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 82

Scope of the Union interest referral

1 Where the interests of the Union are involved, and in particular the interests of public or animal health or of the environment related to the quality, safety or efficacy of veterinary medicinal products, the marketing authorisation holder, one or more of the competent authorities in one or more Member States or the Commission may refer its concern to the Agency for the application of the procedure laid down in Article 83. The matter of concern shall be clearly identified.

2 The marketing authorisation holder, the concerned competent authority or the Commission shall inform the other parties concerned accordingly.

3 The competent authorities in the Member States and marketing authorisation holders shall forward to the Agency on its request all available information relating to the Union interest referral.

4 The Agency may limit the Union interest referral to specific parts of the terms of the marketing authorisation.

Article 83

Union interest referral procedure

1 The Agency shall publish on its website information that a referral has been made in accordance with Article 82 and shall invite interested parties to provide comments.

2 The Agency shall request the Committee referred to in Article 139 to consider the referred matter. The Committee shall issue a reasoned opinion within 120 days of the matter being referred to it. That period may be extended by the Committee for a further period of up to 60 days, taking into account the views of the marketing authorisation holders concerned.

3 Before issuing its opinion, the Committee shall provide the marketing authorisation holders concerned with the opportunity to present explanations within a specified time limit. The Committee may suspend the time limit referred to in paragraph 2 to allow the marketing authorisation holders concerned to prepare the explanations.

4 In order to consider the matter, the Committee shall appoint one of its members to act as a rapporteur. The Committee may appoint independent experts to give advice on specific questions. When appointing such experts, the Committee shall define their tasks and specify the time limit for the completion of their tasks.

5 Within 15 days of its adoption by the Committee, the Agency shall forward the opinion of the Committee to the Member States, the Commission and the marketing authorisation holders concerned, together with an assessment report on one or more veterinary medicinal products and the reasons for its conclusions.

6 Within 15 days of receipt of the opinion of the Committee, the marketing authorisation holder may notify the Agency in writing of its intention to request a re-examination of that opinion. In that case, the marketing authorisation holder shall forward to the Agency the detailed reasons for the request of re-examination within 60 days of receipt of the opinion.

7 Within 60 days of receipt of a request as referred to in paragraph 6, the Committee shall re-examine its opinion. The reasons for the conclusion reached shall be annexed to the assessment report referred to in paragraph 5.

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, Section 6.