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 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.

(**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 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, Section 2.