Proposal for a Regulation on veterinary medicinal products

Revision of the legislation on veterinary medicinal products

Ariane Van Der Stappen, European Commission, Directorate Health and Consumers, Unit D6 Medicinal products - quality, safety and efficacy

Workshop Monograph system

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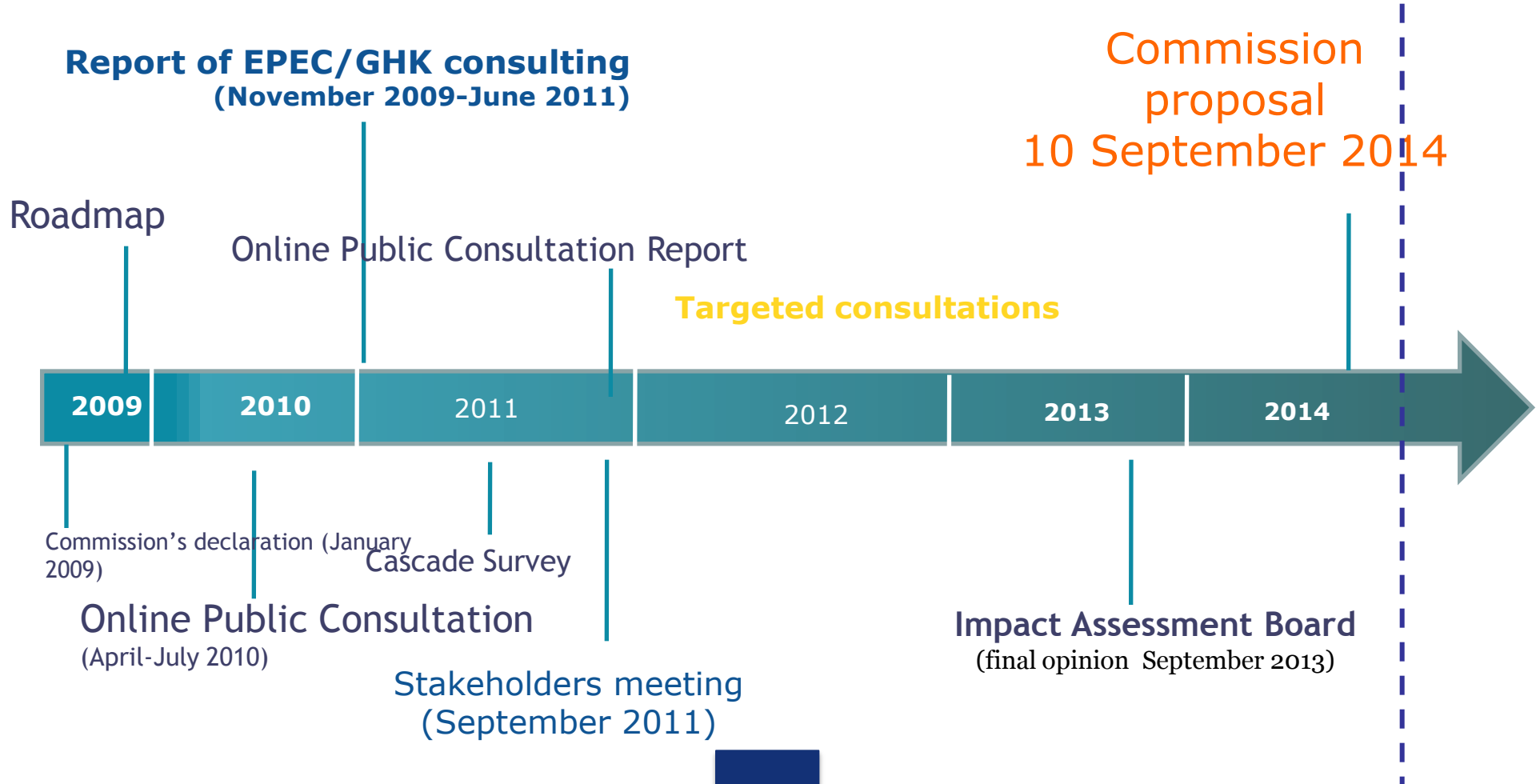
Background

- 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
Roadmap
Online Public Consultation Report
Targeted consultations
2009
2010
2011
2012
2013
2014
Commission's declaration (January 2009)
Online Public Consultation
(April-July 2010)
Cascade Survey
Stakeholders meeting
(September 2011)
Impact Assessment Board
(final opinion September 2013)

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 of the veterinary medicines legislation

✓ **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

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

✓ **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

Revision's objectives

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

- rules on online sale of veterinary medicines
- rules on approval process of clinical trials

Harmonisation of nationally authorised products

Dual approach

- Administrative procedure for low-risk products
- Scientific re-assessment for non low-risk products

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

Antimicrobial resistance measures

- Promoting prudent use
- Providing legal tool for preserving critical antimicrobials for the treatment of human infections
- Providing legal tool for restricting the off-label use of antimicrobials
- Establishing an effective and harmonised monitoring system of veterinary antimicrobials

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

***E-mail**: Sanco-pharmaceuticals-d6@ec.europa.eu*