

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 67*

**Measures to close the procedure for variations requiring assessment**

1 Within 30 days of the completion of the procedure laid down in Article 66 and of receiving the complete translations of the summary of the product characteristics, labelling and package leaflet from the marketing authorisation holder, the competent authority, the Commission or the competent authorities in the Member States listed in accordance with point (e) of Article 62(2), as applicable, shall amend the marketing authorisation or reject the variation in line with the opinion or the assessment report referred to in Article 66 and inform the marketing authorisation holder of the grounds for the rejection.

2 In the case of a centralised marketing authorisation, the Commission shall prepare a draft decision to be taken in respect of the variation. Where the draft decision is not in accordance with the opinion of the Agency, the Commission shall provide a detailed explanation of the reasons for not following the opinion of the Agency. The Commission shall, by means of implementing acts, adopt a decision to amend the marketing authorisation or reject the variation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

3 The competent authority or the Commission, as applicable, shall notify the marketing authorisation holder of the amended marketing authorisation without delay.

4 The competent authority, the Commission, the Agency, or the competent authorities in the Member States listed in accordance with point (e) of Article 62(2), as applicable, shall update the product database accordingly.