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WORKING DOCUMENT
for
DRAFT COMMISSION IMPLEMENTING REGULATION

establishing 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 and repealing Commission Regulation (EC) No 1950/2006

(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 115(5) thereof,

Whereas:

- (1) Regulation (EU) 2019/6 aims to enhance the internal market and to increase the availability of veterinary medicinal products, while guaranteeing the highest level of public and animal health and environmental protection.
- (2) Regulation (EU) 2019/6 lays down rules for use of veterinary medicinal products, including the requirement to use them in accordance with the terms of their marketing authorisations. Where there is no veterinary medicinal product authorised or available in a Member State for food-producing animals of the equine species or for an indication, veterinarians may, in particular to avoid causing unacceptable suffering and under their direct responsibility, use medicinal products outside the terms of their marketing authorisations, in accordance with the rules laid down in Articles 113 and 115 of that Regulation.
- (3) In order to increase the availability of veterinary medicinal products to food-producing animals of the equine species, and by way of derogation from Article 113(1) and (4) of Regulation (EU) 2019/6, Article 115(5) of that Regulation empowers the Commission to 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.
- (4) Commission Regulation (EC) No 1950/2006 ⁽²⁾, as amended by Commission Regulation (EU) No 122/2013 ⁽³⁾, established a list of substances essential for the

⁽¹⁾ OJ L 4, 7.1.2019, p. 43, ELI: <http://data.europa.eu/eli/reg/2019/6/oj>.

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treatment of equidae and of substances bringing added clinical benefit. Regulation (EC) No 1950/2006 aimed at broadening of therapies in order to meet the healthcare and welfare needs of food-producing animals of the Equidae family, without compromising the high level of consumer protection.

- (5) The list referred to in Article 115(5) of Regulation (EU) 2019/6 aims at achieving the same policy objectives as the list set by Commission Regulation (EC) No 1950/2006. Therefore, the list set out in this Regulation should be based on the same principles underpinning Commission Regulation (EC) No 1950/2006.
- (6) A substance should only qualify as an “essential substance” where no satisfactory alternative for the treatment or diagnosis of an indication is available and where the condition would, if untreated, create unnecessary suffering for the animal. A substance should only qualify as “bringing added clinical benefit” where it provides a clinically relevant advantage based on improved efficacy or safety or a major contribution to treatment or diagnosis. This may be the result, inter alia, of different modes of action, different pharmacokinetic or pharmacodynamic profiles, different lengths of treatment or different routes of administration.
- (7) To ensure a high level of consumer protection, substances should only be included in the list set out in this Regulation where they do not pose an unacceptable risk to consumers when used in food-producing animals of the equine species and a six-month withdrawal period is respected.
- (8) The Annex to Commission Regulation (EC) No 1950/2006 was last updated in 2013 by means of Commission Regulation (EU) No 122/2013. Therefore, the experience gained with the use of the substances listed in that Annex should serve as basis for establishing the list referred to in Article 115(5) of Regulation (EU) 2019/6, including the need to update the information on use of those substances, their advantages and alternatives. Furthermore, the need to add other substances as a result of newly available evidence should be considered.
- (9) At the request of the Commission, the European Medicines Agency (“the Agency”) carried out a scientific evaluation of the substances listed in the Annex to Commission Regulation (EC) No 1950/2006, as well as of the substances that were identified in a survey among the competent authorities and relevant stakeholders. The Agency provided scientific advice ⁽⁴⁾ recommending some of those substances as essential or as bringing added clinical benefit and for which a withdrawal period of six months would not pose an unacceptable risk for consumers.

⁽²⁾ Commission Regulation (EC) No 1950/2006 of 13 December 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 and of substances bringing added clinical benefit (OJ L 367, 22.12.2006, p. 33, ELI: <http://data.europa.eu/eli/reg/2006/1950/oj>).

⁽³⁾ Commission Regulation (EU) No 122/2013 of 12 February 2013 amending 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 42, 13/02/2013, p. 1, ELI: <http://data.europa.eu/eli/reg/2013/122/oj>).

⁽⁴⁾ Scientific advice under Article 115(5) of Regulation (EU) 2019/6 for the establishment of 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 (EMA/CVMP/159047/2023, 18 July 2024).

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- (10) Taking into account the Agency's advice, substances recommended as essential or as bringing added clinical benefit should be used for the specific diseases or conditions, treatment or diagnostic needs specified in the Annex to this Regulation while giving consideration to the alternatives listed in that Annex.
- (11) Substances listed in Tables 1 or 2 in the Annex to Commission Regulation (EU) No 37/2010 ⁽⁵⁾, or substances prohibited for use in stockfarming by Council Directive 96/22/EC ⁽⁶⁾, do not qualify as essential or bringing added clinical benefit. Therefore, when substances listed in the Annex to this Regulation are included in Tables 1 or 2 in the Annex to Commission Regulation (EU) No 37/2010, or their use in food-producing animals of the equine species is prohibited by Union legislation, they should no longer be used for the purposes of this Regulation.
- (12) The list of substances set out in the Annex to this Regulation should replace the list provided for under Commission Regulation (EC) No 1950/2006.
- (13) In order to allow the competent authorities, veterinarians, and animal keepers concerned to adapt to the changes resulting from the non-inclusion in the Annex to this Regulation of some substances or indications listed in the Annex to Commission Regulation (EC) No 1950/2006, a sufficient transitional period should be allowed.
- (14) In order to increase the availability of veterinary medicinal products to food-producing animals of the equine species and avoid unacceptable suffering, this Regulation should enter into force on the day following that of its publication in the Official Journal of the European Union. This Regulation should also apply as from the date of its entry into force.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Scope

The list of substances referred to in Article 115(5) of Regulation (EU) 2019/6 is set out in the Annex to this Regulation.

Article 2

Rules on use of substances listed in the Annex

1. Essential substances may be used as specified in the Annex to this Regulation, where no medicinal product authorised for food-producing animals of the equine species or referred to in Article 113 of Regulation (EU) 2019/6 would yield equally satisfactory

⁽⁵⁾ Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1, ELI: [http://data.europa.eu/eli/reg/2010/37\(1\)/oj](http://data.europa.eu/eli/reg/2010/37(1)/oj)).

⁽⁶⁾ Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of β -agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ L 125, 23.5.1996, p. 3, ELI: <http://data.europa.eu/eli/dir/1996/22/oj>).

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results in terms of successfully treating the animal or avoiding unnecessary suffering for the animal.

2. Substances bringing added clinical benefit may be used as specified in the Annex to this Regulation and taking into account the alternatives listed in that Annex, where they provide a clinically relevant advantage based on improved efficacy or safety or a major contribution to treatment compared to medicinal products authorised for food-producing animals of the equine species or referred to in Article 113 of Regulation (EU) 2019/6.
3. Where any of the substances listed in the Annex to this Regulation are entered in Tables 1 or 2 of the Annex to Commission Regulation (EU) No 37/2010, or their use in food-producing animals of the equine species is prohibited by Union legislation, such substances shall no longer be used for the purposes of this Regulation.

Article 3

Repeal

1. Commission Regulation (EC) No 1950/2006 is repealed as from [*date 12 months after the date of application of this Regulation*].
2. References to the repealed Commission Regulation (EC) No 1950/2006 shall be construed as references to this Regulation.

Article 4

Entry into force and application

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

It shall apply from [*insert the date of entry into force*].

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

Done at Brussels,

For the Commission

The President

Ursula VON DER LEYEN