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COMMISSION DELEGATED REGULATION (EU) 2026/863

of 20 April 2026

correcting certain language versions of Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for 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 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ([1]), and in particular Article 23b(2a) thereof,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency ([2]), and in particular Article 16a(3) thereof,

Whereas:

(1) The Bulgarian, Dutch, Estonian, Greek, Lithuanian and Polish language versions of Commission Regulation (EC) No 1234/2008 ([3]) contain an error in Article 20(1), as regards the legal obligation of the marketing authorisation holder to follow the worksharing procedure laid down in paragraphs 3 to 9 of that Article. The error alters the meaning of the provision, affecting its substance.

(2) The Bulgarian, Dutch, Estonian, Greek, Lithuanian and Polish language versions of Regulation (EC) No 1234/2008 should therefore be corrected accordingly. The other language versions are not affected,

HAS ADOPTED THIS REGULATION:

Article 1

(does not concern the English language)

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, 20 April 2026.

For the Commission
The President
Ursula VON DER LEYEN

([1]) OJ L 311, 28.11.2001, p. 67, ELI: http://data.europa.eu/eli/dir/2001/83/oj.
([2]) OJ L 136, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/726/oj.
([3]) Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use (OJ L 334, 12.12.2008, p. 7, ELI: http://data.europa.eu/eli/reg/2008/1234/oj).