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

REGULATION ON VETERINARY MEDICINES

TOPIC: ADMINISTRATIVE BURDEN

What is the issue?

The administrative burden on companies researching, developing and marketing veterinary medicinal products has been estimated at 13% of the sector's turnover (see the EC's Impact Assessment Report page 12-15). This is **DOUBLE** that of the human medicines sector.

As described in the Impact Assessment, of particular concern "are the disproportionate costs of 'mandatory defensive research' for keeping a medicine on the market". These are the result of regulatory requirements for licence renewals, licence variations, pharmacovigilance and requests for new data from the authorities. This is estimated to be 35% of average research budgets and is twice that estimated for the USA.

Studies show that increasing administrative burden for veterinary medicines reduced the number of new product launches by 20% (IFAH Benchmarking Survey 2011).

What is administrative burden? What are the main causes?

The costs a company incurs complying with legislation, excluding the costs the company would incur in the normal course of its business. It also excludes the cost of generating the data on safety, efficacy and quality required for registration. The cost includes:

- The procedures for obtaining (a) a marketing authorisation (**MA**), (b) a variation to a MA, and (c) an MA renewal after 5 years.
- Compliance with labelling requirements
- Compliance with in-market pharmacovigilance obligations

Why is it so high?

- 90% of marketing authorisations for veterinary medicinal products are national licences (from the national, decentralised, and mutual recognition procedures).
- For every 'variation procedure' the cost and work involved is multiplied by the number of member states where the product is licensed; likewise for every other regulatory activity.
- Tasks are duplicated and repeated by the member states, even though the standards and procedures are harmonised at EU level.
- The mutual recognition and decentralised procedures are resource intensive due to the multiple member states involved and several national decision and administrative steps.
- Different interpretation between member states multiples the administrative burden.
- Rules for human medicines are inappropriately transferred to the veterinary sector.
- Turnover in the veterinary sector is limited by small size, wide range of species, cost constraints from pet owners or farmers and the need for extra data that has to be provided to address user, consumer and environmental safety.

What is the solution?

- The veterinary sector is small, so all administrative tasks and regulatory procedures need to be highly efficient and simplified to the greatest extent possible.
- Avoid duplication of tasks by member states; it is better to share tasks between the member states (e.g. true mutual recognition can be achieved by simple majority voting).
- Eliminate unnecessary tasks and procedures, such as the need for MA renewals; the pharmacovigilance system can be streamlined to minimise administrative burden.

PLEASE SUPPORT – see box overleaf

PLEASE SUPPORT in principle
(some amendments will be necessary to the details)

- Deletion of the 5 year renewal (article 5.2)
- More straight forward labelling provisions, including use of pictograms (articles 9 to 15)
- Simple majority voting to bring a decentralised procedure to a close (article 49.3)
- Simplified procedure for extending a product to other member states (article 57)
- A single EU product database (article 51)
- A simplified process for minor modifications (variations procedure) to the marketing authorisation (articles 58 to 67)
- Risk-based pharmacovigilance system (articles 72 to 81), resulting in decreased administrative burden

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IFAH-Europe (International Federation for Animal Health Europe) represents manufacturers of veterinary medicines, vaccines and other animal health products in Europe. It represents both corporate members and national animal health associations in Europe, comprise both local and international companies, and covers 90% of the European market.

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