

An Icelandic appendix to the EFPIA code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals.

Interactions by employees of Frumtök's member companies with health care professionals (HCPs) are based on the EFPIA HCP Code. The EFPIA HCP Code sets out the minimum standards which EFPIA considers mandatory. In a manner compatible with their respective national laws and regulations, member associations must, at a minimum, adopt in their national codes provisions no less rigorous than the provisions contained in the EFPIA HCP Code. Member associations are encouraged to tailor their national codes to adapt to national conditions and to adopt additional provisions which extend further than the minimum standards included in the EFPIA HCP Code.

Regarding art. 9: Informational or Educational Material and Items of Medical Utility

Transmission of informational or educational material is permitted provided it is "inexpensive", directly relevant to the practice of medicine or pharmacy, and directly beneficial to the care of patients. Items of medical utility aimed directly at the education of healthcare professionals and patient care can be provided if they are "inexpensive" and do not offset routine business practices of the recipient. A threshold of max. ISK 3.000 pr. item has been set. Frumtök provides further guidance.

Regarding art. 10: Events and Hospitality

- 1. When a meeting is sponsored in any way by a company, it must be clearly indicated in all relevant material that it has been sponsored by that company.
- 2. Meetings and congresses must be held in an appropriate venue that is conducive to the main purpose of the event and may only offer hospitality when such hospitality is appropriate and otherwise complies with the provisions of any Applicable Code(s). Therefore, meetings and congresses shall not be held at locations renowned for leisure activities. Locations renowned for leisure activities in this context refer to, for example, golf- or ski-resorts, SPAs or casinos.
- 3. Prior to an international event, a written agreement shall be completed, where participation is confirmed. The agreement is between the company that funds the HCP to attend the event and the HCP. Dates of travel shall take notice of the dates of the event. If the HCP, for some specific reasons, has to travel outside the dates of the event, he/she shall him/herself handle the travel arrangements, pay any additional cost and accept responsibility for travel insurance for that part of the travel.
- 4. Neither is it appropriate nor acceptable that a HCP is accompanied by a spouse or other guests.
- 5. All forms of hospitality offered to HCPs shall be "reasonable" in level and strictly limited to the main purpose of the event. "Reasonable" in this context refers to for example:
 - a. Travel arrangements shall generally be confined to economy class (or comparable) or the most economical fare.
 - b. Hotel accommodation shall, in general, be confined to four star Hotels

- c. Meals shall not be offered at restaurants with Michelin stars, or at similarly renowned locations.
- d. A company neither organises nor sponsors any stand-alone leisure activities or entertainment.
- 6. Monetary Thresholds:
 - a. Breakfast: ISK 4.000
 - b. Lunch / light refreshments: ISK 6.000
 - c. Dinner: ISK 15.000
 - d. The monetary threshold set in the country where the event takes place (i.e. the "host country") shall prevail.

Regarding art 19: Enforcement and Annex A, art. 3 and 4:

Reception of Complaints and Processing of Complaints and Sanctions by Member Associations

If disagreement rises or a complaint is filed, Frumtök's Complaints and Compliance Committee shall meet to handle each and every case. The Committee shall be appointed case by case based on Frumtök's Board Agreement.

If the Committee confirms a breach by a company, it can apply sanctions. The company involved, shall confirm in a written statement that the practice/activities have been discontinued and will not be repeated. The Committee can apply sanctions in a level of detail that is consistent with the seriousness and/or persistence of the breach.

Notification of meetings and events:

Frumtök's member companies are offered the option to notify the Frumtök office regarding any meetings or events that are held under the scope of the EFPIA code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals and the EFPIA code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations. Notifications shall be sent in an e-mail to the office, prior to the announced meeting or event. If the office believes the meeting or event is in any detail out of line or in breach with the relevant code, the company involved shall be informed. If not, a confirmation of receiving the notification shall be sent to the company with no comments.

If a member company chooses to notify a meeting or event to Frumtök, it may for example be done like this:

[name of the company] operates and obeys to the framework set out in the EFPIA code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals.

This meeting / event has been notified to Frumtök's office.

The Codes are available at www.frumtok.is

Regarding publication of financial information (disclosure):

- 1. Travel expences (such as airport taxis), lower than ISK 20.000, may be excluded from disclosure.
- 2. Meal-related expences, lower than the monetary thresholds (see art. 10 abowe) may be excluded from disclosure. If expences exceed the set limit, the total cost is to be disclosed.

Frumtök member companies are under obligation to comply with rules on the disclosure of financial information in <u>The Disclosure Code</u> of the European Federation of Pharmaceutical Industries and Associations (EFPIA). As the matter involves the processing of personal information, member companies are strongly adviced to insert a disclaimer such as the following in their contracts with healthcare professionals.

* According to the EFPIA Disclosure Code, public disclosure of information on particular payments from pharmaceutical companies due to co-operation with healthcare professionals and healthcare facilities is mandatory. The payments to which the Code applies include grants to healthcare facilities, consultancy fees for lectures, travel and accommodation costs and registration fees at conferences.

This duty is fulfilled by publishing the information in question in the annual report of the company [on the website of Frumtök]. The processing of information that is considered personal information is subject to the provisions of Act No. 77/2000 on the Protection of Privacy as Regards the Processing of Personal Data, as amended.

- * The information that [company] processes as regards participants in travel to which these travel rules apply and which are publicly disclosed in the above manner is considered general personal information.
- * In accordance with Item 1 of the first paragraph of Article 8 of Act No. 77/2000, cf. Article 3 of Act No. 90/2001, the company does not process the information in question except with the express permission of the participant thereto.
- * By attaching his/her signature below, the participant confirms that he/she has read the above terms on the planned processing of personal information and grants his/her permission for such processing.

December 2017.

This Appendix has been confirmed in Frumtök's Code Committee and Frumtök's Board.