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## **Form of and procedure for submitting the report on advertising of medicinal products**

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Amended by the following acts

Passed	Published	Entry into force
13.10.2010	RT I 2010, 76, 585	01.01.2011
14.02.2014	RT I, 21.02.2014, 2	24.02.2014

This Regulation is established on the basis of subsection 83 (7) of the Medicinal Products Act.

### **§ 1. General provisions**

(1) This Regulation establishes the form of and procedure for submitting to the State Agency of Medicines the report concerning provision of support specified in subsections 86 (2) and (5) of the Medicinal Products Act by a holder of a marketing authorisation in respect of a medicinal product to dispensing chemists, pharmacists and doctors and their associations, organisation of events specified in subsection 86 (6) and patient information events, distribution of samples, and any discounts made.

(2) The submitted data shall be considered public information, with the summarised data published on the website of the State Agency of Medicines by 1 June each year.

### **§ 2. Procedure for submitting the report on advertising of medicinal products**

(1) A marketing authorisation holder shall submit the report on advertising of medicinal products to the State Agency of Medicines by 1 February each year in the form provided in the Annex to this Regulation, or notify the State Agency of Medicines if no reportable marketing activities were carried out in the preceding year.  
[RT I, 21.02.2014, 2 - entry into force 24.02.2014]

(2) A marketing authorisation holder shall submit the report on advertising of medicinal products electronically via the web portal of the State Agency of Medicines (Client Portal).  
[RT I, 21.02.2014, 2 - entry into force 24.02.2014]

### **§ 3. Data to be submitted in the report on advertising of medicinal products**

(1) The following data shall be submitted on medicinal products not subject to medical prescription in the report on advertising of medicinal products:

- 1) presentations of medicinal products or other scientific events organised or initiated by the marketing authorisation holder in Estonia;
- 2) presentations of medicinal products or other scientific events organised or initiated by the marketing authorisation holder outside Estonia, targeting Estonian citizens;
- 3) record of samples of medicinal products, broken down by preparations;
- 4) discounts on medicinal products, broken down by preparations, excluding discounts made under public procurements or price agreements in accordance with subsection 42 (4) of the Health Insurance Act;  
[RT I, 21.02.2014, 2 - entry into force 24.02.2014]
- 5) patient information events organised or initiated by the marketing authorisation holder.

(2) The following data shall be submitted on medicinal products subject to medical prescription in the report on advertising of medicinal products:

- 1) presentations of medicinal products or other scientific events organised or initiated by the marketing authorisation holder in Estonia;

- 2) presentations of medicinal products or other scientific events organised or initiated by the marketing authorisation holder outside Estonia, targeting Estonian citizens;
  - 3) record of samples of medicinal products, broken down by preparations;
  - 4) discounts on medicinal products, broken down by preparations, excluding discounts made under public procurements or price agreements in accordance with subsection 42 (4) of the Health Insurance Act;
- [RT I, 21.02.2014, 2 - entry into force 24.02.2014]

(3) In addition to the data specified in subsections (1) and (2), the following data shall be submitted in the report on advertising of medicinal products:

- 1) support awarded to medical or pharmaceutical events in accordance with subsection 86 (5) of the Medicinal Products Act, broken down by events, specifying the beneficiary, name of the event, purpose of use of the support, and the amount of the support;
- 2) support awarded for participation in medical events in accordance with subsection 86 (2) of the Medicinal Products Act, broken down by support, specifying the beneficiary, name of the event, purpose of use of the support, and the amount of the support;
- 3) health promotion events which are organised or initiated by the marketing authorisation holder, and which, in the opinion of the marketing authorisation holder, are not related to the advertising of medicinal products not subject to medical prescription or medicinal products subject to medical prescription, specifying the target group, purpose of the event, and number of participants.

[Annex](#) Form of the report on advertising of medicinal products  
[RT I, 21.02.2014, 2 - entry into force 24.02.2014]