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 125

Certificate of suitability

In order to verify whether the data submitted for obtaining a certificate of suitability complies with the monographs of the *European Pharmacopoeia*, the standardisation body for nomenclatures and quality norms within the meaning of the Convention on the elaboration of a *European Pharmacopoeia* accepted by Council Decision 94/358/EC[(1)] (European Directorate for the Quality of Medicines and Healthcare ('EDQM')) may ask the Commission or the Agency to request an inspection by a competent authority when the starting material concerned is subject to a *European Pharmacopoeia* monograph.

(**1**) Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).

Status:
Point in time view as at 11/12/2018.

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 125.