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 III

PROCEDURES FOR MARKETING AUTHORISATIONS

Section 1

Marketing authorisations valid throughout the Union ('centralised marketing authorisations')

Article 42

Scope of the centralised marketing authorisation procedure

1 Centralised marketing authorisations shall be valid throughout the Union.

2 Centralised marketing authorisation procedure shall apply in respect of the following veterinary medicinal products:

a veterinary medicinal products developed by means of one of the following biotechnological processes:

(i) recombinant DNA technology;

(ii) controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells;

(iii) hybridoma and monoclonal antibody methods;

b veterinary medicinal products intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals;

c veterinary medicinal products containing an active substance which has not been authorised as a veterinary medicinal product within the Union at the date of the submission of the application;

d biological veterinary medicinal products which contain or consist of engineered allogeneic tissues or cells;

e novel therapy veterinary medicinal products.

3 Points (d) and (e) of paragraph 2 shall not apply to veterinary medicinal products consisting exclusively of blood components.

4 For veterinary medicinal products other than those referred to in paragraph 2, a centralised marketing authorisation may be granted if no other marketing authorisation has been granted for the veterinary medicinal product within the Union.

Article 43

Application for centralised marketing authorisation

1 An application for a centralised marketing authorisation shall be submitted to the Agency. The application shall be accompanied by the fee payable to the Agency for the examination of the application.

2 The application for a centralised marketing authorisation of a veterinary medicinal product shall state a single name for the veterinary medicinal product to be used throughout the Union.

Article 44

Procedure for centralised marketing authorisation

1 The Agency shall assess the application referred to in Article 43. The Agency shall prepare, as an outcome of the assessment, an opinion containing the information referred to in Article 33.

2 The Agency shall issue the opinion referred to in paragraph 1 within 210 days of receipt of a valid application. Exceptionally, where a particular expertise is required, the time limit may be extended by a maximum of 90 days.

3 When an application is submitted for a marketing authorisation in respect of veterinary medicinal products of major interest, particularly from the point of view of animal health and therapeutic innovation, the applicant may request an accelerated assessment procedure. The request shall be duly substantiated. If the Agency accepts the request, the time limit of 210 days shall be reduced to 150 days.

4 The Agency shall forward the opinion to the applicant. Within 15 days of receipt of the opinion, the applicant may provide written notice to the Agency that he or she wishes to request a re-examination of the opinion. In such a case, Article 45 shall apply.

5 Where the applicant has not provided written notice in accordance with paragraph 4, the Agency shall, without undue delay, forward its opinion to the Commission.

6 The Commission may request clarifications from the Agency as regards the content of the opinion, in which case the Agency shall provide a response to this request within 90 days.

7 The applicant shall submit to the Agency 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 Agency, but at the latest on the date that the draft decision is forwarded to the competent authorities in accordance with paragraph 8 of this Article.

8 Within 15 days of receipt of the opinion of the Agency, the Commission shall prepare a draft decision to be taken in respect of the application. Where a draft decision envisages granting of a marketing authorisation, it shall include the opinion of the Agency prepared in accordance with paragraph 1. Where the draft decision is not in accordance with the opinion of the Agency, the Commission shall annex a detailed explanation of the reasons for the differences. The Commission shall forward the draft decision to the competent authorities of Member States and to the applicant.

9 The Commission shall, by means of implementing acts, take a decision to grant or refuse a centralised marketing authorisation in accordance with this Section and on the basis of the opinion of the Agency. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

10 The Agency shall make its opinion publicly available, after deleting any commercially confidential information.

Article 45

Re-examination of the opinion of the Agency

1 Where the applicant requests a re-examination of the opinion of the Agency in accordance with Article 44(4), that applicant shall forward to the Agency detailed grounds for such request within 60 days of receipt of the opinion.

2 Within 90 days of receipt of the detailed grounds for the request, the Agency shall re-examine its opinion. The conclusions reached and the reasons for those conclusions shall be annexed to its opinion and shall form an integral part thereof.

3 Within 15 days of the re-examination of its opinion, the Agency shall forward its opinion to the Commission and the applicant.

4 Subsequent to the procedure set out in paragraph 3 of this Article, Article 44(6) to (10) shall apply.

Section 2

Marketing authorisations valid in a single Member State ('national marketing authorisations')

Article 46

Scope of national marketing authorisation

1 An application for a national marketing authorisation shall be submitted to the competent authority in the Member State for which the authorisation is applied. The competent authority shall grant a national marketing authorisation in accordance with this Section and applicable national provisions. A national marketing authorisation shall be valid only in the Member State of the competent authority which granted it.

2 National marketing authorisations shall not be granted in respect of veterinary medicinal products which fall within the scope of Article 42(2), or for which a national marketing authorisation has been granted, or for which an application for a national marketing authorisation is pending in another Member State at the time of the application.

Article 47

Procedure for national marketing authorisation

1 The procedure for granting or refusing a national marketing authorisation for a veterinary medicinal product shall be completed within a maximum of 210 days of the submission of the valid application.

2 The competent authority shall prepare an assessment report containing the information referred to in Article 33.

3 The competent authority shall make the assessment report publicly available, after deleting any commercially confidential information.

Section 3

Marketing authorisations valid in several Member States ('decentralised marketing authorisations')

Article 48

Scope of decentralised marketing authorisation

1 Decentralised marketing authorisations shall be granted by the competent authorities in the Member States in which the applicant seeks to obtain a marketing authorisation ('Member States concerned') in accordance with this Section. Such decentralised marketing authorisations shall be valid in those Member States.

2 Decentralised marketing authorisations shall not be granted in respect of veterinary medicinal products for which a national marketing authorisation has been granted, or for which an application for a marketing authorisation is pending at the time of the application for a decentralised marketing authorisation, or which fall within the scope of Article 42(2).

Article 49

Procedure for decentralised marketing authorisation

1 An application for a decentralised marketing authorisation shall be submitted to the competent authority in the Member State chosen by the applicant to prepare an assessment report and to act in accordance with this Section ('reference Member State') and to the competent authorities in the other Member States concerned.

2 The application shall list the Member States concerned.

3 If the applicant indicates that one or more of the Member States concerned shall no longer be considered as such, the competent authorities in those Member States shall provide to the competent authority in the reference Member State and to the competent authorities in the other Member States concerned any information they consider relevant with respect to the withdrawal of the application.

4 Within 120 days of receipt of a valid application, the competent authority in the reference Member State shall prepare an assessment report containing the information referred to in Article 33 and shall forward it to the competent authorities in the Member States concerned and to the applicant.

5 Within 90 days of receipt of the assessment report referred to in paragraph 4, the competent authorities in the Member States concerned shall examine the report and inform the competent authority in the reference Member State whether they have any objections to it on the ground that the veterinary medicinal product would pose a potential serious risk to human or animal health or to the environment. The competent authority in the reference Member State shall forward the assessment report resulting from that examination to the competent authorities in the Member States concerned and to the applicant.

6 On the request of the competent authority in the reference Member State or the competent authority in any of the Member States concerned, the coordination group shall be convened to examine the assessment report within the period referred to in paragraph 5.

7 Where the assessment report is favourable and where no competent authority has informed the competent authority in the reference Member State of an objection thereto, as referred to in paragraph 5, the competent authority in the reference Member State shall record that there is an agreement, close the procedure and, without undue delay, inform the applicant and the competent authorities in all Member States accordingly. The competent authorities in the Member States concerned shall grant a marketing authorisation in conformity with the assessment report within 30 days of receipt of both the information on the agreement from the competent authority in the reference Member State and the complete translations of the summary of product characteristics, labelling and package leaflet from the applicant.

8 Where the assessment report is unfavourable and where none of the competent authorities in the Member States concerned has informed the competent authority in the reference Member State of an objection thereto, as set out in paragraph 5, the competent authority in the reference Member State shall record that there is a refusal to grant the marketing authorisation, close the procedure and, without undue delay, inform the applicant and the competent authorities in all Member States accordingly.

9 Where a competent authority in a Member State concerned informs the competent authority in the reference Member State of an objection to the assessment report in accordance with paragraph 5 of this Article, the procedure referred to in Article 54 shall apply.

10 If at any stage of the procedure for a decentralised marketing authorisation the competent authority in a Member State concerned invokes the reasons referred to in Article 110(1) for prohibiting the veterinary medicinal product, that Member State shall no longer be considered as a Member State concerned.

11 The competent authority in the reference Member State shall make the assessment report publicly available, after deleting any commercially confidential information.

Article 50

Request by the applicant for re-examination of the assessment report

1 Within 15 days of receipt of the assessment report referred to in Article 49(5), the applicant may provide written notice to the competent authority in the reference Member State requesting a re-examination of the assessment report. In that case, the applicant shall forward to the competent authority in the reference Member State detailed grounds for such a request within

60 days of receipt of that assessment report. The competent authority in the reference Member State shall without delay forward that request and the detailed grounds to the coordination group.

2 Within 60 days of receipt of the detailed grounds for the request for re-examination of the assessment report, the coordination group shall re-examine the assessment report. The conclusions reached by the coordination group and the reasons for those conclusions shall be annexed to the assessment report and shall form an integral part thereof.

3 Within 15 days of the re-examination of the assessment report, the competent authority in the reference Member State shall forward the assessment report to the applicant.

4 Subsequent to the procedure set out in paragraph 3 of this Article, Article 49(7), (8), (10) and (11) shall apply.

Section 4

Mutual recognition of national marketing authorisations

Article 51

Scope of mutual recognition of national marketing authorisations

A national marketing authorisation for a veterinary medicinal product, granted in accordance with Article 47, shall be recognised in other Member States in accordance with the procedure laid down in Article 52.

Article 52

Procedure for mutual recognition of national marketing authorisations

1 An application for mutual recognition of a national marketing authorisation shall be submitted to the competent authority in the Member State that granted the national marketing authorisation in accordance with Article 47 (‘reference Member State’) and to the competent authorities in the Member States where the applicant seeks to obtain a marketing authorisation (‘Member States concerned’).

2 The application for mutual recognition shall list the Member States concerned.

3 A minimum of six months shall elapse between the decision granting the national marketing authorisation and the submission of the application for mutual recognition of that national marketing authorisation.

4 If the applicant indicates that one or more of the Member States concerned shall no longer be considered as such, the competent authorities in those Member States shall provide to the competent authority in the reference Member State and to the competent authorities in the other Member States concerned any information they consider relevant with respect to the withdrawal of the application.

5 Within 90 days of receipt of a valid application for mutual recognition, the competent authority in the reference Member State shall prepare an updated assessment report containing the information referred to in Article 33 for the veterinary medicinal product and shall forward it to the competent authorities in the Member States concerned and to the applicant.

6 Within 90 days of receipt of the updated assessment report referred to in paragraph 5, the competent authorities in the Member States concerned shall examine it and inform the competent authority in the reference Member State of whether they have any objections to it on the ground that the veterinary medicinal product would pose a potential serious risk to human or animal health or to the environment. The competent authority in the reference Member State shall forward the assessment report resulting from that examination to the competent authorities in the Member States concerned and to the applicant.

7 On the request of the competent authority in the reference Member State or the competent authority in any of the Member States concerned, the coordination group shall be convened to examine the updated assessment report within the period referred to in paragraph 6.

8 Where no competent authority of any Member State concerned has informed the competent authority in the reference Member State of an objection to the updated assessment report, as referred to in paragraph 6, the competent authority in the reference Member State shall record that there is an agreement, close the procedure and, without undue delay, inform the applicant and the competent authorities in all Member States accordingly. The competent authorities in the Member States concerned shall grant a marketing authorisation in conformity with the updated assessment report within 30 days of receipt of both the information on the agreement from the competent authority in the reference Member State and the complete translations of the summary of product characteristics, labelling and package leaflet from the applicant.

9 Where a competent authority in a Member State concerned informs the competent authority in the reference Member State of an objection to the updated assessment report in accordance with paragraph 6 of this Article, the procedure referred to in Article 54 shall apply.

10 If at any stage of the procedure for mutual recognition the competent authority in a Member State concerned invokes the reasons referred to in Article 110(1) for prohibiting the veterinary medicinal product, that Member State shall no longer be considered as a Member State concerned.

11 The competent authority in the reference Member State shall make the assessment report publicly available, after deleting any commercially confidential information.

Section 5

Subsequent recognition in the mutual recognition and decentralised marketing authorisation procedures

Article 53

Subsequent recognition of marketing authorisations by additional Member States concerned

1 After completion of a decentralised procedure laid down in Article 49 or a mutual recognition procedure laid down in Article 52 granting a marketing authorisation, the marketing authorisation holder may submit an application for a marketing authorisation for the veterinary medicinal product to the competent authorities in additional Member States concerned and to the competent authority in the reference Member State referred to in Article 49 or 52, as applicable, in accordance with the procedure laid down in this Article. In addition to the data referred to in Article 8, the application shall include the following:

a a list of all decisions granting, suspending or revoking marketing authorisations which concern the veterinary medicinal product;

b information on the variations introduced since the grant of the marketing authorisation by decentralised procedure laid down in Article 49(7) or by mutual recognition procedure laid down in Article 52(8);

c a summary report on pharmacovigilance data.

2 The competent authority in the reference Member State referred to in Article 49 or 52, as applicable, shall forward within 60 days to the competent authorities in the additional Member States concerned the decision to grant the marketing authorisation and any variations thereto and shall, within that period, prepare and forward an updated assessment report concerning that marketing authorisation and those variations, as applicable, and inform the applicant accordingly.

3 The competent authority in each additional Member State concerned shall grant a marketing authorisation in conformity with the updated assessment report referred to in paragraph 2 within 60 days of receipt of both the data and information referred to in paragraph 1 and the complete translations of the summary of product characteristics, labelling and package leaflet.

4 By derogation from paragraph 3 of this Article, if the competent authority in an additional Member State concerned has reasons for refusing the marketing authorisation on the ground that the veterinary medicinal product would pose a potential serious risk to human or animal health or to the environment, it shall, at the latest within a period of 60 days of receipt of both the data and information referred to in paragraph 1 and updated assessment report referred to in paragraph 2 of this Article raise its objections and provide a detailed statement of the reasons to the competent authority in the reference Member State referred to in Article 49 or 52, as applicable, and to the competent authorities in the Member States concerned, referred to in those Articles, and to the applicant.

5 In the case of objections raised by the competent authority in an additional Member State concerned in accordance with paragraph 4, the competent authority in the reference Member State shall take any appropriate steps in order to seek an agreement as regards the objections made. The competent authorities in the reference Member State and in the additional Member State concerned shall make their best efforts to reach an agreement on the action to be taken.

6 The competent authority in the reference Member State shall provide the applicant with the opportunity to provide, orally or in writing, the applicant's point of view as regards the objections raised by the competent authority in an additional Member State concerned.

7 Where, following the steps taken by the competent authority in the reference Member State, an agreement is reached by the competent authorities in the reference Member State and in the Member States which have already granted a marketing authorisation and the competent authorities in the additional Member States concerned, the competent authorities in the additional Member States concerned shall grant a marketing authorisation in accordance with paragraph 3.

8 If the competent authority in the reference Member State has not been able to find an agreement with the competent authorities in the Member States concerned and additional Member States concerned at the latest within 60 days from the date on which the objections referred to in paragraph 4 of this Article were raised, it shall refer the application together with the updated assessment report referred to in paragraph 2 of this Article and the objections of the competent authorities in the additional Member States concerned to the coordination group in accordance with the review procedure laid down in Article 54.

Section 6

Review procedure

Article 54

Review procedure

1 If the competent authority in a Member State concerned raises, in accordance with Article 49(5), 52(6), 53(8) or 66(8) an objection as referred to in those Articles to, respectively, the assessment report or the updated assessment report, it shall provide without delay a detailed statement of the reasons for any such objection to the competent authority in the reference Member State, to the competent authorities in the Member States concerned and to the applicant or the marketing authorisation holder. The competent authority in the reference Member State shall refer the points of disagreement without delay to the coordination group.

2 The competent authority in the reference Member State shall take, within 90 days of receipt of the objection, any appropriate steps in order to seek an agreement as regards the objection raised.

3 The competent authority in the reference Member State shall provide the applicant or the marketing authorisation holder with the opportunity to provide, orally or in writing, their point of view as regards the objection raised.

4 Where an agreement among the competent authorities referred to in Articles 49(1), 52(1), 53(1) and 66(1) is reached, the competent authority in the reference Member State shall close the procedure and inform the applicant or the marketing authorisation holder. The competent authorities in the Member States concerned shall grant or vary a marketing authorisation.

5 When the competent authorities referred to in Articles 49(1), 52(1), 53(1) and 66(1) reach an agreement by consensus to refuse the marketing authorisation or to reject the variation, the competent authority in the reference Member State shall close the procedure and inform the applicant or the marketing authorisation holder thereof, duly justifying the refusal or the rejection. The competent authorities in the Member States concerned shall thereafter refuse the marketing authorisation or reject the variation.

6 If an agreement among the competent authorities referred to in Articles 49(1), 52(1), 53(1) and 66(1) cannot be reached by consensus, the coordination group shall provide the Commission with the assessment report referred to in Articles 49(5), 52(6), 53(2) and 66(3), respectively, together with information on the points of disagreement at the latest within a period of 90 days from the date on which the objection referred to in paragraph 1 of this Article was raised.

7 Within 30 days of receipt of the report and information referred to in paragraph 6, the Commission shall prepare a draft decision to be taken in respect of the application. The Commission shall forward the draft decision to the competent authorities and to the applicant or the marketing authorisation holder.

8 The Commission may request clarifications from the competent authorities or the Agency. The time limit laid down in paragraph 7 shall be suspended until the clarifications have been provided.

9 For the purpose of the work-sharing procedure in respect of variations requiring assessment in accordance with Article 66, references in this Article to a competent authority in

the reference Member State shall be understood as references to a competent authority agreed upon in accordance with Article 65(3), and references to Member States concerned as references to relevant Member States.

10 The Commission shall, by means of implementing acts, take a decision to grant, change, refuse or revoke a marketing authorisation or to reject a variation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

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, CHAPTER III.