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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

(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 17(3) thereof,

Whereas:

(1) Article 12(1) of Regulation (EU) 2019/6 sets out the information to be contained on the labelling of small immediate packaging units of veterinary medicinal products. That information is limited in order to ensure that all the essential information can be presented on the label in a readable manner.

(2) In accordance with Article 17(3) of Regulation (EU) 2019/6, uniform rules on the size of small immediate packaging units are to be adopted. Such uniform rules should contribute to reducing the administrative burden for marketing authorisation holders, improving the functioning of the internal market and increasing the availability of veterinary medicinal products in the Union.

(3) In accordance with the existing guidance of the Working Group on Quality Review of Documents of the European Medicines Agency, any form of packaging that is in direct contact with the veterinary medicinal product and has a nominal volume of up to and including 50 ml, should be considered as a small immediate packaging unit.

(4) Pursuant to Article 7(2) of Regulation (EU) 2019/6, veterinary medicinal products may be labelled in several languages. Some packaging units with a nominal volume exceeding 50 ml might still be too small or might have a shape or configuration that makes it impossible to accommodate in readable form all the labelling information as set out in Article 10(1) of Regulation (EU) 2019/6 in several national languages. For those cases, a derogation to the 50 ml threshold should be provided for. To ensure that the user is correctly informed on the properties of the product, this derogation should only apply to veterinary medicinal products subject to veterinary prescription.

(5) Veterinary medicinal products authorised before the date of application of this Regulation, or which are subject to an ongoing application for a marketing authorisation on the date of application of this Regulation, might not comply with the requirements of this Regulation. Therefore, to ensure the continued availability of those products it is necessary to provide for a transitional period during which they should be allowed to be placed on the market even if the information contained on their labelling as regards immediate packaging units does not comply with this Regulation.

(6) Applicants intending to submit an application either for marketing authorisation or for a variation would need sufficient time to adapt their applications to make them compliant with the provisions set in this Regulation. Therefore, this Regulation should apply 30 days after the date of entry into force.

(7) 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/oj.

HAS ADOPTED THIS REGULATION:

Article 1

1. The following types of immediate packaging shall be considered to be small immediate packaging units within the meaning of Article 12 of Regulation (EU) 2019/6:

(a) blisters or strips;

(b) ampoules and small single-dose containers other than ampoules;

(c) a container or any other form of packaging that is in direct contact with the veterinary medicinal product and has a nominal volume of up to and including 50 ml.

2. By way of derogation from paragraph 1, point (c), competent authorities of Member States, or where relevant, the Commission, may consider multilingual immediate packaging units not exceeding a nominal volume of 100 ml to qualify as small immediate packaging units where the following conditions are fulfilled:

(a) the immediate packaging unit is too small or has a shape or configuration that makes it impossible to accommodate the information referred to in Article 10(1) of Regulation (EU) 2019/6 in a readable manner, and

(b) the veterinary medicinal product is classified as subject to veterinary prescription in accordance with Article 34 of Regulation (EU) 2019/6.

Article 2

Veterinary medicinal products authorised before 11 May 2024, or which are subject to an ongoing application for a marketing authorisation on 11 May 2024, once authorised, may be placed on the market until 11 April 2031, even if the information contained on their labelling as regards immediate packaging units is not in compliance with this Regulation.

Article 3

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 11 May 2024.

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

Done at Brussels, 21 March 2024.

For the Commission
The President
Ursula VON DER LEYEN