Veterinary and Phytosanitary Regulations Division (VPRD)

Presentation about the Revision of the EU legislation on Veterinary Medicinal Products

Veterinary Medicines Section

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Introduction

Current Legal framework on veterinary medicines (Directive 2001/82/EC). Will be replaced by a REGULATION

•It does not cover finished medicated feed or feed additives

•Extensive analysis of a complex piece of legislation affecting a variety of stakeholders

• It will have a direct effect on the National Legislation

Stakeholders:

- Veterinary pharmaceutical industry
- Veterinary surgeons
- National competent authorities
- Wholesale dealers
- Retailers of veterinary medicines
- Farmers, pet owners
- SMEs

Clear message from stakeholders: a call for change
Concerns:

- Lack of veterinary medicines
- Deficient operation of the internal market
- High administrative burdens
- Problems specific to small Markets (Malta small, small animal population but increasing demands)

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

- Risks to animal health and welfare
- Risks to public health
- Economic consequences to farming
- Legal implications on use of Cascade

Problem drivers

- Multi-species market
- Pluri-national markets
- Complex authorisation requirements
- Complex post authorisation requirements
- Legislation not suited to innovation
- Lack of clarity of the legislation
- One size fits all
- Language problems (on packs)

Regarding Multi-species market

- Expand market beyond top four animal species
- Use of the Cascade
- Information on authorisation of VMPs
- Simplification of data requirements for limited markets
- Data protection incentives

Regarding Pluri-national markets

- Simplify procedures for authorisation in multiple national markets. (Malta may not even be considered as a ‘separate market’ from the point of view of MAH)
- Revision of authorisation procedures
- Tackling the issue of legacy products

Regarding Complex post authorisation requirements

Simplification of:

- Pharmacovigilance (PSUR)
- Variations
- Sunset clause
- Renewals

But more obligations for signal detection of ADR and reporting

Regarding Lack of clarity in legislation

Improve clarity on:

- Internet retailing of veterinary medicines
- Rules for novel treatments
- National controls (Malta will step up controls)
- Application requirements for VMPs for limited markets

Preferred options package

- Improve Cascade
- Improve EU database of VMP
- Reduced data requirements for limited markets
- Reduced data requirements for medicines for bees
- Wider scope of centralised procedure

- Simpler packaging and labelling (pictograms)

- Review of legacy VMPs

- Generic applications may refer to environmental risk assessment data

- Harmonisation of clinical trials

- Risk-based pharmacovigilance (triggered reporting not periodic)

Important Provisions

- Harmonisation of controls on distribution chain (including inspections and control measures)
- Name of Licensed wholesalers/pharmacies put in a Data base
- Measures to allow restrictions on authorisation and use of antimicrobials
- Measures regarding advertising
- Compulsory collection of data on the use of antimicrobials
- Harmonisation of the veterinary prescription and recognition throughout the Union
- Internet sale

Important Provisions

- Regulation 7 will be retained.
- Flexibility of languages (depends on MS)
- More control on the use of AM on farms due to AMR issues. (economic incentives may be scrutinised)
- Rules covering retail pharmacies/dispensing clinics are applied by the individual MS
- Pricing issues may be considered.

THANK YOU