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**APPLICATION REGULATIONS OF THE CODE OF PRACTICE  
ON THE PROMOTION OF MEDICINAL PRODUCTS**

*Approved by the Decision of  
the Meeting of the Members of  
Association of International Research-based Pharmaceutical Manufacturers  
of September 22, 2014  
and  
by the Decision of  
the Meeting of the Members of  
Latvian Generic Medicines Association of September 30, 2014*

**Riga, 2015**  
*(valid since January 1, 2015)*

## **Preamble**

The Association of International Research-based Pharmaceutical Manufacturers (hereinafter referred to as 'SIFFA'), the Latvian Generic Medicines Association (hereinafter referred to as 'LPMA') and their members (hereinafter referred to as SIFFA, LPMA and their members jointly referred to as 'Manufacturers') have adopted these Regulations providing for application of the provisions of the Code of Practice for the Promotion of Medicinal Products (hereinafter referred to as 'Code') and the current legislative acts of the Republic of Latvia in order:

- (1) To promote introduction of the international and local ethical provisions and pharmaceutical industry's enactments so that they may apply to all the participants of Latvia's pharmacy market alike;
- (2) To ensure a uniform application of the Code in Latvia;
- (3) To facilitate elimination of any violations found and prevention of similar violations henceforth.

## **Section I. General Provisions**

1. All promotional, scientific or professional meetings, congresses, conferences, symposiums and similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) ("events"), which are organised or sponsored by Pharmaceutical Companies, must be held at appropriate venues corresponding to the main aim of the event, and hospitality allowances may only be offered wherever appropriate and otherwise in compliance with the current provisions of the Code.

1.1. All hospitality allowances related to promotional, professional or scientific events must be restricted to travel, catering, living accommodation and payment for participation (check-in) in an event if any.

1.2. Hospitality may only be extended to such persons registered as the event participants with participant rights. It is not allowed to cover the hospitality-related expenses to any other persons.

1.3. All kinds of hospitality allowances must be in a reasonable amount and strictly confined to the main aim of the event.

1.4. It is generally accepted that the offered hospitality must not be in excess of such an amount that participants would otherwise afford to pay for their own account.

1.5. It is not allowed to offer compensation of the time spent by participants when attending an event.

1.6. Hospitality must not cover sponsorship or organisation of any entertainment events (e.g., sports or recreational events).

1.7. The part of an event, which is not related to its main aim, must not exceed 30% of the whole duration of the event. A Program/Letter of Invitation to an event must contain a precise indication of the time allocated to the main aim of the event and the time allocated to hospitality.

1.8. A Program/Letter of Invitation to an event must contain a precise indication of the event's organizer and supporter and what exactly is supported.

1.9. The Pharmaceutical Companies must observe the criteria related to the choice of participants and sponsoring their participation in events as provided in the current Code or with regard to the same.

2. If in doubt about any event's compliance with the Code or the present Regulations, it is desirable and advisable to turn to the Ethics Commission with a request for comments on the current enactments of the Republic of Latvia, the Code provisions and these Regulations before organising such an event.

## **Section II. Corporate Events**

3. Corporate events (events not related to distribution of information on medicines – for example, Pharmaceutical Companies' anniversaries celebration parties, receptions in honour of business partners and the like, corporate parties before Christmas Eve, etc.) are allowed.

It is not allowed to invite medical practitioners or pharmacists, representatives of patient organisations to such events.

## **Section III. Sponsorship\***

4. It is allowed to donate to (sponsor):

4.1. Legal entities only;

4.2. Only such matters and events that have a scientific and/or medical goal and directly promote and improve patient care;

4.3. Sponsorship must not provide any personal benefit to the representatives of the sponsored entity;  
4.4. Sponsorship may not be related to the promotion of prescription of medicines manufactured by the relevant Pharmaceutical Company.

5. An issue of sponsorship assignment shall be reviewed and a resolution shall be passed on the ground of a legal entity's request (application) containing a substantiation of the necessity of sponsorship and advantages for scientific and medical development and patient care improvement.

5.1 When a sponsorship or donation is provided to patient organisations and when these organisations are supported financially, provisions of the Code shall apply.

5.2 Pharmaceutical Companies are encouraged to make available publicly information about donations, grants or material benefits made by them.

*\*Note: This Section does not apply to sponsoring of participation in events of healthcare professionals and representatives of patient organisations.*

#### **Section IV. Criteria of choosing healthcare professionals and representatives of patient organisations and sponsoring their participation in events**

6. Participation in events may only be sponsored if:

6.1. a participant directly represents the industry or industries related to the topic of the event;

6.2. a participant may ensure further application of the received knowledge in his/her practice.

7. Sponsorship of healthcare professional's participation in events shall not be related to the promotion of prescription of the sponsor's medicines.

8. An issue of sponsorship assignment for participation in events shall be reviewed and a resolution shall be passed on the ground of a healthcare professional's, representative's of the patient organisation request (application) containing a substantiation of the necessity of sponsorship and information about further application of the received knowledge in his/her practice.

If a healthcare professional or a representative of the patient organisation is invited to take part in an event, sponsorship is assigned on the ground of a healthcare professional's, representative's of the patient organisation justification (information) about further application of the received knowledge in his/her practice.

#### **Section V. Hospitality allowances**

9. Recommended venues of events:

9.1. conference-halls;

9.2. facilities of public organisations (associations, societies);

9.3. medical facilities;

9.4. pharmacies;

9.5. other such places as equipped with a conference-hall.

If an event is organized for the healthcare professionals or representatives of the patient organisation of a certain region of the country, the event may be held at public catering facilities if no such premises as mentioned in Paragraphs 9.1–9.5 above are available.

To hold events elsewhere is not allowed.

10. The following hospitality allowances may be offered in Latvia:

10.1. accommodation at the venue of the event;

10.2. catering. Maximum amount per person per one meal (food and drinks) shall not exceed EUR 60, and the total maximum amount per all meals per day shall not exceed EUR 100 in Latvia;

10.3. transport to the venue of event and backwards.

11. No Pharmaceutical Company is allowed to organise or sponsor an event, which is held outside the domicile region of the healthcare professional or patient („international event") except for such cases as follows:

11.1. If the event is closely related to improvement of the healthcare professional's knowledge and skills needed for his/her work and/or patients knowledge; and

11.2. The majority of guests come from foreign countries (it would be logical to hold the event in the country where the majority of participants come from); or

11.3. In view of the location of the relevant resources, i.e. the object or the subject of the event, it is logical to hold the event in other country, and such an event cannot be organised in Latvia.

12. It is allowed to make the following payments related to an international event (an event held abroad):

- 12.1. To pay economy class airfares, except cases when there are no available economy class tickets to the given flight;
- 12.2. To pay for bus (coach) tickets;
- 12.3. To pay for railroad tickets;
- 12.4. To pay no higher than a medium-class car rent or taxi services to get from the airport to the hotel and back.
- 12.5. For catering expenses, the Pharmaceutical Company shall apply norms/limits valid for the country where the event is held (e.g. the monetary threshold defined in the “host country”).
- 12.6. Hotel accommodation – not more than the price of a 4-star hotel at the corresponding dwelling place with the exception of cases when international events are held in a hotel of a higher rate and participants of the event are accommodated in this hotel.
13. It is not allowed to offer such hospitality as:
  - 13.1. sports and recreational events/activities;
  - 13.2. entertainment events;
  - 13.3. covering expenses on Spa and body care procedures;
  - 13.4. excursions;
  - 13.5. accommodation at resorts and recreational facilities;
  - 13.6. covering expenses incurred by the specialist’s accompanying person;
  - 13.7. accommodation/daily allowances;
  - 13.8. other similar hospitality allowances.

*Note: The prohibition is not limited to the examples listed in the Article 13.*

## **Section VI. Gifts and incentives, informative and educational materials and items of medical utility**

14. No gifts, material advantages or benefits may be provided, offered or promised to a healthcare professional and his/her family members, in particular:

- tickets to entertainment and sports events;
- alcoholic beverages;
- cigarettes;
- money;
- gift cards;
- computers;
- furniture;
- telephones;
- facsimile machines;
- TV sets;
- other similar benefits not directly related to the health care.

*Note:*

*The prohibition is not limited to examples listed in Sections 14.1 to 14.11.*

15. It is allowed to offer, promise or present the following gifts to a healthcare professionals:

- 15.1. according to Sections 8.02 and 8.03 of the Code: items of medical utility, unless the value of one item does not exceed EUR 10 (value-added-tax excluded).
- 15.2. according to Sections 8.01 and 8.03 of the Code: informative or educational materials, unless the value of one material does not exceed EUR 10 (value-added-tax excluded).
- 15.3. Article 12 of the Code and provisions of the Section III hereof shall apply to items of medical utility, informative or educational materials of value above EUR 10 (value-added-tax excluded) to which provisions of the Section 8.01 of the Code do not apply.

## **Section VII. Remuneration of healthcare workers**

16. Cooperation between the Pharmaceutical Company and physicians in clinical, epidemiological and genetic trials is essential for new medicines development, in-depth studies of medicines and gaining information on optimal administration of medicines to the patient’s best interests. All such trials and studies must meet the following principles:

16.1. A Pharmaceutical Company is only entitled to render financial, organisational and other support (incl., remuneration for a physician’s work during the trial/study) to such events as registered by the State Agency of Medicines (SAM). In such cases the Pharmaceutical Company’s contribution must be precisely indicated in the documentation to be submitted to the SAM, handed out to trial participants, trial subjects and so on.

16.2. Physician's remuneration, whatever it may be, must be related to the work performed.

16.3. Remuneration must not be related to any expected trial result.

17. A physician may be paid remuneration for a preparation and deliver of a lecture, for providing a consultation and expert opinions for the industry. Remuneration for the physician's work must be directly related to the volume of the performed work.