRP – issue resolution not simplified = longer time-lines ✗
- EC decision making procedure - timelines no longer transparent ✗
- Pharmacovigilance - no DDPS, no PSURS; signal management ✓??
- Variations – minor variations via database updates, but closed list ✗?
- EU databases – potential for single data entry and re-use data ???

vs Objectives



Measures to control AMR

Impact on use and on product development costs and admin costs
Impact on AMR – to be determined

- Ban on preventive use except in exceptional circumstances
- Restrictions on metaphylactic use
- List of antimicrobials reserved for human use
- Re-stated ban on use of antimicrobials for growth promotion
- Mandatory collection of sales and use data
- Possibility to restrict use in the prescribing ‘cascade’
- Ban on promotional samples
- Member States may further restrict use

Major changes for veterinarians

- **Prescriptions and use**
  - common format, electronic, valid throughout EU; quantity prescribed limited to treatment needs; restrictions for antibiotics and use of autologous vaccines
  - Prophylaxis – only in exceptional cases; metaphylaxis – only if high risk of disease
- **Prescription cascade**
  - simplified, but always veterinary product before human medicinal product; restrictions for antibiotics, including no antimicrobials reserved for human use
- **EU databases giving access to product and pharmacovigilance info**
- **Mandatory collection of use data for antimicrobials**
  - First for livestock
  - Later will be extended to other species and other medicines
- **Implementing measure on rules for oral medication**
  - via drinking water or top dressing

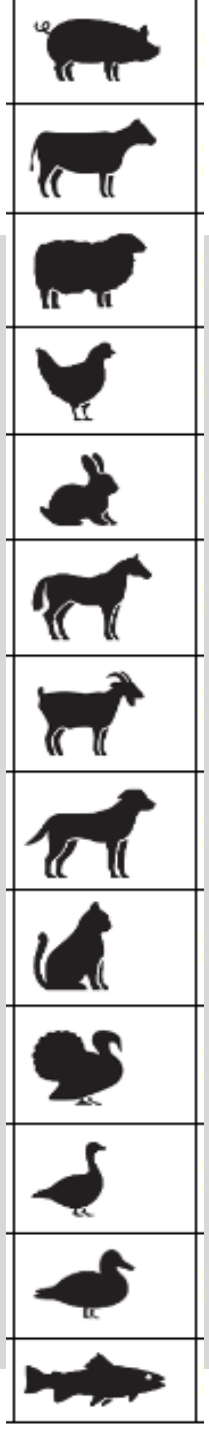
Labelling and packaging

Objectives

- **Improve availability of veterinary medicines**
  - Particularly for small markets
- **Reduction of administrative burden**
- **Improve single market**

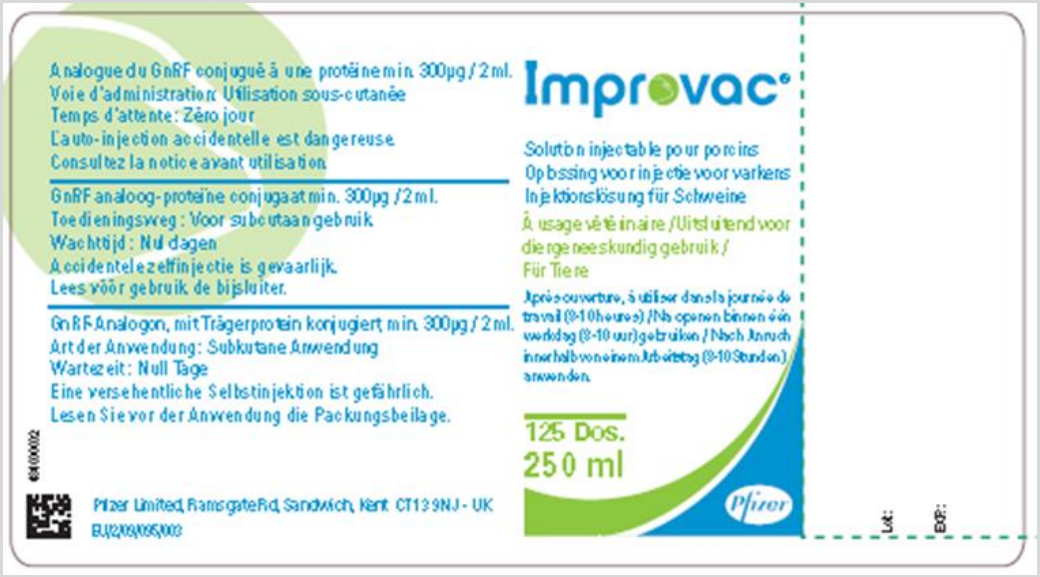
Facilitate multi-lingual labels
Reduce text on label

Pictograms
Std. abbr.



Packaging & medicines availability

Current label example
- multilingual labels difficult to read



Packaging & medicines availability

Minimum mandatory information for the immediate pack label

N.B. the layout and size of the pictograms have not been optimised; this is a mock-up only.

More information on the carton
All instructions for use to be in the package leaflet, including explanation of pictograms

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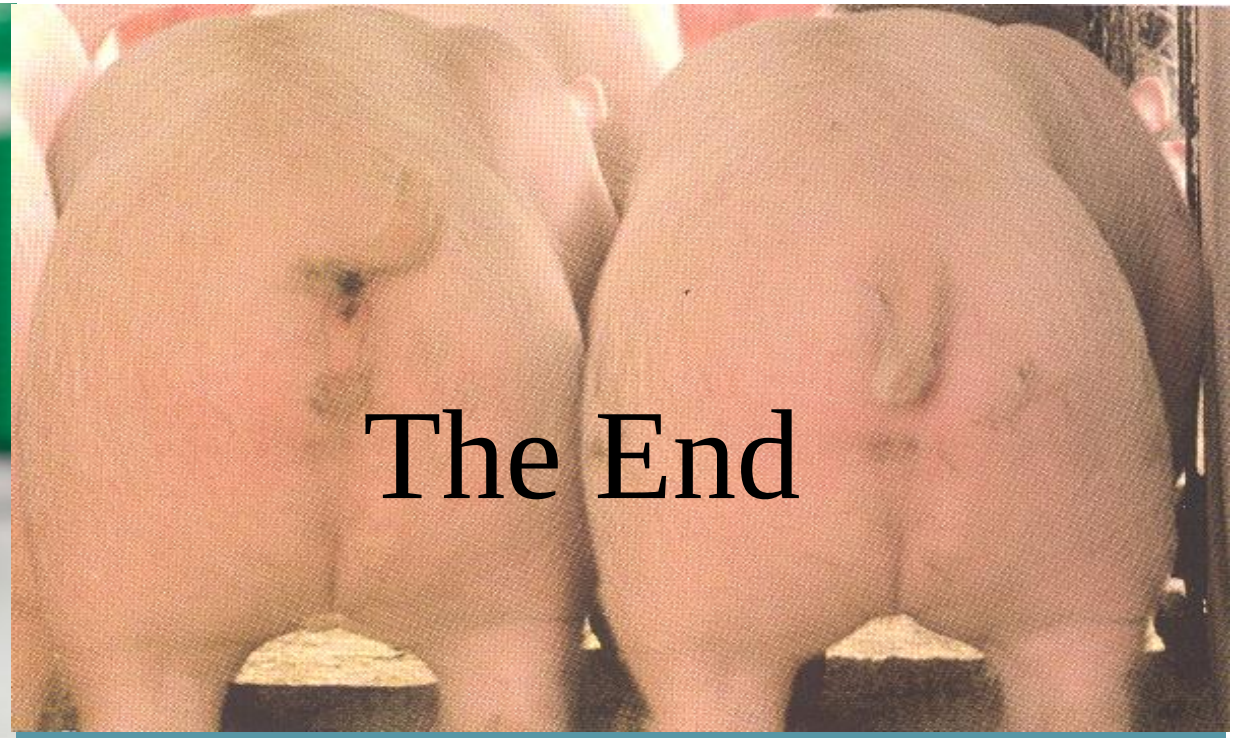

The End

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