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

REGULATION ON VETERINARY MEDICINES

TOPIC: ANTIBIOTICS

What is the issue?

The availability of antibiotics for veterinary use is important for animal health and welfare, farmers' livelihoods, sustainable agriculture, food safety and public health. There are severe challenges to:

- continued availability to the veterinary sector of an adequate range of antibiotics;
- continued research into the development of new antibiotics for the veterinary sector;
- continued or further development of existing veterinary antibiotics.

The COM proposal covers the legal framework for the development and registration of veterinary medicines, including antibiotics, but fails to adequately address the issues.

Continued availability to veterinary antibiotics

The challenges come from:

- The potential for development of antibiotic resistance.
- Reserved-use lists for human medicine, preventing veterinary use of certain products.
- The lack of protection of technical documentation if a company is required to make major investments in the re-development of an existing product (e.g. to modify dosing regimes).

Continued research into the development of new antibiotics

Companies face challenges making decisions for major investments (€millions over a 5 to 10 year research programme) in research into new antibiotics for veterinary medicine under the conditions created by the combination of:

- **Increased product development costs** - additional data requirements introduced
- **No market predictability** – an antibiotic can be reserved for human use only at any time;
- **Additional restrictions on the use** of veterinary antibiotics reduces the market size.
- **Increased maintenance costs** – new post-authorisation studies to monitor resistance development.

What is needed?

- **Science-based regulation**: The Regulation should reflect the recommendations reached by the European Medicine Agency's Antimicrobials Expert Group when considering restrictions on use and reserved lists.
- **Stimulate research** and innovation in the development of new veterinary antibiotics by providing an extended period to protection of the technical documentation necessary for the registration of the product.
- **Protect new data** so that companies can continue to support existing antibiotic products and make some of the "older antibiotics" not often use in human medicine available in more convenient forms for use in animals.
- **Fair competition** - same post authorisation requirements (e.g. resistance monitoring) for all Marketing Authorisation Holders of products with the same active ingredient.

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