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 6

Union interest referral

Article 84

Decision following the Union interest referral

1 Within 15 days of receipt of the opinion referred to in Article 83(5), and subject to the procedures referred to in Article 83(6) and (7), the Commission shall prepare a draft decision. If the draft decision is not in accordance with the opinion of the Agency, the Commission shall also provide a detailed explanation of the reasons for the differences in an annex to that draft decision.

2 The Commission shall forward the draft decision to Member States.

3 The Commission shall, by means of implementing acts, take a decision on the Union interest referral. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2). Unless otherwise stated in the referral notification in accordance with Article 82, the decision of the Commission shall apply to the veterinary medicinal products concerned by the referral.

4 Where the veterinary medicinal products concerned by the referral have been authorised in accordance with the national, mutual recognition or decentralised procedures, the decision of the Commission referred to in paragraph 3 shall be addressed to all Member States and communicated for information to the marketing authorisation holders concerned.

5 Competent authorities and marketing authorisation holders concerned shall take any necessary action with regard to the marketing authorisations for the veterinary medicinal products concerned to comply with the decision of the Commission referred to in paragraph 3 of this Article within 30 days of its notification, unless a different period is laid down in that decision. Such action shall include, where appropriate, a request to the marketing authorisation holder to submit an application for a variation referred to in Article 62(1).

6 In the case of centrally authorised veterinary medicinal products concerned by the referral, the Commission shall send its decision referred to in paragraph 3 to the marketing authorisation holder and shall communicate it also to the Member States.

7 Nationally authorised veterinary medicinal products which have been subject to a referral procedure shall be transferred to a mutual recognition procedure.

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 84.