

## DEFINITIONS

**Unexpected adverse reaction:** an adverse reaction, the nature, extent or outcome of which is not accordant with the Summary of Product Characteristics.

**Serious adverse reaction:** an adverse reaction which endangers the life of the animal, calls for a long-continued treatment, elongates the recovery or induces serious deformations, congenital deficiencies, birth defects or falls.

**Human adverse reaction:** an unintended, harmful effect observed on a person being in contact with the veterinary medicinal product.

**Periodic report about the re-examination of the safety of a veterinary medicinal product (periodic safety update report):** a regularly compiled evaluation of the Marketing Authorization Holder, which summarizes the adverse reactions attributable to the product and reported by the users.