Council of the
European Union

Brussels, 30 November 2022
(OR. en)

15467/1/22
REV 1

AGRILEG 190
VETER 85
PHARM 179
MI 887
SAN 637
DELACT 220

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	23 November 2022
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2022) 8335 final
Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 23.11.2022 amending Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the requirements on compliance with good laboratory practice for veterinary medicinal products set out in Annex II to that Regulation

Delegations will find attached document C(2022) 8335 final.

Encl.: C(2022) 8335 final

EUROPEAN
COMMISSION

Brussels, 23.11.2022
C(2022) 8335 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 23.11.2022

amending Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the requirements on compliance with good laboratory practice for veterinary medicinal products set out in Annex II to that Regulation

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

This Delegated Regulation will amend Regulation (EU) 2019/6 to adapt it to technical and scientific progress.

Following input from the European Medicines Agency, certain references to requirements for pre-clinical studies need to be amended to reflect the fact that compliance with good laboratory practice is not required in relation to efficacy studies, but only for safety studies. Certain provisions of Annex II to Regulation (EU) 2019/6 should be adapted accordingly, thus ensuring that the provisions on compliance with good laboratory practice are applied correctly.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In accordance with Article 147(5) of Regulation (EU) 2019/6, the Commission has carried out written consultation for this delegated act with Member States' experts on veterinary medicinal products.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Article 146(1) of Regulation (EU) 2019/6 empowers the Commission to adopt delegated acts in order to amend Annex II by adapting the requirements regarding the quality, safety and efficacy of veterinary medicinal products to technical and scientific progress.

Point I.1.6, point I.2.3.(1)(b), point I.2.4.(2)(b), point IIIb.3A.(2) and point IIIb.4B.(4)(b) of Annex II to Regulation (EU) 2019/6 should be amended to ensure that the provisions on compliance with good laboratory practice are applied correctly.

COMMISSION DELEGATED REGULATION (EU) …/...

of 23.11.2022

amending Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the requirements on compliance with good laboratory practice for veterinary medicinal products set out in Annex II to 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 146(1) thereof,

Whereas:

(1) Certain references to requirements for pre-clinical studies set out in Annex II to Regulation (EU) 2019/6 need to be adapted to reflect the fact that compliance with good laboratory practice is not required in relation to efficacy studies, but only for safety studies. Point I.1.6, point I.2.3.(1)(b), point I.2.4.(2)(b), point IIIb.3A(2) and point IIIb.4B.(4)(b) of Annex II to Regulation (EU) 2019/6 should be adapted accordingly, thus ensuring that the provisions on compliance with good laboratory practice are applied correctly. The European Medicines Agency has been consulted.

(2) Regulation (EU) 2019/6 should therefore be amended accordingly.

(3) Since Annex II to Regulation (EU) 2019/6, as replaced by Commission Delegated Regulation (EU) 2021/805[2] has applied since 28 January 2022, this Regulation should also apply from that date in order to avoid unnecessary repetition of pharmacological, toxicological, residue and pre-clinical safety studies conducted with respect to applications for marketing authorisations submitted before the entry into force of this Regulation.

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

[2] Commission Delegated Regulation (EU) 2021/805 of 8 March 2021 amending Annex II to Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ L 180, 21.5.2021, p. 3).

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EU) 2019/6 is amended in accordance with the Annex to this Regulation.

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.

Done at Brussels, 23.11.2022

For the Commission
The President
Ursula VON DER LEYEN