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 X

REGULATORY NETWORK

Article 137

Competent authorities

1 Member States shall designate the competent authorities to carry out tasks under this Regulation.

2 Member States shall ensure that adequate financial resources are available to provide the staff and other resources necessary for the competent authorities to carry out the activities required by this Regulation.

3 The competent authorities shall cooperate with each other in the performance of their tasks under this Regulation and shall give the competent authorities of other Member States necessary and useful support to this end. Competent authorities shall communicate the appropriate information to each other.

4 On reasoned request, the competent authorities shall forthwith communicate the written records referred to in Article 123 and control reports referred to in Article 127 to the competent authorities of other Member States.

Article 138

Scientific opinion for international organisations for animal health

1 The Agency may give scientific opinions, in the context of cooperation with international organisations for animal health, for the evaluation of veterinary medicinal products intended exclusively for markets outside the Union. For that purpose, an application shall be submitted to the Agency in accordance with Article 8. The Agency may, after consulting the relevant organisation, draw up a scientific opinion.

2 The Agency shall establish specific procedural rules for the implementation of paragraph 1.

Article 139

Committee for Veterinary Medicinal Products

1 A Committee for Veterinary Medicinal Products (‘the Committee’) is hereby set up within the Agency.

2 The Executive Director of the Agency or his or her representative and representatives of the Commission shall be entitled to attend all meetings of the Committee, working parties and scientific advisory groups.

3 The Committee may establish standing and temporary working parties. The Committee may establish scientific advisory groups in connection with the evaluation of specific types of veterinary medicinal products, to which the Committee may delegate certain tasks associated with drawing up the scientific opinions referred to in point (b) of Article 141(1).

4 The Committee shall establish a standing working party with the sole remit of providing scientific advice to undertakings. The Executive Director, in consultation with the Committee shall set up the administrative structures and procedures allowing the development of advice for undertakings, as referred to in point (n) of Article 57(1) of Regulation (EC) No 726/2004, particularly regarding the development of novel therapy veterinary medicinal products.

5 The Committee shall establish a standing working party for pharmacovigilance with a remit including evaluating potential signals in pharmacovigilance arising from the Union pharmacovigilance system, proposing the options for risk management referred to in Article 79 to the Committee and to the coordination group, and coordinating the communication about pharmacovigilance between the competent authorities and the Agency.

6 The Committee shall establish its own rules of procedure. Those rules shall, in particular, lay down:

a procedures for appointing and replacing the Chair;

b the appointment of members of any working parties or scientific advisory groups on the basis of the lists of accredited experts referred to in the second subparagraph of Article 62(2) of Regulation (EC) No 726/2004 and procedures for consultation of working parties and scientific advisory groups;

c a procedure for urgent adoption of opinions, particularly in relation to the provisions of this Regulation on market surveillance and pharmacovigilance.

The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

7 The Secretariat of the Agency shall provide technical, scientific and administrative support for the Committee, and shall ensure consistency and quality of opinions of the Committee and appropriate coordination between the Committee and other committees of the Agency referred to in Article 56 of Regulation (EC) No 726/2004 and the coordination group.

8 The opinions of the Committee shall be publicly accessible.

Article 140

Members of the Committee

1 Each Member State shall, after consultation of the Management Board of the Agency, appoint for a three-year term which may be renewed, one member and an alternate member of the Committee. The alternates shall represent and vote for the members in their absence and may also be appointed to act as rapporteurs.

2 Members and alternates of the Committee shall be appointed on the basis of their relevant expertise and experience in the scientific assessment of veterinary medicinal products,

in order to guarantee the highest level of qualifications and a broad spectrum of relevant expertise.

3 A Member State may delegate its tasks within the Committee to another Member State. Each Member State may represent no more than one other Member State.

4 The Committee may co-opt a maximum of five additional members chosen on the basis of their specific scientific competence. Those members shall be appointed for a term of three years, which may be renewed, and shall not have alternates.

5 With a view to the co-opting of such members, the Committee shall identify the specific complementary scientific competence of the additional members. Co-opted members shall be chosen among experts nominated by Member States or the Agency.

6 The Committee may appoint, for the purpose of performing its tasks referred to in Article 141, one of its members to act as rapporteur. The Committee may also appoint a second member to act as a co-rapporteur.

7 The members of the Committee may be accompanied by experts in specific scientific or technical fields.

8 Members of the Committee and experts responsible for assessing veterinary medicinal products shall rely on the scientific evaluation and resources available to competent authorities. Each competent authority shall monitor and ensure the scientific level and independence of the evaluation carried out and provide appropriate contribution to the tasks of the Committee, and facilitate the activities of appointed Committee members and experts. To that end, Member States shall provide adequate scientific and technical resources to the members and experts they have nominated.

9 Member States shall refrain from giving Committee members and experts instructions incompatible with their own individual tasks, or with the tasks of the Committee and responsibilities of the Agency.

Article 141

Tasks of the Committee

1 The Committee shall have the following tasks:

a carry out the tasks conferred on it under this Regulation and Regulation (EC) No 726/2004;

b prepare scientific opinions of the Agency on questions relating to the evaluation and use of veterinary medicinal products;

c prepare opinions on scientific matters concerning the evaluation and use of veterinary medicinal products on the request of the Executive Director of the Agency or the Commission;

d prepare opinions of the Agency on questions concerning the admissibility of applications submitted in accordance with the centralised procedure, and on granting, varying, suspending or revoking marketing authorisations for centrally authorised veterinary medicinal products;

e take due account of any request made by Member States for scientific opinions;

f provide guidance on important questions and issues of general scientific nature;

g give a scientific opinion, in the context of cooperation with the World Organisation for Animal Health, concerning the evaluation of certain veterinary medicinal products intended exclusively for markets outside the Union;

h advise on the maximum limits for residues of veterinary medicinal products and biocidal products used in animal husbandry which may be accepted in foodstuffs of animal origin in accordance with Regulation (EC) No 470/2009;

i provide scientific advice on the use of antimicrobials and antiparasitics in animals in order to minimise the occurrence of resistance in the Union, and update that advice when needed;

j provide objective scientific opinions to the Member States on the questions which are referred to the Committee.

2 The members of the Committee shall ensure that there is appropriate coordination between the tasks of the Agency and the work of competent authorities.

3 When preparing opinions, the Committee shall use its best endeavours to reach a scientific consensus. If such consensus cannot be reached, the opinion shall consist of the position of the majority of members and divergent positions, with the grounds on which they are based.

4 If there is a request for re-examination of an opinion where this possibility is provided for in the Union law, the Committee shall appoint a different rapporteur and, where necessary, a different co-rapporteur from those appointed for the opinion. The re-examination procedure may deal only with the points of the opinion initially identified by the applicant and may be based only on the scientific data available when the Committee adopted the opinion. The applicant may request that the Committee consult a scientific advisory group in connection with the re-examination.

Article 142

Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products

1 The coordination group for mutual recognition and decentralised procedures for veterinary medicinal products (‘the coordination group’) shall be set up.

2 The Agency shall provide a secretariat for the coordination group to assist in the operations of the procedures of the coordination group and to ensure an appropriate liaison between this group, the Agency and competent authorities.

3 The coordination group shall draw up its rules of procedure, which shall enter into force after receiving a favourable opinion from the Commission. Those rules of procedure shall be made public.

4 The Executive Director of the Agency or his or her representative and representatives of the Commission shall be entitled to attend all meetings of the coordination group.

5 The coordination group shall cooperate closely with the competent authorities and the Agency.

Article 143

Members of the coordination group

1 The coordination group shall be composed of one representative per Member State appointed for a renewable period of three years. Member States may appoint an alternate representative. Members of the coordination group may arrange to be accompanied by experts.

2 Members of the coordination group and their experts shall rely on the scientific and regulatory resources available to their competent authorities, on the relevant scientific assessments and on the recommendations of the Committee for the fulfilment of their tasks. Each competent authority shall monitor the quality of the evaluations carried out by their representative and facilitate their activities.

3 Members of the coordination group shall use their best endeavours to reach consensus on matters under discussion.

Article 144

Tasks of the coordination group

The coordination group shall have the following tasks:

(a) examine questions concerning mutual recognition and decentralised procedures;

(b) examine advice from the pharmacovigilance working party of the Committee concerning risk management measures in pharmacovigilance related to veterinary medicinal products authorised in Member States and issue recommendations to the Member States and to the marketing authorisation holders, as necessary;

(c) examine questions concerning variations to the terms of marketing authorisations granted by Member States;

(d) provide recommendations to Member States whether a specific veterinary medicinal product or a group of veterinary medicinal products is to be considered a veterinary medicinal product within the scope of this Regulation;

(e) coordinate the selection of the lead authority responsible for the assessment of the results of the signal management process referred to in Article 81(4);

(f) draw up and publish an annual list of reference veterinary medicinal products which shall be subject to harmonisation of the summaries of product characteristics in accordance with Article 70(3).

Status:
Point in time view as at 31/01/2020.

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 X.