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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	29 January 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2021) 436 final
Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 29.1.2021 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

Delegations will find attached document C(2021) 436 final.

Encl.: C(2021) 436 final

EUROPEAN
COMMISSION

Brussels, 29.1.2021
C(2021) 436 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 29.1.2021

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

At present, the rules on identification of equidae, including for the reasons to record certain veterinary medicinal treatment, are laid down in Commission Implementing Regulation (EU) No 2015/262.

Following the adoption of Regulation (EU) 2016/429, the Animal Health Law, the system of identification of equidae was to be reviewed by 20 April 2019 and the outcome of this review to be taken into account when drafting delegated acts on the identification of equine animals.

Regulation (EU) 2019/6 of the European Parliament and of the Council lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of veterinary medicinal products and provides, amongst others, for specific rules on the application of veterinary medicinal products to food-producing animals, including equidae.

In accordance with Article 8 of Regulation (EU) 2019/6, certain information must be submitted to apply for a marketing authorisation. In case of an application concerning a veterinary medicinal product intended for food-producing animals, the pharmacologically active substances therein must be allowed in accordance with Regulation (EC) No 470/2009, or a document must be provided certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency. However this does not apply to veterinary medicinal 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 Article 114(1)(c) of Regulation (EU) 2016/429.

In accordance with Article 112(4) of Regulation (EU) 2019/6, the derogation provided for in Article 112 shall also apply 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 referred to in Article 114(1)(c) of Regulation (EU) 2016/429.

In accordance with Article 115(5), and by way of derogation from Article 113(1) and (4) of Regulation (EU) 2019/6, the Commission shall, by means of implementing acts, establish 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 shall be six months. This list is currently contained in Commission Regulation (EC) No 1950/2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae (OJ L 367, 22.12.2006, p. 33).

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In accordance with Article 264 of Regulation (EU) 2016/429, the Commission has carried out substantial consultation with Member States' experts on delegated acts concerning the identification of terrestrial animals, including equidae.

During these consultations Member States requested to maintain as much as possible the content and format of the information on the status of equine animals as food-producing animals as well as rules on the issuing and secure handling of the single lifetime identification document for equidae as currently laid down in Implementing Regulation (EU) 2015/262,

which meet all the requirements necessary to apply Articles 112(4) and 115(5) of Regulation (EU) 2019/6.

In addition, consultation with Member States' experts in the area of veterinary medicines supported the proposed content and format of information on veterinary medicinal treatments in the single lifetime identification document but also in the database established by Member States in accordance with Article 109 of Regulation (EU) 2016/429.

This draft Delegated Regulation was also made available to the European Parliament and the Council.

There were no comments received from the Council.

There were no comments received from the European Parliament.

In addition, stakeholders' comments on the draft Delegated Regulation were collected in the context of the Better Regulation feedback mechanism during the period between 24 September 2020 and 22 October 2020. In total, feedback from seven stakeholders was received. The comments focused mainly on different issues relating to the identification and treatment with veterinary medicines of equine. The Commission carefully considered and took good note of all the comments received. Nonetheless, the comments were not relevant to the scope of the present draft delegated act. The comments were therefore not taken into account in the context of the present delegated act. As a result, the Commission did not amend the text of the delegated act, following the received feedback.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The requirements for the identification of equidae are laid down in Article 114(1) of Regulation (EU) 2016/429 with particular reference to the single lifetime identification document. In addition, Article 109(1)(d) of that Regulation requires competent authorities to establish and maintain a database in which establishments keeping equidae and their individual identification are recorded.

Article 109(1) of Regulation (EU) 2019/6 empowers the Commission to adopt delegated acts in order to supplement this Regulation 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, i.e. Article 114(1)(c) of Regulation (EU) 2016/429.

Article 109(1) of Regulation (EU) 2019/6 does not empower the Commission to lay down rules on the practical management of the information necessary to apply Articles 112(4) and 115(5) of that Regulation in the context of and in conjunction with the management of identification details of an equine animal for animal health reasons.

4. RELATED LEGAL ACTS

In accordance with Article 120 of Regulation (EU) 2016/429 the Commission is empowered, amongst others, to adopt implementing acts on rules for uniform access to data contained in, and the technical specifications and operational rules of, the computer databases, for the uniform application of the identification and registration system and on the technical specifications and procedures, formats, design and operational rules for the means and methods of identification, including the time periods for the application of the means and methods of identification, as well as on the technical specifications, formats and operational rules for the identification and movement documents. Those implementing acts must be available on the date of application of Regulation (EU) 2016/429.

The implementing act on identification of equidae will be applicable as of 21 April 2021.

However, the date of application of Regulation (EU) 2019/6 – 28 January 2022 - requires to postpone the date of application of the format of the single lifetime identification document to be established in accordance with Article 120(2) of Regulation (EU) 2016/429.

COMMISSION DELEGATED REGULATION (EU) …/...

of 29.1.2021

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 ("single lifetime identification document")[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

[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).

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.

(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.

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[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).

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, 29.1.2021

For the Commission
The President
Ursula VON DER LEYEN