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

Animal Health Advisory Committee
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Revision of the veterinary medicines legislation

✓ **DEVELOPED WITH NEEDS AND CHARACTERISTICS OF THE VETERINARY SECTOR IN MIND**

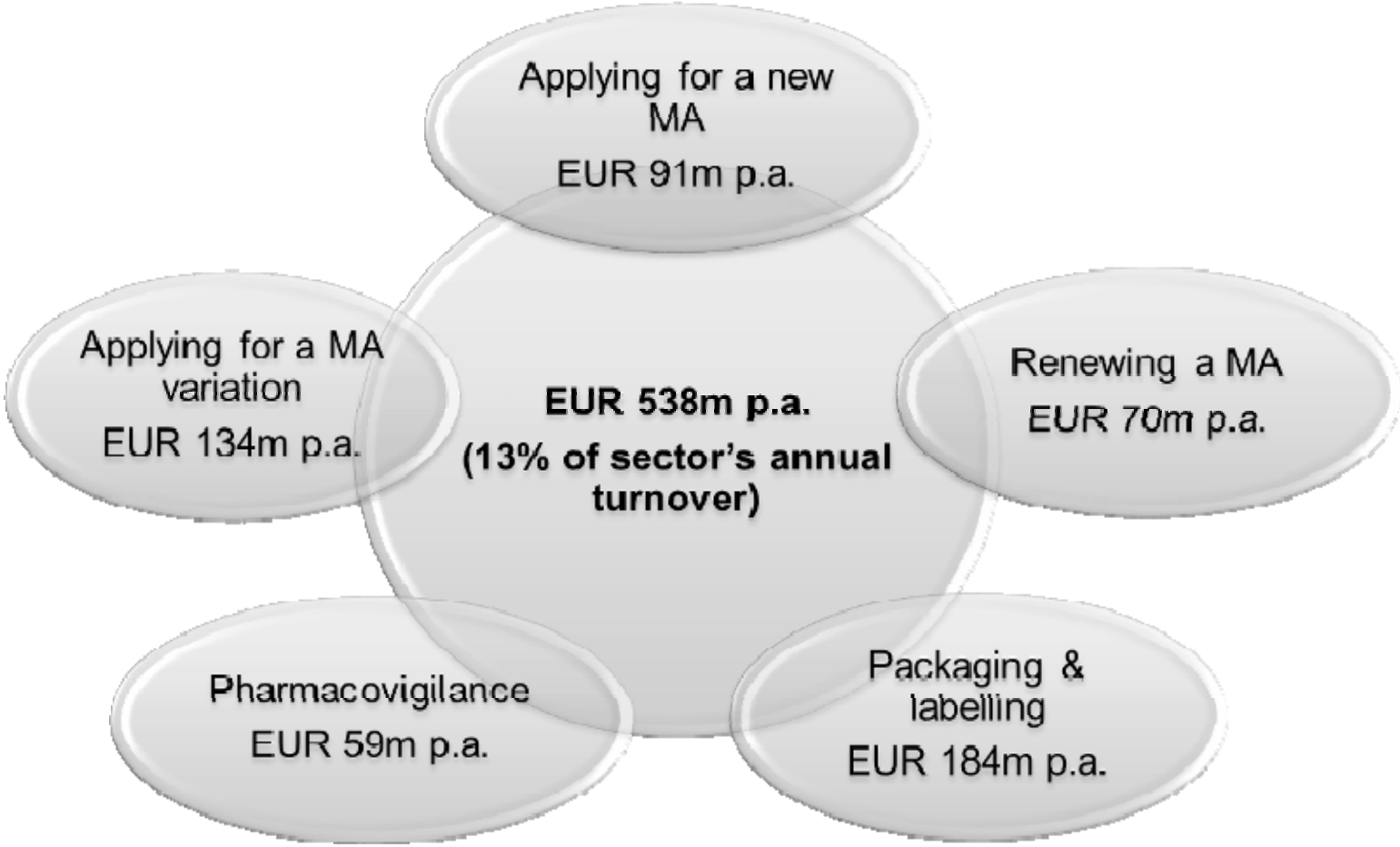
- Rules are diverging from the pharmaceutical legislation for medicinal products for human use
- Bringing together all rules for veterinary medicines in one Regulation

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


Applying for a new MA
EUR 91m p.a.
Applying for a MA variation
EUR 134m p.a.
EUR 538m p.a.
(13% of sector's annual turnover)
Renewing a MA
EUR 70m p.a.
Pharmacovigilance
EUR 59m p.a.
Packaging & labelling
EUR 184m p.a.

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

New legal set up

- Directive 2001/82/EC : full revision and conversion into a new **Regulation**
- Regulation (EC) No 726/2004 : provisions regarding veterinary medicines transferred to the new Regulation
- The new Regulation – **basic act**
- Technical and procedural **details to be set out** by **implementing and delegated** acts and guidelines

Revision's objectives

- ✓ **INCREASING THE AVAILABILITY OF VETERINARY MEDICINES**
- less costs to obtain and to keep a marketing authorisation
- all types of veterinary medicines can obtain EU-wide marketing authorisation by using the centralised procedure
- flexibility for the use of medicines outside the terms of the marketing authorisations ("off-label use")
- specific flexibility for the "off-label use" of medicines for bees
- increased incentives for the industry to develop products in particular for minor species

Revision's objectives

- ✓ **REDUCING ADMINISTRATIVE BURDEN**
- marketing authorisations valid for an unlimited time
- simplified rules on packaging and labelling
- a risk-based approach to controls
- simplified rules on mutual recognition of marketing authorisations
- simplified rules for monitoring of adverse events (pharmacovigilance)
- a risk-based approach for introducing changes to marketing authorisations (variations)
- 4 new EU data base

Revision's objectives

- ✓ **IMPROVING THE FUNCTIONING OF THE INTERNAL MARKET**
- wholesale distribution authorisation valid throughout the EU
- rules on online sale of veterinary medicines
- minimum requirements for veterinary prescriptions
- recognition throughout the EU of veterinary prescriptions
- harmonisation of the marketing authorisations of medicines granted a marketing authorisation by national procedures
- rules on approval process of clinical trials

Marketing authorisations

The MA makes the choice

- *Widened scope of CP*
- *Rolling-out of a product in DCP and MRP*
- *Harmonised approval process of clinical trials*

Changes to marketing authorisations

A risk-based approach

- *Scientific assessment of changes substantially affecting safety and efficacy*
- *Do and tell*

Pharmacovigilance

An updated, risk-based and targeted approach

- *-Monitoring performance of medicines, new approach*
- *-Masterfile*
- *-No PSURs*

Packaging and labelling

A major simplification

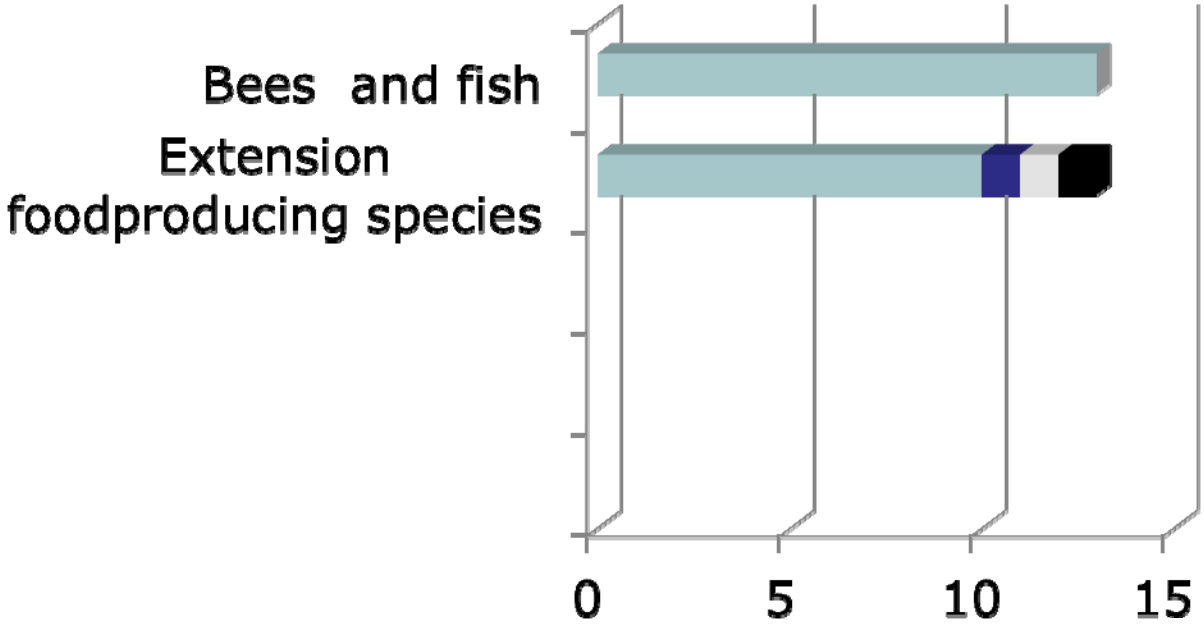
- Reducing the compulsory information
- Harmonised pictograms and abbreviations
- Member States determine language(s)
- Text of P&L in assessment report of RMS

Protection of technical documentation

Benefiting innovation and increasing availability

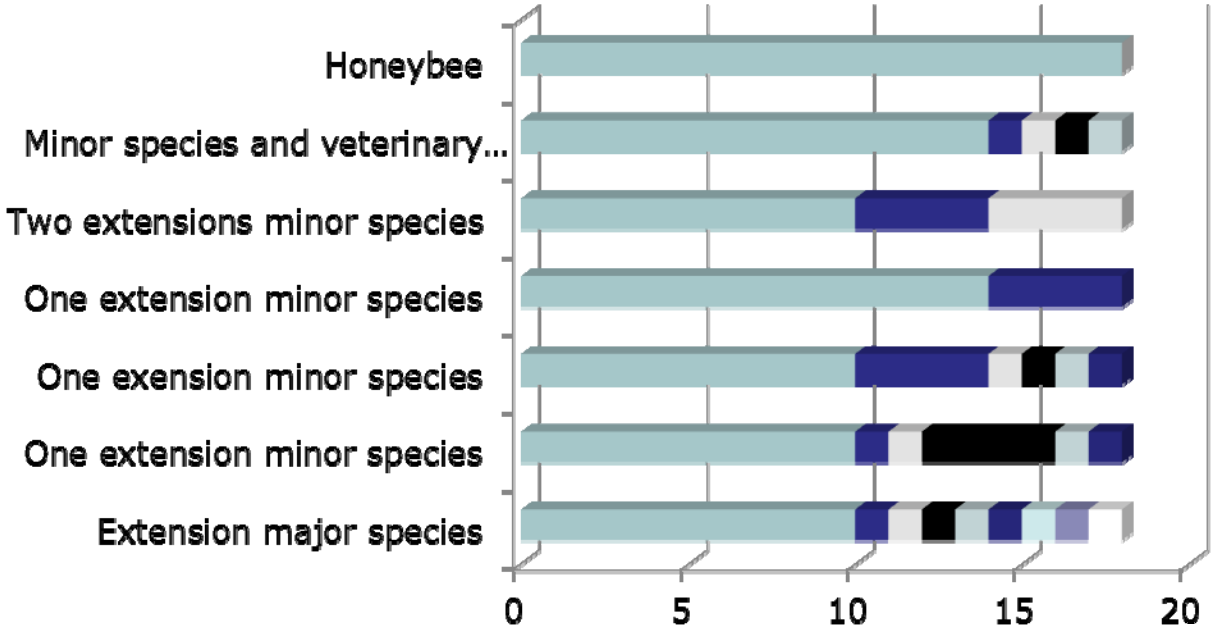
- Balancing two opposing objectives: competition and innovation
- An inclusive method
- Going beyond 'the top-four species'

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 of the veterinary medicines legislation

✓ ADRESSING ANTIMICROBIAL RESISTANCE

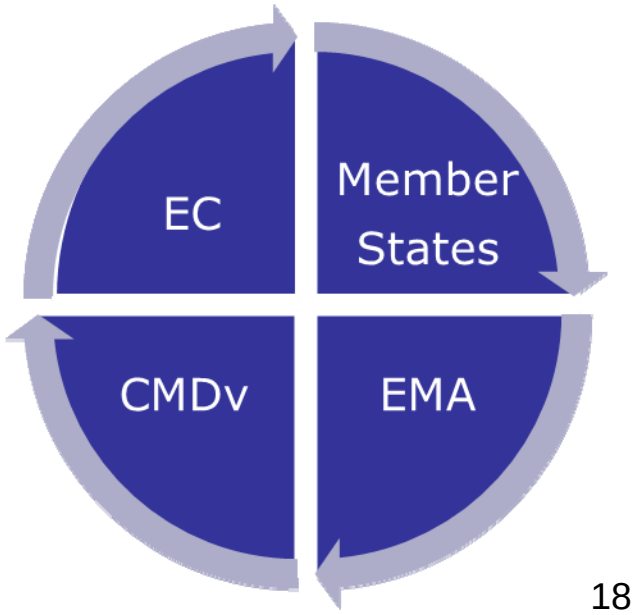
Specific rules included for only one group of veterinary medicines: antimicrobials

- on prudent use, including "off-label use", supply and advertising
- on the evaluation of new marketing authorisation applications
- on preserving critical antimicrobials for treatment of human infections
- on a harmonised monitoring system of veterinary antimicrobials

Revision of the veterinary medicines legislation

✓ **REGULATORY NETWORK**

- no major changes
- regulatory network structure unchanged
- 4 procedures for granting a marketing authorisation:
  - **national**
  - **centralised**
  - **mutual recognition**
  - **decentralised**



Revision of the veterinary medicines legislation

✓ TIMELINE

- Two Council meetings took place on the 9 October and 11 November and will be followed by one other meeting under the IT Presidency in December.
- Next Presidency Latvia
- Rapporteur EP: Françoise Grossetête (ENVI)
- Two to three years discussions expected between EP and Council

Thank you!

Information on the revision of the legislation on veterinary medicines:
http://ec.europa.eu/health/veterinary-use/rev_frame_index_en.htm

Further information: sanco-pharmaceuticals-d6@ec.europa.eu