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 IV

POST-MARKETING AUTHORISATION MEASURES

Section 3

Changes to the terms of the marketing authorisations

Article 66

Procedure for variations requiring assessment

1 If an application for a variation fulfils the requirements laid down in Article 62, the competent authority, the Agency, the competent authority agreed in accordance with Article 65(3), or the competent authority in the reference Member State, as applicable, shall within 15 days acknowledge receipt of a valid application.

2 If the application is incomplete, the competent authority, the Agency, the competent authority agreed in accordance with Article 65(3), or the competent authority in the reference Member State, as applicable, shall require the marketing authorisation holder to provide the missing information and documentation within a reasonable time limit.

3 The competent authority, the Agency, the competent authority agreed in accordance with Article 65(3), or the competent authority in the reference Member State, as applicable, shall assess the application and prepare, respectively, an assessment report or an opinion, in accordance with Article 33, on the variation. That assessment report or opinion shall be prepared within 60 days following the receipt of a valid application. In case the assessment of an application requires more time due to its complexity, the relevant competent authority or the Agency, as applicable, may extend this period to 90 days. In such a case, the relevant competent authority or the Agency, as applicable, shall inform the marketing authorisation holder accordingly.

4 Within the period referred to in paragraph 3, the relevant competent authority or the Agency, as applicable, may require the marketing authorisation holder to provide supplementary information within a set time limit. The procedure shall be suspended until the supplementary information has been provided.

5 Where the opinion referred to in paragraph 3 is prepared by the Agency, the Agency shall forward it to the Commission and to the marketing authorisation holder.

6 Where the opinion referred to in paragraph 3 of this Article is prepared by the Agency in accordance with Article 65(2), the Agency shall forward it to all competent authorities in the relevant Member States, to the Commission and to the marketing authorisation holder.

7 Where the assessment report referred to in paragraph 3 of this Article is prepared by the competent authority agreed in accordance with Article 65(3), or prepared by the competent

authority in the reference Member State, it shall be forwarded to the competent authorities in all relevant Member States and to the marketing authorisation holder.

8 Where a competent authority does not agree with the assessment report referred to in paragraph 7 of this Article it received, the review procedure laid down in Article 54 shall apply.

9 Subject to the outcome of the procedure provided for in paragraph 8, if applicable, the opinion or the assessment report referred to in paragraph 3 shall be forwarded to the marketing authorisation holder without delay.

10 Within 15 days of receipt of the opinion or the assessment report, the marketing authorisation holder may submit a written request to the competent authority, the Agency, the competent authority agreed in accordance with Article 65(3), or the competent authority in the reference Member State, as applicable, for a re-examination of the opinion or the assessment report. Detailed grounds for requesting a re-examination shall be submitted to the competent authority, the Agency, the competent authority agreed in accordance with Article 65(3) or the competent authority in the reference Member State, as applicable, within 60 days of receipt of the opinion or the assessment report.

11 Within 60 days of receipt of the grounds for the request for re-examination, the competent authority, the Agency, the competent authority agreed in accordance with Article 65(3) or the competent authority in the reference Member State, as applicable, shall re-examine the points of the opinion or the assessment report identified in the request for re-examination by the marketing authorisation holder and adopt a re-examined opinion or assessment report. The reasons for the conclusions reached shall be annexed to the re-examined opinion or the assessment report.