



Council of the
European Union

Brussels, 31 January 2022
(OR. fr)

5793/22

AGRILEC 10
VETER 6
PHARM 11
MI 70
SAN 58
DELECT 15

COVER NOTE

From: Secretary-General of the European Commission, signed by Ms Martine
DEPREZ, Director

date of receipt: 27 January 2022

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council
of the European Union

No. Cion doc.: C(2022) 396 final

Subject: COMMISSION DELEGATED REGULATION (EU) .../... of 27.1.2022
correcting Delegated Regulation (EU) 2021/577 as regards certain
references to veterinary medicinal products

Delegations will find attached document C(2022) 396 final.

Encl.: C(2022) 396 final



Brussels, 27.1.2022
C(2022) 396 final

COMMISSION DELEGATED REGULATION (EU) .../...

of 27.1.2022

**correcting Delegated Regulation (EU) 2021/577 as regards certain references to
veterinary medicinal products**

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

This Delegated Regulation will correct Delegated Regulation (EU) 2021/577 as regards certain references to veterinary medicinal products.

During the discussion held in the meeting of the Standing Committee on Veterinary Medicinal Products on 5 May 2021 on the draft implementing act (IA) on the horse passport (Commission Implementing Regulation (EU) 2021/963 adopted on 10 June 2021), Member States pointed to an error in the draft IA where reference to “veterinary medicinal products” is made as opposed to the intended reference to “medicinal products”, covering both human and veterinary products.

The Commission proposed changes in the draft to eliminate that error so that it does not appear in the adopted Commission Implementing Regulation (EU) 2021/963 of 10 June 2021 laying down rules for the application of Regulations (EU) 2016/429, (EU) 2016/1012 and (EU) 2019/6 of the European Parliament and of the Council with regard to the identification and registration of equine animals and establishing model identification documents for those animals (Text with EEA relevance), OJ L 213, 16.6.2021, p. 3.

However, this error also affected the preceding DA (Delegated Regulation (EU) 2021/577 - Medication record in the Horse Passport - published on 9 April 2021). Therefore, the Delegated Regulation (EU) 2021/577 also needs correcting.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

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

3. LEGAL ELEMENTS OF THE DELEGATED ACT

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.

The Commission has adopted the delegated act in line with the empowerment of Article 109(1) of Regulation (EU) 2019/6 on 29 January 2021 (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), OJ L 123, 9.4.2021, p. 3).

This Commission Delegated Regulation (EU) is correcting Delegated Regulation (EU) 2021/577 as regards certain references to veterinary medicinal products.

4. RELATED LEGAL ACTS

This Commission Delegated Regulation (EU) is correcting Delegated Regulation (EU) 2021/577 as regards certain references to veterinary medicinal products.

COMMISSION DELEGATED REGULATION (EU) .../...

of 27.1.2022

correcting Delegated Regulation (EU) 2021/577 as regards certain references to veterinary medicinal products

(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/EC¹, and in particular Article 109(1) thereof,

Whereas:

- (1) The error appears in all language versions of the text of recital (4), as well as point (1)(a) and points (2)(a) and (b) of Annex I and point (1)(c)(ii) of Annex II to Commission Delegated Regulation (EU) 2021/577², as regards the erroneous use of the word 'veterinary' where the text is to be related both to veterinary medicinal products and medicinal products for human use. Therefore, the term 'medicinal product' should be used, encompassing both of those products.
- (2) Delegated Regulation (EU) 2021/577 should therefore be corrected accordingly.
- (3) This Regulation should be applicable from 28 January 2022 in accordance with the date of application of Regulation (EU) 2021/577.
- (4) 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

Delegated Regulation (EU) 2021/577 is corrected as follows:

- (1) Annex I is corrected as follows:
 - (a) point (1)(a) is replaced by 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) of Regulation (EU) 2019/6 or a medicinal product administered in accordance with Article 112(4) of that Regulation’;

¹ OJ L 4, 7.1.2019, p. 43.

² 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 (OJ L 123, 9.4.2021, p. 3).

(b) point (2)(a) and (b) are replaced by the following:

‘(a) contact details of the signing veterinarian responsible who administered a 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 medicinal product referred to in point (a) to the equine animal concerned;’;

(2) in Annex II, point (1)(c)(ii) is replaced by the following:

‘(ii) to document the date of last administration of a 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.’

Article 2

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, 27.1.2022

For the Commission
The President
Ursula VON DER LEYEN