

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 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

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Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2019/6 of the European Parliament and of the Council, Article 136. (See end of Document for details)

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.

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