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If a whole or part of a paragraph has been amended, the date of the amending regulation appears in square brackets at the end of the paragraph. If a whole paragraph or sub-paragraph has been deleted, the date of the deletion appears in square brackets beside the deleted paragraph or sub-paragraph.

Republic of Latvia

Cabinet

Regulation No. 378

Adopted 17 May 2011

## **Procedures for Advertising Medicinal Products and Procedures by Which a Medicinal Product Manufacturer is Entitled to Give Free Samples of Medicinal Products to Physicians**

*Issued pursuant to  
Section 5, Clause 5 and Section 56  
of the Pharmaceutical Law and Section 7, Paragraph two  
of the Advertising Law*

### **I. General Provisions**

1. This Regulation prescribes:

1.1. the procedures for the advertising of medicinal products (except veterinary medicinal products);

1.2. the procedures by which a medicinal product manufacturer or importer is entitled to give free samples of medicinal products to physicians. Medicinal products which are not labelled as free samples but which are delivered free of charge to medical treatment institutions (as a gift or donation), as well as free samples of medicinal products to medical educational and scientific institutions (investigational medicinal products), shall be distributed in accordance with laws and regulations regarding the procedures for the distribution and quality control of medicinal products.

*[25 November 2014]*

2. This Regulation shall apply to any form of notification, activity, and measure if the purpose thereof is to promote the prescription, distribution, or use of medicinal products, including:

2.1. the advertising of medicinal products intended for the general public;

2.2. the advertising of medicinal products intended for those persons who have the right to prescribe or distribute medicinal products (hereinafter – specialist), including:

2.2.1. the provision of information regarding medicinal products which is performed by a person authorised by an advertiser (hereinafter – medical sales representative);

2.2.2. visits of medical representatives to specialists;

2.2.3. transfer of free samples of medicinal products;

2.2.4. the inducement to prescribe or distribute specific medicinal products by offering gifts or any other material or other kind of benefit;

2.2.5. organising and sponsorship of promotional and scientific events attended by specialists, in particular payment of their travelling and accommodation expenses related thereto;

2.2.6. materials support or support of another kind to associations and foundations, which gather specialists, and medical treatment institutions in scientifically and professionally oriented events;

2.2.7. any visual, written, or oral advertisement which is used in the cases referred to in Paragraph 35 of this Regulation.

*[25 November 2014]*

3. This Regulation shall not apply to:

3.1. the labelling and package leaflet of medicinal products, which conform to the requirements specified in the laws and regulations regarding the labelling of medicinal products, if they are not used separately from the medicinal products in order to advertise them;

3.2. correspondence if it is of a non-promotional nature and it is needed to answer a specific question regarding particular medicinal products;

3.3. informative announcements containing data and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general precautions for the use of medicinal products, as well as to trade catalogues and price lists, in which the therapeutic indications of preparations are not indicated or which do not contain an advertising of medicinal products;

3.4. statements relating to human health or diseases, provided there is no reference, even indirect, to medicinal products;

3.5. information provided to an individual patient by a specialist regarding specific medicinal products which are necessary for the patient;

3.6. information of the pharmacy regarding reduction in the price of medicinal products, if it does not contain an advertising of particular medicinal products.

4. It is prohibited to advertise medicinal products, which are not registered in the Republic of Latvia and are not included in the register of medicinal products of Latvia or which have not been registered according to the centralised registration procedure of medicinal products of the European Medicines Agency and registration or re-registration of which is not in effect.

5. Such advertising of medicinal products is prohibited, in which:

5.1. medicinal products are offered as a gift or compensation for the purchase of any goods or receipt of service;

5.2. a gift for the purchase of medicinal products is offered;

5.3. the general public is offered to purchase specific medicinal products with a discount or free of charge;

5.4. in advertising medicinal products, a competition, game, or other similar event is organised, the participants or winners of which receive benefits – gifts for participation or awards for winning;

5.5. it is declared regarding medicinal products that they are safe without a corresponding quality assessment, they are not toxic or do not cause addiction.

*[25 November 2014]*

6. The medicinal products, which in accordance with the laws and regulations regarding compensation of expenses for the purchase of medicinal products intended for outpatient medical treatment have been included in the list of reimbursable medicinal products, shall be distributed only for the pharmacy price specified by the National Health Service, and they may not be offered and distributed in pharmacies with additional discount.

*[10 April 2012]*

7. The requirements for the general advertising of a medicinal product shall be as follows:
- 7.1. the information provided in the advertising conforms to the particulars listed in the description of the medicinal product;
  - 7.2. the information provided in the advertising encourages the rational use of the medicinal product, is objective and does not exaggerate the properties of the medicinal product;
  - 7.3. the advertising is not misleading;
  - 7.4. the comparative advertising of the medicinal product conforms to the requirements specified in this Regulation and the Advertising Law.
8. In the advertising of homeopathic medicinal products that are registered according to a simplified authorisation procedure only the information included on the labelling or in the package leaflet may be used.
9. In advertising medicinal products that are registered as traditional herbal medicinal products the statement “*Tradicionālas augu izcelsmes zāles, ko lieto norādītajām indikācijām, pamatojoties vienīgi uz ilgstošā laikā iegūtiem rezultātiem*” [Traditional herbal medicinal products that are used for specific indications, based exclusively on the results acquired over a long period of time] shall be included in the advertising.

## **II. Advertising of Medicinal Products Intended for the General Public**

10. It shall be permitted to advertise medicinal products, which in accordance with the laws and regulations regarding classification of medicinal products have been specified as non-prescription medicinal products.
11. It is prohibited to advertise the following to the general public:
- 11.1. medicinal products, which in accordance with the laws and regulations regarding classification of medicinal products have been specified as medicinal products, for the use of which a written instruction drawn up by a physician is required (hereinafter – prescription medicinal products);
  - 11.2. medicinal products, which contain psychotropic and narcotic substances controlled in Latvia, doping substances, medicinal products, which the State Agency of Medicines has recognised as narcotic analgesic agents, isotretinoin, thalidomide and lenalidomide;
  - 11.3. medicinal products, the purchase costs of which are partly or fully covered from State budget funds.
12. The prohibitions specified in Paragraph 11 of this Regulation shall not apply to vaccines, which are advertised by the advertiser during a vaccination campaign. An issue regarding a vaccination campaign, on the basis of a submission of the advertiser and the available epidemiological data, shall be examined by the Centre for Disease Prevention and Control within 15 days after receipt of the submission. If the Centre for Disease Prevention and Control takes a decision to approve a vaccination campaign, it shall determine the time period for the vaccination campaign and inform the Health Inspectorate and the advertiser.  
*[10 April 2012]*
13. It is prohibited to distribute medicinal products to the general public for promotional purposes.

14. The advertising of medicinal products to the general public shall be designed in such a way that there could be no doubt that the information distributed is an advertising and the product being advertised is a medicinal product.

15. If the advertising of the medicinal products referred to in Paragraph 11 of this Regulation, which is intended for specialists, is distributed on electronic mass media, the advertiser and distributor of advertising shall ensure that the information is not accessible to the general public.

16. The advertising of medicinal products intended for the general public shall include at least the following information, if particular medicinal products are advertised:

16.1. the name of the medicinal product, as well as the general name specified in the laws and regulations regarding the procedures for labelling of medicinal products and the requirements to be met for the package leaflet of medicinal products, if the medicinal product contains only one active substance;

16.2. information that is necessary for the correct use of the medicinal product;

16.3. an express and legible invitation to read carefully the package leaflet or the relevant information on the packaging;

16.4. an invitation to consult with a physician or pharmacist regarding the use of the medicinal product;

16.5. a warning “*Zāļu nepamatota lietošana ir kaitīga veselībai*” [Unreasonable use of medicinal products is harmful for your health]. Such warning shall take up not less than 10 per cent of the visual amount of the advertising. The size of letters shall be such that the title would take up the largest technically available part of the area intended for a warning text. In video advertising such warning shall be retained throughout advertising; in audio advertising the warning shall be expressed at the end of the advertising text;

16.6. the advertiser.

[25 November 2014]

17. The advertising of a medicinal product intended for the general public may indicate only the name of the medicinal product if the advertising is intended as a reminder of the previously distributed advertising.

18. It is prohibited to include in the advertising of medicinal products intended for the general public information that:

18.1. suggests treatment by mail or providing advice in another similar way and which gives the impression that the diagnosis may be determined without involving a physician;

18.2. suggests that the effects of the medicinal product are guaranteed, use of the medicinal product is unaccompanied by adverse reactions and the effects of the medicinal product are equivalent to, or are better than, those of another method of medical treatment or another medicinal product;

18.3. suggests that the overall health condition of the patient will improve significantly by taking the medicine product;

18.4. suggests that the health of the patient may deteriorate by not taking the relevant medicinal product. This condition shall not apply to the advertising of the vaccines referred to in Paragraph 12 of this Regulation;

18.5. is directed exclusively or principally at children;

18.6. refers to recommendations by scientists, health care professionals, or such persons who are not part of any of the abovementioned categories, but could encourage the consumption of medicinal products because of their celebrity;

18.7. suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;

- 18.8. suggests that the safety and efficacy of the medicinal product is due to the fact that it is natural;
- 18.9. could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- 18.10. refers, in improper, alarming or misleading terms, to claims of recovery;
- 18.11. uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of the medicinal product on the human body or parts thereof;
- 18.12. promotes the purchase of the medicinal product, justifying the necessity of the purchase of the medicinal product with the price of the medicinal product by announcing a special clearance sale or providing a notification that the medicinal product is sold together with another medicinal product (including for a lowered price) or goods.
- [25 November 2014]*

### **III. Advertising of Medicinal Products Intended for Specialists**

19. Advertising of medicinal products intended for specialists shall include at least the following information:

- 19.1. the most essential information which conforms to the description of the medicinal product;
- 19.2. whether the medicinal product belongs to the group of prescription or non-prescription medicinal products;
- 19.3. the date when the advertising was developed or reviewed the last time;
- 19.4. the advertiser.

*[25 November 2014]*

20. Advertising of a medicinal product intended for specialists may only indicate the name of the medicinal product or the international non-proprietary name thereof, or trade mark, if the advertising is intended as a reminder of the previously distributed advertising.

21. Information contained in the advertising intended for specialists shall be:

- 21.1. accurate, up-to-date, verifiable and complete so that the recipient may judge regarding the therapeutic value of the relevant medicinal product;
- 21.2. quoted precisely from medical journals or other scientific publications with references to the source of quotations, tables and other illustrative material.

22. Advertising of medicinal products intended for specialists shall be placed only in scientific and informative press publications intended for specialists or in specially prepared advertising materials, or in electronic mass media intended only for specialists, ensuring that there is a warning prior to opening the advertising that the content of the site is intended only for specialists. The warning must appear every time upon opening the relevant website.

*[25 November 2014]*

23. The owner of a marketing authorisation for medicinal products or an authorised representative thereof, or another person who is the advertiser or distributor of advertising may not offer, promise, or supply any material or other kind of benefit for the prescription or distribution of medicinal products. In advertising medicinal products, the advertiser and the distributor of advertising may supply and the specialist may accept only informative and educating materials or medicinal objects, which are directly intended for education and care for patients and do not substitute such objects, which should be at the disposal of the specialist in accordance with the laws and regulations regarding mandatory requirements for medical treatment institutions or with the provisions regarding operation of pharmacies. In advertising

non-prescription medicinal products, the advertiser or the distributor of advertising may supply and the specialist may accept also carriers of advertising, on which the advertising referred to in Paragraph 20 of this Regulation is placed. The value of abovementioned materials or objects shall not exceed 10 euros (without value added tax).

*[25 November 2014]*

24. Representation expenses in events with professional and scientific orientation shall be subordinated to the main purpose of the event, and they shall be applied only to specialists.

25. Specialists may not solicit, request or accept any material or other kind of benefit that is prohibited in accordance with Paragraph 23 of this Regulation or is contrary to Paragraph 24 of this Regulation.

26. Specialists in medical treatment institutions may be informed regarding medicinal products only outside office hours for accepting patients, co-ordinating the time of the visit with a specialist beforehand and complying with the procedures stipulated by the head of the medical treatment institution. In pharmacies informing of specialists regarding medicinal products is permitted, co-ordinating the time of the visit with the head of the pharmacy beforehand.

*[25 November 2014]*

27. Free samples of medicinal products may be distributed by a manufacturer or importer of medicinal products, an authorised representative thereof, or by a wholesaler of medicinal products, with which the manufacturer or importer of medicinal products has entered into an agreement regarding distribution of free samples of medicinal products (hereinafter – distributor of free samples), in conformity with the following conditions:

27.1. the packaging of the free sample of the medicinal product is the smallest trade unit of the relevant medicinal product;

27.2. the labelling of the free sample of the medicinal product conforms to the laws and regulations regarding the procedures for labelling of medicinal products and the requirements specified for the package leaflet of medicinal products;

27.3. a copy of the description of the medicinal product is appended to each free sample of the medicinal product;

27.4. the term for storage specified in the labelling and package leaflet of medicinal products and the term of validity of medicinal products is conformed to;

27.5. free samples of medicinal products, for the purpose of introduction, are supplied only to persons who have the right to prescribe the particular medicinal products;

27.6. free samples of medicinal products may be distributed only according to a written request signed and dated by a medical practitioner or the head of the medical treatment institution, in which the name, strength, or concentration of the medicinal products, the pharmaceutical form and number of packagings are indicated;

27.7. the distributor of free samples of medicinal products, upon distributing free samples of medicinal products, appends an accompanying document thereto, in which at least the following information is indicated:

27.7.1. the date of the supply;

27.7.2. the name, pharmaceutical form and strength or concentration of the medicinal product;

27.7.3. the term of validity of the medicinal product;

27.7.4. the serial number of manufacture of the medicinal product;

27.7.5. the number of free samples of the medicinal product;

27.7.6. the manufacturer of the medicinal product;

27.7.7. the name, address of the medical treatment institution and given names, surnames, specialities of medical practitioners;

27.7.8. the name and address of the distributor of free samples of medicinal products;

27.7.9. information shall be appended to the medicinal products, the use of which may result in increased risk to health, that the measures for reduction of risk developed by the owner of registration of medicinal products and co-ordinated with the State Agency of Medicines must be conformed to for safe and efficient use of the particular medicinal products;

27.8. each person who has the right to prescribe the particular medicinal product, may distribute not more than four free samples of prescription medicinal product of the same name within a year, and all persons together – not more than 1000 free samples of prescription medicinal products of the same name within a year;

27.9. free samples of medicinal products may be distributed to a person who has the right to prescribe the particular medicinal product not more than two years after the relevant person or head of the medical treatment institution has requested free samples of the particular medicinal products for the first time;

27.10. the distributor of free sample of medicinal products shall establish a system for accounting and control of the free samples of medicinal products supplied, in which the information indicated in the accompanying document referred to in Sub-paragraph 27.7 of this Regulation has been included.

*[25 November 2014]*

27.<sup>1</sup> Distribution of free samples of medicinal products with the purpose of using them for medical treatment of patients or as the incitation to prescribe, recommend, purchase, sell, or use specific medicinal products is prohibited.

*[25 November 2014]*

27.<sup>2</sup> Distribution of free samples of medicinal products is prohibited, if:

27.<sup>2</sup> 1. the medicinal product contains narcotic and psychotropic substances to be controlled in Latvia;

27.<sup>2</sup> 2. the medicinal product contains doping substances;

27.<sup>2</sup> 3. the State Agency of Medicines has recognised the medicinal product as narcotic analgesic preparation;

27.<sup>2</sup> 4. the medicinal product contains isotretinoin, thalidomide, and lenalidomide.

*[25 November 2014]*

28. The distributor of free samples of medicinal products shall each year (by 31 January) notify to the State Agency of Medicines the data regarding the free samples of medicinal products distributed in the previous calendar year, indicating:

28.1. the registration number of the medicinal product;

28.2. the name, pharmaceutical form, strength, or concentration of the medicinal product;

28.3. the number of samples distributed;

28.4. the date of supply;

28.5. the recipient.

*[25 November 2014]*

**IV. Requirements for the Owner of a Marketing Authorisation of the Medicinal Products to be Advertised, the Authorised Representatives Thereof, Advertisers, Distributors of Advertising, and Medical Sales Representatives**

*[25 November 2014]*

29. An owner of a marketing authorisation for medicinal products shall establish a scientific service, which prepares information regarding the medicinal products represented thereby, and compiles information provided by medical sales representatives regarding the results of the use of medicinal products.

*[25 November 2014]*

30. An owner of a marketing authorisation for medicinal products or an authorised representative thereof, or another person who is an advertiser or distributor of advertising, shall ensure that:

30.1. the requested information necessary for monitoring regarding the advertising material of medicinal products (text, picture, audio recording or video recording, carrier of advertising), the method of distributing the advertising, the commencement date for distribution and the target audience to whom the advertising is addressed, as well as advertising materials of medicinal products in electronic form is provided, without delay, to officials of the Health Inspectorate;

30.2. the advertising of medicinal products conforms to this Regulation and other laws and regulations regulating advertising and commercial practice;

30.3. the medical sales representatives under its supervision are trained appropriately, with sufficient knowledge in order to be able to provide as accurate and complete information as possible regarding the medicinal products being advertised, and to perform their duties in accordance with this Regulation.

*[25 November 2014]*

31. In advertising medicinal products to a specialist, a medical sales representative shall also issue a description of the medicinal product being advertised.

32. A medical sales representative shall provide to the scientific service referred to in Paragraph 29 of this Regulation all information regarding the results of the use of the medicinal products being advertised, with particular reference to the observed adverse reactions in accordance with the information provided by specialists.

32.<sup>1</sup> In organising and sponsoring the events with professional and scientific orientation referred to in Paragraph 24 of this Regulation, as well as providing material or other support to associations, foundations, and medical treatment institutions for participation of specialists in such events, the owner of a marketing authorisation for medicinal products or an authorised representative thereof, or another person who is the advertiser or distributor of advertising shall ensure storage of documents and information in accordance with Paragraph 35.<sup>1</sup> of this Regulation and shall conform to the following conditions:

32.<sup>1</sup> 1. it is not a sports, tourism, recreational event or an entertainment event of other kind;

32.<sup>1</sup> 2. the event is directly related to a benefit to the development of science and medicine and improvement of health care;

32.<sup>1</sup> 3. if the event is organised outside Latvia, a justification of the association, foundation, or medical treatment institutions for participation of the specialist in the event has been received;

32.<sup>1</sup> 4. for specialists who are registered for participation in an event (also in an event where medicinal products are not advertised) it is only permitted to cover the registration fee,



study materials, travel and accommodation expenses, including catering expenses within the scope of the event programme;

32.<sup>1</sup> 5. material or other support does not promote prescribing or use of medicinal product of a specific name.

*[25 November 2014]*

32.<sup>2</sup> The person referred to in Paragraph 32.<sup>1</sup> of this Regulation shall once a year (by 31 March) submit a notification to the Health Inspectorate regarding the material or other support provided to associations, foundations, and medical treatment institutions in the previous year, in writing, including using the website [www.latvija.lv](http://www.latvija.lv). The abovementioned information shall be accessible to the public on the website of the Health Inspectorate. The following shall be indicated in the notification:

32.<sup>2</sup> 1. the provider of material or other support (name, address);

32.<sup>2</sup> 2. the recipient of material or other support:

32.<sup>2</sup> 2.1. the name and legal address of the association, foundation;

32.<sup>2</sup> 2.2. the name and address of the medical treatment institution;

32.<sup>2</sup> 2.3. the given name, surname, and speciality of the specialist who participated in the event;

32.<sup>2</sup> 3. the amount of material or other support in monetary terms (if there are several recipients of material or other support, the amount of material or other support shall be indicated for each recipient individually);

32.<sup>2</sup> 4. the purpose of material or other support (shall be indicated for each recipient individually);

32.<sup>2</sup> 5. the name, place, and time of activities of the event.

*[25 November 2014]*

## **V. Monitoring of Advertisements for Medicinal Products**

33. The advertiser shall, 15 days prior to commencement of the vaccination campaign referred to in Paragraph 12 of this Regulation, submit to the Health Inspectorate the advertising material of vaccine, which has been prepared in accordance with the requirements of this Regulation, if an approval of the Centre for Disease Prevention and Control for the relevant vaccination campaign has been received.

*[10 April 2012]*

34. If amendments have been approved to the registration documentation of a medicinal product or the data of clinical trials have been published, which is in contradiction with the advertising material for medicinal products, the advertiser or distributor of advertisement shall, without delay, suspend the distribution of the advertising.

35. If seminars, conferences, congresses, competitions, exhibitions, and other events, in which medicinal product are advertised, are organised, the organiser of the event or the advertiser, if the advertiser is not the organiser of the event, shall submit information to the Health Inspectorate not later than seven days before the relevant event, including using the website [www.latvija.lv](http://www.latvija.lv), indicating the organiser and sponsor of the event, the advertiser of medicinal products, the persons responsible for advertising of medicinal products, the range of participants invited, the place and time of the activities of the event, as well as providing a description of the programme of the event.

*[25 November 2014]*

35.<sup>1</sup> The organisers and advertisers of the events referred to in Paragraphs 32.<sup>1</sup> and 35 of this Regulation shall, in accordance with the laws and regulations regarding conducting and

organisation of accounting, ensure storage of the documentation related to organising of events, including storage of corroborative documents regarding funding of events and provision of support, as well as storage of advertising materials according to the record-keeping procedures specified in the institution or undertaking, but not less than two years.

[25 November 2014]

36. Non-governmental organisations that are related to the field of pharmacy may develop and approve a joint code of ethics for the advertising of medicinal products, which conforms to the Advertising Law, this Regulation and the international ethical norms for the advertising of medicinal products.

37. Conformity with this Regulation shall be monitored by the Health Inspectorate. The Health Inspectorate shall commence an inspection regarding possible violations in the field of the advertising of medicinal products on the basis of a submission or complaint or upon its own initiative. The Health Inspectorate has the right to request and receive documents and information regarding preparation and distribution of advertising, as well as regarding funding of the events referred to in Paragraphs 32.<sup>1</sup> and 35 of this Regulation and payment of the participation fee for specialists in order to ensure supervision of conformity with this Regulation.

[25 November 2014]

## **VI. Closing Provisions**

38. Cabinet Regulation No. 167 of 6 March 2007, Procedures for Advertising of Medicinal Products and the Procedures by Which a Medicinal Product Manufacturer is Entitled to Give Free Samples of Medicinal Products to Physicians (*Latvijas Vēstnesis*, 2007, No. 41, 63; 2008, No. 53; 2009, No. 126), is repealed.

39. The advertising materials, the distribution of which was commenced until to the day of coming into force of this Regulation, shall be revised according to the requirements of this Regulation until 1 July 2011.

40. The advertising materials, the distribution of which was commenced until 1 January 2015, shall be revised according to the requirements provided for in Sub-paragraphs 16.6 and 19.4 of this Regulation until 30 June 2015.

[25 November 2014]

41. The notification referred to in Paragraph 32.<sup>2</sup> of this Regulation regarding year 2015 shall be submitted for the first time by 31 March 2016.

[25 November 2014]

## **Informative Reference to the European Union Directives**

This Regulation contains legal norms arising from:

1) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use;

2) Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use; and

3) Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Prime Minister

V. Dombrovskis

Acting for the Minister for Health, Minister for Education and Science

R. Broks