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The Conditions and Procedure for Classifying a Substance or Product as a Medicinal Product

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Amended by the following acts

Passed	Published	Entry into force
21.02.2011	RT I, 01.03.2011, 14	04.03.2011

This Regulation is established on the basis of clause 15 (5) 1) of the Medicinal Products Act.

§ 1. Scope of application

This Regulation establishes the basis for classifying a substance or product (hereinafter the product) as a medicinal product and the procedure for classifying a product as a medicinal product.

§ 2. Classification of a product

(1) A product shall be classified either on the initiative of the State Agency of Medicines or based on the application of a person pursuing the classification of a product (hereinafter the applicant for classification).

(2) An applicant for classification shall submit a written application to the State Agency of Medicines in order to classify a product.

(3) In addition to the name of the product and the name of the manufacturer of the product, the application shall contain data on the composition and characteristics of the product, as well as the package leaflet accompanying the product.

(4) An applicant for classification shall submit to the State Agency of Medicines data identical with the data on a product currently on the market or a product to be placed on the market.

(5) A product sample shall be submitted to the State Agency of Medicines upon request. Where the classification is initiated by the State Agency of Medicines, the State Agency of Medicines shall have the right to request from the supplier of the product the data required for classification, specified in subsection (3), as well as a product sample.

§ 3. The basis for classification of a product as a medicinal product

(1) The State Agency of Medicines shall decide on the classification of a product as a medicinal product on a case-by-case basis, taking account of all the characteristics of the product, in particular its composition, pharmacological properties, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail.
[RT I, 01.03.2011, 14 – entered into force 04.03.2011]

(2) A product shall be classified as a medicinal product:
1) if the product is presented as having properties for treating, preventing or alleviating disease in human beings, or
2) if the product is used in or administered to human beings with a view to making a medical diagnosis, or to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action.
[RT I, 01.03.2011, 14 – entered into force 04.03.2011]

(3) In classifying vitamins and their combinations as medicinal products, the daily intake, the upper safe level and the quantity required for producing a therapeutic effect shall be taken into consideration.

(4) [Repealed - RT I, 01.03.2011, 14 – entered into force 04.03.2011]

(5) In case of doubt, i.e. in cases where, taking account of all product characteristics, the product may be classified either as a medicinal product or a product regulated by other legal acts, the State Agency of Medicines shall have the right to classify the product as a medicinal product.
[RT I, 01.03.2011, 14 – entered into force 04.03.2011]

(6) The State Agency of Medicines shall publish on its website the list of therapeutic substances and herbs contained in the products classified as medicinal products.
[RT I, 01.03.2011, 14 – entered into force 04.03.2011]

§ 4. Processing of the application

(1) The State Agency of Medicines shall review the application within 30 days.

(2) Based on the data submitted, a written decision shall be passed on the classification of the product as a medicinal product, including a medicinal product for human use or a veterinary medicinal product.

(3) The classification of the product shall be free of charge.
* 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), Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30.04.2004, pp 34–57).

Annex