CHAPTER B

DISCLOSURE OF TRANSFERS OF VALUE BY PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

A. INTRODUCTION

A.1. Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs) with whom pharmaceutical companies work, provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and scientific experience. This expertise makes an important contribution to the industry's efforts to improve the quality of patient care, with benefits for individuals and society at large. Healthcare Professionals and Healthcare Organisations should be fairly compensated for the legitimate expertise and services they provide to the industry.

A.2. Medicinal products developed by the industry are complex products designed to address the needs of patients. In parallel, the pharmaceutical industry supports the education of HCP about medicines and the diseases they treat, to the benefit of patients. The pharmaceutical industry sponsors high-calibre scientific events for the education of HCPs and the exchange of knowledge among HCPs and e industry..

A.3. SFEE believes that interactions between the pharmaceutical industry and HCPs have a profound and positive influence on the quality of patient treatment and the value of future research. At the same time, the integrity of the decision of a HCP to prescribe a medicine is one of the pillars of the healthcare system. SFEE recognises that interactions between the industry and HCPs can create the potential for conflicts of interest. Consequently, SFEE adopted the present Chapter of the Code of Ethics and other guidelines (reflected in the relevant Q&As) to ensure that these interactions meet the high integrity standards that patients, the state and other stakeholders expect.

A.4. In the context of the European Commission initiative on Ethics and Transparency in the pharmaceutical sector, the industry's self-regulation must respond to the growing need of society for more integrity and transparency, in order to continue to be effective.

A.5. This Chapter of the Code in compliance with the current legislation in force, requires the detailed disclosure of the nature and size of any transfer of value to HCPs and HCOs. In this manner, SFEE aims to ensure transparency and build confidence in the relationships of its member pharmaceutical companies with HCPs and HCOs.

A.6. This Chapter of the Code shall take effect from 1 January 2016, starting with the disclosure of transfers of value made during the calendar year 2015.

B. SCOPE OF THE CODE

B.1. The present Chapter of the Code governs the disclosure of transfers of value effected by pharmaceutical companies (whether resident in Greece or abroad) to HCPs and HCOs resident in Greece. The present Chapter applies in parallel with Chapter A of the Code and the "SFEE Code of Ethics for the Relationships between Pharmaceutical Companies and Patient Associations".

B.2. Consequently, it applies to all SFEE member companies. Pharmaceutical companies which are not members of SFEE may voluntarily adhere to this Chapter of the Code, if they so wish, by submitting a declaration to this effect to the President of SFEE. Such companies will be set out in a separate list, which shall be updated regularly and shall constitute part of the Code. All the provisions of this present Chapter of the Code shall fully apply to the said companies.

B.3. The definitions at the end of this Chapter constitute an integral part of the Code.

C. Definitions used in Chapter B regarding the Disclosure of Transfers of Value by Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations

C.1. Donations and Grants

Collectively, means donations under the meaning of article 16 Chapter A of this present Code, and grants (either cash or benefits in kind) for the promotion of prescription and non-prescription medicinal products.

C.2. Events

All promotional, scientific or professional meetings, congresses, conferences, board meetings, symposia and other similar events that are not associated with Research & Development (including, but not limited to type A, B, C & D events in accordance with EOF Circulars, as applicable from time to time, on scientific events) organised or sponsored by or on behalf of a company (Articles 17, 18 and 19, Chapter A of this Code).

C.3. Healthcare Professionals (HCPs)

Any natural person that is a member of the medical, dental, pharmacy or nursing profession or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Greece. For the avoidance of doubt, the term "Healthcare Professional" includes: (i) any official or employee of a government agency or other organisation (whether in the public or in the private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a SFEE Member Company whose primary occupation is that of a practising HCP. This latter category excludes: (a) all private physicians having a lasting collaboration with a SFEE member company SFEE under an employment contract, an agency contract agreement or contract

for work; and (b) all wholesalers or distributors of medicinal products.

C.4. Healthcare Organisations (HCOs)

Any legal person:

(i) that is a healthcare, medical or scientific association (scientific society or an association of HCPs) or healthcare organisation (irrespective of the legal or organisational form), such as a hospital, clinic, foundation, university or other educational institution or learned society of any type (e.g. NGOs) sponsored by pharmaceutical companies (except for patient associations within the scope of the SFEE Code of Ethics on the Relationships between Pharmaceutical Companies and Patient Associations), which has registered office or is active in Greece; or

(ii) through which one or more HCPs provide healthcare services, including private Primary Healthcare Providers (Presidential Decree 84/2001, Gov. Gazette 70/A/10.4.2001).

C.5. Medicinal Products

Medicinal products as used in this Code are those products specified in Article 2 of Ministerial Decision ΔΥΓ3α/ΓΠ32221/29.4.2013 (Gov. Gazette 1049/B/2013) as currently in force, including immunological medicinal products, radiopharmaceuticals and medicinal products derived from human blood or plasma, for which a marketing authorisation has been granted pursuant to Directive 2001/83/EC, as currently in force.

C.6. Recipient

Any HCP or HCO whose primary practice, principal professional address or registered office is in Greece.

C.7. Service and Consultancy

Education/Training (in-house for company employees or externally to other HCPs), advisory boards Committees (advisory boards or pharmaco-economics expert panels), speeches/lectures, general consultancy (i.e. regarding medical information brochures, preparation of programmes for informing HCPs and/or the public on diseases).

The above term indicatively includes: education, article authoring, translation.

C.8. Research and Development transfers of value

Transfers of value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (*as defined in the OECD Principles on Good Laboratory Practice*); (ii) clinical trials (phase I, II, III & IV, as defined in Directive 2001/20/EC); and (iii) prospective non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study (Articles 25 and 26, Chapter A of this Code).

C.9. Transfer of value

Any transfer of objects and rights, either in the form of fee for service or in the form of a grant for an educational/training activity. The definition includes all direct or indirect transfers of value, whether in cash, in kind or otherwise, made for promotional or other purposes, in connection with the development and sale of generic or branded medicinal products, intended exclusively for human use. **Direct** transfers of value are those made directly by a Member Company for the benefit of a Recipient. **Indirect** transfers of value are those made on behalf of a Member-Company for the benefit of a Recipient, where the Member-Company is known or can be identified by the Recipient.

Article 1.
DISCLOSURE OBLIGATION

1.1. *General Disclosure Obligation.* Subject to the terms of the present Code, each Member Company shall document and disclose on their website and on the EOF website platform, within six months' by the end of each calendar year at the latest, individually by name all Transfers of Value it makes, directly or indirectly, to or for the benefit of a Recipient, as described in more detail in Article 3. The supervision of the above obligation falls within the competence of EOF.

1.2. *Exclusion from the Disclosure Obligation*. Excluded from the scope of the disclosure obligation described in Section 1.1. of this Code are transfers of value that:

i. are solely related to over-the-counter medicines;

ii. are not listed in Article 3 of this Code, such as meals and drinks (see Article 19, Chapter A of the Code), medical samples (see Article 13, Chapter A of the Code) and medical utility items of insignificant value set out in Article 14, Chapter A of the Code; and

iii. are part of ordinary course purchases and sales by and between pharmaceutical companies and HCPs engaging in the business of medicine trading (such as pharmacists, wholesalers) and/or HCOs, i.e. financial transactions within the distribution chain of medicinal products.

Article 2.
FORM OF DISCLOSURE

2.1. *Annual Disclosure Cycle.* Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year (the "**Reporting Period**"). The first Reporting Period shall be the calendar year 2015 and the first disclosure shall take place in 2016.

2.2. *Time of Disclosure.* Disclosures shall be made by each Member Company within 6 months after the end of the relevant Reporting Period and the information disclosed shall remain available in the public domain for a minimum of 3 years, unless the Law or the Hellenic Data Protection Authority defines a shorter or longer period after the time such information is first disclosed in accordance with Section 2.4.

2.3. *Disclosure Template.* Subject to Section 2.4, disclosures shall be made using a standardised template which is consistent with the provisions of the present Chapter of the Code.

2.4. *Platform of Disclosure.* Disclosures shall be made on EOF and each member company's website by every Member-Company in accordance with Section 2.5. and

shall be unrestricted and publicly available. Disclosure of all data shall be effected on 1 July of each year or on the first business day following that date, on EOF's and each member company's website platform.

2.5. *Applicable National Code*. Disclosures for all HCPs and HCOs resident in Greece shall be made pursuant to the present Code. If a pharmaceutical company is not resident or does not have a subsidiary or an affiliate in Greece, it shall disclose such transfers of value to HCPs or HCOs resident in Greece in a manner consistent with the current Greek legislation in force and this present Chapter of the Code.

2.6. *Language of Disclosure.* Disclosures shall mandatorily be made in the Greek language.

2.7. *Documentation and Retention of Records*. Each Member Company shall document all Transfers of Value required to be disclosed pursuant to Section 1.1. and maintain the relevant records of the disclosures made under this Code for a minimum of 5 years after the end of the relevant Reporting Period.

Article 3. INDIVIDUAL AND AGGREGATE DISCLOSURE

3.1. ***Individual Disclosure***. Except as expressly provided by this Chapter of the Code, transfers of value shall be disclosed on an individual basis. Each Member Company shall disclose, on an individual basis for each clearly identifiable recipient (name, surname, and speciality), the amounts of transfers of value to such recipient in each Reporting Period which may be reasonably allocated to one of the following categories.

3.1.1. *Transfers of value to HCOs related to:*

a. Donations and grants: Any kind of donation or grant (either cash or benefits in kind) governed by with Article 16, Chapter A of the Code.

b. Sponsorship of Events: Sponsorships of events organised by HCOs or PCOs such as:

i. Group registration fees for HCPs (when participating HCPs are not selected by the sponsor, but by the organising entity); ii. Amount of sponsorship, as specified in agreements with HCOs or third parties appointed by an HCO to manage an event, provided that the sponsorship is not intended for a specific HCP.

Note: Any costs related to the participation of a HCP in a conference in a special capacity (speaker, moderator, etc.) referred to in the sponsorship agreement between the company and the organising entity of the event, shall be published on an individual basis by the sponsor company (after the signing of the relevant agreement), taking into account the relevant restrictions.

c. Fees for service and consultancy. Fees resulting from or related to contracts between Member Companies and HCOs, under which HCOs provide any type of services to a Member Company or any other type of funding not covered in other categories (e.g. fee for service and consultancy which is payable directly to a HCP). Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

3.1.2. *Transfers of value to HCPs related to:*

a. Events, such as:

i. Registration fee

ii. Travel and accommodation expenses (*to the extent permitted by Article 19, Chapter A of the Code*).

b. Fees for Service and Consultancy. Fees resulting from or related to contracts between Member Companies and HCPs, under which HCPs provide any type of services to a Member Company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

3.2. ***Aggregate Disclosure. Payments related to Research and Development activities***. / ***Payments related to HCP refusing consent***. Transfers of value concerning Research and Development activities for each Reference Period shall be disclosed by each Member Company on an aggregated basis. Costs related to events that are auxiliary to activities falling within the scope of this section (e.g. investigator meetings) shall be disclosed on an aggregate basis.

3.3. ***Non Duplication***. Where a transfer of value required to be disclosed pursuant to Section 3.1. or 3.2. is made to an individual HCP indirectly via an HCO, such transfer of value shall only be disclosed once. Such disclosure shall be made on an individual basis, indicating the name of the HCO in accordance with Section 3.01(2).

3.4. ***Methodology***. Each Member Company shall publish a note summarising the methodology applied for the disclosure and identification of transfers of value for each category described in Section 3.1. The note, which shall include a general summary, shall describe the methodology applied and include the handling approach of multi-year contracts, VAT and other tax issues, currency issues and other issues related to the timing and amount of Transfers of Value for the purposes of the present Chapter of the Code.

Article 4. ENFORCEMENT

4.1. *Applicability and Sanctions.* The provisions of the present Chapter of the Code are binding on Member Companies. Non-compliance with such provisions shall entail the imposition of sanctions provided for in Section 4.2. below. Chapter C of the present Code on the complaints procedure shall apply by analogy.

4.2. *Sanctions.*

a) The First-Instance Committee of Article 1, Chapter C (Compliance Monitoring Process) of the present Code, if, after examining an allegation/complaint received by it, rules that there is a violation of Articles 1, 2 and 3 of this Chapter B of the Code, may impose to the non-compliant SFEE member company a financial a penalty of up to EUR 25,000. Such penalty shall be enforced after the period for referring the case to the Second-Instance Com-

mittee has elapsed without effect or after the issuance of the decision of the Second Instance Committee, unless the respondent accepts the violation or part thereof. The amount of the penalty shall be deposited by the pharmaceutical company to a dedicated bank account held by SFEE.

b) The Second Instance Committee of Article 1, Chapter C of the present Code may impose to a SFEE member company that does not comply with the decision of the First Instance Committee a financial penalty of up to EUR 50,000, further to the sanctions mentioned above. These amounts shall be deposited by the pharmaceutical company to a dedicated bank account held by SFEE, not later than 30 business days of the date of issuance of the decision.

Any final decision imposing any of the sanctions in above shall be promptly publicized on SFEE's locked website for a three (3) month period.

In the event that the SFEE member company has not complied, or has not properly complied, with the sanction imposed on it by the Second Instance Committee, the Second Instance Committee shall meet upon request of the complainant and shall decide on further sanctions, which may amount up to three times the initially imposed sanction.

In the event that the SFEE member company still fails to comply with the decision of the Second Instance Committee, the latter shall refers the issue to the Disciplinary Board of SFEE, which may decide the expulsion of the member.