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Conditions and procedure for classification of proprietary medicinal products[1]

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This Regulation is established on the basis of clause 15 (5) 2) of the Medicinal Products Act.

§ 1. General provisions

This Regulation establishes the conditions and procedure for classification of proprietary medicinal products upon grant of or renewal of a marketing authorisation for a medicinal product, including a veterinary medicinal product, or upon occurrence of circumstances prompting a change of classification of and grant of a permit of use of a proprietary medicinal product.

§ 2. Bases for classification of proprietary medicinal products

(1) Proprietary medicinal products shall be classified as follows:
1) medicinal products subject to medical prescription – medicinal products dispensed by pharmacies to consumers in the meaning of the Consumer Protection Act (hereinafter *consumer*) on the basis of a medical prescription (labelled with the letter «R»);
2) medicinal products not subject to medical prescription – medicinal products which do not require a medical prescription when dispensed by pharmacies to consumers (hereinafter *medicinal products not subject to medical prescription*) (labelled with the letter «K»);
3) medicinal products subject to restricted use.

(2) A proprietary medicinal product shall be classified as a medicinal product subject to medical prescription in the following cases:
1) the use of the proprietary medicinal product (including appropriate use in accordance with the requirements) without medical supervision may pose a direct or indirect threat to the health of the user, or in case of a veterinary medicinal product, the health of the animal, the person administering the veterinary medicinal product and the consumer of the animal product, as well as the environment;
2) the proprietary medicinal product is often and widely used unreasonably, or unreasonable use thereof is likely, thus potentially posing a direct or indirect threat to the health of humans or animals;
3) the proprietary medicinal product contains a substance or substances, the effect(s) of or adverse reaction(s) to which require further investigation (a new medicinal product, little user experience, new strength, new dosage, new method of administration, new therapeutic indication, new combination of the proprietary medicinal product, insufficient user experience in some patient groups);
[RT I, 10.05.2013, 1 - entry into force 13.05.2013]
4) the proprietary medicinal product is intended for parenteral administration or prepared by a pharmacy for veterinary use in agricultural animals; or
[RT I, 10.05.2013, 1 - entry into force 13.05.2013]
5) the veterinary medicinal product is intended for administration to agricultural animals.
[RT I, 10.05.2013, 1 - entry into force 13.05.2013]

(2^1) The veterinary medicinal products specified in clause (2) 5) need not be classified as medicinal products subject to medical prescription, if all of the following conditions are met:

1) the administration of the veterinary medicinal product is limited to proprietary medicinal products the use of which does not require special knowledge or skills;
2) the veterinary medicinal product does not pose any threats described in clause (2) 1);
3) the summary of product characteristics of the veterinary medicinal product does not contain any warnings against serious adverse reaction in case of appropriate use;
4) no frequent serious adverse reaction reports have previously been filed with regard to the veterinary medicinal product or any other proprietary medicinal product containing the same active substance;
5) the summary of product characteristics does not contain contra-indications with regard to other veterinary medicinal products usually dispensed without a medical prescription;
6) the veterinary medicinal product does not require special conditions for storage;
7) even if used incorrectly, the veterinary medicinal product does not pose any threat to consumer safety with regard to medicinal product residue in food products of animal origin, to whom the medicinal product has been administered;
8) even if used incorrectly, the veterinary medicinal product containing the active substances poses no threat to human or animal health by triggering resistance to antibiotics or anthelmintics.
[RT I, 10.05.2013, 1 - entry into force 13.05.2013]

(3) The direct and indirect threat referred to in clauses (2) 1) and 2) shall be assessed as follows:
1) direct threat – the overall toxicity, reproductive toxicity, genotoxic or carcinogenic characteristics, potential adverse reactions and interactions with other medicinal products;
2) indirect threat – the possibility that symptomatic treatment will complicate the diagnosis of the actual cause of the disorder or that wide-scale use of the medicinal product will add to the risk of resistance to the medicinal product among the general population.

(4) In the case described in clause (2) 1), the proprietary medicinal product shall be classified as a medicinal product subject to medical prescription, if the therapeutic indication, contra-indications, interactions, warnings, duration and frequency of the symptoms cannot be adequately measured by the patient or, in case of a veterinary medicinal product, owner of the animal.

(5) When classifying proprietary medicinal products, the State Agency of Medicines may, in order to ensure safe and purposeful use, classify medicinal products subject to medical prescription into the following sub-categories of medicinal products subject to restricted use:
1) proprietary medicinal products dispensed on the basis of a medical prescription for a narcotic drug (labelled with the letter «N»);
[RT I, 30.09.2011, 2 - entry into force 03.10.2011]
2) proprietary medicinal products dispensed on the basis of medical prescriptions issued by specialised doctors and intended for use in a narrow speciality of specialised medical care (labelled with the letter «E»);
[RT I, 30.09.2011, 2 - entry into force 03.10.2011]
3) proprietary medicinal products used only in the provision of in-patient health services (labelled with the letter «H»).
[RT I, 30.09.2011, 2 - entry into force 03.10.2011]

(6) A proprietary medicinal product shall be classified as a proprietary medicinal product dispensed on the basis of a medical prescription for a narcotic drug in the following cases:
1) the proprietary medicinal product contains a substance included in Schedule II of narcotic drugs and psychotropic substances, or
2) use of the proprietary medicinal product involves a risk of misuse, which may lead to dependency and illegal use of the proprietary medicinal product.

(7) A proprietary medicinal product shall be classified as a proprietary medicinal product dispensed on the basis of a medical prescription issued by a specialised doctor or used only as part of provision of in-patient health services, if:
1) the proprietary medicinal product can, due to its pharmaceutical characteristics or advanced therapy or in the interests of user health, only be administered during provision of in-patient health services;
2) the proprietary medicinal product is used for treatment of symptoms which need to be diagnosed with the help of adequate diagnostic procedures during provision of in-patient health services, or
3) the proprietary medicinal product is intended for outpatients, but use thereof may trigger very serious adverse reactions, requiring specialist supervision during the entire treatment;
4) the size of the packaging is not suitable for retail marketing.

(8) Based on the maximum single dose of the proprietary medicinal product, its maximum daily dose, strength, effect, pharmaceutical form, size of the packaging, certain type of packaging or other circumstances, the State Agency of Medicines may waive classification of the proprietary medicinal product into the sub-category specified in subsection (5), if this does not pose any threat to the user.

(9) The State Agency of Medicines shall classify a proprietary medicinal product as a medicinal product subject to medical prescription or medicinal product not subject to medical prescription upon grant of marketing authorisation or permit of use. The corresponding notation with regard to classification of the proprietary medicinal product shall be made on the marketing authorisation and permit of use.

§ 3. Change of classification of proprietary medicinal products

(1) Upon renewal of marketing authorisation for a proprietary medicinal product or occurrence of new circumstances, the State Agency of Medicines may, based on the marketing authorisation holder's application or on its own initiative, change the classification of the proprietary medicinal product on the basis of classification provided in section 2.

(2) Where the change of classification of a proprietary medicinal product is applied for by a marketing authorisation holder, the marketing authorisation holder shall submit to the State Agency of Medicines the corresponding application, together with the supplementary documentation.

(3) Where a proprietary medicinal product has been classified within the framework of the centralised EU registration procedure, the State Agency of Medicines shall acknowledge the corresponding decision on the basis of the marketing authorisation applicant's application without a separate expert analysis.

(4) The supplementary documentation of the application for change of classification of a proprietary medicinal product shall contain the following information:
1) for scientific justification of the application, the opinion of the expert conducting the expert clinical analysis shall contain a critical analysis prepared on the basis of the criteria listed in subsection 2 (2);
2) data on the safety of the proprietary medicinal product shall be submitted when applying for classification from a medicinal product subject to medical prescription to a medicinal product not subject to medical prescription;
3) data on the efficacy of the proprietary medicinal product shall be submitted when the application for change of classification includes the application for a new indication or new posology for the proprietary medicinal product.

(5) The supplementary documentation submitted with regard to the safety of the proprietary medicinal product specified in clause (4) 2) shall comply with the following requirements:
1) the supplementary documentation shall contain summaries of or references to animal and human testing, indicating low general toxicity and the absence of significant reproductive, genotoxic or carcinogenic characteristics;
2) data on user experience shall be submitted, including use within Estonia;
3) overview of the adverse reactions and interactions of the proprietary medicinal products as well as the risks involved in the misuse of the medicinal product shall be provided;
4) where the proprietary medicinal product has already been classified as a medicinal product not subject to medical prescription in another country, a list of the corresponding countries and an overview of the user experience in these countries shall be provided.

(6) Where an application for change of a certain packaging of a proprietary medicinal product is submitted, an overview of size of the packaging, treatment period and the indication shall be provided in correlation with the efficacy of the medicinal product specified in clause (4) 3).

(7) The State Agency of Medicines shall make the corresponding decision within 60 days after receipt of the application and notify the applicant of the decision in writing thereof.

(8) Where the decision of the State Agency of Medicines is negative, the applicant may, within 30 days, supplement the application in accordance with the requirements set forth by the State Agency of Medicines. If the applicant fails to supplement the application within 30 days, the application shall be considered as rejected.

(9) Where the State Agency of Medicines changes the classification of a proprietary medicinal product on its own initiative, the State Agency of Medicines shall notify the marketing authorisation holder thereof 30 days before the entry into force of the decision, and its justifications. The marketing authorisation holder may challenge the decision.

(10) Where the change of classification of a proprietary medicinal product requires change of data or introduction of data on the proprietary medicinal product in the summary of product characteristics, labelling or package leaflet, the change shall be coordinated with the State Agency of Medicines.

§ 4. Entry into force of the Regulation

This Regulation shall enter into force on 1 March 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), 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, 28.11.596, pp 67–128), Directive 2004/28/EC of the European Parliament and of the Council amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (OJ L 136, 30.04.2004, pp 58-84), Regulation (EC) No 596/2009 of the European Parliament and of the Council, adapting a number of

instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny (OJ L 188, 18.7.2009, pp 1-91), Commission Directive 2006/130/EC, implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription (OJ L 349, 12.12.2006, pp 15-16).
[RT I, 10.05.2013, 1 - entry into force 13.05.2013]