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)

COMMISSION REGULATION (EC) No 1234/2008

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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)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[(1)], and in particular Article 39(1) thereof,

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[(2)], and in particular Article 35(1) thereof,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[(3)], and in particular of Article 16(4) and Article 41(6) thereof,

Whereas:

(1) The Community legal framework regarding variations to the terms of marketing authorisations is laid down in Commission Regulation (EC) No 1084/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State[(4)] and Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[(5)]. In the light of practical experience in the application of those two Regulations, it is appropriate to proceed to their review in order to establish a simpler, clearer and more flexible legal framework, while guaranteeing the same level of public and animal health protection.

(2) The procedures laid down in Regulations (EC) No 1084/2003 and (EC) No 1085/2003 should therefore be adjusted, without departing from the general principles on which those procedures are based. For reasons of proportionality, homeopathic and traditional herbal medicinal products which have not been granted a marketing authorisation but

are subject to a simplified registration procedure should remain excluded from the scope of the Regulation.

(3) Variations to medicinal products can be classified in different categories, depending on the level of risk to public or animal health and the impact on the quality, safety and efficacy of the medicinal product concerned. Definitions for each of those categories should therefore be laid down. In order to bring further predictability, guidelines on the details of the various categories of variations should be established and regularly updated in the light of scientific and technical progress, taking in particular account of developments regarding international harmonisation. The European Medicines Agency (hereinafter the Agency) and the Member States should also be empowered to give recommendations on the classification of unforeseen variations.

(4) It should be clarified that certain changes which have the highest potential impact on the quality, safety or efficacy of medicinal products require a complete scientific assessment, in the same way as for the evaluation of new marketing authorisation applications.

(5) In order to further reduce the overall number of variations procedures and to enable competent authorities to focus on those variations that have a genuine impact on quality, safety or efficacy, an annual reporting system should be introduced for certain minor variations. Such variations should not require any prior approval and should be notified within 12 months following implementation. However, other types of minor variations whose immediate reporting is necessary for the continuous supervision of the medicinal product concerned should not be subject to the annual reporting system.

(6) Each variation should require a separate submission. Grouping of variations should nevertheless be allowed in certain cases, in order to facilitate the review of the variations and reduce the administrative burden. Grouping of variations to the terms of several marketing authorisations from the same marketing authorisation holder should be allowed only insofar as all concerned marketing authorisations are affected by the exact same group of variations.

(7) In order to avoid duplication of work in the evaluation of variations to the terms of several marketing authorisations, a worksharing procedure should be established under which one authority, chosen amongst the competent authorities of the Member States and the Agency, should examine the variation on behalf of the other concerned authorities.

(8) Provisions should be established reflecting those laid down in Directive 2001/82/EC and Directive 2001/83/EC as regards the role of the coordination groups established under Article 31 of Directive 2001/82/EC and Article 27 of Directive 2001/83/EC, to increase cooperation between Member States and allow for the settlement of disagreements in the evaluation of certain variations.

(9) This Regulation should clarify when the holder of a marketing authorisation is allowed to implement a given variation as such clarification is essential for economic operators.

(10) A transitional period should be established in order to give all interested parties, in particular Member States authorities and the industry, time to adapt to the new legal framework.

(11) The measures provided for in this Regulation are in accordance with the opinions of the Standing Committee on Medicinal Products for Human Use and the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

(**1**) OJ L 311, 28.11.2001, p. 1.

(**2**) OJ L 311, 28.11.2001, p. 67.

(**3**) OJ L 136, 30.4.2004, p. 1.

(**4**) OJ L 159, 27.6.2003, p. 1.

(**5**) OJ L 159, 27.6.2003, p. 24.

Status:
Point in time view as at 24/11/2008.

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.