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 1

Union product database

Article 55

Union database on veterinary medicinal products

1 The Agency shall establish and, in collaboration with the Member States, maintain, a Union database on veterinary medicinal products ('product database').

2 The product database shall contain at least the following information:

a for veterinary medicinal products authorised within the Union by the Commission and by the competent authorities:

(i) name of the veterinary medicinal product;

(ii) active substance or substances, and the strength of the veterinary medicinal product;

(iii) summary of product characteristics;

(iv) package leaflet;

(v) the assessment report;

(vi) list of sites where the veterinary medicinal product is manufactured; and

(vii) the dates of the placing of the veterinary medicinal product on the market in a Member State;

b for homeopathic veterinary medicinal products registered in accordance with Chapter V within the Union by the competent authorities:

(i) name of the registered homeopathic veterinary medicinal product;

(ii) package leaflet; and

(iii) lists of sites where the registered homeopathic veterinary medicinal product is manufactured;

c veterinary medicinal products allowed to be used in a Member State in accordance with Article 5(6);

d the annual volume of sales and information on the availability for each veterinary medicinal product.

3 The Commission shall, by means of implementing acts, adopt the necessary measures and practical arrangements laying down:

a the technical specifications of the product database including the electronic data exchange mechanism for exchanging with the existing national systems and the format for electronic submission;

b the practical arrangements for the functioning of the product database, in particular to ensure protection of commercially confidential information and security of exchange of information;

c detailed specifications of the information to be included, updated and shared in the product database and by whom;

d contingency arrangements to be applied in case of unavailability of any of the functionalities of the product database;

e where appropriate, data to be included in the product database in addition to the information referred to in paragraph 2 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 56

Access to the product database

1 The competent authorities, the Agency and the Commission shall have full access to the information in the product database.

2 Marketing authorisation holders shall have full access to the information in the product database as regards their marketing authorisations.

3 The general public shall have access to information in the product database, without the possibility to change the information therein, as regards the list of the veterinary medicinal products, the summary of product characteristics, package leaflets and, after the deletion of any commercially confidential information by the competent authority, assessment reports.

Section 2

Collection of data by Member States and responsibilities of marketing authorisation holders

Article 57

Collection of data on antimicrobial medicinal products used in animals

1 Member States shall collect relevant and comparable data on the volume of sales and on the use of antimicrobial medicinal products used in animals, to enable in particular the direct or indirect evaluation of the use of such products in food-producing animals at farm level, in accordance with this Article and within the time limits set out in paragraph 5.

2 Member States shall send collated data on the volume of sales and the use per animal species and per types of antimicrobial medicinal products used in animals to the Agency in accordance with paragraph 5 and within the time limits referred to therein. The Agency shall cooperate with Member States and with other Union agencies to analyse those data and shall

publish an annual report. The Agency shall take into account those data when adopting any relevant guidelines and recommendations.

3 The Commission shall adopt delegated acts in accordance with Article 147, in order to supplement this Article, establishing the requirements as regards:

a the types of antimicrobial medicinal products used in animals for which data shall be collected;

b the quality assurance that Member States and the Agency shall put in place to ensure quality and comparability of data; and

c the rules on the methods of gathering data on the use of the antimicrobial medicinal products used in animals and on the method of transfer of those data to the Agency.

4 The Commission shall, by means of implementing acts, set up the format for the data to be collected in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

5 Member States shall be allowed to apply a progressive stepwise approach regarding the obligations set out in this Article so that:

a within two years from 28 January 2022, data shall be collected at least for the species and categories included in Commission Implementing Decision 2013/652/EU[(1)] in its version of 11 December 2018;

b within five years from 28 January 2022, data shall be collected for all food-producing animal species;

c within eight years from 28 January 2022, data shall be collected for other animals which are bred or kept.

6 Nothing in point (c) of paragraph 5 shall be understood to include an obligation to collect data from natural persons keeping companion animals.

Article 58

Responsibilities of the marketing authorisation holders

1 The marketing authorisation holder shall be responsible for the marketing of its veterinary medicinal products. The designation of a representative shall not relieve the marketing authorisation holder of legal responsibility.

2 The marketing authorisation holder shall, within the limits of its responsibilities, ensure appropriate and continued supplies of its veterinary medicinal products.

3 After a marketing authorisation has been granted, the marketing authorisation holder shall, in respect of the methods of manufacture and control stated in the application for that marketing authorisation, take account of scientific and technical progress and introduce any changes that may be required to enable the veterinary medicinal product to be manufactured and controlled by means of generally accepted scientific methods. The introduction of such changes shall be subject to the procedures laid down in Section 3 of this Chapter.

4 The marketing authorisation holder shall ensure that the summary of product characteristics, package leaflet and labelling is kept up to date with current scientific knowledge.

5 The marketing authorisation holder shall not place generic veterinary medicinal products and hybrid veterinary medicinal products on the Union market until the period of the protection of technical documentation for the reference veterinary medicinal product, as set out in Articles 39 and 40, has elapsed.

6 The marketing authorisation holder shall record in the product database the dates when its authorised veterinary medicinal products are placed on the market, information on the availability for each veterinary medicinal product in each relevant Member State and, as applicable, the dates of any suspension or revocation of the marketing authorisations concerned.

7 On the request of the competent authorities, the marketing authorisation holder shall provide them with sufficient quantities of samples to enable controls to be made on its veterinary medicinal products placed on the Union market.

8 On the request of a competent authority, the marketing authorisation holder shall provide technical expertise to facilitate the implementation of the analytical method for detecting residues of the veterinary medicinal products in the European Union reference laboratory designated under Regulation (EU) 2017/625.

9 On the request of a competent authority or the Agency, the marketing authorisation holder shall, within the time limit set in that request, provide data demonstrating that the benefit-risk balance remains positive.

10 The marketing authorisation holder shall without delay inform the competent authority which has granted the marketing authorisation or the Commission, as applicable, of any prohibition or restriction imposed by a competent authority or by an authority of a third country and of any other new information which might influence the assessment of the benefits and risks of the veterinary medicinal product concerned, including from the outcome of the signal management process carried out in accordance with Article 81.

11 The marketing authorisation holder shall provide the competent authority, the Commission or the Agency, as applicable, within the time limit set, with all data in its possession relating to the volume of sales of the veterinary medicinal product concerned.

12 The marketing authorisation holder shall record in the product database the annual volume of sales for each of its veterinary medicinal products.

13 The marketing authorisation holder shall without delay inform the competent authority which has granted the marketing authorisation or the Commission, as applicable, of any action which the holder intends to take in order to cease the marketing of a veterinary medicinal product prior to taking such action, together with the reasons for such action.

Article 59

Small and medium-sized enterprises

Member States shall, in accordance with their national law, take appropriate measures to advise small and medium-sized enterprises on compliance with the requirements of this Regulation.

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.

Section 4

Harmonisation of the summaries of product characteristics for nationally authorised products

Article 69

Scope of the harmonisation of summaries of product characteristics of a veterinary medicinal product

A harmonised summary of product characteristics shall be prepared in accordance with the procedure laid down in Articles 70 and 71 for:

(a) reference veterinary medicinal products which have the same qualitative and quantitative composition of their active substances and the same pharmaceutical form and for which marketing authorisations have been granted in accordance with Article 47 in different Member States for the same marketing authorisation holder;

(b) generic and hybrid veterinary medicinal 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 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.

Article 71

Procedure for harmonisation of summaries of product characteristics for generic and hybrid veterinary medicinal products

1 When the procedure referred to in Article 70 has been closed and a harmonised summary of product characteristics for a reference veterinary medicinal product has been agreed, the marketing authorisation holders of generic veterinary medicinal products shall apply, within 60 days of the decision by the competent authorities in each Member State and in accordance with Article 62, for the harmonisation of the following sections of the summary of product characteristics for the generic veterinary medicinal products concerned, as applicable:

a target species;

b clinical information referred to in point (c) of Article 35(1);

c the withdrawal period.

2 By way of derogation from paragraph 1, in the case of a marketing authorisation for a hybrid veterinary medicinal product supported by additional pre-clinical studies or clinical trials, the relevant sections of the summary of product characteristics referred to in paragraph 1 shall not be considered to be subject to harmonisation.

3 The marketing authorisation holders of generic and hybrid veterinary medicinal products shall ensure that the summaries of products characteristics of their products shall be essentially similar to those of the reference veterinary medicinal products.

Article 72

Environmental safety documentation and environmental risk assessment of certain veterinary medicinal products

The list referred to in Article 70(1) shall not contain any reference veterinary medicinal product authorised before 1 October 2005 and which is identified as potentially harmful to the environment and has not been subject to an environmental risk assessment.

Where the reference veterinary medicinal product is authorised before 1 October 2005 and is identified as potentially harmful to the environment and has not been subject to an environmental risk assessment, the competent authority shall request the marketing authorisation holder to update the relevant environmental safety documentation referred to in point (b) of Article 8(1), taking into account the review referred to in Article 156, and, if applicable, the environmental risk assessment of generic veterinary medicinal products of such reference medicinal products.

Section 5

Pharmacovigilance

Article 73

Union pharmacovigilance system

1 Member States, the Commission, the Agency and marketing authorisation holders shall collaborate in setting up and maintaining a Union pharmacovigilance system to carry out pharmacovigilance tasks with respect to the safety and efficacy of authorised veterinary medicinal products in order to ensure continuous assessment of the benefit-risk balance.

2 Competent authorities, the Agency and marketing authorisation holders shall take the necessary measures to make available means to report and encourage reporting of the following suspected adverse events:

a any unfavourable and unintended reaction in any animal to a veterinary medicinal product;

b any observation of a lack of efficacy of a veterinary medicinal product following its administration to an animal, whether or not in accordance with the summary of product characteristics;

c any environmental incidents observed following the administration of a veterinary medicinal product to an animal;

d any noxious reaction in humans exposed to a veterinary medicinal product;

e any finding of a pharmacologically active substance or marker residue in a product of animal origin exceeding the maximum levels of residues established in accordance with Regulation (EC) No 470/2009 after the set withdrawal period has been respected;

f any suspected transmission of an infectious agent via a veterinary medicinal product;

g any unfavourable and unintended reaction in an animal to a medicinal product for human use.

Article 74

Union pharmacovigilance database

1 The Agency shall, in collaboration with Member States, establish and maintain a Union pharmacovigilance database for the reporting and recording of suspected adverse events referred to in Article 73(2) (the 'pharmacovigilance database'), which shall also include the information on qualified person responsible for pharmacovigilance as referred to in Article 77(8), the reference numbers of the pharmacovigilance system master file, the results and outcomes of the signal management process and results of pharmacovigilance inspections in accordance with Article 126.

2 The pharmacovigilance database shall be interconnected with the product database referred to in Article 55.

3 The Agency shall, in collaboration with the Member States and the Commission, draw up the functional specifications for the pharmacovigilance database.

4 The Agency shall ensure that information reported is uploaded in the pharmacovigilance database and made accessible in accordance with Article 75.

5 The system of the pharmacovigilance database shall be established as a data-processing network allowing transmission of data between Member States, the Commission, the Agency and the marketing authorisation holders to ensure that in the event of an alert related to pharmacovigilance data, options for risk management and any appropriate measures can be considered as referred to in Articles 129, 130 and 134.

Article 75

Access to the pharmacovigilance database

1 The competent authorities shall have full access to the pharmacovigilance database.

2 Marketing authorisation holders shall have access to the pharmacovigilance database with respect to data related to the veterinary medicinal products for which they hold a marketing authorisation and to other non-confidential data related to veterinary medicinal products for which they do not hold a marketing authorisation to the extent necessary for them to comply with their pharmacovigilance responsibilities as referred to in Articles 77, 78 and 81.

3 The general public shall have access to the pharmacovigilance database, without the possibility to change the information therein, as regards the following information:

a the number and at the latest within two years from 28 January 2022 the incidence of suspected adverse events reported each year, broken down by veterinary medicinal product, animal species and type of suspected adverse event;

b the results and outcomes referred to in Article 81(1) that arise from the signal management process performed by the marketing authorisation holder for veterinary medicinal products or groups of veterinary medicinal products.

Article 76

Reporting and recording of suspected adverse events

1 Competent authorities shall record in the pharmacovigilance database all suspected adverse events which were reported to them and that occurred in the territory of their Member State, within 30 days of receipt of the suspected adverse event report.

2 Marketing authorisation holders shall record in the pharmacovigilance database all suspected adverse events which were reported to them and that occurred within the Union or in a third country or that have been published in the scientific literature with regard to their authorised veterinary medicinal products, without delay and no later than within 30 days of receipt of the suspected adverse event report.

3 The Agency may request the holder of a marketing authorisation for centrally authorised veterinary medicinal products, or for nationally authorised veterinary medicinal products in cases where they fall within the scope of a Union interest referral referred to in Article 82, to collect specific pharmacovigilance data additional to the data listed in Article 73(2) and to carry out post-marketing surveillance studies. The Agency shall state in detail the reasons for the request, set an appropriate time limit and inform competent authorities thereof.

4 Competent authorities may request the holder of a marketing authorisation for nationally authorised veterinary medicinal products to collect specific pharmacovigilance data, additional to the data listed in Article 73(2) and to carry out post-marketing surveillance studies. The competent authority shall state in detail the reasons for the request, set an appropriate time limit and inform other competent authorities and the Agency thereof.

Article 77

Pharmacovigilance responsibilities of the marketing authorisation holder

1 Marketing authorisation holders shall establish and maintain a system for collecting, collating and evaluating information on the suspected adverse events concerning their authorised veterinary medicinal products, enabling them to fulfil their pharmacovigilance responsibilities (‘pharmacovigilance system’).

2 The marketing authorisation holder shall have in place one or more pharmacovigilance system master files describing in detail the pharmacovigilance system with respect to its authorised veterinary medicinal products. For each veterinary medicinal product, the marketing authorisation holder shall not have more than one pharmacovigilance system master file.

3 The marketing authorisation holder shall designate a local or regional representative for the purpose of receiving reports of suspected adverse events who is able to communicate in the languages of the relevant Member States.

4 The marketing authorisation holder shall be responsible for the pharmacovigilance of the veterinary medicinal product for which it holds a marketing authorisation and shall

continuously evaluate by appropriate means the benefit-risk balance of this veterinary medicinal product and, if necessary, take appropriate measures.

5 The marketing authorisation holder shall comply with good pharmacovigilance practice for veterinary medicinal products.

6 The Commission shall, by means of implementing acts, adopt necessary measures on good pharmacovigilance practice for veterinary medicinal products and also on the format and content of the pharmacovigilance system master file and its summary. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

7 Where the pharmacovigilance tasks have been contracted out by the marketing authorisation holder to a third party, those arrangements shall be set out in detail in the pharmacovigilance system master file.

8 The marketing authorisation holder shall designate one or more qualified persons responsible for pharmacovigilance to carry out the tasks provided for in Article 78. Those qualified persons shall reside and operate in the Union and shall be appropriately qualified and be permanently at the disposal of the marketing authorisation holder. Only one such qualified person shall be designated for each pharmacovigilance system master file.

9 The tasks, set out in Article 78, of the qualified person responsible for pharmacovigilance referred to in paragraph 8 of this Article may be outsourced to a third party under the conditions set out in that paragraph. In such cases, those arrangements shall be specified in detail in the contract and included in the pharmacovigilance system master file.

10 The marketing authorisation holder shall, based on the assessment of the pharmacovigilance data, and where necessary, submit without undue delay an application for a variation to the terms of a marketing authorisation in accordance with Article 62.

11 The marketing authorisation holder shall not make a public announcement on pharmacovigilance information in relation to its veterinary medicinal products without giving prior or simultaneous notification of its intention to the competent authority having granted the marketing authorisation or to the Agency, as applicable.

The marketing authorisation holder shall ensure that such public announcement is presented objectively and is not misleading.

Article 78

Qualified person responsible for pharmacovigilance

1 The qualified person responsible for pharmacovigilance as referred to in Article 77(8) shall ensure that the following tasks are carried out:

a elaborating and maintaining the pharmacovigilance system master file;

b allocating reference numbers to the pharmacovigilance system master file and communicating that reference number to the pharmacovigilance database for each product;

c notifying the competent authorities and the Agency, as applicable, of the place of operation;

d establishing and maintaining a system which ensures that all suspected adverse events which are brought to the attention of the marketing authorisation holder are collected and recorded in order to be accessible at least at one site in the Union;

e compiling the suspected adverse event reports referred to in Article 76(2), evaluating them, where necessary, and recording them in the pharmacovigilance database;

f ensuring that any request from the competent authorities or the Agency for the provision of additional information necessary for the evaluation of the benefit-risk balance of a veterinary medicinal product is answered fully and promptly;

g providing competent authorities or the Agency, as applicable, with any other information relevant to detecting a change to the benefit-risk balance of a veterinary medicinal product, including appropriate information on post-marketing surveillance studies;

h applying the signal management process referred to in Article 81 and ensuring that any arrangements for the fulfilment of responsibilities referred to in Article 77(4) are in place;

i monitoring the pharmacovigilance system and ensuring that if needed, an appropriate preventive or corrective action plan is prepared, implemented and, where necessary, ensuring changes to the pharmacovigilance system master file;

j ensuring that all personnel of the marketing authorisation holder involved in the performance of pharmacovigilance activities receives continued training;

k communicating any regulatory measure that is taken in a third country and is related to pharmacovigilance data to the competent authorities and to the Agency within 21 days of receipt of such information.

2 The qualified person referred to in Article 77(8) shall be the contact point for the marketing authorisation holder regarding pharmacovigilance inspections.

Article 79

Pharmacovigilance responsibilities of the competent authorities and the Agency

1 Competent authorities shall lay down the necessary procedures to evaluate the results and outcomes of the signal management process recorded in the pharmacovigilance database in accordance with Article 81(2) as well as suspected adverse events reported to them, consider options for risk management and take any appropriate measures referred to in Articles 129, 130 and 134 concerning marketing authorisations.

2 Competent authorities may impose specific requirements on veterinarians and other healthcare professionals in respect of the reporting of suspected adverse events. The Agency may organise meetings or a network for groups of veterinarians or other healthcare professionals, where there is a specific need for collecting, collating or analysing specific pharmacovigilance data.

3 Competent authorities and the Agency shall make publicly available all important information on adverse events relating to the use of a veterinary medicinal product. It shall be done in a timely manner by any publicly available means of communication with a prior or simultaneous notification to the marketing authorisation holder.

4 Competent authorities shall verify, by means of controls and inspections referred to in Articles 123 and 126, that marketing authorisation holders comply with the requirements relating to pharmacovigilance laid down in this Section.

5 The Agency shall lay down the necessary procedures to evaluate suspected adverse events reported to it regarding centrally authorised veterinary medicinal products, and recommend risk management measures to the Commission. The Commission shall take

any appropriate measures referred to in Articles 129, 130 and 134 concerning marketing authorisations.

6 The competent authority or the Agency, as applicable, may at any time request the marketing authorisation holder to submit a copy of the pharmacovigilance system master file. The marketing authorisation holder shall submit that copy at the latest within seven days of receipt of the request.

Article 80

Delegation of tasks by competent authority

1 A competent authority may delegate any of the tasks entrusted to it as referred to in Article 79 to a competent authority in another Member State subject to the written agreement of the latter.

2 The delegating competent authority shall inform the Commission, the Agency and other competent authorities of the delegation as referred to in paragraph 1 and make that information public.

Article 81

Signal management process

1 Marketing authorisation holders shall carry out a signal management process for their veterinary medicinal products, if necessary, taking into account sales data and other relevant pharmacovigilance data of which they can reasonably be expected to be aware and which may be useful for that signal management process. That data may include scientific information gathered from scientific literature reviews.

2 Where the outcome of the signal management process identifies a change to the benefit-risk balance or a new risk, marketing authorisation holders shall notify it without delay and no later than within 30 days to the competent authorities or to the Agency, as applicable, and take the necessary action in accordance with Article 77(10).

The marketing authorisation holder shall record, at least annually, all results and outcomes of the signal management process, including a conclusion on the benefit-risk balance, and, if applicable, references to relevant scientific literature in the pharmacovigilance database.

In the case of veterinary medicinal products referred to in point (c) of Article 42(2), the marketing authorisation holder shall record in the pharmacovigilance database all results and outcomes of the signal management process, including a conclusion on the benefit-risk balance, and, if applicable, references to relevant scientific literature according to the frequency specified in the marketing authorisation.

3 The competent authorities and the Agency may decide to perform a targeted signal management process for a given veterinary medicinal product or a group of veterinary medicinal products.

4 For the purpose of paragraph 3, the Agency and the coordination group shall share the tasks related to the targeted signal management process and shall jointly select for each veterinary medicinal product or group of veterinary medicinal products a competent authority or the Agency as responsible for such targeted signal management process (‘lead authority’).

5 When selecting a lead authority, the Agency and the coordination group shall take into account the fair allocation of tasks and shall avoid duplication of work.

6 Where the competent authorities or the Commission, as applicable, consider that follow-up action is necessary, they shall take appropriate measures as referred to in Articles 129, 130 and 134.

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.

(**1**) Commission Implementing Decision 2013/652/EU of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria (OJ L 303, 14.11.2013, p. 26).

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 IV.