Proposal for a Regulation on veterinary medicinal products

European Commission
Directorate Health and Food Safety
Health systems and products
Medicinal products - quality, safety and efficacy

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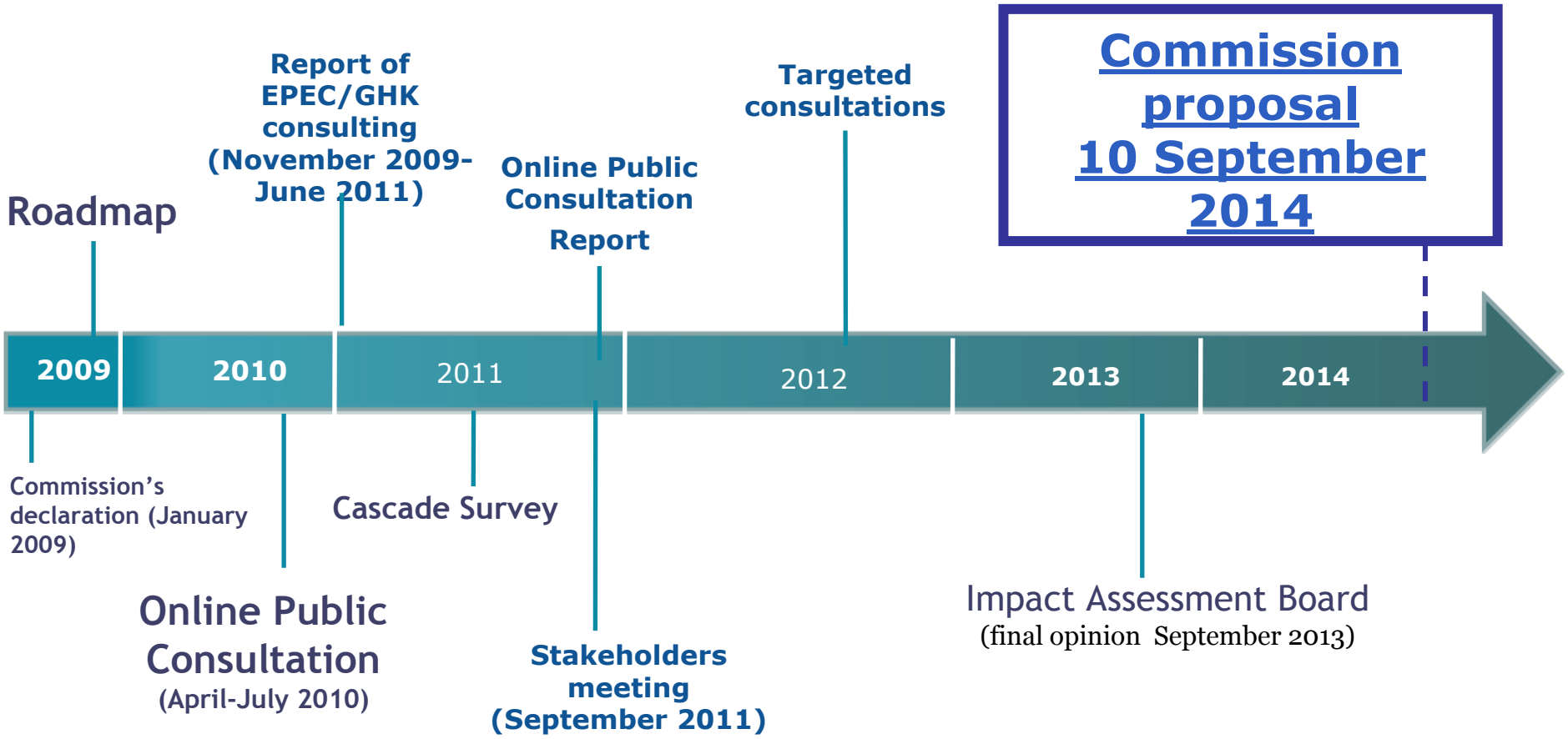
Background

- The proposal 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

All rules on veterinary medicines in **one** regulatory act

Preparatory work - timeline



Problems

1. Overall lack of authorised veterinary medicines in the Union (particularly for minor species and minor uses) leading to:

- Risks to animal health and welfare
- Risks to public health
- Economic consequences to farming
- Legal implications for veterinarians

2. Antimicrobial resistance: a health threat

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

Revision's objectives

✓ **INCREASING THE AVAILABILITY OF VETERINARY MEDICINES**

- all types of veterinary medicines can obtain EU-wide marketing authorisation by using the centralised procedure
- increased incentives for the industry to develop products in particular for minor species

INCREASING THE AVAILABILITY OF VETERINARY MEDICINES

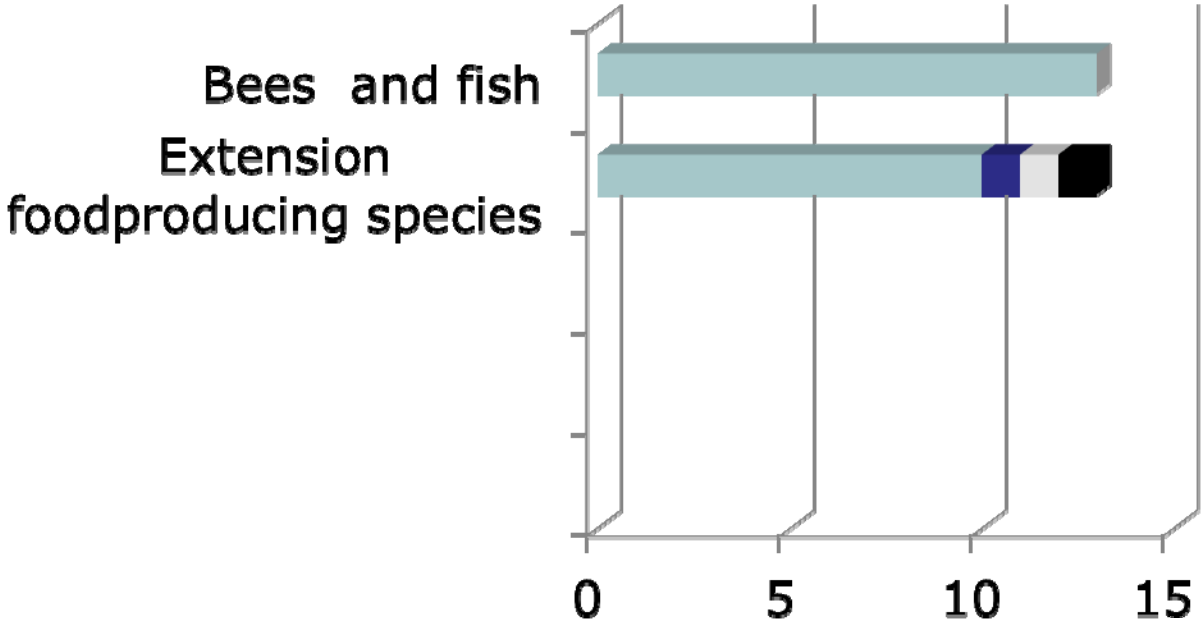
Rewarding innovation

- The level of protection of expanding the product to additional species is linked to the initial marketing authorisation

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

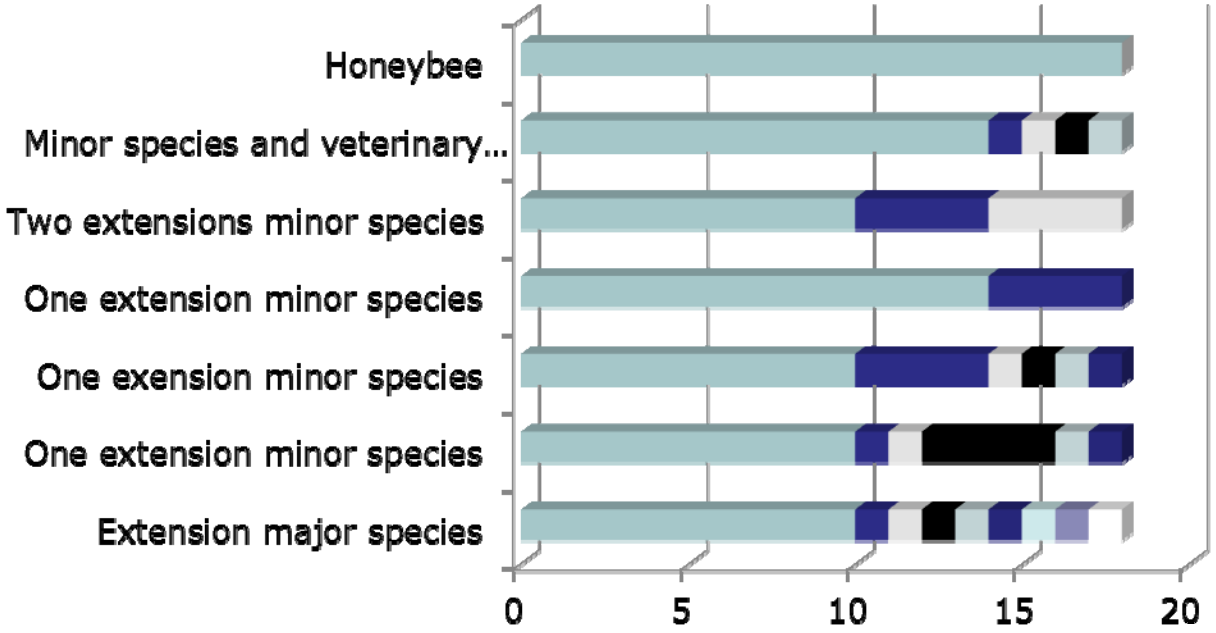
- Prolongation of protection period by 4 years for extending the product to a minor species and by 1 year to a major species

Rewarding innovation in current situation (Directive 2001/82/EC)



Window of opportunity: within five years after the granting of the initial marketing authorisation

Better rewarding innovation



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

Revision's objectives

✓ **INCREASING THE AVAILABILITY OF VETERINARY MEDICINES**

- Providing more legal certainty:
  - Clear scope
  - New definitions
  - Rules on approval process of clinical trials
  - Streamlined procedures
  - Union databases

Revision's objectives

✓ **REDUCING ADMINISTRATIVE BURDEN**

- marketing authorisations valid for an unlimited time
- simplified rules on packaging and labelling
- simplified rules for monitoring of adverse events (pharmacovigilance)

Revision's objectives

✓ **IMPROVING THE FUNCTIONING OF THE INTERNAL MARKET**

- EU rules on online sale of veterinary medicines
- recognition throughout the EU of veterinary prescriptions
- harmonisation of the marketing authorisations of medicines granted by national procedures

Revision's objectives

✓ **ANTIMICROBIAL RESISTANCE MEASURES**

- Today: No distinction in the legislation between antimicrobials and other types of veterinary medicinal products

- Proposal: Specific requirements for veterinary antimicrobials

Science-based approach

Revision's objectives

✓ **ANTIMICROBIAL RESISTANCE MEASURES**

- Promoting prudent use
- Providing legal tools for preserving critical antimicrobials for the treatment of human infections
- Establishing an effective and harmonised monitoring system of veterinary antimicrobials
- Refusing marketing autorisation if presented as growth promoter

Thank you for your attention!