COMMISSION DELEGATED REGULATION (EU) 2021/577

of 29 January 2021

supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the content and format of the information necessary to apply Articles 112(4) and 115(5) and to be contained in the single lifetime identification document referred to in Article 8(4) of that Regulation

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ([1]), and in particular Article 109(1) thereof,

Whereas:

(1) In accordance with Article 8(4) of Regulation (EU) 2019/6, certain data, normally required for the marketing authorisation of a veterinary medicinal product, do not need to be submitted for products intended for animals of the equine species that have been declared as not being intended for slaughter for human consumption in the 'single lifetime identification document' referred to in point (c) of Article 114(1) of Regulation (EU) 2016/429 of the European Parliament and of the Council ([2]).

(2) Article 112 of Regulation (EU) 2019/6 provides for a derogation in respect of non-food-producing animal species from the rule that a veterinary medicinal product must be used in accordance with the terms of the marketing authorisation. In accordance with Article 112(4), that derogation also applies to the treatment by a veterinarian of an animal of the equine species provided that it is declared as not being intended for slaughter for human consumption in the single lifetime identification document.

(3) Article 115(5) of Regulation (EU) 2019/6 empowers the Commission to establish, by means of implementing acts, a list of substances which are essential for the treatment of equine species, or which bring added clinical benefit compared to other treatment options available for equine species and for which the withdrawal period for equine species is six months. In order to ensure consumer protection, details of a treatment applied in accordance with Article 115(5) should be documented in the single lifetime identification document.

(4) Taking into account the longevity of equids and the singularity of their accompanying identification document, valid identification documents issued in accordance with Commission Decisions 93/623/EEC ([3]) and 2000/68/EC ([4]), Commission Regulation (EC) No 504/2008 ([5]) and Commission Implementing Regulation (EU) 2015/262 ([6]) should be deemed to meet the content and format requirements as regards the information necessary to apply a treatment with a veterinary medicinal product applied in accordance with Article 112(4) or containing a substance listed in accordance with Article 115(5) of Regulation (EU) 2019/6 in the format laid down in this Regulation.

([1]) OJ L 4, 7.1.2019, p. 43.

([2]) Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1).

([3]) Commission Decision 93/623/EEC of 20 October 1993 establishing the identification document (passport) accompanying registered equidae (OJ L 298, 3.12.1993, p. 45).

([4]) Commission Decision 2000/68/EC of 22 December 1999 amending Commission Decision 93/623/EEC and establishing the identification of equidae for breeding and production (OJ L 23, 28.1.2000, p. 72).

([5]) Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae (OJ L 149, 7.6.2008, p. 3).

([6]) Commission Implementing Regulation (EU) 2015/262 of 17 February 2015 laying down rules pursuant to Council Directives 90/427/EEC and 2009/156/EC as regards the methods for the identification of equidae (Equine Passport Regulation) (OJ L 59, 3.3.2015, p. 1).

(5) This Regulation should be applicable from 28 January 2022 in accordance with the date of application provided for in Regulation (EU) 2019/6.

(6) In accordance with Article 147(5) of Regulation (EU) 2019/6, the Commission has consulted experts designated by each Member State,

HAS ADOPTED THIS REGULATION:

Article 1

Content and format of the information necessary to apply Articles 112(4) and 115(5) of Regulation (EU) 2019/6

The content and format of the information necessary to apply Articles 112(4) and 115(5) of Regulation (EU) 2019/6 and to be contained in the single lifetime identification document shall comply with the requirements set out in Annexes I and II to this Regulation.

Article 2

Transitional measures

By way of derogation from Article 1, the following shall be deemed to meet the content and format requirements of information referred to in Article 1:

(a) the content and format of the information in 'Section IX Medicinal Treatment' of the identification document set out in the Annex to Decision 93/623/EEC and issued in accordance with Article 43(1)(a) of Implementing Regulation (EU) 2015/262;

(b) the content and format of the information in 'Section IX Administration of veterinary medicinal products' of the identification document as set out in Annex I to Implementing Regulation (EC) No 504/2008 and issued in accordance with Article 43(1)(b) and (c) of Implementing Regulation (EU) 2015/262;

(c) the content and format of the information in 'Section II Administration of veterinary medicinal products' of the identification document set out in Part 1 of Annex I to Implementing Regulation (EU) 2015/262 issued in accordance with Article 9 or 14 of that Regulation.

Article 3

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.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 29 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

1. The content of the information necessary to apply Article 112(4) of Regulation (EU) 2019/6 shall be the following:

   (a) contact details of the signing veterinarian responsible who treated the equine animal concerned with a veterinary medicinal product authorised under the exemption provided for in Article 8(4) or administered in accordance with Article 112(4) of Regulation (EU) 2019/6;

   (b) the declaration for the equine animal concerned that it is not intended for slaughter for human consumption to be done by the veterinarian responsible in consent with the owner or operator of the equine animal.

2. The content of the information necessary to apply Article 115(5) of Regulation (EU) 2019/6 shall be the following:

   (a) contact details of the signing veterinarian responsible who administered a veterinary medicinal product containing a substance included in the list established in accordance with Article 115(5) of Regulation (EU) 2019/6;

   (b) date and place of the last administration of the veterinary medicinal product referred to in point (a) to the equine animal concerned;

   (c) details of the substance referred to in point (a).

ANNEX II

1. The information necessary to apply Articles 112(4) and 115(5) of Regulation (EU) 2019/6 shall be included in a dedicated section that:

   (a) shall be indivisibly integrated in the single lifetime identification document;

   (b) shall contain titled form fields to be completed in accordance with detailed instructions; those titled form fields and the instructions for their completion shall be displayed in French, English and the official language of the Member State in which the single lifetime identification document is issued;

   (c) shall consist of at least two parts providing form fields for the entry of information necessary:

      (i) to declare the equine animal as not intended for slaughter for human consumption in order to apply Article 112(4);

      (ii) to document the date of last administration of a veterinary medicinal product containing a substance included in the list established in accordance with Article 115(5) of Regulation (EU) 2019/6, and details of that substance.

2. The format of the information necessary to apply Article 112(4) of Regulation (EU) 2019/6 shall meet the following additional criteria:

   (a) the format of the dedicated section referred to in paragraph 1 shall ensure that at least the declaration on the exclusion from slaughter for human consumption can be protected from fraudulent alterations;

   (b) the format of the declaration referred to in point (a) shall be compatible with a corresponding entry in the database referred to in Article 109(1)(d) of Regulation (EU) 2016/429.