

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 and veterinary medicinal products (Text with EEA relevance)

CHAPTER V

FINAL PROVISIONS

Article 25

Continuous monitoring

Where requested by a relevant authority, the holder shall supply without delay any information related to the implementation of a given variation.

Article 26

Review

By two years from the date referred to in the second subparagraph of Article 28, the Commission services shall assess the application of this Regulation as regards the classification of variations, with a view to proposing any necessary amendments to adapt Annexes I, II and V to take account of scientific and technical progress.

Article 27

Repeal and transitional provision

1 Regulations (EC) No 1084/2003 and (EC) No 1085/2003 are hereby repealed.

References to the repealed Regulations shall be construed as references to this Regulation.

2 By way of derogation from paragraph 1, Regulations (EC) Nos 1084/2003 and 1085/2003 shall continue to apply to valid notifications or applications for variations which are pending at the date referred to in the second subparagraph of Article 28.

Article 28

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2010.

By way of derogation from the second subparagraph, the recommendations on unforeseen variations provided for in Article 5 may be requested, delivered and published from the date of entry into force referred to in the first subparagraph.

Changes to legislation:

There are outstanding changes not yet made to Commission Regulation (EC) No 1234/2008. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

[View outstanding changes](#)

Changes and effects yet to be applied to :

- Regulation revoked in part by [S.I. 2019/775 Sch. 9 para. 1\(p\)](#)