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 IX

RESTRICTIONS AND PENALTIES

Article 129

Temporary safety restrictions

1 The competent authority and, in the case of centrally authorised veterinary medicinal products, also the Commission may, in the event of a risk to public or animal health or to the environment that requires urgent action, impose temporary safety restrictions on the marketing authorisation holder and other persons having obligations under this Regulation. Those temporary safety restrictions may include:

a restriction of supply of the veterinary medicinal product at the request of the competent authority and, in the case of centrally authorised veterinary medicinal products, also at the request of the Commission to the competent authority;

b restriction of the use of the veterinary medicinal product at the request of the competent authority and, in the case of centrally authorised veterinary medicinal products, also at the request of the Commission to the competent authority;

c suspension of a marketing authorisation by the competent authority having granted that marketing authorisation and, in the case of centrally authorised veterinary medicinal products, by the Commission.

2 The competent authority concerned shall inform, at the latest on the following working day, the other competent authorities and the Commission of any temporary safety restriction imposed. In the case of centralised marketing authorisations, the Commission shall inform, within the same time, the competent authorities of any temporary safety restriction imposed.

3 Competent authorities and the Commission may, at the same time as imposing a restriction in accordance with paragraph 1 of this Article, refer the issue to the Agency in accordance with Article 82.

4 Where applicable, the marketing authorisation holder shall submit an application for a variation to the terms of the marketing authorisation in accordance with Article 62.

Article 130

Suspending, revoking, or varying the terms, of marketing authorisations

1 The competent authority or, in the case of centralised marketing authorisations, the Commission shall suspend or revoke the marketing authorisation or request the marketing authorisation holder to submit an application for a variation to the terms of the marketing authorisation if the benefit-risk balance of the veterinary medicinal product is no longer positive or is insufficient to ensure food safety.

2 The competent authority or, in the case of centralised marketing authorisations, the Commission, shall revoke the marketing authorisation if the marketing authorisation holder no longer fulfils the requirement on establishment in the Union referred to in Article 5(4).

3 The competent authority or, in the case of centralised marketing authorisations, the Commission may suspend or revoke the marketing authorisation or request the marketing authorisation holder to submit an application for a variation to the terms of the marketing authorisation, as applicable, in the case of one or more of the following reasons:

a the marketing authorisation holder does not comply with the requirements set out in Article 58;

b the marketing authorisation holder does not comply with the requirements set out in Article 127;

c the pharmacovigilance system established in accordance with Article 77(1) is inadequate;

d the marketing authorisation holder does not fulfil its obligations laid down in Article 77;

e the qualified person responsible for pharmacovigilance does not fulfil his or her tasks as laid down in Article 78.

4 For the purpose of paragraphs 1, 2 and 3, in the case of centralised marketing authorisations, before taking action, the Commission shall request, where appropriate, the opinion of the Agency within a time limit which it shall determine in view of the urgency of the matter, in order to examine the reasons referred to in those paragraphs. The holder of the marketing authorisation for the veterinary medicinal product shall be invited to provide oral or written explanations within a given time limit set by the Commission.

Following an opinion of the Agency, the Commission shall adopt, where necessary, provisional measures, which shall be applied immediately. The Commission shall, by means of implementing acts, take a final decision. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

5 Member States shall lay down procedures for application of paragraphs 1, 2 and 3.

Article 131

Suspending or revoking a wholesale distribution authorisation

1 In the event of non-compliance with the requirements laid down in Article 101(3), the competent authority shall suspend or revoke the wholesale distribution authorisation of veterinary medicinal products.

2 In the event of non-compliance with the requirements laid down in Article 101, other than paragraph 3 thereof, the competent authority may, without prejudice to any other appropriate measures under national law, take one or more of the following measures:

a suspend the wholesale distribution authorisation;

b suspend the wholesale distribution authorisation for one or more categories of veterinary medicinal products;

c revoke the wholesale distribution authorisation for one or more categories of veterinary medicinal products.

Article 132

Removal of importers, manufacturers and distributors of active substance from the manufacturing and wholesale distribution database

In the event of non-compliance by importers, manufacturers and distributors of active substances with the requirements laid down in Article 95, the competent authority shall, temporarily or definitively, remove those importers, manufacturers and distributors from the manufacturing and wholesale distribution database.

Article 133

Suspending or revoking manufacturing authorisations

In the event of non-compliance with the requirements laid down in Article 93, the competent authority shall, without prejudice to any other appropriate measures under national law, take one or more of the following measures:

(a) suspend the manufacture of veterinary medicinal products;

(b) suspend imports of veterinary medicinal products from third countries;

(c) suspend or revoke the manufacturing authorisation for one or more pharmaceutical forms;

(d) suspend or revoke the manufacturing authorisation for one or more activities in one or more manufacturing sites.

Article 134

Prohibiting the supply of veterinary medicinal products

1 In the event of a risk to public or animal health or to the environment, the competent authority or, in the case of centrally authorised veterinary medicinal products, the Commission, shall prohibit the supply of a veterinary medicinal product and require the marketing authorisation holder or suppliers to cease the supply or recall of the veterinary medicinal product from the market if any of the following conditions apply:

a the benefit-risk balance of the veterinary medicinal product is no longer positive;

b the qualitative or quantitative composition of the veterinary medicinal product is not as stated in the summary of the product characteristics referred to in Article 35;

c the recommended withdrawal period is insufficient to ensure food safety;

d the control tests referred to in Article 127(1) have not been carried out; or

e the incorrect labelling might lead to a serious risk to animal or public health.

2 The competent authorities or the Commission may confine the prohibition on supply and recall from the market solely to the contested production batches of the veterinary medicinal product concerned.

Article 135

Penalties imposed by Member States

1 Member States shall lay down rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive.

Member States shall, by 28 January 2022, notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendments affecting them.

2 The competent authorities shall ensure the publication of information on the type and number of cases where financial penalties were imposed, having regard to the legitimate interest of the concerned parties for the protection of their business secrets.

3 Member States shall inform the Commission immediately of any litigation against the holders of marketing authorisations for centrally authorised veterinary medicinal products brought for infringement of this Regulation.

Article 136

Financial penalties imposed by the Commission on holders of marketing authorisation for centrally authorised veterinary medicinal products

1 The Commission may impose financial penalties in the form of fines or periodic penalty payments on the holders of marketing authorisation for centrally authorised veterinary medicinal products granted under this Regulation if they fail to comply with any of their obligations laid down in Annex III in connection with the marketing authorisations.

2 The Commission may, insofar as specifically provided for in the delegated acts referred to in point (b) of paragraph 7, impose the financial penalties referred to in paragraph 1 also on a legal entity or legal entities other than the marketing authorisation holder provided that such entities form part of the same economic entity as the marketing authorisation holder and that such other legal entities:

a exerted a decisive influence over the marketing authorisation holder; or

b were involved in, or could have addressed, such failure to comply with the obligation by the marketing authorisation holder.

3 Where the Agency or a competent authority of a Member State is of the opinion that a marketing authorisation holder has failed to comply with any of the obligations, as referred to in paragraph 1, it may request the Commission to investigate whether to impose financial penalties pursuant to that paragraph.

4 In determining whether to impose a financial penalty and in determining its appropriate amount, the Commission shall be guided by the principles of effectiveness, proportionality and dissuasiveness and take into consideration, where relevant, the seriousness and the effects of the failure to comply with the obligations.

5 For the purposes of paragraph 1, the Commission shall also take into account:

a any infringement procedure initiated by a Member State against the same marketing authorisation holder on the basis of the same legal grounds and the same facts; and

b any sanctions, including penalties, already imposed on the same marketing authorisation holder on the basis of the same legal grounds and the same facts.

6 Where the Commission finds that the marketing authorisation holder has failed, intentionally or negligently, to comply with its obligations, as referred to in paragraph 1, it may adopt a decision imposing a fine not exceeding 5 % of the marketing authorisation holder's Union turnover in the business year preceding the date of that decision.

Where the marketing authorisation holder continues to fail to comply with its obligations referred to in paragraph 1, the Commission may adopt a decision imposing periodic penalty payments per day not exceeding 2,5 % of the marketing authorisation holder's average daily Union turnover in the business year preceding the date of that decision.

Periodic penalty payments may be imposed for a period running from the date of notification of the relevant Commission's decision until the failure to comply with the obligation by the marketing authorisation holder, as referred to in paragraph 1, has been brought to an end.

7 The Commission shall adopt delegated acts in accordance with Article 147 in order to supplement this Regulation by laying down:

a procedures to be applied by the Commission when imposing fines or periodic penalty payments, including rules on the initiation of the procedure, measures of inquiry, rights of defence, access to file, legal representation and confidentiality;

b further detailed rules on the imposition by the Commission of financial penalties on legal entities other than the marketing authorisation holder;

c rules on duration of procedure and limitation periods;

d elements to be taken into account by the Commission when setting the level of, and imposing, fines and periodic penalty payments, as well as the conditions and methods for their collection.

8 When conducting the investigation on a failure to comply with any of the obligations referred to in paragraph 1, the Commission may cooperate with national competent authorities and rely on resources provided by the Agency.

9 Where the Commission adopts a decision imposing a financial penalty, it shall publish a concise summary of the case, including the names of the marketing authorisation holders involved and the amounts of, and reasons for, the financial penalties imposed, having regard to the legitimate interest of the marketing authorisation holders for the protection of their business secrets.

10 The Court of Justice of the European Union shall have unlimited jurisdiction to review decisions whereby the Commission has imposed financial penalties. The Court of Justice of the European Union may cancel, reduce or increase the fine or periodic penalty payment imposed by the Commission.

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 IX.