

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 4

Harmonisation of the summaries of product characteristics for nationally authorised products

Article 70

Procedure for harmonisation of summaries of product characteristics for the reference veterinary medicinal products

1 The competent authorities shall submit annually to the coordination group a list of reference veterinary medicinal products and their summary of product characteristics for which a marketing authorisation has been granted in accordance with Article 47 if, according to the competent authority, they should be subject to the procedure for harmonisation of their summaries of product characteristics.

2 The marketing authorisation holder may apply for the procedure of harmonisation of summaries of product characteristics for a reference veterinary medicinal product by submitting to the coordination group the list of different names of this veterinary medicinal product and the different summaries of product characteristics for which a marketing authorisation has been granted in accordance with Article 47 in different Member States.

3 The coordination group shall, taking into account the lists provided by the Member States in accordance with paragraph 1 or any application received from a marketing authorisation holder in accordance with paragraph 2, draw up annually and publish a list of reference veterinary medicinal products which shall be subject to harmonisation of their summaries of product characteristics and shall appoint a reference Member State for each reference veterinary medicinal product concerned.

4 When drawing up the list of reference veterinary medicinal products which shall be subject to harmonisation of their summaries of product characteristics, the coordination group may decide on prioritising its work on harmonisation of summaries of product characteristics, taking into account the recommendations of the Agency on class or group of reference veterinary medicinal products that shall be harmonised in order to protect human or animal health or the environment, including mitigation measures to prevent the risk to the environment.

5 On the request of the competent authority in the reference Member State referred to in paragraph 3 of this Article, the marketing authorisation holder shall provide the coordination group with a summary that specifies the differences between the summaries of product characteristics, its proposal for a harmonised summary of product characteristics, package leaflet and labelling in accordance with Article 7, supported by the appropriate existing data

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 70. (See end of Document for details)

submitted in accordance with Article 8 and which are relevant to the proposal for harmonisation concerned.

6 Within 180 days of receipt of the information referred to in paragraph 5, the competent authority in the reference Member State shall examine, in consultation with the marketing authorisation holder, the documents submitted in accordance with paragraph 5, prepare a report and submit it to the coordination group and to the marketing authorisation holder.

7 After receipt of the report, if the coordination group agrees by consensus on the harmonised summary of product characteristics, the competent authority in the reference Member State shall record that there is an agreement, close the procedure, inform the marketing authorisation holder accordingly and transmit to the same marketing authorisation holder the harmonised summary of product characteristics.

8 The marketing authorisation holder shall submit to the competent authorities in each relevant Member State the necessary translations of the summary of product characteristics, package leaflet and labelling in accordance with Article 7, within the time limit set by the coordination group.

9 Following an agreement in accordance with paragraph 7, the competent authorities in each relevant Member State shall amend the marketing authorisation in conformity with the agreement within 30 days of receipt of the translations referred to in paragraph 8.

10 The competent authority in the reference Member State shall take any appropriate steps in order to seek an agreement within the coordination group before the initiation of the procedure referred to in paragraph 11.

11 Where the agreement is not reached because of lack of consensus in favour of a harmonised summary of product characteristics following the efforts referred to in paragraph 10 of this Article, the procedure for a Union interest referral referred to in Articles 83 and 84 shall apply.

12 In order to maintain the level of harmonisation of the summary of product characteristics achieved, any future variation of the marketing authorisations concerned shall follow the mutual recognition procedure.

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