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

TITLE III U.K.

PLACING ON THE MARKET

CHAPTER 3 U.K.

Procedures relevant to the marketing authorization

[F1 Article 23b U.K.

[F2 1 Variations shall be classified in different categories depending on the level of risk to public health and the potential impact on the quality, safety and efficacy of the medicinal product concerned. Those categories shall range from changes to terms of the marketing authorisation that have the highest potential impact on the quality, safety or efficacy of the medicinal product, to changes that have no or minimal impact thereon.

2 The procedures for examination of applications for variations shall be proportionate to the risk and impact involved. Those procedures shall range from procedures that allow implementation only after approval based on a complete scientific assessment to procedures that allow immediate implementation and subsequent notification by the marketing authorisation holder to the competent authority.

2a The Commission is empowered to adopt delegated acts in accordance with Article 121a in order to supplement this Directive by:

a specifying the categories in which variations shall be classified; and

b establishing procedures for the examination of applications for variations to the terms of marketing authorisations.

3 When adopting the delegated acts referred to in this Article, the Commission shall endeavour to make possible the submission of a single application for one or more identical changes made to the terms of different marketing authorisations.

4 A Member State may continue to apply national provisions on variations applicable at the time of entry into force of Commission Regulation (EC) No 1234/2008[(1)] to marketing authorisations granted before 1 January 1998 to medicinal products authorised only in that Member State. Where a medicinal product subject to national provisions in accordance with this Article is subsequently granted a marketing authorisation in another Member State, Regulation (EC) No 1234/2008 shall apply to that medicinal product from that date.**]**

5 Where a Member State decides to continue to apply national provisions pursuant to paragraph 4, it shall notify the Commission thereof. If a notification has not been made by 20 January 2011, **[**F2 Regulation (EC) No 1234/2008**]** shall apply.**]**

Textual Amendments

F1 Inserted by Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive 2001/82/EC and Directive 2001/83/EC, as regards variations to the terms of marketing authorisations for medicinal products (Text with EEA relevance).

F2 Substituted by Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use (Text with EEA relevance).

(1) **[**[F1]**[**[F2]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 (OJ L 334, 12.12.2008, p. 7).**]]**

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