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 97

Qualified person responsible for manufacturing and batch release

1 The holder of a manufacturing authorisation shall have permanently at its disposal the services of at least one qualified person who fulfils the conditions laid down in this Article and is responsible, in particular, for carrying out the duties specified in this Article.

2 The qualified person referred to in paragraph 1 shall hold a university degree in one or more of the following scientific disciplines: pharmacy, human medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, or biology.

3 The qualified person referred to in paragraph 1 shall have acquired practical experience over at least two years, in one or more undertakings which are authorised manufacturers, in the activities of quality assurance of medicinal products, of qualitative analysis of medicinal products, of quantitative analysis of active substances and the checking necessary to ensure the quality of veterinary medicinal products.

The duration of practical experience required in the first subparagraph may be reduced by one year where a university course lasts for at least five years and by a year and a half where the university course lasts for at least six years.

4 The holder of the manufacturing authorisation, if a natural person, may assume the responsibility referred to in paragraph 1, if he or she personally fulfils the conditions referred to in paragraphs 2 and 3.

5 The competent authority may lay down appropriate administrative procedures to verify that a qualified person referred to in paragraph 1 fulfils the conditions referred to in paragraphs 2 and 3.

6 The qualified person referred to in paragraph 1 shall ensure that each batch of the veterinary medicinal products is manufactured in compliance with good manufacturing practice, and tested in compliance with the terms of the marketing authorisation. That qualified person shall draw up a control report to that effect. Such control reports shall be valid throughout the Union.

7 Where veterinary medicinal products are imported, the qualified person referred to in paragraph 1 shall ensure that each imported production batch has undergone in the Union a full qualitative and a quantitative analysis of at least all the active substances, and all the other tests necessary to ensure the quality of the veterinary medicinal products in accordance with the requirements of the marketing authorisation and that the batch manufactured is in compliance with good manufacturing practice.

8 The qualified person referred to in paragraph 1 shall keep records in respect of each released production batch. Those records shall be kept up to date as operations are carried out and shall remain at the disposal of the competent authority for one year after the date of expiry of the batch or at least five years from recording, whichever is longer.

9 Where veterinary medicinal products manufactured in the Union are exported and subsequently imported back into the Union from a third country, paragraph 6 shall apply.

10 Where veterinary medicinal products are imported from third countries with which the Union has made arrangements regarding application of standards of good manufacturing practice at least equivalent to those laid down in accordance with Article 93(2) and it is demonstrated that the tests referred to in paragraph 6 of this Article have been carried out in the exporting country, the qualified person may draw up the control report referred to in paragraph 6 of this Article without the necessary tests referred to in paragraph 7 of this Article being carried out, unless the competent authority of the Member State of importation decides otherwise.

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 97.