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 XII

TRANSITIONAL AND FINAL PROVISIONS

Article 149

Repeal

Directive 2001/82/EC is repealed.

References to the repealed Directive shall be construed as references to this Regulation and shall be read in accordance with the correlation table set out in Annex IV.

Article 150

Relation with other Union acts

1 Nothing in this Regulation shall be understood to affect the provisions of Directive 96/22/EC.

2 Commission Regulation (EC) No 1234/2008[(1)] shall not apply to veterinary medicinal products covered by this Regulation.

3 Commission Regulation (EC) No 658/2007[(2)] shall not apply to veterinary medicinal products covered by this Regulation.

Article 151

Prior applications

1 The procedures concerning the applications for marketing authorisations for veterinary medicinal products or for variations that have been validated in accordance with Regulation (EC) No 726/2004 before 28 January 2022 shall be completed in accordance with Regulation (EC) No 726/2004.

2 The procedures concerning the applications for marketing authorisations for veterinary medicinal products that have been validated in accordance with Directive 2001/82/EC before 28 January 2022 shall be completed in accordance with that Directive.

3 Procedures initiated on the basis of Articles 33, 34, 35, 39, 40 and 78 of Directive 2001/82/EC before 28 January 2022 shall be completed in accordance with that Directive.

Article 152

Existing veterinary medicinal products, marketing authorisations and registrations

1 Marketing authorisations of veterinary medicinal products and registrations of homeopathic veterinary medicinal products granted in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 before 28 January 2022 shall be deemed to have been issued in accordance with this Regulation, and are, as such, subject to the relevant provisions of this Regulation.

The first subparagraph of this paragraph shall not apply to marketing authorisations for antimicrobial veterinary medicinal products containing antimicrobials which have been reserved for treatment in humans in accordance with implementing acts referred to in Article 37(5).

2 Veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 may continue to be made available until 29 January 2027, even if they are not in compliance with this Regulation.

3 By way of derogation from paragraph 1 of this Article, the periods of protection referred to in Article 39 shall not apply to reference veterinary medicinal products for which an authorisation has been granted before 28 January 2022 and, instead, the corresponding provisions in the repealed acts referred to in paragraph 1 of this Article shall continue to apply in that respect.

Article 153

Transitional provisions regarding delegated and implementing acts

1 The delegated acts referred to in Article 118(2) and the implementing acts referred to in Articles 37(5), 57(4), 77(6), 95(8), 99(6) and 104(7) shall be adopted before 28 January 2022. Such delegated and implementing acts shall apply from 28 January 2022.

2 Without prejudice to the date of application of this Regulation, the Commission shall adopt the delegated acts referred to in Article 37(4) at the latest by 27 September 2021. Such delegated acts shall apply from 28 January 2022.

3 Without prejudice to the date of application of this Regulation, the Commission shall adopt the delegated acts referred to in Articles 57(3) and 146(2) and the implementing acts referred to in Articles 55(3) and 60(1) at the latest by 27 January 2021. Such delegated and implementing acts shall apply from 28 January 2022.

4 Without prejudice to the date of application of this Regulation, the Commission shall adopt the delegated acts referred to in Article 109(1) and the implementing acts referred to in Articles 17(2) and (3), 93(2), 109(2) and 115(5) at the latest by 29 January 2025. Such delegated and implementing acts shall apply at the earliest on 28 January 2022.

5 Without prejudice to the date of application of this Regulation, the Commission is empowered to adopt delegated and implementing acts provided for in this Regulation as from 27 January 2019. Such delegated and implementing acts, unless otherwise provided in this Regulation, shall apply from 28 January 2022.

When adopting the delegated and implementing acts referred to in this Article, the Commission shall allow sufficient time between their adoption and their start of application.

Article 154

Establishment of the pharmacovigilance database and of the manufacturing and wholesale distribution database

Without prejudice to the date of application of this Regulation, the Agency, in collaboration with the Member States and the Commission, shall, in accordance with Articles 74 and 91 respectively, ensure the establishment of the pharmacovigilance database and of the manufacturing and wholesale distribution database at the latest by 28 January 2022.

Article 155

Initial input to the product database by competent authorities

At the latest by 28 January 2022, the competent authorities shall submit, electronically, information on all veterinary medicinal products authorised in their Member State at that time to the Agency, using the format referred to in point (a) of Article 55(3).

Article 156

Review of rules for environmental risk assessment

By 28 January 2022, the Commission shall present a report to the European Parliament and to the Council on a feasibility study of an active substance based review system (‘monographs’) and other potential alternatives for the environmental risk assessment of veterinary medicinal products, to be accompanied, if appropriate, by a legislative proposal.

Article 157

Commission report on traditional herbal products used to treat animals

The Commission shall report to the European Parliament and to the Council by 29 January 2027, on traditional herbal products used to treat animals in the Union. If appropriate, the Commission shall make a legislative proposal in order to introduce a simplified system for registering traditional herbal products used to treat animals.

The Member States shall provide information to the Commission on such traditional herbal products within their territories.

Article 158

Review of measures regarding animals of the equine species

No later than 29 January 2025, the Commission shall present a report to the European Parliament and to the Council on its assessment of the situation as regards the treatment

with medicinal products of animals of the equine species and their exclusion from the food chain, including with regard to imports of animals of the equine species from third countries, to be accompanied by any appropriate action by the Commission taking into account, in particular, public health, animal welfare, the risks of fraud and the level playing field with third countries.

Article 159

Transitional provisions regarding certain certificates of good manufacturing practice

Without prejudice to the date of application of this Regulation, the obligations regarding certificates of good manufacturing practice for inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the same epidemiological unit or for the treatment of an animal or animals in a unit having a confirmed epidemiological link shall only start to apply from the date of application of the implementing acts laying down specific measures on good manufacturing practice for those veterinary medicinal products referred to in Article 93(2).

Article 160

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 28 January 2022.

(**1**) Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, p. 7).

(**2**) Commission Regulation (EC) No 658/2007 of 14 June 2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 155, 15.6.2007, p. 10).