Pharmacovigilance Inspection of Medicinal Products for Veterinary Use

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Veterinary pharmacovigilance inspection

The main purpose of Pharmacovigilance Inspection of Medicinal Products for Veterinary Use is to verify how the marketing authorization holder of veterinary medicinal products meets the requirements of Polish and EU regulations in regards to monitoring the safety of medicinal products intended for veterinary use.

Grounds for inspection

The veterinary pharmacovigilance inspection is performed by inspectors from the Department of Medicinal Products Inspections according to the President's of the Office authorization. The inspectors are entitled to:

- inspect the market authorization holders' pharmacovigilance system
- request the market authorization holder to present documentation regarding pharmacovigilance
- request the market authorization holder to provide explanations regarding the assurance of functioning of the pharmacovigilance system

Veterinary pharmacovigilance inspection

Inspection process

The veterinary pharmacovigilance inspection includes:

- verification of documentation,
- conduction of interviews with personnel involved in the process (including the QPPV),
- checking data bases.

Inspection

A pharmacovigilance inspection begins with an opening meeting, during which the lead inspector introduces the inspection team and clarifies the objectives and scope of the inspection.

The inspection team will need a room for interviewing the relevant personnel and viewing system documentation.

On the last day of inspection a closing meeting takes place, during which the lead inspector summarizes the outcome of the inspection and presents his/hers observations. Moreover, the leader inspector discusses the process of preparing the protocol and the response of the inspectee to the post inspection recommendations.

What sort of information is expected from a Marketing Authorization Holder during an inspection?

During an inspection, the pharmacovigilance system documentation and all locations associated with the pharmacovigilance system will be verified.

The inspectee should prepare:

- a brief description of the pharmacovigilance system
- SOPs and work instructions
- information about individual serious adverse reactions
- periodic safety update reports (PSURs)
- risk management plans of veterinary medicinal products
- job descriptions, CVs and training history of personnel involved in pharmacovigilance

Inspection protocol

The results of the inspection are presented in a protocol, which is prepared within 30 days from the end of inspection and then immediately forwarded to the President of the Office for approval. An accepted protocol is send as an attachment to the cover letter of the President of the Office by registered post with acknowledgement of receipt.

Additionally, the inspectee may receive a password protected electronic version of the protocol in PDF format by e-mail.