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 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[(1)] and Articles 7 and 14(1) of Regulation (EC) No 1394/2007 of the European Parliament and of the Council[(2)] 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.

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

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