II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2023/997

of 23 May 2023

amending Implementing Regulation (EU) 2021/17 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council

(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 60(1) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) 2021/17 ([2]) sets out a list of variations not requiring assessment.

(2) The European Medicines Agency ('the Agency') and the Coordination Group on Veterinary Medicinal Products ('CMDv') advised the Commission, on 20 December 2022, to amend points B.12 and B.24 of the Annex to Implementing Regulation (EU) 2021/17 to reflect new developments. Both the Agency and the CMDv received requests for classification of three changes to the terms of a marketing authorisation not listed in the Annex to Implementing Regulation (EU) 2021/17 that had not arisen before as variations not requiring assessment. These changes concern production equipment or processes related to production equipment, and changes in relation to the manufacturer responsible for batch release.

(3) The Commission took into account the advice of the Agency and the CMDv, the criteria listed in Article 60(2) of Regulation (EU) 2019/6, as well as all necessary conditions and the most current documentation requirements, to ensure that the new variations not requiring assessment do not present a risk to public health, animal health or the environment.

(4) Implementing Regulation (EU) 2021/17 should therefore be amended accordingly to include these new types of variations currently not listed in the Annex to that Implementing Regulation.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

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

([2]) Commission Implementing Regulation (EU) 2021/17 of 8 January 2021 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ L 7, 11.1.2021, p. 22).

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2021/17 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*.

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

Done at Brussels, 23 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In the Annex to Implementing Regulation (EU) 2021/17, point B is amended as follows:

(1) in point 12, the following point is added:

'h)	— to production equipment (when described in the dossier) including processes related to the equipment	The change shall not result in any changes or modifications of the production process or quality of the product.	Amendment of the relevant section(s) of the dossier.'

(2) point 24 is replaced by the following:

'24	Replacement or addition of a manufacturer responsible for:	The manufacturer or the site shall already be introduced in the Union IT systems storing and providing organisational data. The site shall be appropriately authorised and satisfactorily inspected.	Amendment of the relevant section(s) of the dossier, including revised product information, as appropriate. Qualified person (QP) declaration.'
a)	— batch release including batch control or testing of a sterile or non-sterile finished product	The change shall not be applicable to a biological or immunological medicinal product. Method transfer from the former to the new site shall have been successfully completed.	
b)	— batch release not including batch control or testing of a sterile or non-sterile finished product	At least one batch control/testing site remains within the EEA or in a country where an operational and suitably scoped GMP mutual recognition agreement (MRA) exists between the country concerned and the EU, that is able to carry out product testing for the purpose of batch release within the EEA.	