2024/916

27.3.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/916

of 26 March 2024

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) Commission Implementing Regulation (EU) 2024/875 ([3]) sets out a list of abbreviations and pictograms common throughout the Union to be used on the packaging of veterinary medicinal products for the purposes of Article 10(2) and Article 11(3) of Regulation (EU) 2019/6. Veterinary medicinal products authorised before the date of application of that Regulation might not contain such abbreviations or pictograms or might contain abbreviations or pictograms that do not yet comply with the requirements established therein, and therefore require a variation of the terms of the marketing authorisation. Such variations do not require any scientific assessment and should be included in the Annex to Implementing Regulation (EU) 2021/17.

(3) Commission Implementing Regulation (EU) 2024/878 ([4]) sets out uniform rules on the size of small immediate packaging units of veterinary medicinal products. Veterinary medicinal products authorised before the date of application of that Regulation might not yet comply with the requirements established therein, and therefore require a variation of the terms of the marketing authorisation. Such variations do not require any scientific assessment and should be included in the Annex to Implementing Regulation (EU) 2021/17.

(4) The Commission has taken into account all necessary conditions to be fulfilled for the variation to be classified as a variation not requiring assessment and the documentation to be submitted with the application for the variation not requiring assessment. In order to ensure the good use of the veterinary medicinal product, the listing as a variation not requiring assessment should be conditional on the addition not having an impact on the readability of the label.

(5) Implementing Regulation (EU) 2021/17 should therefore be amended accordingly.

(6) 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, ELI: http://data.europa.eu/eli/reg/2019/6/2022-01-28

([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, ELI: http://data.europa.eu/eli/reg_impl/2021/17/oj).

([3]) Commission Implementing Regulation (EU) 2024/875 of 21 March 2024 adopting a list of abbreviations and pictograms common throughout the Union to be used on the packaging of veterinary medicinal products for the purposes of Article 10(2) and Article 11(3) of Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ L 2024/875, 22.3.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/875/oj).

([4]) Commission Implementing Regulation (EU) 2024/878 of 21 March 2024 adopting uniform rules on the size of small immediate packaging units of veterinary medicinal products as referred to in Article 12 of Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ L 2024/878, 22.3.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/878/oj).

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, 26 March 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In the Annex to Implementing Regulation (EU) 2021/17, part C, entry 10, the following points are added:

	Variation	**Requirements** The requirements indicated in the line for the main section are valid for each sub-section of the given section. Any additional requirement specified in the sub-section should be read together with the requirements indicated in the main section.	
Number		Conditions	Documents to be provided
‘d)	— replacement of information on the immediate or outer packaging by an abbreviation or pictogram — replacement of an existing abbreviation or pictogram on the immediate or outer packaging that is not compliant with Commission Implementing Regulation (EU) 2024/875 by another abbreviation or pictogram	The new abbreviation or pictogram is included in Annex I or Annex II to Commission Implementing Regulation (EU) 2024/875 adopting a list of abbreviations and pictograms common throughout the Union to be used on the packaging of veterinary medicinal products for the purposes of Article 10(2) and Article 11(3) of Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ L, 2024/875, 22.3.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/875/oj). The addition does not have a negative impact on the readability of the labelling.	
e)	Alignment of the labelling of the immediate packaging with the requirements laid down in Article 12 of Regulation (EU) 2019/6	The packaging qualifies as a small immediate packaging unit under Commission Implementing Regulation (EU) 2024/878 adopting uniform rules on the size of small immediate packaging units of veterinary medicinal products as referred to in Article 12 of Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ L, 2024/878, 22.3.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/878/oj).’	