**Manufacturer of veterinary medicinal products (except of autogenous vaccines)**
A manufacturer is obliged accroding to Section 23 (1) of Act on pharmaceuticals in case of adverse reaction occurence to evaluate the relevance and adopt relevant measures to eliminate negative impact of veterinary medicinal product as much as possible, including eventual recall of product from the market. A manufacturer is also obliged to report within 15 days to ÚSKVBL any suspicion of unexpected adverse reactions or adverse reactions which happened to human beings by using template "Form for manufacturers and wholesalers to report adverse reaction", which is available in part Forms for reporting of adverse reactions.

**Manufacturer of veterinary autogennous vaccines**
A manufacturer of VAV is obliged according to Section 72 (4) of Act on pharmaceuticals to report to ÚSKVBL within 30 days after receive such information any suspicion of adverse reaction linked to use of its autogenous vaccine. For reporting the template "Form for manufacturers and wholesalers to report adverse reaction" should be used.

**Wholesaler/distributor of veterinary medicinal products**
A wholesaler is obliged according to Section 23 (1) of Act on pharmaceuticals in case of adverse reaction occurence to evaluate the relevance and adopt relevant measures to eliminate negative impact of veterinary medicinal product as much as possible, including eventual recall of product from the market in cooperation with manufacturer and marketing authorisation holder. In case of suspicion of unexpected adverse reactions or adverse reactions which happened to human beings the wholesaler has to inform ÚSKVBL using template "Form for manufacturers and wholesalers to report adverse reaction", which is available in part Forms for reporting of adverse reactions

**Retail seller of certain veterinary medicinal products**
Retail seller is obliged according to Section 23 (1) of Act on pharmaceuticals in case of adverse reaction occurence to evaluate the relevance and adopt relevant measures to eliminate negative impact of veterinary medicinal product as much as possible. In case of suspicion of unexpected adverse reactions or adverse reactions which happened to human beings the retail seller has to inform ÚSKVBL using template "Form for retail seller to report adverse reaction", which is available in part Forms for reporting of adverse reactions.

**Clinical trial sponzor**
In accordance with Section 61 of Act on pharmaceuticals the clinical trial sponzor is obliged to inform ÚSKVBL about any new important information concerning tested product including

serious adverse reactions. In case serious unexpected adverse reaction, unexpected adverse reaction which lead to death or serious illness of testing animals the report has to be sent within 7 days, in other cases within 15 days. Details which have to be included in the report are defined in Section 30 of Decree No. 226/2008 Coll., on good clinical practice (at least site of clinical trial, name of sponzor, name of clinical trial, identification of affected animal(s) and description of adverse reaction, name of tested product including details about dose and application).

**Pharmaceutical companies responsible for post-authorisation studies**

The pharmaceutical  company has to assure that any serious adverse reaction reported to the company are within 15 days reported to ÚSKVBL. All non-serious events can be reported in final report or PSUR.