Reporting of adverse reactions

Breeders

The breeder of animals is not obliged to report to ÚSKVBL or MA holder the adverse reactions occurred in his animals, but ÚSKVBL welcome the reporting of these events using template Form for breeders for reporting of adverse reaction suspicion.

It is common practice that breeder consults his veterinarian in case of adverse raction who evaluates situation and decides on further treatment. the veterinarian is then obliged to report adverse reaction to MA holder and/or ÚSKVBL.

Veterinarians

According Section 94 (1) of Act on pharmaceuticals the veterinarian is obliged without delay to report to MA holder and/or ÚSKVBL an occurence of serious adverse reaction, unexpected adverse reaction or adverse reaction linked to human being in connection with veterinary medicinal product even in off-label use, misuse or wrong use.

To report adverse reaction the veterinarian should use template EU Form for veterinarians to report adverse reactions of veterinary medicinal products. In case of serious violation of obligations by veterinarian - the ÚSKVBL can suspend the veterinarian´s right to prescribe, dispense or use veterinary medicinal products during veterinary care. The ÚSKVBL hands over such decision to Czech veterinary Chamber for further proceeding.

In case of autogenous vaccines, according Section 72, § 5 letter b) of Act on pharmaceuticals the veterinarian is obliged to report within 15 days as the latest to the manufacturer of autogenous vaccine any suspicion of adverse reaction linked to the use of this autogenous vaccine.

Bulletin on veterinary pharmacovigilance activities within 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

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any comments to current structure or content ot the Bulletin.