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Review of veterinary medicines legislation

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Key initiatives of the last four years

- New Regulation on Maximum Residue Limits (R. 470/2009)
- New Annex I (D. 2009/9/EC)
- New Variations Regulation (R. 1234/2008) and Directive (D. 2009/53/EC)

However, criticism persists

- Limited availability of medicines
- Lack of innovation
- High administrative burden
- Limited benefits of the Common Market

Mandate, declaration by the Commission in the context of co-decision procedure on MRLs

"The Commission is aware of concerns expressed by citizens, veterinarians, Member States and the animal health industry…, the Commission will present in 2010 an assessment of the problems in the application of the veterinary medicinal products directive with a view to making, where appropriate, legal proposals".

I. Questions brought up by interested parties

1. Are the relevant differences between the human and veterinary sector adequately reflected in legislation?
2. Is there a need to develop mechanisms that address the specific needs and characteristics of the veterinary sector?
3. Would there be a risk that such mechanisms influence the legal environment for human medicinal products?

II. Questions brought up by interested parties

4. What would the possibilities to provide incentives, in particular for small markets (geographical area covered by authorised products, minor species, minor uses), for

   - the development of new veterinary medicinal products

   - the scope of existing medicinal products to be extended?

III. Questions brought up by interested parties

5. Is it required to have a better framework for the treatment of animals in the absence of authorised products?
6. Can the legal framework reply adequately to new veterinary medical needs?

IV. Questions brought up by interested parties

7. What would be the impact of simplifying, harmonizing and/or streamlining marketing authorisation procedures for medicines?
8. What would be the potential of simplifying the data requirements for authorisation, for pharmacovigilance, for packaging and labelling, and for the distribution chain?

Process

1. In 2010 Impact Assessment
2. Subsequently, where appropriate, legal proposals

Key analytical steps in Impact Assessment

- Defining the scope
- Identifying the problems
- Define the objectives
- Develop main policy options
- Analyse the impacts of the options (Standard Cost Model)
- Compare the options

General objectives

- To increase availability of veterinary medicinal products
- To improve functioning of the internal market
- To decrease administrative burden

...while not compromising public and animal health!

Public consultation

- **Not** necessarily to outline possible detailed legal amendments
- Basis for discussion on key items where possible improvements of the legislative framework have been identified

Next steps

- Defining problems, objectives and main options
- Contractant will start to collect data for the review from the beginning of 2010
- Launching public consultation document