New EU Regulation on Veterinary Medicinal Products

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Rick Clayton
Technical Director, HealthforAnimals

New EU Regulation on VMPs

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   - reducing admin burden and use of IT systems

What are the Drivers and what are the Solutions

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About the EU Regulation 2019/6 on VMPs

Why the review of the legislation; drivers

- Existing legislation from 2004, with 10-year review clause
- 2014 EC report and impact assessment identified some issues,
- Conclusion: updated legislation necessary with 5 objectives

- Stimulate innovation
- Reduce administrative burden
- Facilitate EU single market
- Increase medicines availability
- Control of antimicrobial resistance

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About the EU Regulation 2019/6 on VMPs

Transition periods

- Regulation 2019/6 adopted in January 2019
- 3 year transition period (to put in place many new rules and systems)
- Became applicable in January 2022
- From January 2022, 5 years transition period to move existing products to new packaging rules (little impact on product safety)

- **Adequate transition periods essential to avoid chaos**
- **Size of the task x risk = length of transition period**

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About the EU Regulation 2019/6 on VMPs

Regulatory procedures

- Centralised procedure – open to all product types
  - EMA – one assessment and one pan-EU marketing authorisation
- De-centralised procedure / mutual recognition procedure –
  - One assessment (reference member state)
  - From 2 to 27 national agencies, but one decision
  - From 2 to to 27 aligned national marketing authoristions

- **EU regulatory convergence over a period of 40 years**
- **Use of international standards, VICH and CODEX MRLs**

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Stimulate innovation

Increased protection periods for the technical documentation

Basic principles

- If a competitor can copy your investment before you have the opportunity to obtain a return on your investment,

  why would you bother to invest
- Original product = authorised with a complete data dossier
- Generic product = an abridged dossier in EU law (data derogations but with complete Quality/CMC part)
- 10 years protection before a generic product application can cross refer to the original product authorisation

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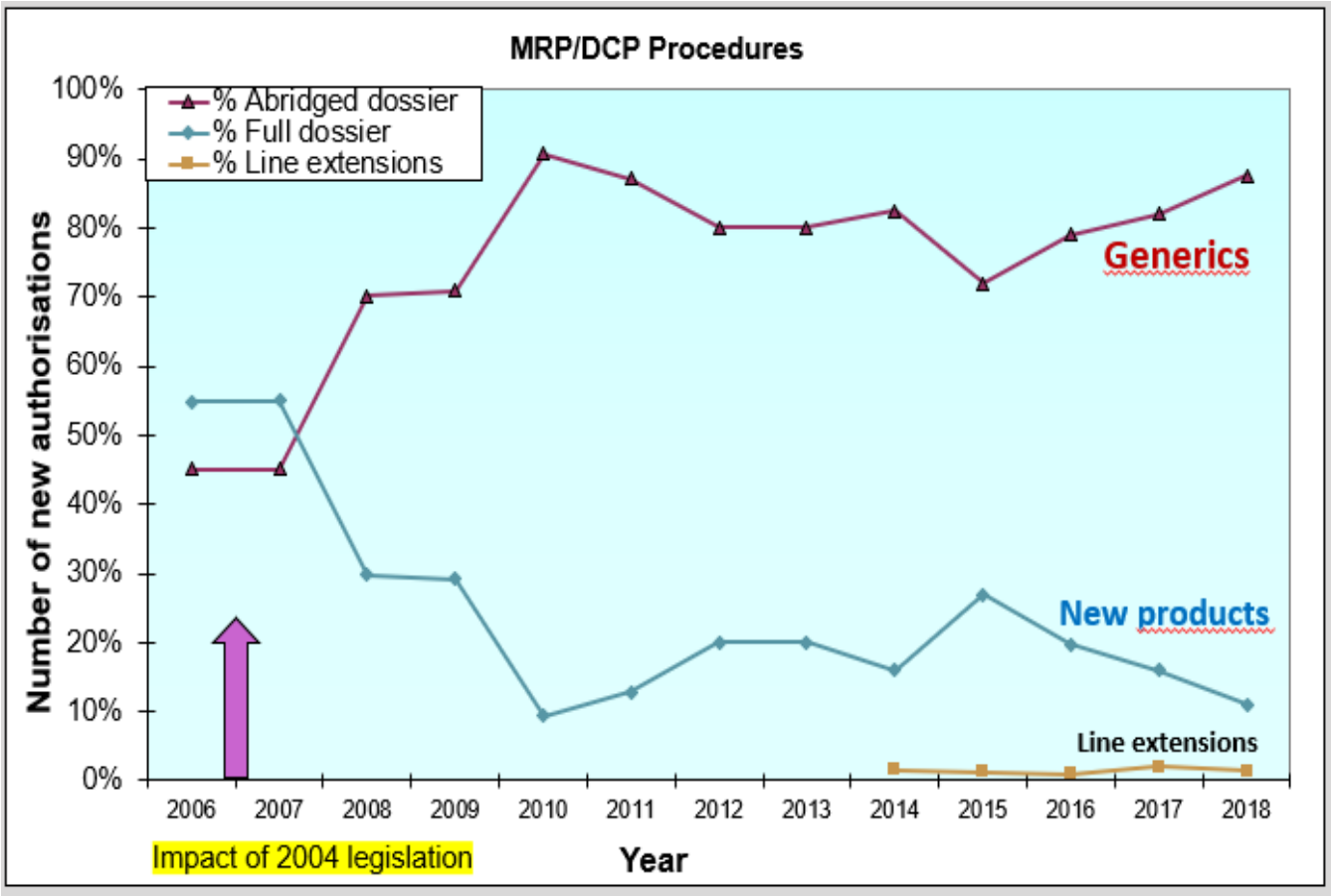
Stimulate innovation – the drivers

MRP Products coming onto the EU Market

2006 - 2018

- The switch to generics (abridged dossiers)
- Unintended consequences of 2004 legislation?



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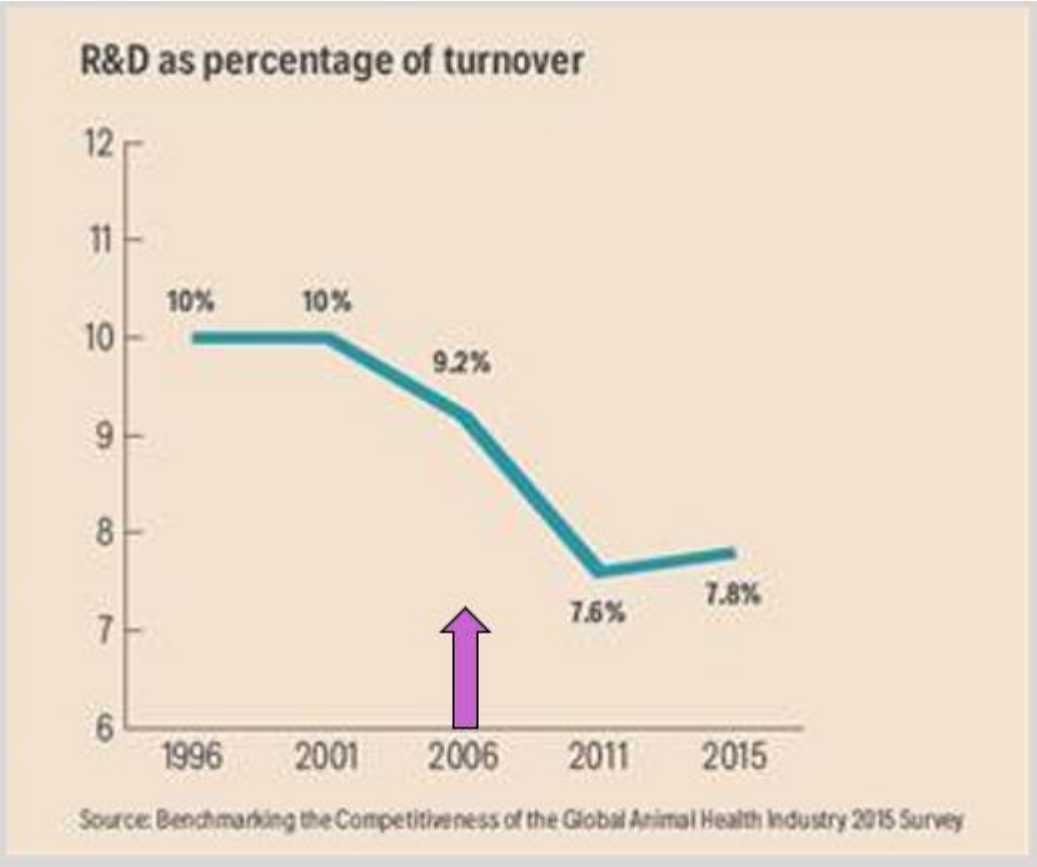
Stimulate innovation – the drivers

Global Benchmarking Survey 2015

Decline in investment in regulated veterinary medicines



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Stimulate innovation – the solutions

Increased protection of the technical documentation

- 10 years protection before a generic can cross refer to the original product – not changed
- but increased protection or stimulation for
  - products for 'minor species' / including bees 14 / 18 years
  - NEW - new antibiotics 14 years
  - NEW – innovation on existing products 4 years
    - Must result in an improvement of the benefit-risk balance
    - Specific example: a reduction in the [*risk]* of antimicrobial or antiparasitic resistance;

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Stimulate innovation – the solutions

Regulatory requirements – remove hurdles

- **Novel therapies - a regulatory route to market is created**
  - Definitions and clarification, data requirements and flexibility
  - Dedicated scientific advice, scientific guidelines
- **Exceptional circumstances**
  - If benefits of immediate availability outweigh risks of reduced data
  - Valid for 1 year, can be extended until conditions no longer met
- **Limited markets**
  - Diseases that occur infrequently or in limited geographical areas
  - Reduced data requirements if benefits of product outweigh risks
- **Reduced admin burden**
  - Reduce ‘defensive research’ for product maintenance
  - More R&D budget spent on new research

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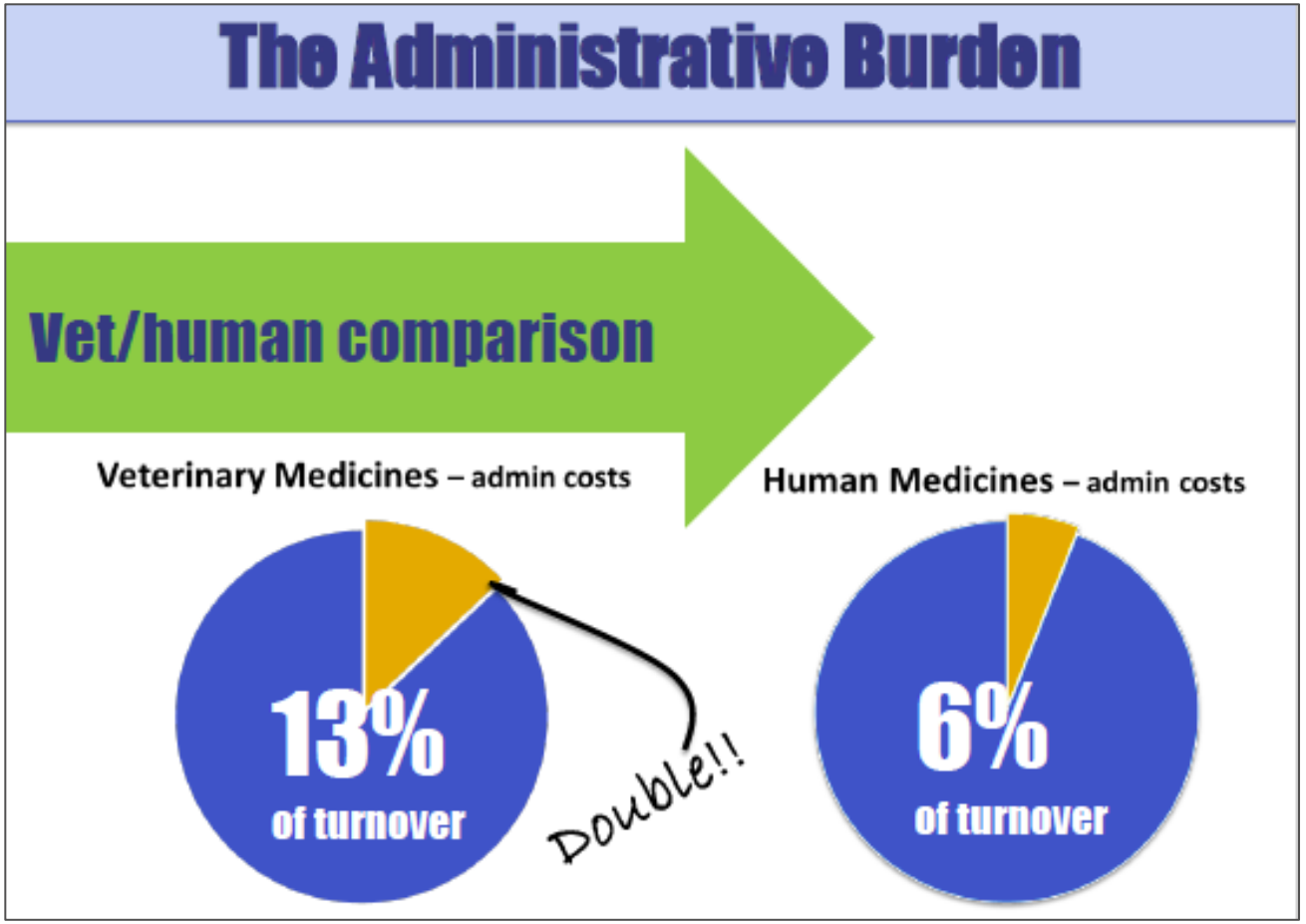
Innovation in regulatory affairs – the drivers

European Commission Impact Assessment

Cost to industry of complying with EU Regulations



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Innovation in regulatory affairs – the solutions

Reduction of administrative burden

- **No 5-year renewals - product authorisation of unlimited duration**
  - Supported by more efficient variations and pharmacovigilance systems
- **Increased efficiencies from modern IT systems**
  - E-submission system, a legal basis, mandatory
  - Use of 4 **EU databases**
  - Only enter data once; re-use of data, e.g. from application form
  - Minor variations – just notification to the product D-B
  - **Pharmacovigilance** signal detection and signal management
- **Use of "master files"**
  - To avoid repeated common data in every product dossier

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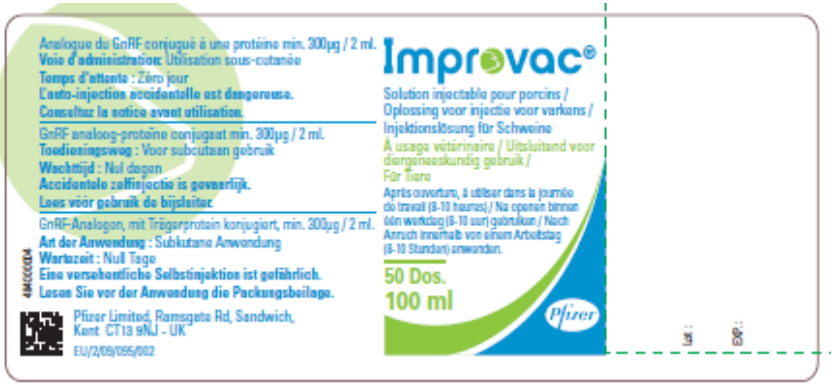
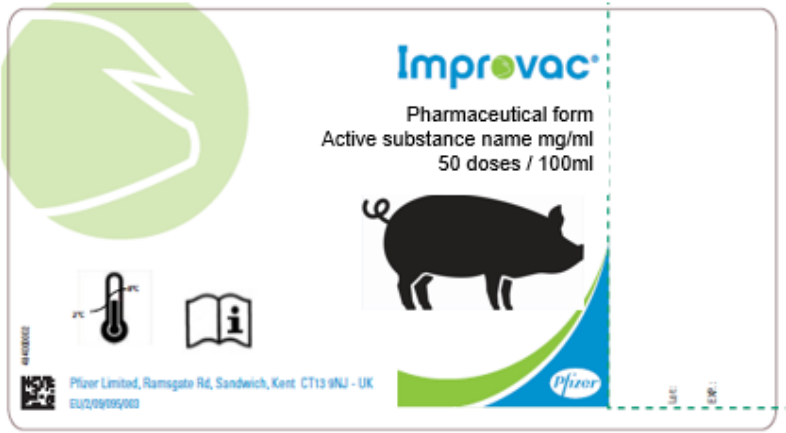
Innovation in regulatory affairs – the solutions

Reduction of administrative burden

- Limiting the text on labels -mandatory maximum limit to label content
  - Simplifying discussions on label text (EU = 24 languages)
  - Use standard pictograms and abbreviations to replace text
  - Less text to translate or check
  - More multi-lingual labels & increased availability in small markets?





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Innovation in regulatory affairs – the solutions

Reduction of administrative burden

- **Pharmacovigilance – only produce reports when necessary**
  - periodic reporting (PSURs) replaced by signal detection in EU PhV database
- **Pharmacovigilance "master files"**
  - Previously: every dossier contained a detailed description of the PHV system
  - Same description in every product dossier of a manufacturer
  - Something changes = a multitude of variations required

- **Active substance master file**
- **Vaccine platform technologies**
  - The vaccine platform technology is assessed once
  - Specific vaccine data dossiers - platform technology not re-assessed

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Innovation in regulatory affairs – the solutions

Reduction of administrative burden

- **Variations**
  - Minor variations – simple notifications to UPD within 12 months
  - Grouping of variations
    - similar variations across a range of products (e.g. change in company name)
    - several variations to same product dossier
  - Worksharing – one assessment by reference member state, MRP

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Innovation in regulatory affairs

Use of IT

- **Aim to reduce admin and make procedures efficient**
  - Avoid IT driven solutions; must be business case driven
  - Admin burden may increase during the initial deployment
- **E-submission**
  - Became mandatory in Regulation 2019/6
  - E-application form, E-dossier format (VICH GL on use of PDF)
- **Use of databases**
  - Now an integral part of the Regulation / legal basis & specifications
  - Union Product D-B, GMP registrations D-B, wholesaler/distributor D-B, Pharmacovigilance D-B (VICH/international data exchange)
  - D-Bs should be linked (enter product data only once, e.g. E-application form; re-use of data; reduces errors; one truth);

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Innovation in regulatory affairs

Use of IT

- Union product database and reduction in administrative burden
  - All products authorised in EU (centrally/EMA and national/MRP)
  - Information can be linked or inter-connected
    - E.g. Products linked to a PHV master file and to PHV data
  - Simple notifications and updates (MAH/reg.auth.) become possible
    - Minor variations (no assessment needed)
    - Sales data (pharmacovigilance; monitoring targets in AB use reduction)
    - Updates to product status (available, withdrawn, supply disruption)

- Removes need for legalised certificates and paper GMP certificates
- Simple for external body to verify a product is authorised in EU
- **EMA only issues E-certificates (no more paper, no official stamps)**

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Innovation in regulatory affairs

Use of IT

- Use of websites
  - Transparency in requirements = encourages commercial activity
  - Access to all scientific guidelines and procedural guidance
  - Tracking of dossiers through the assessment and authorisation process
  - Contact points
  - News and information

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Innovation in regulatory affairs

- Sufficient transition periods to introduce innovative approaches
- Support and stimulate innovation
- Make good use of limited resources
  - MRP, centralised procedure, worksharing, simple notifications, master files
- Use of international standards and regulatory convergence
- Reduce administrative tasks
- Use of IT, driven by the business case
  - E-submission, E-application forms, reuse data, databases

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Thank you for listening

Questions to rick@healthforanimals.org

Many thanks to
HealthforAnimals Middle East and North Africa WG
menawg@healthforanimals.org