The European veterinary medicine reform

The new veterinary medicines regulation and other new legislative acts

Josa Preuß, European Commission,
Directorate Health and Food
Animal nutrition and veterinary medicines

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New legislation

- **Proposed** Commission Regulation establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009
- **Proposal** for a Regulation of the European Parliament and of the Council on veterinary medicinal products
- **Regulation (EU) 2017/852** of the European Parliament and of the Council of 17 May 2017 on Mercury

Objectives

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

While safeguarding public and animal health and protection of the environment

Objective

- Stimulate competitiveness and innovation
  - **simplified procedures and clear data requirements**
    - Harmonised frame for clinical trials (e.g. timeline)
    - Marketing autorisation procedures streamlined and more flexible (e.g. opening up of the CAP)
    - Harmonised data requirements for MUMS
  - **Adequate protection of technical documentation**
    - Rewarding innovation
    - Increasing the period for data protection

Proposed Commission Regulation establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009

Technical standard in the Annex refer to VICH guidelines

VICH GL33 "Studies to evaluate the safety of residues of veterinary drugs in human food: general approach to testing" and VICH GL47

Proposal for a Regulation of the European Parliament and of the Council on veterinary medicinal products

- Developed with the needs and characteristics of the veterinary sector in mind

  - Rules are diverging from the pharmaceutical legislation for medicinal products for human use
  - Bringing together veterinary medicines rules in one Regulation

Proposal for a Regulation of the European Parliament and of the Council on veterinary medicinal products

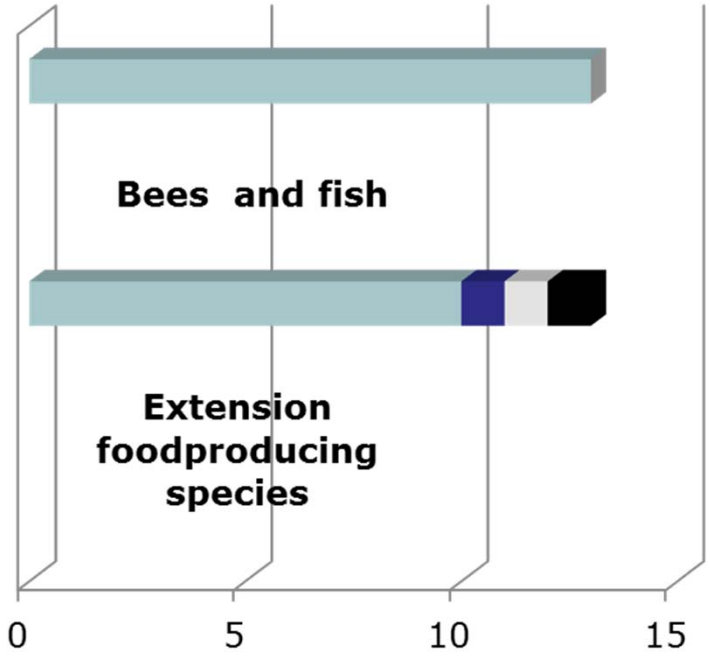
- Developed with the needs and characteristics of the veterinary sector in mind

  - Providing transparent and predictable rules and data requirements
  - Providing sufficient protection of technical documentation
  - A balanced and proportionate approach

Protection of technical documentation under the current directive

A maximum protection period of 13 years

Prolongation of the protection period by 1 year for exending the medicine to minor and major species



Rewarding innovation

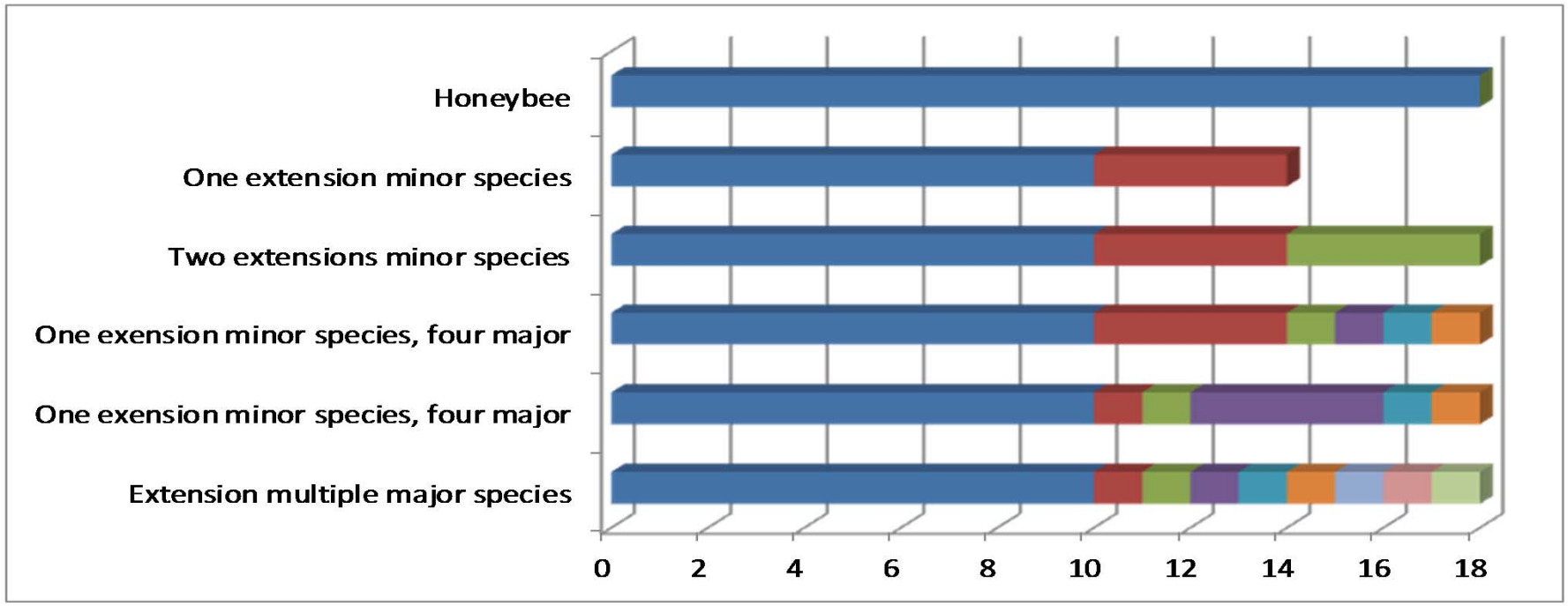
A maximum protection period of 18 years

10,14 and 18 years for initial marketing authorisation respectively for major species, minor species and bees

Prolongation of the protection period by 1 and 4 years for exending the medicine to major and minor species

Rewarding innovation

Proposal from Commission and Parliament



Window of opportunity: three years before the expiration of data protection period

Rewarding innovation:

Proposals from the EP and Council

EP AM 138: *Benefit from the start of the prolongation of the data protection period where the first marketing authorisation is granted for* ***more*** *than one species* instead of the obligation to introduce a variation:

Proposal of the EP:

- **data protection period: as proposed**
- **Reduction of unnecessary admin burden related to variations**

→ *Under consideration*

Rewarding innovation:

Proposals from the EP and Council

EP AM 312 and new article 135 (5) of the Council

Additional periods of technical documentation for existing product not benefiting anymore from protection of technical documentation periods linked to the global marketing authorisation for innovation regarding the ***pharmaceutical form, administration route or dosage*** *for the purpose of* ***reducing resistance or improving the risk-benefit balance***

Proposal: protection of up to 4 years for the results of concerned clinical studies → *Under consideration*

Rewarding innovation:

Proposals from the Commission and Council

Commission: authorisation for limited uses / minor species with reduced data package on quality, safety and/or efficacy in Article 21 *"Reduced data requirements for applications for limited markets"*

- **Proposal of the Commission:**

  quality and/or efficacy documentation required

- **Proposal of the Council:**

  safety and/or efficacy documentation required

→ *Under consideration*

Regulation (EU) 2017/852 of the European Parliament and of the Council on Mercury

INVENTORY OF 'EXISTING' MERCURY-ADDED PRODUCTS In accordance with Article 8(7):

Vaccines in which mercury and mercury compounds, including thiomersal, are used as antimicrobial preservative in final bulk and finished product to prevent spoilage or adverse events caused by microbial contamination.

Regulation (EU) 2017/852 of the European Parliament and of the Council on Mercury

INVENTORY OF 'EXISTING' MANUFACTURING PROCESSES In accordance with Article 8(7):

- Antimicrobial preservative in bulk antigen harvests to prevent replication of the bioburden and the subsequent build-up of bacterial/fungal extraneous cellular components in the bulk fluids;
- Antiactivating agent to inactivate certain organisms that are sensitive to thiomersal.

Thank you for your attention!

European Commission
Directorate-General for Health and Food Safety
DG SANTE E5
Animal feed and Veterinary medicines
Josa-Nicole.PREUSS@ec.europa.eu