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 VIII

INSPECTIONS AND CONTROLS

Article 126

Specific rules on pharmacovigilance inspections

1 The competent authorities and the Agency shall ensure that all pharmacovigilance system master files in the Union are regularly checked and that the pharmacovigilance systems are being correctly applied.

2 The Agency shall coordinate and the competent authorities shall carry out inspections on the pharmacovigilance systems of veterinary medicinal products authorised in accordance with Article 44.

3 The competent authorities shall carry out inspections on the pharmacovigilance systems of veterinary medicinal products authorised in accordance with Articles 47, 49, 52 and 53.

4 The competent authorities of the Member States in which the pharmacovigilance system master files are located shall carry out inspections of the pharmacovigilance systems master files.

5 Notwithstanding paragraph 4 of this Article and pursuant to Article 80, a competent authority may enter into any work-sharing initiatives and delegation of responsibilities with other competent authorities to avoid the duplication of inspections of pharmacovigilance systems.

6 The results of the pharmacovigilance inspections shall be recorded in the pharmacovigilance database as referred to in Article 74.

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 126.