

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 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

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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.

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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.

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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;

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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.

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## 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.

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