Chapter B of the Code of Ethics of SFEE titled: Disclosure of Transfers of Value By Pharmaceutical Companies to Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs)

Frequently Asked Questions

This document is provided to the Companies-Members of SFEE in order to assist them in preparing their systems so as to ensure the uniform application of the **Code of Disclosure of Interactions between Pharmaceutical Companies & Healthcare Professionals**

It is noted that even though no enacted relevant obligation imposes so, no deviation is permitted from the **Code of Disclosure of Interactions between Pharmaceutical Companies & Healthcare Professionals** by the Companies-Members, from which it is required to incorporate and fully implement the Code, following the unanimous resolution adopted in the Extraordinary general Assembly of SFEE which was held on 27/11/2013.

Clarifications and Definitions

Scope of Application

The Code of Ethics of SFEE determines the minimum standards that must apply to all Companies-Members thereof.

Companies-members are expected, where possible, to apply the **Code of Disclosure of Interactions between Pharmaceutical Companies & Healthcare Professionals** in its whole (without any deviations).

Issues that will emerge during the disclosure – i.e. possible application issues – must not be impediments to the application of the code and they will be examined during the phase of application. The Company-Member (to which the data belongs) will be responsible to obtain the consent of the Recipient of the transfer of value and proceed with the relevant disclosure to the Personal Data Protection Authority.

Research and Development

In order to verify if an activity falls into the scope of Research and Development, first it must be examined if the said activity meets the definition of Research and Development, which is quoted below:

- If **yes**, then disclosure must be collectively made at the platform, in accordance with article 3.02.
- If **not**, then the Company-Member must proceed with the declaration, as applicable, on an individual basis/platform, according to the provisions of article 3.01.

The Disclosure Code defines as "**Fees for Research and Development**" the fees paid to HCPs or HCOs associated with the design and conduct:

i. **Non-clinical trials** (as set out in the *Principles of Good Laboratory Practice of OECD*)
ii. **Clinical trials** (as set out in the Directive 2001/20/EC) or
iii. **Non-interventional trials** with a perspective character that concern the collection of data that relates to patients, from individuals, groups or Healthcare Professionals or on behalf thereof, especially in relation to the study (*articles 25 and 26 of Chapter A of the Code*).

Definitions included in the relevant legal and regulatory provisions

i. Non-clinical trials as set out in the Principles of Good Laboratory Practice of OECD

The Principles of Good Laboratory Practice of the OECD (last revision: 1997) define the non-clinical trials as follows (Section I – 2. Definitions, article 2.3.1):

Non-clinical health and environmental safety study, henceforth referred to simply as "study", means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities.

For the full text, please visit www.oecd.org

ii. Interventional trials (as defined in the Directive 2001/20/EC)

The Directive 2001/20/EC of the European Union (article 2 par. a) defines the clinical trials as follows:

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy.

iii. Non- interventional trials

The Directive 2001/20/EC of the European Union (article 2 par. c) defines the non-interventional trials as follows:

A study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include

the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data.

Non-interventional trials are subject to the provisions of article 26 of Chapter A of the Code.

FREQUENTLY ASKED QUESTIONS

INTRODUCTION – VALIDITY OF THE CODE

1. ***Question:*** **What efforts have been made so as to ensure that transparency is achieved without sacrificing the legal interests of protecting the private life of healthcare Professionals?**

Answer: During the incorporation of the Disclosure Code of SFEE for the Healthcare Professionals or the Healthcare Organizations, the legal department of SFEE took into account all applicable laws and regulations and obtained the positive consent of the Personal Data Protection Authority.

In the imminent future SFEE will inform and commence a dialogue with scientific and medical associations at a national level, for the purposes of ensuring that the provisions of the **Code of Disclosure of Interactions between Pharmaceutical Companies & Healthcare Professionals** are fully understood.

2. *Question:* From the moment SFEE has incorporated the **Code of Disclosure of Interactions between Pharmaceutical Companies & Healthcare Professionals / Healthcare Organizations in the Code of Ethics thereof, should the Companies-Members observe the Disclosure Code in every country they operate, even if another country in which they are active, has not incorporated the said Code?**

Answer: All members of EFPIA (Associations & Pharmaceutical companies) are obliged to adopt the Rules of EFPIA in full and comply with the said regulations. EFPIA is entitled to disqualify any member – Company or Association –provided that it does not perform the above obligations.

When a Company-Member of SFEE is active in a country where the respective Association-Member has transposed the Code of EFPIA in its national Code within the deadline provided for, but with a deviation with which EFPIA agreed, the said Company-Member is obliged to comply with the Code of the Association-Member.

When a Company-Member is active in a country where the respective Association-Member has transposed the Code of EFPIA in its national Code within the deadline provided for, the said Company-Member is obliged to comply with the Code of EFPIA directly in the said country – i.e. in this case, the Code of EFPIA will have a "straight application" in the said country.

If a Company-Member of SFEE is not a member of EFPIA, then it agrees, as a consequence of it being a member of SFEE, to be bound by the Code, either it is active in and/or outside Greece.

ARTICLE

3. *Question (article 1.01)*: What is the procedure followed by the Companies-Members? What must a Company-Member do if it does not obtain the consent of the Healthcare Professional or the healthcare Organization, for the disclosure on an individual basis?

Answer: Companies-Members must put all possible efforts in order to timely obtain the necessary consents for the disclosure of transfers of value at an individual level. It is particularly recommended to the Companies-Members to see to that the clear commitments they undertake, are clearly described in a written agreement which is/will be executed with the Healthcare Professional/Healthcare Organization.

When the Companies-Members grant a transfer of Value to the HCPs/HCOs, also in their written agreements with the HCPs/HCOs, Companies-Members are encouraged to include a

consent clause of the Recipient for the disclosure of Transfers of Value in accordance with the provisions of the Code. Moreover, Companies-Members are encouraged to renegotiate the existing agreements as soon as possible, so as to include the above consent in the disclosure.

The consent must be depicted at the text of the agreement with the HCPs/HCOs. A suggested consent text is the following:

"*The undersigned Healthcare Professional …… hereby grant my consent so that the pharmaceutical company …… will disclose the fee I will receive for the service I will provide under this agreement, which is related with ……., in performance of Chapter B of the Code of Ethics of SFEE for the disclosure of transfers of value by pharmaceutical companies to Healthcare Professionals*".

Companies-Members, as the entities in charge for the data processing, are urged to proceed with the relevant notifications and obtain the relevant approval from the competent Personal Data Protection Authority and to create and keep evidence that prove that the consent has been requested/granted. In case of report/complaint, the Company-Member must be able to prove that its disclosures were accurate at the time they were effected and must be able to respond to the requests of the Recipient or of the competent authorities.

In case the Recipient refuses from the start the disclosure of the transfer of value, then the pharmaceutical company cannot enter into an agreement therewith.

If at a later stage the Recipient revokes its consent, then this cannot have a retrospective effect. If in this case, in the context of the performance of the relevant agreement, services are pending to be offered and respective transfers of value remain to be paid, then the respective amounts will be disclosed in the aggregate from the date the consent was revoked and thereafter. The Companies-Members must evaluate the impact of the revocation for each case separately and they are encouraged to seek independent legal advice. The Companies-Members are invited to take into account the revocation of the consent at a later stage for their future co-operations with the HCPs and the HCOs.

4. *Question (article 1.01):* The disclosure obligation concerns the net value of the transfer of value which is paid by the Companies-Members to HCPs/HCOs or should upon the disclosure the amount paid by the Companies-Members be depicted?

Answer: the disclosure obligation concerns the net value of the transfers of value realized by the Companies-Members to HCPs/HCOs and not the gross amount. This practically means that for each HCPs/HCOs the amount by which it is actually benefited will be disclosed, while any other amounts (taxes, withholdings of ELKE/ELKEA, other legal charges) will be separately disclosed. Based on the same rationale, the contributions for the TSAY paid by the Companies-Members in favour of the HCPs who are contracted for the provision of consultancy services will be separately disclosed and shall not appear in the amount corresponding to the transfer of value to the HCP. The above withholdings, legal charges etc. Will be disclosed in the aggregate.

5. Question *(article 1.01):* What is the date taken into account for the disclosure of the transfer of value?

Answer: In order to determine the date of the transfer of value to be disclosed, the date of the legal voucher that was issued (receipt/invoice) will be taken into account and not the date the agreement was concluded.

6. *Question (article 1.02):* In case the companies have various departments covering non-medical products, diagnostic products and other fields of the health sector, what should they disclose, in accordance with the Code? What exactly are the requirements of the disclosure obligation?

The Code aims at disclosing transfers of value to HCPs or HCOs that concern both the prescribed and the non-prescribed medicinal products (OTC).

The following areas do not fall into the scope of application of the Code:

- those not set out in article 3 of Chapter B of the Code of Ethics (e.g. meals and drinks, medical samples, the items of insignificant value set out in article 14 of Chapter A of the Code). On the contrary, the training material with a cost of up to euro 100 (including the VAT) to the HCPs and above Euro 100 (including VAT) to the HCOs is subject to the disclosure obligation.
- they constitute part of the usual purchases and sales of pharmaceutical products.

In addition, transfers of value that are related with prescribed or OTC medicinal products (e.g. combined products/ diagnostic and medicinal products) must be disclosed in full, in accordance with the disclosure requirements of the Code.

7. ***Question (articles 2.04 and 2.05):* What legal entities are liable for disclosure? Do the disclosures by the parent company suffice or is it necessary for the local subsidiaries to proceed with their own disclosures? Can the subsidiaries of the same company in a country disclose a portion of the Transfer of Value?**

Answer: Each Company-Member is obliged to disclose the transfers of value to HCPs and HCOs with registered office or who reside in Greece, at the public electronic platform of SFEE. In addition, each Company-Member may post this information at its own corporate public platform. Nevertheless, the relevant disclosures must be accessible to the public.

If a pharmaceutical company does not have its registered office nor does it have a subsidiary or it is not a n affiliate in Greece and effects a transfer of value to HCPs or HCOs who resides or has its place of business/registered office in Greece, then the pharmaceutical company must disclose the transfer of value in a manner that complies with SFEE's Code.

When a Company-Member of SFEE represents in Greece more foreign pharmaceutical companies, then it must be made clear what company do the transfers of value disclosed, concern.

8. *Question (Application, par. 2 and par. 6):* How must Companies-Members that conclude an agreement for joint promotion disclose any transfers of Value which are effected based on the agreement? Should the disclosure be effected based on the percentile cost allocation, as such allocation is provided for in the relevant agreement?

Answer: Each Company-Member which concludes an agreement for joint promotion will disclose the Transfers of Value it effects. The main principle is that the Company-Member concluding the agreement and remunerates the HCPs/HCOs – thus in practice, it is related to the HCPs/HCOs – is responsible for disclosing any Transfer of Value related to the agreement.

9. *Question (article 2.05):* When an advisor is employed in another country, should the disclosure be made?

Answer: Transfers of value to an HCP/HCO who resides or has its place of business/registered office in Europe, must be disclosed in the country of residence/ place of business of the Recipient, in accordance with the national code of the relevant country.

The Code requires transparency as to the transfers of value based on the country of residence/ place of business of the HCPs/registered office of the HCOs, so that the patient or any other parties involved may easily seek and find this information. The address of the residence/place of business of the HCP/ registered office of the HCO must serve as the criterion for the specification of the disclosure country.

Examples:

- A Company-Member of SFEE realizes a transfer of value to a Healthcare Professional who resides in Sweden for an activity in Germany. It must therefore disclose the transfer of value to Sweden (according to the applicable laws and regulations and the national code of Sweden).
- A Company-Member of SFEE realizes a transfer of value to a Healthcare Professional who resides in Italy in order to serve as an expert in a hospital in Tunisia. It must therefore disclose the transfer of value in Italy (in performance of the Italian laws and regulations of the national codes in Italy).
- A Company-Member of SFEE realizes a transfer of value to an American expert for consultancy services that will be rendered in Argentina. It is not obliged to disclose the transfer of value based on SFEE's Code. However, a disclosure may be required in other countries such as the U.S., based on the Sunshine Act.

10. *Question (article 2.05):* A parent American company-member of EFPIA with a subsidiary active in Greece realizes a transfer of value to a (Greek) Healthcare Professional. Must this transfer of value be disclosed in accordance with SFEE's Code by the subsidiary – and not by the parent company? What company will sustain any sanctions?

Answer: Dislcosures are realized in accordance with the national code of the country where the Recipient has its place of business/resides. Consequently, the said transfer of value must be affected at SFEE's platform by the subsidiary in consultation with the parent company. The public must be able to easily find and have access to the amount of the transfer of value disclosed and the legal entity who realised the transfer of value.

In case the Company-Member of SFEE breaches the above obligation, SFEE will impose sanctions to its Company-Member, since it falls under its jurisdiction.

11. *Question (article 3.01):* What does the phrase "sufficiently identified recipient" means?

Answer: The Companies-Members must ensure that each Recipient is identified in such manner so that no doubts will rise as to the identity of the Healthcare Professional / Healthcare Organization receiving the transfer of value. The necessary data that identify the Recipient is: the name and surname/corporate name and the TAX/ VAT Registration Number.

12. *Question (article 3.01):* How should the "relevant expenses" that have been agreed in the context of the transfer of value for consultancy services be dealt with?

Answer: The "relevant expenses" agreed upon in the context of a transfer of value for consultancy services must at first, be disclosed in the respective category of the disclosure template – i.e. the amount of the fee will be depicted separately from the relevant expenses agreed upon in the context of the fee for the provision of services.

When an agreement for the provision of consultancy services has been executed, the relevant expenses include for example, the transportation and stay cost which is related to the provision of consultancy services and consequently, does not form part of the fee paid. When these expenses are unsubstantial (e.g. of no significant value), the Companies-Members may not separate them in terms of reporting, from the fees paid. If the analysis of the costs, according to the accounting entries of the companies is not expedient or easily accomplished, the Companies-Members must explain the manner in which they deal with the case.

13. *Question (article 3.01):* If the transfer of value concerns conferences organized by third parties (e.g. PCO) at the instructions of the HCOs, should the relevant expenses be disclosed as "Contribution to the cost of events" or as "Fee for consultancy and other services"?

Answer: In this example, services are rendered by the Healthcare Professionals / Healthcare Organizations. Consequently, they must be disclosed at the category "**Contribution to the cost of events".**

14. *Question (article 3.01):* How should the lease of stands or projection areas in events be disclosed?

Answer: The lease of stands or projection areas in events is primarily deemed as a "Contribution to the cost of events" "Sponsorship agreement with HCOs /Third parties who organize the event under the instruction of the HCOs".

When third parties are in charge for organizing the event, the sponsorship could be deemed as indirect transfer of value. Disclosure must be made in the country where the HCO has its registered office.

The Companies-Members are instructed to include in their "Sponsorships Agreement" a consent clause for the disclosure.

15. *Question (article 3.01 (b) (i)):* What kind of transfers of value to Healthcare Organizations must be disclosed in the category "Cost of Group Entries of HCOs"?

Answer: The total amount of the expenses paid in a calendar year to a HCO and concern group entries, when the HCO is not selected by the pharmaceutical company but by the conference organizer.

16. ***Question (article 3.01 (2) (a) (i)):*** **What kind of transfers of value to Healthcare Professionals must be disclosed at the category "Entry Cost"?**

Answer: The total amount that has been paid in a calendar year to an HCP, who is a clearly identified Recipient, which must be disclosed on an individual basis in the category "Contribution to the cost of events".

17. ***Question (article 3.01 (1) (b) (ii)):*** **What details must be disclosed in the category "Sponsorship Cost" with Healthcare Organizations or third parties to whom a Healthcare Organization assigns the responsibility to organize an event?**

Answer: The "Sponsorship Cost" is included in the agreement, which describes the object of the sponsorship and the relevant transfers of value.

Examples of activities that must at least be covered under the title "Sponsorship Cost":

- Lease of stands or projection areas in events
- Advertisements (in printed, electronic or other form)
- Satellite symposiums/lectures in a conference
- Sponsorship to speakers
- Beverage or meals granted by the organizing entities (they are included in the sponsorship package of the event)
- Seminars granted by an HCO (where the Company-Member selects the HCPs who will participate).

18. ***Question (article 3.01 (1) (c) and (2) (b)):*** **What details must be declared in the category "Fees for consultancy and other services" to a Healthcare Professional/Healthcare Organization?**

Answer: To begin with, the Companies-Members will enclose this co-operation with the agreement form describing the object of the transfer of value.

Examples of transfers of value that could be covered by the category "Fees for consultancy and other services":

- Fees of speakers
- Seminars of speakers
- Medical trials preparation
- Data analysis
- Development of training material
- General consultancy services /provision of advice.

The amount paid to the person rendering the services – who may be a Healthcare Professional or a Healthcare Organization – will be disclosed as a transfer of value thereto.

19. ***Question (article 2.04):*** **Must the Procedures Manual be disclosed at the central disclosure platform of SFEE and of the Companies-Members (those who chose to disclose at individual platforms also) obligatorily or des its disclosure only at the central platform of SFEE suffice?**

Answer: It would be wise that the Procedures Manual would be accessible together with the data it aims at clarifying and consequently be disclosed at both platforms (individual and central).

20. *Question (article 3.01, 2, ii):* What should be disclosed under the title "Expenses for transportation and stay"?

Answer: This category should include all expenses that relate to transportation and stay, such as airplane tickets, railway tickets, lease of vehicles, tolls, parking cost, taxi and expenses for hotel accommodation.

The Code does not necessitate the allocation of the Transfers of value to the members of a group of Healthcare Professionals. For example, when group transportation is scheduled (e.g. with a bus/coach) for an event, the cost may be disclosed on an aggregate basis and needs no allocation/allotted to each separate Healthcare Professional who benefited from the said transportation and stay.

For the avoidance of any doubt, "meals and beverage" need no disclosure based on the Code.

> *When the monetary value of "meals and beverage" does not exceed the applicable limit, then no disclosure is required.*

21. *Question (article 3.01):* The identity of the participants in market research studies is usually not revealed and the studies are conducted via market research companies. However, the Companies-Members usually know the number of the Healthcare Professionals participating and the fees they receive. In this case, should the Companies-Members disclose the relevant Transfers of value on a aggregate basis?

Answer: The Code does not require the disclosure of the Transfers of value made to market research companies, if the identity of the HCPs/HCOs who participates in the market research study is not revealed.

To begin with, one of the main principles of the market research is the right of the participants to preserve their anonymity, which is established in the definitions of the market research and the relevant codes of ethics at a worldwide level. However, when the Company-Member is aware of the identity of the HCP/HCO participating in activities, which are defined as market research, the Company-Member must disclose the relevant transfers of value in the category "Fee for consultancy and other services". In such exceptional cases, it is expected that the Company-Member will ensure via the execution of the relevant agreement, the consent for the disclosure.

22. *Question:* Should a Company-Member disclose expenditures that relate to independent training seminars for treatments for half a day or general scientific meetings – where the Company-Member covers the cost for the premises, a meal and fees of the movers? If yes, in which category should these costs be disclosed?

Answer: The independent scientific events fall into the scope of application of the Code. Transfers of value that relate to these events will be disclosed in the respective categories (as the case may be: "Events", "Fee for consultancy and other services", "Fees for Research and Development").

Companies-Members are not obliged to disclose any expenses for material and technical infrastructure, e.g. lease of premises of an individual event.

***23. Question (article 3.02):* What transfers of value are subjected to this article?**

Answer: The aggregate disclosure includes:

A) Transfers of value that relate to the planning and conduct:

(i) of non-clinical trials (as defined in the OECD Principles of Good Laboratory Practice)

(ii) clinical trials (Phase I,II, III & IV, as defined in the Directive 2001/20/EE) and

(iii) non-interventional trials with a perspective nature that concern the collection of patients data by or on behalf of a group of Healthcare Professionals specifically for the trial.

B) the following events which are associated with Research and Development activities:

- Investigator meetings,
- advisory boards for clinical trial,
- steering committee meetings, consultancy meetings for clinical aggregate (e.g. biostatistics, epidemiologic etc.),
- Technical training for clinical research (e.g. laboratory procedures, training for equipment or systems etc.)