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Lead committee: ENVI **Opinion committee: AGRI**

REGULATION ON VETERINARY MEDICINES
TOP PRIORITIES

Common goal:

Improved availability of authorised veterinary medicinal products. Main objectives for industry and all other stakeholders (including the European Commission):

- Stimulate innovation – improved data protection for technical data
- Improve the functioning of the internal market for all veterinary medicines
- Reduce administrative burden with an efficient regulatory system

To get there we need:

- A **Regulation** (to replace the Directive) - and separate legislation from human medicines
- **Simplification of procedures**: simplified marketing authorisation (**MA**) procedure for all products; plus simplified management of variations, pharmacovigilance and labelling
- **Single EU decisions**: improved internal market, consistency in decisions, EU-wide availability of products (need an EU MA), remove unnecessary administration
- **Improved data protection:** adapt to small size of veterinary market and multiple species

Top priorities – support, amend or reject Commission Proposals

1. Stimulate and protect innovation (articles 33-36) **for all significant investments and for all species** (**amendments needed**): without protection of technical documentation there is no investment. We need protection for all innovations, including for significant data packages submitted to bring improvements to existing products (e.g. new formulations; new dosing regimen).

2. Improved internal market for existing products (articles 68-71): **support the principle** of harmonisation of product summaries ("SmPCs") of existing products – *but for identical products only*; **reject** harmonisation by class of products (involving multiple companies). **Reject** restrictive qualification criteria. **Amend** to allow the process to result in an EU marketing authorisation.

3. Reduced administrative burden: support and defend the reduced administrative burden and risk-based approach in the chapters on **pharmacovigilance** and **variations** (but amendments to the details); also **support E-submissions** (art. 6.3) and removal of MA **renewals** (art. 5.2).

4. Improved procedures and internal market for new products:

- **Support** the opening up of the centralised procedure to all products (art. 38);
- **Support** simple majority voting at CMDv[1] and **amend** to result in an EU MA (art. 49.3).

5. **Labelling & package leaflet** (art. 9-15) are simplified (**support**), more flexibility for languages and the use of pictograms and abbreviations (**support**), but is also overly- restrictive (**amend**).

6. **Antibiotics**: (a) safeguard science-based product evaluation and responsible use of antibiotics in line with EMA's[2] recommendation; (b) stimulate innovation and development of antibiotics; and (c) support collection of sales data.

7. Other: **amend** (art. 115-116) to re-introduce the prescribing decision tree for 'off-label' use (the "cascade") to give priority to medicines authorised for veterinary use, where these are available.

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[1] CMDv – Coordination Group for Mutual Recognition and Decentralised Procedures – Veterinary
[2] EMA – European Medicines Agency