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Types of and formal requirements for applications for marketing authorisations regarding medicinal products, the list of supplementary documentation, the requirements for supplementary documentation, the amount of the fee payable for professional assessment of applications by application type, and the procedure for the calculation and payment of the fee

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19.11.2010	RT I, 30.11.2010, 3	03.12.2010
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06.05.2013	RT I, 10.05.2013, 1	13.05.2013
20.03.2014	RT I, 25.03.2014, 3	28.03.2014

This regulation is enacted in accordance with section 65(12)(1) of the Medicinal Products Act.
[RTL 2010, 20, 365 - entry into force 24.04.2010]

§ 1. Scope of application

This regulation establishes the types of and formal requirements for applications for marketing authorisations regarding medicinal products, the list of supplementary documentation, the requirements for supplementary documentation, the amount of the fee payable for professional assessment of applications by application type, and the procedure for the calculation and payment of the fee.

§ 2. Types of and formal requirements for applications for marketing authorisations regarding medicinal products

(1) The types of application for marketing authorisations of medicinal products are the following:
1) independent application;
2) generic application.
[RTL 2009, 34, 445 – entry into force 12.04.2009]

(2) The generic application is submitted in the cases provided in section 65(4)(2) of the Medicinal Products Act.
[RTL 2010, 20, 365 – entry into force 24.04.2010]

(3) The types of independent application are the following:
1) the application based on original research;

2) the application based on published literature, i.e. bibliographic application, which, instead of referring to the results of pharmacological and toxicological tests or clinical trials, contains detailed references to published research literature, provided it is shown that the active substance or substances of the medicinal product have a well-established medicinal use, recognised efficacy and acceptable level of safety;
3) the application seeking a marketing authorisation for a medicinal product that contains a fixed combination of recognised active substances which have hitherto not been used in combination for therapeutic purposes;
4) the application including informed consent, in the case of which the medicinal product is entirely similar with (has same quantitative and qualitative composition of active substances and the same pharmaceutical form) and bioequivalent to a medicinal product that has a valid marketing authorisation in Estonia and whose marketing authorisation holder has declared in writing that the chemical, pharmaceutical, pharmacological, toxicological and clinical data attached to the marketing authorisation holder's application may be used in connection with the new application for marketing authorisation.
[RT I, 12.07.2012, 2 – entry into force 21.07.2012]

(4) The State Agency of Medicines publishes on its website the application form for the marketing authorisation of medicinal products for human use and of veterinary medicinal products, the application form to be used in the case of the procedure of a decentralised marketing authorisation and the application form for the renewal of a marketing authorisation. The application must be submitted to the State Agency of Medicines in the form published on the website.
[RT I, 12.07.2012, 2 – entry into force 21.07.2012]

§ 3. Supplementary documentation to the application for marketing authorisation for a proprietary medicinal product

(1) The supplementary documentation to the application for the marketing authorisation for a medicinal product for human use must contain the following information:
1) the administrative information: the name of the proprietary medicinal product, summary of the product characteristics, package leaflet, labelling, list of member states in which the application for marketing authorisation has been submitted, the manufacturing and marketing authorisations granted in other countries and the decisions regarding refusal to grant marketing authorisations;
[RT I, 12.07.2012, 2 – entry i nto force 21.07.2012]
2) information on the quality of the proprietary medicinal product: chemical-pharmaceutical and biological data and test results;
2^1) a written declaration of the manufacturer of the medicinal product stating that it has audited the manufacturer of the active substance and that the manufacturing of the active substance complies with good manufacturing practices, including the reference to the date of the audit;
[RT I, 10.05.2013, 1 – entry i nto force 13.05.2013, to be implemented as of 2.07.2013]
3) the safety information: toxicological and pharmacological information; a summary of the safety information, and of the information in periodical safety update reports and in reports of possible side effects where available; the risk management plan and a summary of the applicant's system of pharmacovigilance, the information in which must conform to Article 8(3)(ia) of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, pp. 67–128) A, or Article 12(3)(k) of Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, pp. 1–66);
[RT I, 12.07.2012, 2 – entry into force 21.07.2012]
4) the efficacy information: clinical particulars.

(2) [Repealed – RTL 2005, 105, 1604 – entry into force 21.10.2005]

(3) In the case of an application for a veterinary medicinal product, documentation containing the following information must, where necessary, be submitted in addition to the information set out in subsection 1:
[RT I, 10.05.2013, 1 – entry i nto force 13.05.2013]
1) a description of the precautions to be taken in the storage, administration and disposal of the residue of the proprietary veterinary medicinal product;
2) a description of the potentially harmful effect of the proprietary veterinary medicinal product on the environment, flora, the health of humans or animals;
3) the information on the withdrawal period: in the case of a medicinal product intended for use on food-producing animals, the applicant must submit and prove the maximum residue limits of the active substance of the medicinal product in foodstuffs obtained from the animals, which are allowed and considered safe for the health of the consumer, and which must comply with the requirements of Regulation (EC) No. 470/2009 of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No. 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No. 726/2004 of the European Parliament and of the Council, and must set out the methods for the determination of the residue of the active substance of the medicinal product.
[RT I, 10.05.2013, 1 – entry i nto force 13.05.2013]

(4) In addition to the information listed in subsections 1 and 2, the supplementary documentation of the application for marketing authorisation of a radionuclide generator must contain the following information:
1) a general description of the system together with a detailed description of the components of the system which may affect the composition or quality of the daughter nuclide preparation;
2) qualitative and quantitative particulars of the eluate or the sublimate.

(5) In the case of applying for marketing authorisation for a non-biological medicinal product according to the terms and conditions set out in section 65(4)(2) of the Medicinal Products Act, the information provided in Modules 1, 2 and 3 referred to in section 4(3) of this regulation and the information provided in Module 5 with regard to the bioavailability and bioequivalence of the product or the information proving other therapeutic equivalence of the product must be submitted as the supplementary documentation enclosed with the application. In the case of a veterinary medical product, the information included in Part I and II referred to in section 4(5) of this regulation and the information in Part IV regarding the bioavailability and bioequivalence of the product or the information proving other therapeutic equivalence of the product must be submitted as the supplementary documentation enclosed with the application.
[RT I, 12.07.2012, 2 – entry into force 21.07.2012]

(6) When applying for marketing authorisation for a medicinal product containing a fixed combination of active substances, the safety and efficacy information must be based on the combination and not on the active substances separately.

(7) In the case of an application for marketing authorisation for a proprietary medicinal product characterized by complete biological similarity, the State Agency of Medicines decides, on an ad hoc basis, the scope of the data required in addition to the information provided in Modules 1, 2 and 3 referred to in section 4(3) and, in the case of a veterinary medicinal product, in addition to the information set out in Part I and II referred to in section 4(5) of this regulation.
[RT I, 12.07.2012, 2 – entry into force 21.07.2012]

(8) When applying for marketing authorisation for a traditional oral, inhaled or topical herbal preparation, the supplementary documentation of the application must include the data presented in Modules 1, 2 and 3 referred to in section 4(2), and an expert opinion on safety.

(9) When applying for the renewal of a marketing authorisation, the following must be submitted as the supplementary documentation:
1) a summary of the characteristics of the proprietary medicinal product, updated by the marketing authorisation holder;
2) a package leaflet, updated by the marketing authorisation holder;
3) an updated summary of the data on the quality, safety and efficacy of the proprietary medicinal product, based on reliable updated information and experience obtained in the course of use of the proprietary medicinal product;
[RT I, 12.07.2012, 2 – entry into force 21.07.2012]
4) a summary of the periodical safety update reports;
[RT I, 12.07.2012, 2 – entry into force 21.07.2012]
5) applications in the required format concerning any modifications in the proprietary medicinal products not previously applied for following the procedure established in accordance with section 77(3) of the Medicinal Products Act.

(10) When applying for a renewal of a marketing authorisation for a homeopathic preparation, updated data on the safety of the preparation, based on reliable, updated information and on the experience obtained in the course of use of the proprietary medicinal product, must be submitted as the supplementary documentation in addition to the data set out in paragraphs 2, 4 and 5 of subsection 4.

§ 4. Requirements for the supplementary documentation to the application for marketing authorisation for a proprietary medicinal product

(1) The supplementary documentation enclosed with the application for marketing authorisation for a medicinal product must be in Estonian or English. The summary of the properties of the medicinal product, the package leaflet and labelling on the package must be in Estonian.
[RT I, 12.07.2012, 2 – entry into force 21.07.2012]

(2) [Repealed – RT I, 25.03.2014, 3 – entry into force 28.03.2014]

(2^1) [Repealed – RT I, 12.07.2012, 2 – entry into force 21.07.2012]

(3) The information to be presented in the supplementary documentation to the application for marketing authorisation for a medicinal product for human use must comply with Annex 1 of Directive 2001/83/EC and must be grouped as follows:
[RT I, 12.07.2012, 2 – entry into force 21.07.2012]
1) Module 1: Administrative information;
2) Module 2: Summaries and overviews;
3) Module 3: Chemical, pharmaceutical and biological information;
4) Module 4: Non-clinical reports;
5) Module 5: Clinical study reports.
[RTL 2010, 4, 71 – entry into force 29.01.2010]

(4) Modules 1, 2, 3, 4 and 5 must be presented electronically, paper copies must be presented upon the relevant demand of the State Agency of Medicines. Additionally, the Module 1 may be submitted partly or fully on paper.
[RT I, 12.07.2012, 2 – entry into force 21.07.2012]

(5) The information presented in the supplementary documentation to the application for marketing authorisation for a veterinary medicinal product must comply with Annex 1 of Directive 2001/82/EC and must be grouped as follows:
[RT I, 12.07.2012, 2 – entry into force 21.07.2012]
1) part I;
2) part II;
3) part III;
4) part IV.
[RTL 2010, 4, 71 – entry into force 29.01.2010]

(6) Parts I, II, III and IV of the documentation supplementing the application for marketing authorisation for a veterinary medical product must be presented electronically; paper copies must be submitted upon the relevant demand of the State Agency of Medicines. Part 1 may additionally be submitted partly or fully on paper.
[RT I, 12.07.2012, 2 – entry into force 21.07.2012]

(7) The summary of the product properties must contain the following information:
1) the name of the proprietary medicinal product, followed by the strength of the medicinal product and the pharmaceutical form;
2) the qualitative and quantitative composition (the International Non-Proprietary Name is used in both Estonian and Latin);
3) the pharmaceutical form;
4) the clinical particulars: therapeutic indications, posology and the method of administration, contraindications, warnings and precautions for use, interaction with other medicinal products and other forms of interactions, use during pregnancy and breastfeeding, effects on the ability to drive and to operate machinery, adverse reactions, overdose information;
4^1) the instruction requesting the notification of the State Agency of Medicines of any adverse reactions by using the electronic form available on the website of the State Agency of Medicines or the paper notice, except in the case of a veterinary medicinal product;
[RT I, 12.07.2012, 2 – entry into force 21.07.2012]
5) the pharmacological properties: pharmacodynamic properties and pharmacokinetic properties, preclinical safety data;
6) the pharmaceutical particulars: the list of excipients, major incompatibilities, shelf life, special precautions for storage, characterisation and contents of the package, special precautions for the disposal and handling of the medicinal product;
[RTL 2009, 34, 445 – entry into force 12.04.2009]
7) the name or business name and the residence or registered office of the marketing authorisation holder;
8) with regard to radiopharmaceuticals, full details of internal radiation dosimetry;
9) with regard to radiopharmaceuticals, additional detailed instructions for extemporaneous preparation and quality control of such preparation and, where appropriate, maximum storage time during which any intermediate preparation such as an eluate or the ready-to-use pharmaceutical conforms to its specifications;
10) in the case of a veterinary medicinal product, additional information about the species of animals for whom the proprietary medicinal product is intended, special warnings by species of animals, and in the case of a proprietary medicinal product administered to food-producing animals, also information regarding the withdrawal period concerning the use the relevant animal products;
[RT I, 12.07.2012, 2 – entry into force 21.07.2012]
11) the number of the marketing authorisation
[RTL 2010, 4, 71 – entry into force 29.01.2010]
12) the date of the issue of the initial authorisation or the renewal of the authorisation;
[RTL 2010, 4, 71 – entry into force 29.01.2010]
13) the date of review of the text.
[RTL 2010, 4, 71 – entry into force 29.01.2010]

(8) The package leaflet must be in conformity with the summary of the product properties and include the following information:
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]
1) the name of the medicinal product, followed by its strength and pharmaceutical form and, if necessary, a notice on whether the medicinal product is intended for infants, children or adults, as well as the name of the active substance where the proprietary medicinal product has an invented name and only contains a single active substance;
2) the complete qualitative composition of the active substances and excipients and the quantitative composition of the active substances, using their common names;
3) the pharmaceutical forms and their quantity by weight, volume or number of doses;
4) the pharmacotherapeutic group or type of effect in a format that the patient can easily understand;
5) the name or business name and residence or registered office of the marketing authorisation holder, including the name or business name and residence or registered office of the holder of the licence for parallel import and the name or business name and residence or registered office of the manufacturer responsible for the batch release, in the case of a licence for parallel import, the name or business name and residence or registered

office of the re-packager (where applicable) and the name or business name and residence or registered office of the Estonian representative of the marketing authorisation holder (where applicable);
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]
6) therapeutic indication(s);
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]
7) the information required for the administration of the medicinal product: contra-indications, precautions related to the use of the medicinal product if necessary, interactions with other medicinal products and other substances (e.g., alcohol, tobacco, foodstuffs) which may affect the effect of the medicinal product, special warnings;
8) instructions for the proper use of the medicinal product: dosage, method of administration, frequency of administration, while specifying, if necessary, the appropriate time at which the medicinal product may or must be administered, the duration of treatment in the case that it ought to be limited owing to the nature of the product, the action to be taken in the case of an overdose (e.g., symptoms, emergency procedures) or the course of action to take when one or more doses have been skipped, indicating, if necessary, the risk of withdrawal effects;
8^1) instructions on informing a health care professional, veterinarian or the State Agency of Medicines of an adverse reaction using the electronic form available on the website of the State Agency of Medicines or a paper notice, except in the case of a veterinary medicinal product;
[RT I, 25.03.2014, 3 – entry into force 28.03.2014]
9) a description of possible adverse reactions in the course of standard use of the medicinal product, and, where necessary, instructions to be followed in the event of experiencing the adverse reactions;
[RT I, 12.07.2012, 2 – entry into force 21.07.2012]
9^1) where this is necessary, owing to the nature of the medicinal product, a specific recommendation to consult with the pharmacist or physician concerning the use of the medicinal product;
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]
10) a reference to the expiry date indicated on the packaging, and the following information: a warning against the use of the product after the expiry date, special storage precautions where appropriate, a warning, where necessary, not to use the medicinal product if it shows visible signs of deterioration;
11) the date on which the package leaflet was last revised;
12) in the case of a veterinary medicinal product, additional information about the species of animal for which the proprietary medicinal product is intended, special warnings by species of animal, and in the case of a proprietary medicinal product administered to food-producing animals, also information regarding the withdrawal period during which products derived from the animals may not be used;
[RT I, 12.07.2012, 2 – entry into force 21.07.2012]
13) – 15) [Repealed – RTL 2010, 4, 71 – entry into force 29.01.2010]

(8^1) The package leaflet must reflect the results of consultations with target patient groups to ensure that it is clear and user-friendly. At the demand of an organisation representing the patients, the holder of the marketing authorisation must ensure the availability of the package leaflet in a format suitable to blind patients or patients with partial loss of sight. Where the consultations have not been carried out, the corresponding reasons must be submitted to the State Agency of Medicines.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

(9) The list of information set out at point 7 of subsection 8 must consider the use of the medicinal product by children, pregnant or breastfeeding women, the elderly, persons with specific pathological conditions, and, if appropriate, mention the possible effects on the ability to drive vehicles or to operate machinery. A list of excipients that may affect the effects and safety of the medicinal product must be presented in accordance with Annex VI of the regulation.

(9^1) If the medicinal product is included in the list referred to in Article 23 of Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.04.2004, pp. 1–33), the summary of the product characteristics and the package leaflet must include the sentence ‘Käesoleva ravimi suhtes kohaldatakse täiendavat järelevalvet [This medicinal product is subject to additional monitoring]’, preceded by the black symbol specified in the Annex to Commission Implementing Regulation (EU) No. 198/2013 on the selection of a symbol for the purpose of identifying medicinal products for human use that are subject to additional monitoring (OJ L 65, 08.03.2013, pp. 17–18), and followed by the relevant standard explanatory sentence.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

(10) The draft design of the outer packaging and immediate packaging must be presented under Module 1.

(11) The following information must appear on the outer packaging, or on the immediate packaging if no outer packaging is used:
1) the name of the medicinal product, including the strength and pharmaceutical form and, if necessary, a note on whether the medicinal product is intended for infants, children or adults, and, if the medicinal product contains up to three active substances, the names of the active substances in Estonian or Latin;

[RTL 2009, 34, 445 – entry into force 12.04.2009]
2) the qualitative and quantitative content of active substances in a single dose (tablet, capsule) or per volume or weight unit, depending on the method of administration, using the common names of the active substances;
3) the pharmaceutical form and size of packaging, expressed as a measure of weight or volume, or the number of doses or units;
[RTL 2010, 20, 365 – entry into force 24.04.2010]
4) the list of excipients that have a recognised effect, including, in the case of medicinal products in injectable form, for topical use or for use in the eye, the complete list of excipients;
5) the route of administration and, if necessary, the method of administration;
6) a special warning that the medicinal product must be stored out of the reach and sight of children;
7) where necessary, other special warnings;
8) the expiry date in definite terms (month and year in the format mm/yyyy);
9) special storage precautions if established;
10) if necessary, special precautions for the disposal of unused medicinal products or waste materials from medicinal products;
11) the name or business name and residence or registered office of the marketing authorisation holder, including of the holder of the licence for parallel import;
12) the registration number of the marketing authorisation;
13) the manufacturer's batch number;
14) in the case of medicinal products not subject to medical prescription, therapeutic indication and instructions for using the medicinal product;
[RTL 2009, 34, 445 – entry into force 12.04.2009]
15) the terms and conditions of dispensation of the medicinal product (medicinal product subject to medical prescription/medicinal product not subject to medical prescription);
15^1) the information concerning the security features of a medicinal product for human use subject to medical prescription, except in the case of radiopharmaceuticals and of medicinal products that are included in the list referred to in Article 54a(2)(b) of Directive 2001/83/EU of the European Parliament and of the Council;
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]
15^2) the information concerning the security features of a medicinal product for human use not subject to medical prescription if the medicinal product is included in the list referred to at point 151 of this subsection;
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]
16) in the case of veterinary medicinal products, the species of the animal; in the case of medicinal products administered to food-producing animals, also the withdrawal period;
17) in the case of a licence for parallel import, the name and address of the manufacturer responsible for batch release and the re-packager (if applicable);
18) where the appearance (e.g., colour, scoring) of a proprietary medicinal product licensed for parallel import differs from the appearance of the proprietary medicinal product imported directly, the corresponding information must be shown on the outer packaging.

(11^1) The outer packaging or the package leaflet may include symbols or pictograms designed to clarify the information listed in subsections 8 and 11 as well as other information consistent with the summary of the product characteristics, except for elements of promotional nature.
[RT I, 30.11.2010, 3 – entry into force 03.12.2010]

(12) In addition to the information referred to in point 1 of subsection 11, the name and the strength of the medicinal product must be represented in Braille, using the Latin alphabet. Where the medicinal product is marketed in a single strength version, only the name of the medicinal product must be presented in Braille. This requirement does not apply to radiopharmaceuticals, vaccines and proprietary medical products used only for the provision of in-patient health care services.

(13) The following information must appear on the immediate packaging (small immediate inner packaging):
1) the name of the medicinal product, to be followed by the strength and pharmaceutical form of the medicinal product and, where necessary, a notice on whether the medicinal product is intended for infants, children or adults, and, if the medicinal product contains up to three active substances, the names of the active substances;
2) the route of administration and, if necessary, the method of administration;
3) the expiry date in definite terms (month and year in the format mm/yyyy);
4) the manufacturer's batch number;
5) the contents of the package by weight, volume or number of units.

(14) The following information must appear on the immediate packaging (blister or grip-and-tear package):
1) the name of the medicinal product, to be followed by the strength and pharmaceutical form of the medicinal product and, where necessary, a notice on whether the medicinal product is intended for infants, children or adults, and, if the medicinal product contains up to three active substances, the names of the active substances;
2) the expiry date in definite terms (month and year in the form mm/yyyy);
3) the manufacturer's batch number;
4) the name or business name and residence or registered office of the marketing authorisation holder, including of the holder of the licence for parallel import;

(15) When applying for a marketing authorisation of a medicinal product, the information referred to in subsections 7, 8, 11, 13 and 14 must be presented in the form provided on the website of the State Agency of Medicines

[RT I, 12.07.2012, 2 – entry into force 21.07.2012]

(16) In the cases referred to in subsections 7, 8 and 11, the substances listed in Annex 6 to the regulation must be listed.

(17) When applying for a renewal of a marketing authorisation, the differences between the last approved version of the summary of the product's characteristics and the summary of the new version of the characteristics must be clearly pointed out.

§ 5. Amount of the fee payable for professional assessment of applications

(1) The amount of the fee payable for the professional assessment of the application for marketing authorisation is the following:
1) 1,275 euros per proprietary medicinal product in the case of an application for marketing authorisation of a medicinal product for human use referred to in section 2(1)(1) of this regulation;
2) 958 euros per proprietary medicinal product in the case of an application for marketing authorisation of a medicinal product for human use referred to in section 2(1)(2) of this regulation or an application for marketing authorisation of a veterinary medicinal product specified in section 2(1)(1) or 2(1)(2) of this regulation;
3) 639 euros per country of origin of the proprietary medicinal product, in the case of an application for a licence for parallel import;
4) 511 euros per each additional method of administration, pharmaceutical form and strength of the proprietary medicinal product of the same marketing authorisation holder that contains the same active substance;
5) 958 euros each traditional herbal or homeopathic preparation.

(2) The fees payable for the professional assessment of applications for a renewal of a marketing authorisation are as follows:
1) 639 euros per proprietary medicinal product;
2) 383 euros per each additional method of administration, pharmaceutical form and strength of a proprietary medicinal product of the same marketing authorisation holder that contains the same active substance;
3) 383 euros for each traditional herbal or homeopathic preparation.
[RT I 2010, 76, 585 – entry into force 01.01.2011]

§ 6. Calculation and payment of the fee for the professional assessment of an application

(1) The State Agency of Medicines issues the invoice for the fee for the professional assessment of an application within 10 days after the opening of proceedings concerning the application.

(2) The applicant must pay the fee for the professional assessment within 40 days after the presentation of the invoice.

§ 6[1]. Implementation of the regulation

(1) A summary conforming to section 4(7)(4[1]) of the properties of the medicinal product and the package leaflet conforming to sections 4(8)(8[1]) and 4(8)(9) must be submitted at the latest on 21 July 2013 if the marketing authorisation of the medicinal product has not been renewed or the terms of the marketing authorisation have not been modified such that this results in a modification of the summary of the properties of the medicinal product or of the package leaflet.
[RT I, 12.07.2012, 2 – entry into force 21.07.2012]

(2) Section 3(1)(2[1]) is to be applied as of 2 July 2013.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

(3) Section 4(11)(15[1]) is to be applied after three years have passed from the date of publication of the delegated act of the European Commission referred to in paragraph 2 of Article 54a of Directive 2001/83/EU of the European Parliament and of the Council.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

§ 7. Entry into force of this regulation

Section 4(12) of this regulation enters into force on 1 November 2005.

[1]Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, pp. 1–66), amended by Directives 2004/28/EC (OJ L 136, 30.04.2004, pp. 58–84), 2009/9/EC (OJ L 44, 14.02.2009, pp. 10–61) and 2009/53/EC (OJ L 168, 30.06. 2009, pp. 33–34); Directive 2001/83/EC of the European Parliament and of the Council on the Community

code relating to medicinal products for human use (OJ L 311, 28.11.2001, pp. 67–128), amended by Directives 2002/98/EC (OJ L 033, 08.02.2003, pp. 30–40), 2003/63/EC (OJ L 159, 27.06.2003, pp. 46–94), 2004/24/EC (OJ L 136, 27.06.2003, pp. 85–90), 2004/27/EC (OJ L 136, 30.04.2004, pp. 34–57), 2008/29/EC (OJ L 81, 20.03.2008, pp. 51–52), 2009/53/EC (OJ L 168, 30.06.2009, pp. 33–34), 2009/120/EC (OJ L 242, 15.09.2009, pp. 3–12) and 2010/84/EU (OJ L 348, 31.12.2010, pp. 74–99).
[RT I, 12.07.2012, 2 - entry into force 21.07.2012]

Annex 1 Application for marketing authorisation for a medicinal product
[Repealed – RT I, 12.07.2012, 2 - entry into force 21.07.2012]

Annex 2 Application for marketing authorisation for a veterinary medicinal product
[Repealed – RT I, 12.07.2012, 2 - entry into force 21.07.2012]

Annex 3 Application for the renewal of marketing authorisation for a medicinal product
[Repealed – RT I, 12.07.2012, 2 - entry into force 21.07.2012]

Annex 4 Summary of the characteristics of a medicinal product
[Repealed – RT I, 12.07.2012, 2 - entry into force 21.07.2012]

Annex5 Summary of the characteristics of a medicinal product
[Repealed – RT I, 12.07.2012, 2 - entry into force 21.07.2012]

Annex6 Excipients in the package labelling and package leaflet of medicinal products for human use
[RTL 2010, 4, 71 - entry into force 29.01.2010]