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 VI

MANUFACTURING, IMPORT AND EXPORT

Article 94

Certificates of good manufacturing practice

1 Within 90 days of an inspection, the competent authority shall issue a certificate of good manufacturing practice of the manufacturer for the manufacturing site concerned if the inspection establishes that the manufacturer in question is in compliance with the requirements laid down in this Regulation and with the implementing act referred to in Article 93(2).

2 If the outcome of the inspection referred to in paragraph 1 of this Article is that the manufacturer does not comply with good manufacturing practice, such information shall be entered into the manufacturing and wholesale distribution database referred to in Article 91.

3 The conclusions reached following an inspection of a manufacturer shall be valid throughout the Union.

4 A competent authority, the Commission or the Agency may require a manufacturer established in a third country to undergo an inspection as referred to in paragraph 1, without prejudice to any arrangements which may have been concluded between the Union and a third country.

5 Importers of veterinary medicinal products shall ensure, before those products are supplied to the Union, that the manufacturer established in a third country is in possession of a certificate of good manufacturing practice issued by a competent authority or, where the third country is party to an arrangement concluded between the Union and the third country, there is an equivalent confirmation.

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Point in time view as at 11/12/2018.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 94.