Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (Text with EEA relevance)

CHAPTER IV

POST-MARKETING AUTHORISATION MEASURES

Section 5

Pharmacovigilance

Article 79

Pharmacovigilance responsibilities of the competent authorities and the Agency

1 Competent authorities shall lay down the necessary procedures to evaluate the results and outcomes of the signal management process recorded in the pharmacovigilance database in accordance with Article 81(2) as well as suspected adverse events reported to them, consider options for risk management and take any appropriate measures referred to in Articles 129, 130 and 134 concerning marketing authorisations.

2 Competent authorities may impose specific requirements on veterinarians and other healthcare professionals in respect of the reporting of suspected adverse events. The Agency may organise meetings or a network for groups of veterinarians or other healthcare professionals, where there is a specific need for collecting, collating or analysing specific pharmacovigilance data.

3 Competent authorities and the Agency shall make publicly available all important information on adverse events relating to the use of a veterinary medicinal product. It shall be done in a timely manner by any publicly available means of communication with a prior or simultaneous notification to the marketing authorisation holder.

4 Competent authorities shall verify, by means of controls and inspections referred to in Articles 123 and 126, that marketing authorisation holders comply with the requirements relating to pharmacovigilance laid down in this Section.

5 The Agency shall lay down the necessary procedures to evaluate suspected adverse events reported to it regarding centrally authorised veterinary medicinal products, and recommend risk management measures to the Commission. The Commission shall take any appropriate measures referred to in Articles 129, 130 and 134 concerning marketing authorisations.

6 The competent authority or the Agency, as applicable, may at any time request the marketing authorisation holder to submit a copy of the pharmacovigilance system master file. The marketing authorisation holder shall submit that copy at the latest within seven days of receipt of the request.

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2019/6 of the European Parliament and of the Council, Article 79.