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

REGULATION ON VETERINARY MEDICINES

TOPIC: PHARMACOVIGILANCE

What is the issue?

This is the fastest growing area for increased administrative burden in the veterinary sector.

Pharmacovigilance is the system for monitoring the safety of medicines in the market. Any adverse events should be reported, collected in a database and analysed for trends. If necessary measures can be taken to address any apparent safety issues.

The pharmacovigilance system for veterinary medicines needs to be proportionate and adapted to the resources and the risks that are characteristic of the sector. To avoid unnecessary administrative burden, the system needs to be focussed towards any likely risks – a risk-based system. Modern information technology tools and software need to be harnessed to make the system efficient, effective and "E-telligent".

What is proposed?

A system is proposed that addresses the issues described above, including:

- a single European database for pharmacovigilance data;
  - *this is essential to pool data and increase the power of signal detection;*
- a pharmacovigilance system master file approach to avoid useless duplication of work;
  - *this is essential to reduce unnecessary administrative burden;*
- removal of systematic periodic safety update reports (PSURs) for all products (currently PSURs must be generated even if there have been no adverse reactions reported);
  - *for greater efficiency a risk-based approach is proposed where product safety surveillance and reporting can be focussed where it is needed – i.e. on products with known or potentially higher risks (e.g. products entering the market for the first time);*
- more focus on signal detection to trigger a report or action (i.e. the risk-based approach);
  - *these reports will replace the routine periodic safety update reports;*
- and clear identification of the responsibilities of each party.

What needs to be done?

Support the approach taken by the European Commission for a risk-based approach.

Support amendments bringing clarity to some of the wording.

Reject amendments seeking to re-introduce PSURs and other administrative tasks that are counter to the objective of reducing the administrative burden.

For more information contact Rick Clayton, Technical Director, IFAH-Europe
Tel.: +32 (0)2 543 75 69, email: r.clayton@ifahsec.org