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 IV

SECTION 2

Amendments to the decision granting the marketing authorisation and implementation

Article 24

Implementation of variations

1 A minor variation of type IA may be implemented any time before completion of the procedures laid down in Articles 8 and 14.

Where a notification concerning one or several minor variations of type IA is rejected, the holder shall cease to apply the concerned variation(s) immediately after receipt of the information referred to in Articles 11(1)(a) and 17(1)(a).

2 Minor variations of type IB may only be implemented in the following cases:

a after the competent authority of the reference Member State has informed the holder that it has accepted the notification pursuant to Article 9, or after the notification is deemed accepted pursuant to Article 9(2);

b after the Agency has informed the holder that its opinion referred to in Article 15 is favourable, or after that opinion is deemed favourable pursuant to Article 15(2);

c after the reference authority referred to in Article 20 has informed the holder that its opinion is favourable.

3 Major variations of type II may only be implemented in the following cases:

a 30 days after the competent authority of the reference Member State has informed the holder that it has accepted the variation pursuant to Article 10, under the condition that the documents necessary for the amendment to the marketing authorisation have been provided to the Member States concerned;

b after the Commission has amended the decision granting the marketing authorisation in accordance with the accepted variation and notified the holder accordingly;

c 30 days after the reference authority referred to in Article 20 has informed the holder that its final opinion is favourable, unless an arbitration procedure in accordance with Article 13 or a referral procedure in accordance with Article 35 of Directive 2001/82/EC or Article 31 of Directive 2001/83/EC has been initiated.

4 An extension may only be implemented after the relevant authority or, in the case of extensions to a centralised marketing authorisation, the Commission has amended the decision granting the marketing authorisation in accordance with the approved extension and notified the holder accordingly.

5 Urgent safety restrictions and variations which are related to safety issues shall be implemented within a time frame agreed by the holder and the relevant authority and, in the case of a centralised marketing authorisation, the Commission.

By way of derogation from the first subparagraph, urgent safety restrictions and variations related to safety issues which concern marketing authorisations granted in accordance with Chapter 4 of Directive 2001/82/EC or Chapter 4 of Directive 2001/83/EC shall be implemented within a time frame agreed by the holder and the competent authority of the reference Member State, in consultation with the other relevant authorities.