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**CODE OF GOOD PRACTICE AND ETHICS**

**RULES OF APPLICATION**

*Approved by*

*Association of International Innovative Pharmaceuticals Producers*

*Decision of the 16 September 2020 members' meeting*

*and*

*Latvian Generic Medicines Association*

*Decision of the 24 March 2020 members' meeting*

**Riga, 2020**

(Enters into force on 1 December 2020)

**Preamble**

Association of International Innovative Pharmaceuticals Producers (hereinafter - SIFFA), Latvian Generic Medicines Association (hereinafter - LPMA) and their members (hereinafter SIFFA, LPMA and their members together - Producers) approve the Code of Good Practice and Ethics (hereinafter - the Code) standard and the regulations for the application of the legislation(hereinafter - the Regulations) in force in the Republic of Latvia in order to:

(1) promote the implementation of international and local ethical norms and regulatory enactments of the pharmaceutical industry so that they apply equally to all participants of the pharmaceutical market in Latvia;

(2) ensure uniform application of the Code in Latvia;

(2) contribute to the prevention of detected violations and the avoidance of similar infringements in the future.

**Section 10. Events and Hospitality**

1. All promotional activities, scientific or professional meetings, congresses, conferences, symposiums and other similar events (including, but not limited to advisory board meetings, visits to research or manufacturing establishments, planning, training or research meetings, clinical trials of medicinal products and use observations) (hereinafter - Events) organised or sponsored by the Producers must take place in appropriate locations consistent with the main purpose of the Event, be directly related to the benefits of scientific and medical progress and improved healthcare, and hospitality can only be offered if appropriate and otherwise in accordance with the provisions of the Code.

1.1. Hospitality related to the Events (including those where medicines are not advertised) should be limited to travel, meals (within the Event programme), accommodation and participation (registration) fees, if any, as well as training materials.

1.2. Hospitality can only be extended to persons identified as participants in the Event with the rights of participants. It is not allowed to pay hospitality expenses for other persons.

1.3. All types of hospitality offered must be of a reasonable level, proportionate and strictly limited to the main purpose of the Event.

1.4. It is generally accepted that the hospitality offered should not exceed what the participants would be willing to pay for themselves.

1.5. No payment may be offered to compensate the time spent by the participant when attending the Event.

1.6. Hospitality must not include sponsorship or the organisation of any entertainment events (e.g., sports, tourism, leisure or other entertainment events).

1.7. Scientific part of the Event should fill most (preferably at least two thirds) of the total time of the event. The programme/invitation of the event must specify the time allocated for the main purpose of the event and the time for hospitality.

1.8. The event programme/invitation must specify exactly who the organiser and supporter of the event is, indicating what exactly is supported.

1.9. Producers must comply with the criteria relating to the selection and sponsorship of participants for participation in the Events, as set out in the Code in force or related to it.

1.10. If the Event is organised outside Latvia, the Producer must receive a justification of the association, foundation or medical institution for the participation of HCP in the Event.

2. If there are doubts about the compliance of an Event with the Code or these Regulations, it is desirable and advisable to apply to the Ethics Commission with a request for an explanation of the legal acts in force in the Republic of Latvia, the Code and these Regulations.

3. Recommended venues for events:

3.1. conference halls;

3.2. premises of public organisations (associations, societies);

3.3. medical institutions;

3.4. pharmacies;

3.5. other places where there are conference rooms and which are not directly connected with entertainment venues. It is permissible to organise Events in public catering companies if there are no appropriate premises in the relevant territory, referred to in Clauses 3.1-3.5. It is forbidden to organise Events in other places. Venues that are “extravagant” or “famous” for their entertainment should be avoided for organising Events.

4. The following hospitality can be offered in Latvia:

4.1. stay at the Event venue;

4.2. catering. The maximum amount of expenditure per person per meal (food and drink) may not exceed EUR 60, and the total maximum amount of expenditure per meal per day may not exceed EUR 120, including value added tax (VAT);

4.3. transport to and from the Event venue.

5. Producers may not organise or sponsor an Event that takes place outside the region of residence of HCP or the patient (an “international event”), excluding cases, when:

5.1. The event is directly related to the development of the knowledge and skills required for the work of HCP and/or the knowledge of patients and most of the invitees come from other countries (considering the countries from which the majority of the invitees come, it is logical to organise the event in the country from which the majority of the invitees come from) or,

5.2. taking into account the location of the relevant resources, which is the object or subject of the Event, it is logical to organise the Event in another country and it is not possible to organise such an Event in Latvia.

6. The following costs are allowed in connection with an international Event (Event Abroad):

6.1. economy class air tickets, except for in cases where economy class tickets are not available for the flight in question, bus and rail tickets, not higher than mid-range car rental or taxi services to and from the airport;

6.2. for catering expenses the Producer applies the norms/limits of the country where the Event takes place (i.e. according to the financial threshold set in the “host country”);

6.3. accommodation in a hotel- not higher than 4 stars, except for in cases when international Events take place in hotels of a higher category and the participants of the Event stay in this hotel.

7. The following hospitality may not be offered: for example, sports and leisure events/activities, entertainment, payment for *spa* and body treatment procedures, excursions, stays in resorts and recreation areas, payment of expenses for HCS accompanying persons, accommodation/daily allowance, other similar hospitality. The examples given in this paragraph are not exhaustive.

8. Representatives of HCS and PO are not allowed to be invited to corporate events (events that are not related to the dissemination of medical information, such as anniversary events of Producers, events for cooperation partners and similar corporate events before Christmas, etc.).

**Section 11. Prohibition of Gifts**

1. It is forbidden to supply, offer or promise any gifts, material benefits or benefits for personal use to representatives of HCS, HCO or PO and their family members, in particular: tickets for entertainment and sports events, alcoholic beverages, cigarettes, money, gift cards, computers, furniture, phones, TV, other similar benefits. The examples given in this paragraph are not exhaustive.

2. When advertising medicines, the advertiser and the distributor of the advertisement may supply and the specialist may only accept educational materials, which are directly intended for the education of HCS and the value of which does not exceed EUR 10 (excluding VAT).

3. Producers may only provide stationery (pens) and/or sticky notes with the company logo at an Event organised by the company (Producer). These products do not include a specific product brand and are not expensive. Companies cannot distribute stationery or sticky notes on exhibition stands. Pens or sticky notes included in conference kits for the participants may not bear a specific brand (neither product, nor company).

**Section 12 Donations and grants (targeted support)**

1. It is allowed to donate:

2.1. only for legal entities;

2.2. only for things and Events which have a scientific and/or medical purpose and which directly promote and improve health care, scientific research or education;

2.3. the donation and grant may not bring personal benefits to the representatives of the sponsor;

2.4. the donation and grant may not be related to the promotion of the prescription or use of the medicinal product by the respective Producer.

3. The basis for reviewing the issue and making a decision on granting a donation and grant is a request (submission) of a legal person with justification for the necessity of support and benefits for the development of science and medicine, improvement of patient care.

4. Producers must disclose information about donations, grants or material benefits they have provided.

*\* Explanation. This section of the Regulations does not apply to the sponsorship of healthcare specialists(HCS) and representatives of patients' organizations (PO) to participate in events.*

**Section****13. Support and sponsorship**

1. HCS participation in the Events may only be supported if:

1.1. the participant directly represents the sector or sectors corresponding to the theme of the event;

1.2. the participant can ensure the further use of the knowledge gained in the event in practice.

2. HCS support for participation in events must not be linked to the promotion of prescribing and use of the supporter’s medicine.

3. The basis for examining the issue and making a decision on granting support for participation in the Events is a request (submission) of the representative of HCS and PO with a justification of the need for support and information on further use of the acquired knowledge in practice.

4. Sponsorship applies to legal entities- HCO and PO.

**Section 15. Contracted Services**

1. Cooperation between Producers and HCS in clinical, epidemiological and genetic research is essential for the development of new medicines, the acquisition of in-depth knowledge about medicines and the acquisition of knowledge about the optimal use of medicines in the interests of patients. All studies should follow the following principles:

1.1. The Producer may only financially support, assist in organising and otherwise promote (including the payment of remuneration to HCS for work during the study) studies registered with the State Agency of Medicines (SAM). In such cases, the Producer's contribution must be clearly indicated in the documentation submitted to the SAM, distributed to the study participants, research objects or otherwise distributed;

1.2. the remuneration to HCS, whatever it may be, must be linked to the work done;

1.3. the remuneration must not be linked to any expected results of the study.

2. The HCS can receive remuneration for preparing and giving lectures and acting as a consultant and expert to the industry. Remuneration for the work of HCS must be directly related and appropriate to the work performed and its amount.

3. Limited market research (such as one-off phone interviews or mail/e-mail/internet questionnaires) is excluded from the scope of Section 15, provided that the consultations of HCS, HCO or PO representative are not used in a recurring manner and that the remuneration is minimal, including costs up to EUR 50, including taxes.

**Section 17. Informational or Educational Materials, and Items of Medical Utility**

The value of informative or educational materials may not exceed EUR 10 (excluding VAT).

**Section 21.3. Cooperation with Patient Organisations**

Any financial support provided (direct and indirect) to PO is considered significant. The significance of indirect support and/or non-financial support is determined by each Producer.

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