Reporting of adverse reactions

Act on pharmaceuticals defines that marketing authorisation holder is obliged to record and within 15 days after receipt to report to ÚSKVBL any cases of adverse reactions (including suspicion) or adverse reactions which happened in connection with veterinary medicinal product to human beings and which happened in the teritorry of the Czech Republic. The MAH is also obliged to report within 15 days to ÚSKVBL any suspicion of unexpected adverse reactions or adverse reactions which happened to human beings or any suspicion of infectious disease agent transfer by veterinary medicinal products in the third countries. These information are reported electronically in accordance with guidelines published by the European Commission or EMEA.

All above mentioned types of adverse reactions together with all relevant information are also reported by MAH in PSU reports.

Bulletin on activities in the area of veterinary pharmacovigilance in the European Union

Working group of Standing Committee for veterinary medicinal products deals also with veterianry pharmacovigilance and issues since 2003 annually Bulkletin on activities in the area of veterinary pharmacovigilance in the EU. This Bulletin is one of several ways of communication with MAH and also with veterinarians and other professionals used by the EMEA.

Bulletins for 2003 - 2008 are publicly available at the EMEA address: http://www.emea.europa.eu/htms/vet/phvwp/bulletins.htm

We would appreciate if you can send to address brychta@uskvbl.cz any comments to current structure or content ot the Bulletin.