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 I

GENERAL PROVISIONS

Article 1

Subject matter and scope

1 This Regulation lays down provisions concerning the examination of variations to the terms of the following marketing authorisations for medicinal products for human use and veterinary medicinal products:

a authorisations granted in accordance with Council Directive 87/22/EEC[(1)], Articles 32 and 33 of Directive 2001/82/EC, Articles 28 and 29 of Directive 2001/83/EC and Regulation (EC) No 726/2004;

b authorisations granted following a referral, as provided for in Articles 36, 37 and 38 of Directive 2001/82/EC or Articles 32, 33 and 34 of Directive 2001/83/EC, which has led to complete harmonisation.

2 This Regulation shall not apply to transfers of a marketing authorisation from one marketing authorisation holder (hereinafter holder) to another.

3 Chapter II shall apply only to variations to the terms of marketing authorisations granted in accordance with Directive 87/22/EEC, Chapter 4 of Directive 2001/82/EC or Chapter 4 of Directive 2001/83/EC.

4 Chapter III shall apply only to variations to the terms of marketing authorisations granted in accordance with Regulation (EC) No 726/2004 (hereinafter centralised marketing authorisations).

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

1. ‘Variation to the terms of a marketing authorisation’ or ‘variation’ means an amendment to the contents of the particulars and documents referred to in:

   (a) Articles 12(3), 13, 13a, 13b, 13c, 13d and 14 of Directive 2001/82/EC and Annex I thereto, and Article 31(2) of Regulation (EC) No 726/2004 in the case of veterinary medicinal products;

   (b) Articles 8(3), 9, 10, 10a, 10b, 10c and 11 of Directive 2001/83/EC and Annex I thereto, Article 6(2) of Regulation (EC) No 726/2004, point (a) of Article 7(1) and Article 34(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council[(2)] and Articles 7 and 14(1) of Regulation (EC)

No 1394/2007 of the European Parliament and of the Council[3] in the case of medicinal products for human use;

2. 'Minor variation of type IA' means a variation which has only a minimal impact, or no impact at all, on the quality, safety or efficacy of the medicinal product concerned;

3. 'Major variation of type II' means a variation which is not an extension and which may have a significant impact on the quality, safety or efficacy of the medicinal product concerned;

4. 'Extension of a marketing authorisation' or 'extension' means a variation which is listed in Annex I and fulfils the conditions laid down therein;

5. 'Minor variation of type IB' means a variation which is neither a minor variation of type IA nor a major variation of type II nor an extension;

6. 'Member State concerned' means a Member State whose competent authority has granted a marketing authorisation for the medicinal product in question;

7. 'Relevant authority' means:

   (a) the competent authority of each Member State concerned;

   (b) in the case of centralised marketing authorisations, the Agency;

8. 'Urgent safety restriction' means an interim change to the product information due to new information having a bearing on the safe use of the medicinal product, concerning in particular one or more of the following items in the summary of product characteristics: therapeutic indications, posology, contra-indications, warnings, target species and withdrawal periods.

Article 3

Classification of variations

1 In relation to any variation which is not an extension the classification laid down in Annex II shall apply.

2 A variation which is not an extension and whose classification is undetermined after application of the rules provided for in this Regulation, taking into account the guidelines referred to in point (a) of Article 4(1) and, where relevant, any recommendations delivered pursuant to Article 5, shall by default be considered a minor variation of type IB.

3 By way of derogation from paragraph 2, a variation which is not an extension and whose classification is undetermined after application of the rules provided for in this Regulation shall be considered a major variation of type II in the following cases:

a upon request from the holder when submitting the variation;

b where the competent authority of the reference Member State as referred to in Article 32 of Directive 2001/82/EC and Article 28 of Directive 2001/83/EC (hereinafter the reference Member State), in consultation with the other Member States concerned or, in the case of a centralised marketing authorisation, the Agency concludes, following the assessment of validity of a notification in accordance with Article 9(1) or Article 15(1) and taking into account the recommendations delivered pursuant to Article 5, that the variation may have a significant impact on the quality, safety or efficacy of the medicinal product concerned.

Article 4

Guidelines

1 The Commission shall, after consulting the Member States, the Agency and interested parties, draw up:

a guidelines on the details of the various categories of variations;

b guidelines on the operation of the procedures laid down in Chapters II, III and IV of this Regulation as well as on the documentation to be submitted pursuant to these procedures.

2 Guidelines referred to in point (a) of paragraph 1 shall be drawn up by the date referred to in the second subparagraph of Article 28 and shall be regularly updated, taking into account the recommendations delivered in accordance with Article 5 as well as scientific and technical progress.

Article 5

Recommendation on unforeseen variations

1 Prior to submission or examination of a variation whose classification is not provided for in this Regulation, a holder or a competent authority of a Member State may request the coordination group referred to in Article 31 of Directive 2001/82/EC or in Article 27 of Directive 2001/83/EC (hereinafter the coordination group) or, in the case of a variation to the terms of a centralised marketing authorisation, the Agency to provide a recommendation on the classification of the variation.

The recommendation referred to in the first subparagraph shall be consistent with the guidelines referred to in point (a) of Article 4(1). It shall be delivered within 45 days following receipt of the request and sent to the holder, the Agency and the competent authorities of all Member States.

2 The Agency and the two coordination groups referred to in paragraph 1 shall cooperate to ensure the coherence of the recommendations delivered in accordance with that paragraph and publish those recommendations after deletion of all information of commercial confidential nature.

Article 6

Variations leading to the revision of product information

Where a variation leads to the revision of the summary of product characteristics, labelling or package leaflet, this revision shall be considered as part of that variation.

Article 7

Grouping of variations

1 Where several variations are notified or applied for, a separate notification or application as laid down in Chapters II, III and IV shall be submitted in respect of each variation sought.

2 By way of derogation from paragraph 1, the following shall apply:

a where the same minor variations of type IA to the terms of one or several marketing authorisations owned by the same holder are notified at the same time to the same relevant authority, a single notification as referred to in Articles 8 and 14 may cover all such variations;

b where several variations to the terms of the same marketing authorisation are submitted at the same time, a single submission may cover all such variations provided that the variations concerned fall within one of the cases listed in Annex III or, if they do not fall within one of those cases, provided that the competent authority of the reference Member State in consultation with the other Member States concerned or, in the case of a centralised marketing authorisation, the Agency agrees to subject those variations to the same procedure.

The submission referred to in point (b) of the first subparagraph shall be made by means of the following:

— a single notification as referred to in Articles 9 and 15 where at least one of the variations is a minor variation of type IB and all variations are minor variations;

— a single application as referred to in Articles 10 and 16 where at least one of the variations is a major variation of type II and none of the variations is an extension;

— a single application as referred to in Article 19 where at least one of the variations is an extension.

(**1**) OJ L 15, 17.1.1987, p. 38.

(**2**) OJ L 378, 27.12.2006, p. 1.

(**3**) OJ L 324, 10.12.2007, p. 121.

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

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EC) No 1234/2008, CHAPTER I.