

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 XI

COMMON AND PROCEDURAL PROVISIONS

Article 145

Standing Committee on Veterinary Medicinal Products

- 1 The Commission shall be assisted by the Standing Committee on Veterinary Medicinal Products ('the Standing Committee'). The Standing Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
- 2 Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 146

Amendments to Annex II

- 1 The Commission is empowered to adopt delegated acts in accordance with Article 147(2) in order to amend Annex II by adapting the requirements regarding the technical documentation on the quality, safety and efficacy of veterinary medicinal products to technical and scientific progress.
- 2 The Commission shall adopt delegated acts in accordance with Article 147(3) amending Annex II in order to achieve a sufficient level of detail that ensures legal certainty and harmonisation as well as any necessary updating, while avoiding unnecessary disruption with Annex II, including as regards the introduction of specific requirements for novel therapy veterinary medicinal products. When adopting those delegated acts, the Commission shall have due regard to animal and public health and environmental considerations.

Article 147

Exercise of the delegation

- 1 The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
- 2 The power to adopt delegated acts referred to in Articles 37(4), 57(3), 106(6), 109(1), 115(3), 118(2), 136(7) and 146(1) and (2) shall be conferred on the Commission for a period of five years from 27 January 2019. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for the periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

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 XI. (See end of Document for details)

3 The power to adopt delegated acts referred to in Article 146(2) shall be conferred on the Commission for a period from 27 January 2019 until 28 January 2022.

4 The delegation of power referred to in Articles 37(4), 57(3), 106(6), 109(1), 115(3), 118(2), 136(7) and 146(1) and (2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

5 Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law Making.

6 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

7 A delegated act adopted pursuant to Articles 37(4), 57(3), 106(6), 109(1), 115(3), 118(2), 136(7) and 146(1) and (2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 148

Data protection

1 Member States shall apply Regulation (EU) 2016/679 of the European Parliament and of the Council⁽¹⁾ to the processing of personal data carried out in the Member States pursuant to this Regulation.

2 Regulation (EU) 2018/1725 of the European Parliament and of the Council⁽²⁾ shall apply to the processing of personal data carried out by the Commission and the Agency pursuant to this Regulation.

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 XI. (See end of Document for details)

- (1) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).
- (2) Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

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 XI.