Holders of approval of veterinary preparation

Holders of approval are obliged according Section 66a (1) of Act No. 166/1999 Coll., on veterinary care in case of adverse reaction or in case of quality defect to implement all necessary measures to reduce negative impact of veterinary preparation to minimum, including possible recall from the market. Holder of approval is also obliged to report within 15 days to ÚSKVBL occurence of serious adverse reaction and inform about adopted measures.

Manufacturers of veterinary preparations

A manufacturer is obliged according to Section 66a (2) of Act No. 166/1999 Coll., on veterinary care, to inform holder of approval about all important facts concerning quality and safety and cooperate with aprooval holder in fulfilment of obligations defined in Act on veterinary care.

Persons placing veterinary preparations to the market or handling with them

These persons are obliged according to Section 66a (3) of Act No. 166/1999 Coll., on veterinary careto report within 15 days to ÚSKVBL and holder of approval an occurence of serious adverse reaction.

Above mentioned persons should use according to Section 9 (2) of Decree No. 290/2003 Coll. the reporting template available in section Forms for download.