30 November 2012
EMA/MB/732279/2012 Rev.1

EudraVigilance Report 2012 – Veterinary medicinal products

Management Board meeting 13 December 2012

Background note

The Board is provided at Annex 1 with a progress report regarding the implementation of pharmacovigilance surveillance procedures and systems for centrally authorised veterinary medicinal products.

The periodic update report on the development of EudraVigilance Veterinary 3 is not provided to the Board on this occasion due to the work ongoing within the Agency to align the strategy for development of EVVet 3 with the revised ICT Strategy for the Agency, particularly with respect to harmonised data structures for veterinary medicinal products and substances. This document will be presented to the Board in early 2013 once the revised strategy has been developed.

Matters for consideration

Pharmacovigilance surveillance of veterinary centrally authorised products is based on a risk based approach where rapporteurs and their experts perform signal detection by remotely accessing specific data warehouse queries. One year's experience of this new process shows great promise to further reduce the administrative burden and at the same time allow the CVMP to focus on significant findings (see Annex 1). The Agency also has managed to 'recode' the majority of data related to non-centrally authorised products for those Member States having submitted their product data via Eudrapharm (i.e. assign in a reliable way reports to products in the database). This enables those Member States to have the opportunity to use the signal detection queries developed and approved by CVMP for their nationally authorised products which some Member States are starting to use.

These developments have started to deliver one of the key benefits of centralising pharmacovigilance, namely to reduce the administrative burden for authorities as well as industry while allowing the identification of relevant risk-based findings. The further development of this objective remains one of the key topics of the ongoing discussions regarding changes to the veterinary pharmacovigilance legislative requirements.

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ANNEX 1: Veterinary pharmacovigilance surveillance systems and developments

The risk-based surveillance for centrally authorised products was implemented by the CVMP in August 2011 and uses 3 systems:

1. EVVET2: The current EudraVigilance system to collect all adverse events for all authorised EU VMPs.
2. the EudraVigilance DataWareHouse: containing specific signal detection queries
3. the VPhS database: a Filemaker database developed by the Veterinary Unit to allow for the collection of the analysis findings.

Table 1: Routine surveillance intervals	
3-monthly	For products up to 2 years following initial placing on the market or following authorisation of e.g. a significant new indication, addition of a new target species or sub-group/age-group etc., as recommended by CVMP
6-monthly	For the next 2 years
Yearly	Thereafter

Key properties of the risk-based signal detection process:

- Easy online access to perform the analysis as well as record the findings.
- Signal detection on all data available for a particular product and relative to the full EVVET dataset, so not only e.g. data from the latest PSUR or surveillance period are considered but all cumulative data.
- Prioritisation and in depth analysis only for events considered most important. Only relevant matters should reach CVMP for discussion.

Following the agreed surveillance scheduling for all veterinary centrally authorised products, during each month an average of 22 products undergo signal detection resulting in the following outcome:

Table 2: Signal detection outcomes	
No potential signals identified or signal not confirmed	41%
No immediate action – to be monitored in the next period.	22%
Signal detected for discussion at PhVWP-V	4%
No adverse event data available	33%

Signals detected that have led to discussions on the need for regulatory action:

- laryngeal irritation in human
- neurological disorders and hepatic disorders in dogs
- meningitis-like clinical signs in pigs
- seizures in dogs
- death following shock and anaphylactic reaction in pigs

Interim conclusions of the surveillance procedure for centrally authorised products

The feedback from the experts on the overall functioning of the systems and the signal detection approach has been positive.

The process ensures that all available data are considered but at the same time allows to prioritise and to assess the data from a risk-based approach. Critical and new to the process is that it allows easily recording and storing of the analysis outcome for each product.

A PhVWP-V subgroup on signal detection is further expanding on the recommendations for signal detection and signal management.

The surveillance process needs to be further synchronised with the PSUR cycle and in relation to the revision of legislation. Further consideration is required as to how to prevent duplication between these two procedures to optimise public and animal health protection with the least administrative burden.