COMMISSION DELEGATED REGULATION (EU) 2022/2239

of 6 September 2022

amending Regulation (EU) No 536/2014 of the European Parliament and of the Council as regards labelling requirements for unauthorised investigational and unauthorised auxiliary medicinal products for human use

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC ([1]), and in particular Article 70 thereof,

Whereas:

(1) Regulation (EU) No 536/2014 sets out detailed rules for the labelling of investigational and auxiliary medicinal products, in particular of unauthorised products, in order to eliminate divergences of approach among Member States. That Regulation requires that the immediate and outer packaging of investigational and auxiliary medicinal products must be appropriately labelled in order to ensure subject safety and the reliability and robustness of data generated in clinical trials, and in order to allow for the distribution of those products to clinical trial sites throughout the Union.

(2) In particular, Regulation (EU) No 536/2014 requires sponsors to display the period of use on the outer and immediate packaging of unauthorised investigational and unauthorised auxiliary medicinal products.

(3) Frequent updates of the period of use on the immediate packaging of unauthorised medicinal products used in clinical trials can be associated in certain cases with potential risks affecting the quality and safety of those products. One such potential risk may be damages stemming from the need to open the packaging by breaking tamper evident seals and disassembling the multilayer kit. Another potential risk may stem from the prolonged exposure to light or higher temperatures for medicinal products with specific sensitivities. Those risks apply in particular to medicinal products where the immediate and outer packaging are provided together as well as when the immediate packaging takes the form of blister packs or small units. In those cases, it is appropriate and proportionate to the nature and the extent of the risk that the period of use is omitted from the immediate packaging.

(4) Regulation (EU) No 536/2014 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex VI to Regulation (EU) No 536/2014 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 158, 27.5.2014, p. 1.

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

Done at Brussels, 6 September 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annex VI to Regulation (EU) No 536/2014 is amended as follows:

(1) Section A is amended as follows:

(a) in Section A.2.1.4, points (e) and (f) are replaced by the following:

'(e) the subject identification number and/or the treatment number and, where relevant, the visit number.';

(b) in Section A.2.2.5, points (e) and (f) are replaced by the following:

'(e) the subject identification number/treatment number and, where relevant, the visit number.';

(2) Section B is amended as follows:

(a) the number of point '6.' is replaced by '6.1.';

(b) the following paragraphs B.6.2 and B.6.3 are added:

'6.2. In the case where the immediate and outer packaging are intended to remain together, the outer package shall carry the particulars listed in Section B.6.1. The immediate packaging shall carry the particulars listed in Section B.6.1 with the exception of the period of use (expiry date or retest date as applicable) that can be omitted.

6.3. If the immediate packaging takes the form of blister packs or small units such as ampoules, on which the particulars listed in Section B.6.1 cannot be displayed, an outer packaging shall be provided bearing a label with those particulars. The immediate packaging shall contain the particulars listed in Section B.6.1 with the exception of the period of use (expiry date or retest date as applicable) that can be omitted.';

(3) Section D is amended as follows:

(a) in Section D.9 points (b), (c) and (d) are replaced by the following:

'(b) paragraph 4, points (b), (c) and (e);

(c) paragraph 5, points (b), (c) and (e);

(d) paragraph 6.1, points (b), (d), (e) and (h);';

(b) in Section D.9 the following point (e) is added:

'(e) paragraph 6.1, point (i), with the exception of cases in which the period of use (expiry date or retest date as applicable) can be omitted from the inner packaging in accordance with Sections B.6.2 and B.6.3.'.