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Types of variations to conditions which constitute basis for grant of marketing authorisation, and conditions and procedure for application for variations

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This Regulation is established on the basis of subsection 77 (3) of the Medicinal Products Act.

§ 1. Scope of application

This Regulation establishes the types of variations to the conditions which constitute the basis for grant of marketing authorisation, and the conditions and procedure for application for variations.

§ 2. Definitions

In this Regulation, the following definitions are used:
1) "variation of type IA" means a variation which has only a minimal impact, or no impact at all, on the quality, efficacy or safety of the medicinal product;
2) "variation of type IB" means a variation which is neither a variation of type IA nor a variation of type II nor an extension of the marketing authorisation;
3) "variation of type II" means a variation which may have a significant impact on the quality, efficacy or safety of the medicinal product;
4) "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;
5) "extension of a marketing authorisation" means a variation which is listed in Annex 1 to this Regulation and which requires submission of a new application for marketing authorisation.

§ 3. Types of variations to the conditions which constitute the basis for grant of marketing authorisation

(1) The variations to the conditions which constitute the basis for grant of marketing authorisation are classified as follows:
1) variation of type IA, listed in Annex 2 to this Regulation;
2) variation of type IB;
3) variation of type II, listed in Annex 2 to this Regulation, including an urgent safety restriction;
4) extension of a marketing authorisation listed in Annex 1 to this Regulation.

(2) By way of derogation, a variation which is not an extension of a marketing authorisation and which has not been listed in Annex 2 to this Regulation shall be considered a variation of type II upon request of the marketing authorisation holder or if the assessment of the variation of type IB reveals that the variation may have a significant impact on the quality, safety or efficacy of the medicinal product.

§ 4. General procedure for application for variations, including notification of variations

(1) In order to amend the conditions which constituted the basis for grant of marketing authorisation, the marketing authorisation holder shall submit to the State Agency of Medicines an application or notification

together with the documentation which serves as the basis of the variation, and pay the state fee stipulated in subsection 77 (2) of the Medicinal Products Act and a professional assessment fee in case of a variation of type II.

(2) The application for variations to the conditions which constituted the basis for grant of marketing authorisation shall be carried out in accordance with Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, pp 7–24), and the guidelines of the European Commission.

(3) The State Agency of Medicines shall publish on its webpage the application or notification form, a list of documents accompanying the variations and the guidelines for classification of variations in accordance with Annexes 1 and 2 to this Regulation.

(4) The application for or notification of a variation shall be submitted in respect of each variation sought.

(5) By way of derogation from subsection (4) of this section, the following shall apply:
1) where the same variations of type IA to the terms of one or several marketing authorisations owned by the same marketing authorization holder are notified at the same time, a single notification may cover all such variations;
2) 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 the variations stipulated in Annex 3 to this Regulation, or provided that the State Agency of Medicines previously agrees to subject those variations to the same procedure;
3) where at least one of the variations is a minor variation of type IB and all variations are minor variations, a single notification of variation of type IB may cover all such variations, with the notification to be processed pursuant to the procedure provided in section 6 of this Regulation;
4) where at least one of the variations is a variation of type II and none of the variations is an extension of a marketing authorisation, a single application for variation of type II may cover all such variations, with the application to be processed pursuant to the procedure provided in section 7 of this Regulation.

(6) where at least one of the variations is an extension of a marketing authorisation, the application shall be assessed in accordance with Regulation No 29 of the Minister of Social Affairs of 18 February 2005 "Conditions and procedure for application for grant and renewal of marketing authorisations in respect of medicinal products, processing of applications and recognition of assessments provided by competent authority of Member State of European Economic Area".

(7) Where a variation leads to or is the consequence of other variations to the terms of the same marketing authorisation, a description of the relation between these variations shall be submitted.

(8) Where a variation requires revision of the summary of product characteristics, labelling or package leaflet, the revision shall be considered as part of that variation and shall be coordinated with the State Agency of Medicines in the course of assessment of the variation. In order to coordinate the revision of the information, the revised information in Estonian and the source text for the translation shall be submitted in electronic form.

(9) The variations shall be approved or rejected with the decision of the State Agency of Medicines. The State Agency of Medicines refuses to approve the variations, if at least one of the circumstances specified in subsection 74 (1) of the Medicinal Products Act exists.

(10) The decision on the approval of the variation of type II, and the decision on the rejection of the variations of type IA, IB and II shall be sent to the applicant in writing.

§ 5. Notification of minor variations of type IA

(1) Notification of a variation of type IA shall be submitted to the State Agency of Medicines within twelve months following the implementation of the variation.

(2) Notification of a variation of type IA requiring immediate notification for continuous supervision of the medicinal product shall be submitted immediately after the implementation of the variation.

(3) For notification of a variation of type IA, the notification shall be submitted to the State Agency of Medicines together with the documentation which serves as the basis for the variation, indicating the date of implementation of the variation or variations.

(4) The notification of a variation of type IA shall be reviewed within 30 days. If within 30 days following the acknowledgement of receipt of a notification, the State Agency of Medicines has failed to send the marketing authorisation holder a decision concerning rejection of the variation, the variation shall be deemed approved.

(5) The variation of type IA may be implemented at any time before the closing of the procedures. Where a variation is rejected, the marketing authorisation holder shall immediately cease to apply the variation.

§ 6. Notification of minor variations of type IB

(1) For notification of a variation of type IB, the notification shall be submitted to the State Agency of Medicines together with the documentation which serves as the basis for the variation.

(2) The notification of a variation of type IB shall be reviewed within 30 days. If within 30 days following the acknowledgement of receipt of a notification, the State Agency of Medicines has failed to send the marketing authorisation holder a decision concerning rejection of the variation, the variation shall be deemed approved and may be implemented.

§ 7. Application for major variations of type II

(1) For application for a variation of type II, the application shall be submitted to the State Agency of Medicines together with the documentation which serves as the basis for the variation.

(2) The application for the variation shall be reviewed and the corresponding decision adopted within 60 days. The term for processing of the application may be extended to 90 days in case of modification of an existing therapeutic indication or addition of a new therapeutic indication.

(3) The term for processing of the application shall be 90 days for the following variations:
1) variations concerning a change to or addition of a non-food producing target species;
2) variations concerning the replacement or addition of a serotype, strain, antigen or combination of serotypes, strains or antigens for a veterinary vaccine against avian influenza, foot-and-mouth disease or bluetongue;
3) variations concerning the replacement of a strain for a veterinary vaccine against equine influenza.

(4) The variation of type II may be only implemented after its approval by the State Agency of Medicines, except for urgent safety restrictions implemented in accordance with Regulation No 32 of the Minister of Social Affairs of 18 February 2005, "Procedure for communication of information concerning safety of medicinal products, and procedure for calculation of fee for monitoring safety and quality of medicinal products".

§ 8. Application for variations to the conditions which constitute the basis for grant of licence for parallel import

(1) A holder of the licence for parallel import shall submit to the State Agency of Medicines the application for a variation in the following cases:
1) in case of revision, in Estonia, of the summary of product characteristics or package leaflet of a proprietary medicinal product concerning which a first marketing authorisation was issued;
2) in case of any changes related to the packaging;
3) in case of any changes in the conditions of the marketing authorisation valid in the source country.

(2) Where a new source country is added, a new application for a licence for parallel import shall be submitted.

(3) The State Agency of Medicines shall decide on the approval or rejection of the variation within 30 days.

§ 9. Regulation No 34 of the Minister of Social Affairs of 18 December 2005 "Types of variations to conditions which constitute basis for grant of marketing authorisation, and conditions and procedure for application for variations" (RTL 2005, 23, 319; 2006, 31, 550) is repealed.