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 90

Procedure for granting of manufacturing authorisations

1 Before granting a manufacturing authorisation, the competent authority shall carry out an inspection of the manufacturing site.

2 The competent authority may require the applicant to submit further information in addition to that supplied in the application pursuant to Article 89. Where the competent authority exercises that right, the time limit referred to in paragraph 4 of this Article shall be suspended or revoked until the applicant has submitted the additional data required.

3 A manufacturing authorisation shall apply only to the manufacturing site and the pharmaceutical forms specified in the application referred to in Article 89.

4 Member States shall lay down procedures for granting or refusing manufacturing authorisations. Such procedures shall not exceed 90 days from receipt by the competent authority of an application for manufacturing authorisation.

5 A manufacturing authorisation may be granted conditionally, subject to a requirement for the applicant to undertake actions or introduce specific procedures within a given time period. Where a manufacturing authorisation has been conditionally granted, it shall be suspended or revoked if the requirements are not complied with.