COMMISSION DELEGATED REGULATION (EU) 2023/183

of 23 November 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.

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*.

([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).

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, 23 November 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annex II to Regulation (EU) 2019/6 is amended as follows:

(1) point I.1.6 is replaced by the following:

I.1.6 'Pharmacological, toxicological, residue and pre-clinical safety studies shall be carried out in conformity with the provisions related to Good Laboratory Practice (GLP) laid down in Directives 2004/10/EC (*) and 2004/9/EC (**) of the European Parliament and of the Council;

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(*) Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44).

(**) Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (OJ L 50, 20.2.2004, p. 28).'

(2) in point I.2.3(1), subpoint (b) is replaced by the following:

'(b) statement of compliance with GLP for pre-clinical safety studies, where applicable, together with a discussion of the contribution that any non-GLP study may make to the overall risk assessment, and justification of non-GLP status';

(3) in point I.2.4(2), subpoint (b) is replaced by the following:

'(b) a statement of compliance with GLP for pre-clinical safety studies, where applicable, together with a discussion of the contribution that any non-GLP study may make to the overall risk assessment, and justification of non-GLP status';

(4) in point IIIb.3A, subpoint (2) is replaced by the following:

'(2) Pre-clinical safety studies shall be carried out in compliance with GLP requirements.

Non-GLP studies may be accepted for non-target species studies as well as studies evaluating immunological, biological or genetic properties of the vaccine strains, under adequately controlled conditions. Other deviations shall be justified';

(5) in point IIIb.4B, subpoint (4)(b) is deleted.