Issuer:	Minister of Social Affairs
Type:	regulation
In force from:	21.07.2012
In force until:	In force
Translation published:	15.10.2014

Terms and procedure for granting and renewing of a marketing authorisation of a medicinal product and handling of an application, and recognising of the evaluation of a competent institution of amember state of the European EconomicArea[1]

Passed 18.02.2005 No. 29
RTL 2005, 23, 314
Entry into force 01.03.2005

Amended by the following acts

Passed	Published	Entry into force
07.10.2005	RTL 2005, 105, 1604	21.10.2005
03.04.2009	RTL 2009, 34, 444	12.04.2009
15.04.2010	RTL 2010, 20, 365	24.04.2010
02.09.2011	RT I, 07.09.2011, 3	10.09.2011
05.07.2012	RT I, 12.07.2012, 2	21.07.2012

The Regulation is established according to clause 3 of section 12 of § 65 of the Medicinal Products Act.
[RTL 2010, 20, 365 - entry into force 24.04.2010]

§ 1. Scope of application

The present Regulation establishes the terms and procedure for granting and renewal of marketing authorisations for medicinal products, handling of applications, including the events when Estonia participates in the handling of an application as a reference member state in mutual recognition or decentralised marketing authorisation procedure of the European Economic Area, and the recognition of the assessment of a competent authority of a member state of the European Economic Area.
[RTL 2009, 34, 444 – entered into force 12.04.2009]

§ 2. Application for granting and renewing of a marketing authorisation of a medicinal product

(1) To apply for granting and renewing of a marketing authorisation of a proprietary medicinal product, an application for marketing authorisation shall be submitted to the State Agency of Medicines according to the application type established in the regulation based on clause 1 of section 12 of § 65 of the Medicinal Products Act, and in the format provided in the above stated regulation.
[RTL 2010, 20, 365 – entered into force 24.04.2010]

(2) An application shall be submitted separately for every proprietary medicinal product, including in the event that they are different pharmaceutical forms containing the same active ingredient and proprietary medicinal products containing the same active ingredient in different quantity.

(3) If a holder of a marketing authorisation informs the State Agency of Medicines of the commencement of actual marketing of a medicinal product according to section 3 of § 64 of the Medicinal Products Act, a sample of the launched proprietary medicinal product shall be submitted.
[RT I, 12.07.2012, 2 – entered into force 21.07.2012]

(3^1) If certified reference materials of active ingredients, degradation compounds of active ingredients, impurities or excipients are not available to the State Agency of Medicines, the State Agency of Medicines

has a right to request a necessary quantity of those for free from the applicant to carry out a control analysis of medicinal products or precursors of the medicinal products according to the methods of the applicant.
[RT I, 07.09.2011, 3 – entered into force 10.09.2011]

(4) The applicant shall be responsible for the truthfulness of information submitted about the proprietary medicinal products in and with the application.

(5) If the applicant wishes for Estonia to participate as a reference member state in the mutual recognition or decentralised marketing authorisation procedure of the European Economic Area, the State Agency of Medicines shall be informed thereof before the submission of an application.
[RTL 2009, 34, 444 – entered into force 12.04.2009]

§ 3. Handling of an application for granting and renewing of a marketing authorisation of a medicinal product

(1) Applications are reviewed in the order of reception.

(2) The State Agency of Medicines has a right to include non-staff experts in the handling of a marketing authorisation, whose work regulations are drafted by the State Agency of Medicines.

(3) Before starting procedures with an application, the State Agency of Medicines evaluates the compliance of the application and enclosed documents with requirements established according to clause 1 of section 12 of § 65 of the Medicinal Products Act and in the present Regulation, assigning a term for elimination of shortcomings to the applicant, if necessary. In accordance with the Administrative Procedure Act, the State Agency of Medicines may decide that in the event of a failure to eliminate the shortcomings by the term assigned the application shall not be accepted for handling.
[RTL 2010, 20, 365 – entered into force 24.04.2010]

(4) An applicant has a right to withdraw an application during the procedures, submitting a relevant written petition. Materials submitted to the Stage Agency of Medicines are not returned and they are stored at the State Agency of Medicines for five years.

(5) The time for handling of an application includes the time the State Agency of Medicines needs to evaluate the documentation on the safety, quality and effectiveness of the medicinal product submitted by the applicant, as well as bringing the labelling, package leaflet and the summary of product characteristics of the medicinal product to be launched in Estonia into compliance with the valid legislation in cooperation with the applicant, as well as the time necessary for the check of the quality of the medicinal product in laboratory, if necessary.

(5^1) The State Agency of Medicines drafts an evaluation report on the effectiveness, safety and quality of a medicine, which includes explanations about the results of pharmaceutical, pre-clinical and clinical research of the medicinal product and the main file of risk management system and the main file of the pharmacovigilance system, as well as reasons separately for every applied indication.
[RT I, 12.07.2012, 2 – entered into force 21.07.2012]

(6) If upon granting of a marketing authorisation an exception is made to the requirement of a package in Estonian under clause 1 of section 12 of § 65 of the Medicinal Products Act, the package shall be approved with a sticker in Estonian, provided that the design of the marketed package and the design and placement of the sticker on the package are the same for the package in a foreign language and in Estonian. If the exception is based on the actual or estimated sales of a medicinal product, the State Agency of Medicines shall re-evaluate the exception on annual basis.
[RTL 2010, 20, 365 – entered into force 24.04.2010]

(7) Mutual recognition procedure or decentralised procedure shall be applied only to those traditional herbal products for which the Committee on Herbal Medicinal Products has drafted a monograph, or which contain a drug or herbal product or combinations thereof belonging into the list drafted by the above stated committee.
[RTL 2005, 105, 1604 – entered into force 21.10.2005]

(8) If an application is submitted for receiving a marketing authorisation for a traditional herbal medicinal product medically used in a member state of the European Economic Area for less than 15 years, but complying with the requirements provided in section 2 of § 8 of the Medicinal Products Act in other aspects, the State Agency of Medicines shall submit relevant documents associated with the application to the Committee on Herbal Medicinal Products located at the European Medicines Agency.
[RTL 2005, 105, 1604 – entered into force 21.10.2005]

§ 4. Handling of an application for a marketing authorisation of a medicinal product in the event of participation of Estonia as a country referenced in mutual recognition or decentralised marketing authorisation procedure of the European Economic Area

[RTL 2009, 34, 444 – entered into force 12.04.2009]

(1) In the event of participation of Estonia as a reference member state in mutual recognition or decentralised marketing authorisation procedure of the European Economic Area, the State Agency of Medicines shall prepare

an initial assessment report of the application in English, initial summary of product characteristics of the medicinal product and the package leaflet latest within 90 days after the reception of the application in the event of the mutual recognition procedure and latest within 120 days after the reception of the application in the event of the decentralised procedure, and send those to the applicant and the competent authorities of the member states of the European Economic Area (hereinafter called member state) associated with the application.
[RTL 2009, 34, 444 – entered into force 12.04.2009]

(2) Before the submission of an application of mutual recognition to other member states the applicant shall inform the State Agency of Medicines of the submission of the application and of changes made to the initial file.

(3) An applicant for a marketing authorisation shall submit all information and documents necessary for checking the identity of the files to the State Agency of Medicines upon a relevant request by the latter.

(4) If an applicant wishes to start a marketing authorisation procedure of mutual recognition in regard to a proprietary medicinal product for which a marketing authorisation has been issued in Estonia, the State Agency of Medicines shall issue an assessment report to the applicant and the competent authority of member states associated with the application within 90 days.

(5) If a proprietary medicinal product has received a marketing authorisation according to the mutual recognition or decentralised marketing authorisation procedure, where Estonia is a reference member state, and the applicant wishes to start a repeated marketing authorisation procedure, the State Agency of Medicines shall issue an updated assessment report to the applicant and competent authorities of the member states associated with the application within 90 days.
[RTL 2009, 34, 444 – entered into force 12.04.2009]

(6) In the event of renewal of a marketing authorisation, if a marketing authorisation has been granted to a proprietary medicinal product by the procedure of mutual recognition or a decentralised procedure of the European Economic Area and Estonia is a referemce member state the State Agency of Medicines shall issue an initial assessment report to other member states associated with the application within 40 days and the final updated assessment report within 60 days.
[RTL 2009, 34, 444 – entered into force 12.04.2009]

§ 5. Recognition of the assessment of a competent governmental authority of a member state of the European Economic Area

(1) If the State Agency of Medicines learns that a competent authority of another member state has started the procedures for handling the application for marketing authorisation of the relevant medicinal product or issued a marketing authorisation for the medicinal product, the State Agency of Medicines shall suspend the procedures associated with the application. The State Agency of Medicines shall inform the member state(s) associated with the application, and wait for the assessment report of a competent governmental authority of the relevant country pertaining to the application for marketing authorisation and supplementing documentation.

(2) Upon application for recognition the applicant shall declare that the whole documentation submitted to apply for marketing authorisation by mutual recognition is identical to the documentation submitted in the referenced country, including all of the documentation regarding the changes applied for, which is confirmed by the competent authority of the referenced country before the submission of the application to the State Agency of Medicines, as well as regarding the liabilities following the acquisition of marketing authorisation, if any.

(3) The draft summary of product characteristics of the medicinal product submitted with the application shall be a translation of the latest summary of product characteristics of the medicinal product confirmed by mutual recognition.

(4) If the State Agency of Medicines does not recognise the assessment report, summary of the product characteristics of the medicinal product and the package leaflet, the State Agency of Medicines shall send the reasons to the competent authorities of the reference member state, concerned member state and the applicant, and to the Co-ordination Group for Mutual Recognition and Decentralised Procedures.

(5) If the member states cannot reach an agreement within 60 days in the event of a decentralised marketing authorisation procedure and within 90 days in the event of a mutual recognition procedure, section 8 of § 68 of the Medicinal Products Act shall be applied.

§ 6. Entry of the Regulation into force

The regulation shall enter into force on March 1st, 2005.

[1]Directive 2001/82/EC of the European Parliament and Council regarding the Community regulations on veterinary medicinal products (OJ L 311, 28.11.2001, pages 1–66), amended by Directives 2004/28/EC (OJ

L 136, 30.04.2004, pages 58–84), 2009/9/EC (OJ L 44, 14.02.2009, pages 10–61) and 2009/53/EC (OJ L 168, 30.06. 2009, pages 33–34); Directive 2001/83/EC of the European Parliament and Council regarding the Community regulations on medicinal products for human use (OJ L 311, 28.11.2001, pages 67–128), amended by Directives 2002/98/EC (OJ L 033, 08.02.2003, pages 30–40), 2003/63/EC (OJ L 159, 27.06.2003, pages 46–94), 2004/24/EC (OJ L 136, 27.06.2003, pages 85–90), 2004/27/EC (OJ L 136, 30.04.2004, pages 34–57), 2008/29/EC (OJ L 81, 20.03.2008, pages 51–52), 2009/53/EC (OJ L 168, 30.06.2009, pages 33–34), 2009/120/EC (OJ L 242, 15.09.2009, pages 3–12) and 2010/84/EU (OJ L 348, 31.12.2010, pages 74–99).
[RT I, 12.07.2012, 2 - entry into force 21.07.2012]