The European veterinary medicine reform: Favorable conditions for innovation?

Revision of the legislation on veterinary medicinal products

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Medicinal products - quality, safety and efficacy

Animal Health: a key actor in tomorrow's innovations

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Background

- 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
Report of EPEC/GHK consulting (November 2009-June 2011)

Commission proposal 10 September 2014

Online Public Consultation Report

Targeted consultations

Roadmap

2009
Commission’s declaration (January 2009)

Online Public Consultation (April-July 2010)

2011
Cascade Survey

2012
Stakeholders meeting (September 2011)

2013
Impact Assessment Board (final opinion September 2013)

2014
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
Rewarding innovation

- The level of protection of expanding the product to additional species is linked to the initial marketing authorisation and earlier extensions (Global Marketing Authorisation concept)

- 10, 14 and 18 years for initial MA of major species, minor species and bees

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

- Bees and fish
- Extension food-producing species
Better rewarding innovation

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

- Clear scope
- New definitions
- Rules on approval process of clinical trials
- Streamlined procedures
- Union data bases
Administrative burden

- Renewing a MA: EUR 70m p.a.
- Packaging & labelling: EUR 184m p.a.
- Pharmacovigilance: EUR 59m p.a.
- Applying for a MA variation: EUR 134m p.a.

EUR 538m p.a. (13% of sector’s annual turnover)
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

- rules on online sale of veterinary medicines
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 for your attention

Website

http://ec.europa.eu/health/veterinary-use/rev_frame_index_en.htm

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