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 60

Variations

1 The Commission shall, by means of implementing acts, establish a list of variations not requiring assessment. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

2 The Commission shall take account of the following criteria when adopting the implementing acts referred to in paragraph 1:

a the need for a scientific assessment of changes in order to determine the risk to public or animal health or to the environment;

b whether changes have an impact on the quality, safety or efficacy of the veterinary medicinal product;

c whether changes imply no more than a minor alteration to the summary of product characteristics;

d whether changes are of an administrative nature.

Article 61

Variations that do not require assessment

1 Where a variation is included in the list established in accordance with Article 60(1), the marketing authorisation holder shall record the change including, as applicable, the summary of product characteristics, labelling or package leaflet in languages referred to in Article 7, in the product database within 30 days following the implementation of that variation.

2 If necessary, competent authorities or, where the veterinary medicinal product is authorised under the centralised marketing authorisation procedure, the Commission shall, by means of implementing acts, amend the marketing authorisation in accordance with the change recorded as referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

3 The competent authority of the reference Member State or, in the case of variation to the terms of a national marketing authorisation, the competent authority of the relevant Member State, or the Commission, as applicable, shall inform the marketing authorisation holder and the

competent authorities in the relevant Member States as to whether the variation is approved or rejected by recording that information in the product database.

Article 62

Application for variations requiring assessment

1 Where a variation is not included in the list established in accordance with Article 60(1), the marketing authorisation holder shall submit an application for a variation requiring assessment to the competent authority which has granted the marketing authorisation or to the Agency, as applicable. The applications shall be submitted electronically.

2 The application referred to in paragraph 1 shall contain:

a a description of the variation;

b data referred to in Article 8 relevant to the variation;

c details of the marketing authorisations affected by the application;

d where the variation leads to consequential variations to the terms of the same marketing authorisation, a description of those consequential variations;

e where the variation concerns marketing authorisations granted under the mutual recognition or decentralised procedures, a list of Member States which granted those marketing authorisations.

Article 63

Consequential changes to product information

Where a variation entails consequential changes to the summary of the product characteristics, the labelling or the package leaflet, those changes shall be considered as part of that variation for the purposes of the examination of the application for a variation.

Article 64

Groups of variations

When the marketing authorisation holder applies for several variations not included in the list established in accordance with Article 60(1) regarding the same marketing authorisation or for one variation not appearing in that list in respect of several different marketing authorisations, that marketing authorisation holder may submit one application for all variations.

Article 65

Work-sharing procedure

1 When the marketing authorisation holder applies for one or more variations which are identical in all relevant Member States and which do not appear in the list established in accordance with Article 60(1) regarding several marketing authorisations which are held by the same marketing authorisation holder and which have been granted by different competent authorities or the Commission, that marketing authorisation holder shall submit an identical

application to competent authorities in all relevant Member States and, where a variation to a centrally authorised veterinary medicinal product is included, to the Agency.

2 Where any of the marketing authorisations referred to in paragraph 1 of this Article is a centralised marketing authorisation, the Agency shall assess the application in accordance with the procedure laid down in Article 66.

3 Where none of the marketing authorisations referred to in paragraph 1 of this Article is a centralised marketing authorisation, the coordination group shall agree upon a competent authority among those having granted the marketing authorisations to assess the application in accordance with the procedure laid down in Article 66.

4 The Commission may, by means of implementing acts, adopt the necessary arrangements regarding the functioning of the worksharing procedure. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

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.

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.

Article 68

Implementation of variations requiring assessment

1 A marketing authorisation holder may implement a variation requiring assessment only after a competent authority or the Commission, as applicable, has amended the decision granting the marketing authorisation in accordance with that variation, has set a time limit for the implementation and has notified the marketing authorisation holder thereof in accordance with Article 67(3).

2 Where requested by a competent authority or the Commission, a marketing authorisation holder shall supply, without delay, any information related to the implementation of a variation.

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 3.