

EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals

(EFPIA HCP CODE)

Frequently Asked Questions – FAQ

This document is provided as a support to Member Associations with a view to ensuring consistent implementation of the EFPIA HCP Code.

In a manner compatible with their respective national laws and regulations, Member Associations must, as a minimum adopt in their national codes provisions no less rigorous than the provisions contained in the EFPIA HCP Code.

These FAQs provide clarification and interpretation of the EFPIA Code provisions in the Final Consolidated Version of the Code as approved by the General Assembly on 6 June 2014. They are provided as guidance and in addition relevant national association codes and related guidance have to be considered.

The answers to the questions included in this document have been developed with input from the Drafting Group of the Compliance Committee Steering Group (CCSG).

This version will annul and supersede the February 2014 Edition

GENERAL

Question General 1 (previously question 1): Are the amendments to the EFPIA HCP Code consistent with Directive 2001/83/EC on the Community code relating to medicinal products for human use?

Answer: Yes. Under the Directive, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised unless they are both inexpensive and relevant to the practice of medicine or pharmacy. The amendments to the HCP Code constitute additional guidance with regard to the existing provisions and are intended to provide greater clarity around items that may and may not be provided to HCPs.

INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY

ARTICLE 9 OF THE EFPIA HCP CODE

ITEMS OF MEDICAL UTILITY / INFORMATIONAL OR EDUCATIONAL MATERIALS

Items of medical utility generally include items that are beneficial to enhancing the provision of medical services and patient care, and have no personal benefit to the HCP. *Items of medical utility* might include inhalation devices (with no active ingredient) and devices intended to assist patients to learn how to self-inject.

Informational or educational materials generally include items that advance disease or treatment education, are designed for the education of patients or HCPs, and have no personal benefit to the HCP. *Informational or educational materials* might include educational brochures on diseases, patient self-assessment and tracking tools, and brochures that HCPs use when instructing patients about adherence to medicine regimens, healthy lifestyle choices or the availability of patient assistance programmes.

Question 9-1 (previously question 3): In what circumstances may items of medical utility be considered as “offsetting routine business practices” of an HCP?

Answer: A HCP practice generates certain routine costs, such as rent, administrative costs, office supplies (including stationary, pens, etc.) or items that are needed in order to conduct patient consultation *i.e. gloves, tissues, stethoscopes, sphygmomanometers, etc.* As a general principle, Member Companies should not provide such items to HCPs.

Consequently, the amended EFPIA HCP Code allows Member Companies to provide certain inexpensive *items of medical utility* to HCPs only to the extent that they do not offset costs that would otherwise be routinely incurred by a HCP.

Question 9-2 (previously question 4): Are the new HCP Code provisions applicable to educational materials provided on-line?

Answer: Yes. The HCP Code provisions apply to on-line educational materials as they would for any other educational materials. Such educational materials must be “inexpensive”, be directly relevant to

the practice of medicine or pharmacy, and directly relevant to the care of patients. “Inexpensive” is defined by Member Associations (but does not require to be defined *per se* as a monetary value).

Question 9-3 (previously question 5): What materials would be considered *informational or educational materials*?

Answer: Materials with informational or educational content, which are inexpensive and directly designed for the education of patients or HCPs and are relevant to the practice of medicine or pharmacy are considered to fall within the *informational or education materials* category.

Examples of such materials might include informational brochures, which help patients to understand their disease, provide more detailed instructions on how to use their medication, or be part of a patient support programme. Materials provided have to comply with relevant provisions of the Code.

Member Associations may provide further guidance on materials falling into this category.

Question 9-4 (previously question 6): Are memory sticks containing *informational or educational materials* permissible?

Answer: As a general rule, memory sticks (and other electronic storage devices like DVDs, etc.) containing *informational or educational materials* can be provided to HCPs. Such items may only be provided to an HCP if they are “inexpensive” and contain informational or education content that is directly relevant to the practice of medicine or pharmacy and beneficial to the care of patients.

Member Associations may wish to provide further guidance on what is and is not acceptable.

Question 9-5 (previously question 7): What is the meaning of the term “inexpensive” as used in the EFPIA HCP Code?

Answer: Each Member Association must explain what is meant by “inexpensive”. A monetary value does not have to be set; however Member Associations wishing to set such a monetary threshold can do so.

Question 9-6 (previously question 8): If *informational or education materials* and *items of medical utility* are provided to a HCP in compliance with the provisions of the HCP Code, are Member Companies also required to disclose them as Transfers of Value under the EFPIA Disclosure Code?

Answer: No. *Informational or education materials* and *items of medical utility* provided to HCPs in compliance with the EFPIA HCP Code and applicable national codes do not fall within the scope of the Disclosure Code.

Question 9-7 (previously question 10): Does the amended EFPIA HCP Code allow for the provision of items that are used by HCPs when instructing patients and/or given to patients?

Answer: The amended HCP Code permits the provision of *items of medical utility*, provided that they are aimed directly at the education of HCPs and patient care, are inexpensive and do not offset routine business practices of the Recipient. HCPs may use such items to instruct patients or to familiarise them with their treatment and its application.

Examples of such items might include inhalation devices (with no active ingredient) and devices intended to assist patients to learn how to self-inject. Such items must also comply with all other applicable provisions of the HCP Code.

Member Associations may wish to provide further guidance on what is and is not acceptable.

Question 9-8: Should costs of producing electronic mobile applications or educational brochures, that are free for final use, also be considered as the costs of *informational or educational materials*?

Answer: As a rule, materials and items, even when given free for final use, fall within scope of the provisions on the Code (relevant to healthcare practice, inexpensive and benefiting the patient).

Member Associations are asked to provide guidance on the meaning of “*inexpensive*” *informational or educational materials and items of medical utility*, but there is no obligation to fix a monetary value.

When issuing such guidance, the Member Associations may consider clarifying the costs to be considered.

Question 9-9: Can the *informational or educational materials* be provided as Educational Grants to Institutions, and therefore not be subject to the concept “inexpensive”?

Answer: Educational materials may be provided as an Educational Grant. In such case, Article 11 of the HCP Code will apply:

Section 11.01 of the EFPIA HCP Code: “*Donations and grants (in cash or in kind or otherwise) to institutions, organisations or associations that are comprised of healthcare professionals and/or that provide healthcare or conduct research (that are not otherwise covered by the EFPIA HCP Code or the EFPIA PO Code are only allowed if: (i) they are made for the purpose of supporting healthcare or research; (ii) they are documented and kept on record by the donor/grantor; and (iii) they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. Donations and grants to individual healthcare professionals are not permitted under this section. (...)*”

The EFPIA Codes do not provide for a threshold on the value involved in Grants. However, Grants should not be a way of circumventing the provisions on *informational or educational materials and items of medical utility*.

Transfers of Value provided as Grants should be disclosed in the relevant category as required by the EFPIA Disclosure Code.

Question 9-10: Can *items of medical utility* be company branded?

Answer: The EFPIA Code does not prevent branding of *items of medical utility*. However, where such items would be passed on to patients, legal provisions regarding patient information may apply.

A reasonable approach might be that if *items of medical utility* are issued directly by a company, they would normally include that company’s logo. In addition, it might also be acceptable to use the product branding, when the item is used with that medicine, within the limits permitted by laws and regulations.

However, if the *item of medical utility* comes from a third party, the use of the company logo in addition to the manufacturer's logo may not be appropriate. This is to help avoid that the *item of medical utility* is being used to circumvent the prohibition of gifts or the ban on offering items that offset routine business expenses.

Member Associations may provide guidance in this area.

EVENTS & HOSPITALITY

ARTICLE 10 OF THE EFPIA HCP CODE

Question 10-1: Do the thresholds for meals & drinks only apply to Europe (i.e. EFPIA scope)?

Answer: The EFPIA Code requires that Member Associations set a monetary value for any meal (food & beverages) offers to a HCP in their respective national codes. The monetary value set in each national code will apply to all events taking place in the country (i.e. "host country" principle), even when the threshold applicable in the country of the HCP is different (unless laws and regulations, the HCP is submitted to would not allow exceeding the threshold applicable in his/her home country).

EFPIA's jurisdiction being limited to the countries where it has a Member Association, it cannot enforce its Codes beyond the 33 countries it represents.

Member Associations may provide additional guidance, where appropriate.

Under section 10.05 of the HCP Code, the amount of food & beverages below the national threshold do not need to be disclosed by Member Company. However, it is forbidden to provide food & beverages with amount above the national threshold.

Question 10-2: If sponsoring an HCP to take part in an event outside Europe, does the national code of the country where the sponsoring Member Company is located apply, or the national code of the country where the event takes place?

Answer: Member Associations shall provide guidelines on the applicable threshold outside Europe (for example: applying of the national threshold of the HCPs' country or applying of the national threshold of the country where the event take place).

FEES FOR SERVICE

ARTICLE 12 OF THE EFPIA HCP CODE

Question 12-1: Is it in accordance with the HCP Code to pay an HCP for his/her travel time in relation to performing services?

Answer: The payment of travel time for either Fee for Service activity (Article 12) or the Use of Consultants (Article 14) can be paid providing all aspects of the Code are complied with and such payments are included in a written contract/agreement. National codes may be stricter than the EFPIA HCP Code.

Any such payments would constitute a Transfer of Value subject to the requirements of the EFPIA Disclosure Code, and will be reported accordingly.

Question 12-2: Can Member Companies sponsor the distribution of treatment guidelines issued by Learned Societies?

Answer: Treatment guidelines issued by Learned Societies are based on evidence-based clinical research and approved in consensus meeting confirming state-of-the-art healthcare. Support provided for the distribution of such guidelines – either in printed or electronic format – constitutes an activity that is permitted under Article 9 of the EFPIA Code, provided it conforms to Code requirements.

Related costs would constitute Transfers of Value and have to be reported according to the provisions of the EFPIA Disclosure Code.

Question 12-3: Is it allowed for Member Companies to provide sponsorship of Internet Access/Wifi connections at a congress? Should it be allowed that such sponsorship is acknowledged by the organisation (such as: logo and company name appearing at the start of access)?

Answer: The EFPIA Code does allow Member Companies to sponsor events. The content of the sponsorship should however not be such that it supports activities that would not be permissible under the Code (such as the ban on gifts, providing materials and items that are not allowed under the Code).

Transfers of Value connected to such sponsorship are submitted to the requirements of the EFPIA Disclosure Code/Patient Organisations Code.

PROHIBITION OF GIFTS

ARTICLE 17 OF THE EFPIA HCP CODE

Question 17-1 (previously question 12): Does EFPIA intend to provide an exhaustive list of items that are considered “gifts” and are prohibited?

Answer: No. As a general rule, no gifts or items that offset routine business practices of the Recipient are allowed, unless they fall into a category of materials or items that are otherwise permitted under the EFPIA HCP Code (i.e. *informational or educational materials or items of medical utility*).

When providing guidance, Member Associations shall ensure that the scope of materials and items that can be given is defined in such a way that they not constitute a circumvention of the ban on gifts.

Question 17-2 (previously question 13): Are branded “leave behinds” (such as pens, post-its, note pads etc.) considered promotional materials or gifts?

Answer: “Leave behinds” are considered gifts unless they fall into a category of materials or items that are otherwise permitted under the HCP Code (i.e. *informational or educational materials and items of medical utility*).

In general, pens, post-its, note pads, etc. are considered as office supplies. Member companies should not provide such items.

However, pens or paper pads can be provided exclusively during company-organised meetings, as long as they are unbranded and inexpensive. Companies are not allowed to distribute pens or paper pads at exhibition stands. Pens or paper pads included in conference bags should not bear company or product names and/or logos.

Question 17-3 (previously question 14): Is a laptop loan that is an integral part of a Fee-for-Service activity or R&D activity a gift?

Answer: If a laptop (or other IT equipment or other equipment) loan is an integral part of an otherwise legitimate Fee-for-Service activity (for example: as a part of the legitimate fee for a clinical trial as defined in the EFPIA Code), it will not be considered a gift. Such a loan, including rationale and when it is to be returned, should be clearly documented in the contract supporting the Fee-for-Service activity.

However, if the HCP was to request to keep the laptop (or the equipment) after the Fee-for-Service activity (e.g. R&D activity) after completion of the legitimate collaboration, leaving the laptop behind will be considered a gift and therefore prohibited under the EFPIA HCP Code.

Question 17-4: Is it correct to interpret the Prohibition of Gifts to mean that it is forbidden to sponsor the congress bags, blocks, pens, USB devices, lanyards and similar items (even without reference to the name of the company / products)?

Answer: As a general rule, no gifts or items that offset routine business practices of the Recipient are allowed, unless they fall into a category of items that are otherwise permitted under the EFPIA HCP Code (i.e. *informational or educational materials* and *items of medical utility*). When providing guidance, Member Associations shall ensure that the scope of materials and items that can be given is defined in such a way that they not constitute a circumvention of the ban on gifts.

Therefore, it is hard to consider bags as *informational or educational materials and items of medical utility*, and therefore providing bags is prohibited. However, when sponsoring a congress, it should be possible to use part of the financial contribution for the bags when they are used for carrying *informational or educational materials*. It is obvious that they should not have the sponsoring company logo.

See other questions under this section “Prohibition of Gifts” and section “Informational & Education Materials and Items of Medical Utility”.

Member Associations may provide additional guidance, where appropriate.
