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 92

Changes to manufacturing authorisations on request

1 If the holder of a manufacturing authorisation requests a change in that manufacturing authorisation, the procedure for examining such a request shall not exceed 30 days from the day on which the competent authority receives the request. In justified cases, including when an inspection is necessary, that period of time may be extended by the competent authority to 90 days.

2 The request referred to in paragraph 1 shall contain a description of the requested change.

3 Within the period referred to in paragraph 1, the competent authority may require the holder of the manufacturing authorisation to provide supplementary information within a set time limit and may decide to perform an inspection. The procedure shall be suspended until such time as the supplementary information has been provided.

4 The competent authority shall assess the request referred to in paragraph 1, inform the holder of the manufacturing authorisation of the outcome of the assessment and, where appropriate, amend the manufacturing authorisation, and update, where appropriate, the manufacturing and wholesale distribution database.