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 1

Special procedures

Article 19

Extensions of marketing authorisations

1 An application for an extension of a marketing authorisation shall be evaluated in accordance with the same procedure as for the initial marketing authorisation to which it relates.

2 An extension shall either be granted a marketing authorisation in accordance with the same procedure as for the granting of the initial marketing authorisation to which it relates or be included in that marketing authorisation.

Article 20

Worksharing procedure

1 By way of derogation from Article 7(1) and Articles 9, 10, 15 and 16, where a minor variation of type IB, a major variation of type II or a group of variations in the cases of point (b) of Article 7(2) which does not contain any extension relates to several marketing authorisations owned by the same holder, the holder of such authorisations may follow the procedure laid down in paragraphs 3 to 9 of this Article.

2 For the purposes of paragraphs 3 to 9, 'reference authority' shall mean one of the following:

a the Agency where at least one of the marketing authorisations referred to in paragraph 1 is a centralised marketing authorisation;

b the competent authority of a Member State concerned chosen by the coordination group, taking into account a recommendation of the holder, in the other cases.

3 The holder shall submit to all relevant authorities an application containing the elements listed in Annex IV, with an indication of the recommended reference authority.

If the application fulfils the requirements laid down in the first subparagraph, the coordination group shall chose a reference authority and that reference authority shall acknowledge receipt of a valid application.

Where the chosen reference authority is the competent authority of a Member State which has not granted a marketing authorisation for all the medicinal products affected by the application, the coordination group may request another relevant authority to assist the reference authority in the evaluation of that application.

4 The reference authority shall issue an opinion on the valid application referred to in paragraph 3 within one of the following periods:

a a period of 60 days following acknowledgement of receipt of a valid application in the case of minor variations of type IB or major variations of type II;

b a period of 90 days following acknowledgement of receipt of a valid application in the case of variations listed in Part 2 of Annex V.

5 The reference authority may reduce the period referred to in point (a) of paragraph 4, having regard to the urgency of the matter, or extend it to 90 days for variations listed in Part 1 of Annex V.

6 Within the period referred to in paragraph 4, the reference authority may request the holder to provide supplementary information within a time limit set by the reference authority. In this case:

a the reference authority shall inform the other relevant authorities of its request for supplementary information;

b the procedure shall be suspended until such supplementary information has been provided;

c the reference authority may extend the period referred to in point (a) of paragraph 4.

7 Where the reference authority is the Agency, Article 9(1), (2) and (3) and Article 34(1), (2) and (3) of Regulation (EC) No 726/2004 shall apply to the opinion on a valid application referred to in paragraph 4.

Where the opinion on a valid application is favourable:

a the Commission shall, within 30 days following receipt of the final opinion and on the basis of a proposal from the Agency, amend where necessary the concerned centralised marketing authorisations and update the Community Register of Medicinal Products provided for in Article 13(1) and Article 38(1) of Regulation (EC) No 726/2004 accordingly;

b the Member States concerned shall, within 30 days following receipt of the final opinion of the Agency, approve that final opinion, inform the Agency thereof and amend where necessary the concerned marketing authorisations accordingly, unless a referral procedure in accordance with Article 35 of Directive 2001/82/EC or Article 31 of Directive 2001/83/EC is initiated within 30 days following receipt of the final opinion.

8 Where the reference authority is the competent authority of a Member State:

a it shall send its opinion on the valid application to the holder and to all relevant authorities;

b without prejudice to Article 13 and within 30 days following receipt of the opinion, the relevant authorities shall approve that opinion, inform the reference authority and amend the concerned marketing authorisations accordingly.

9 Upon request from the reference authority, the Member States concerned shall provide information related to the marketing authorisations affected by the variation for the purpose of verifying the validity of the application and of issuing the opinion on the valid application.

Article 21

Pandemic situation with respect to human influenza

1 By way of derogation from Articles 12, 18 and 19, where a pandemic situation with respect to human influenza is duly recognised by the World Health Organisation or by the

Community in the framework of Decision 2119/98/EC of the European Parliament and of the Council[(1)], the relevant authorities or, in the case of centralised marketing authorisations, the Commission may exceptionally and temporarily accept a variation to the terms of a marketing authorisation for a human influenza vaccine, where certain non-clinical or clinical data are missing.

2 Where a variation is accepted pursuant to paragraph 1, the holder shall submit the missing non-clinical and clinical data within a time limit set by the relevant authority.

Article 22

Urgent safety restrictions

1 Where, in the event of a risk to public health in the case of medicinal products for human use or, in the case of veterinary medicinal products, in the event of a risk to human or animal health or to the environment, the holder takes urgent safety restrictions on its own initiative, it shall forthwith inform all relevant authorities and, in the case of a centralised marketing authorisation, the Commission.

If no relevant authority or, in the case of a centralised marketing authorisation, the Commission has raised objections within 24 hours following receipt of that information, the urgent safety restrictions shall be deemed accepted.

2 In the event of a risk to public health in the case of medicinal products for human use or, in the case of veterinary medicinal products, in the event of a risk to human or animal health or to the environment, relevant authorities or, in the case of centralised marketing authorisations, the Commission may impose urgent safety restrictions on the holder.

3 Where an urgent safety restriction is taken by the holder or imposed by a relevant authority or the Commission, the holder shall submit the corresponding application for variation within 15 days following the initiation of that restriction.

SECTION 2

Amendments to the decision granting the marketing authorisation and implementation

Article 23

Amendments to the decision granting the marketing authorisation

1 The amendment to the decision granting the marketing authorisation resulting from the procedures laid down in Chapters II and III shall be made:

a within 30 days following receipt of the information referred to in Article 11(1)(c) and Article 17(1)(c), where the concerned variation leads to a six-month extension of the period referred to in Article 13(1) and (2) of Council Regulation (EEC) No 1768/92[(2)], in accordance with Article 36 of Regulation (EC) No 1901/2006;

b within two months following receipt of the information referred to in Article 11(1)(c) and Article 17(1)(c), in the case of major variations of type II and minor variations of type IA which do not require immediate notification for the continuous supervision of the medicinal product concerned;

c within six months following receipt of the information referred to in Article 11(1)(c) and Article 17(1)(c), in the other cases.

2 Where the decision granting a marketing authorisation is amended as a result of one of the procedures laid down in Chapters II, III and IV, the relevant authority or, in the case of centralised marketing authorisations, the Commission shall notify the amended decision without delay to the holder.

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.

(**1**) OJ L 268, 3.10.1998, p. 1.

(**2**) OJ L 182, 2.7.1992, p. 1.