European Federation of Pharmaceutical Industries and Associations

EFPIA HCP/HCO DISCLOSURE CODE

EFPIA CODE ON DISCLOSURE OF TRANSFERS OF VALUE FROM PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

CONSOLIDATED VERSION 2014
Approved by the General Assembly of 6 June

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PREAMBLE

Healthcare professionals and healthcare organisations with whom they work provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and management 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.

Prescription medicines developed by the industry are complex products designed to address the needs of patients and educating healthcare professionals about medicines and the diseases they treat benefits patients. The pharmaceutical industry can provide a legitimate forum for the education of healthcare professionals and the exchange of knowledge among healthcare professionals and industry.

EFPIA believes that interactions between the pharmaceutical industry and healthcare professionals 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 healthcare professional to prescribe a medicine is one of the pillars of the healthcare system. EFPIA recognises that interactions between the industry and healthcare professionals can create the potential for conflicts of interest. Consequently, professional and industry associations, including EFPIA and its member associations, have adopted codes and guidelines to ensure that these interactions meet the high standards of integrity that patients, governments and other stakeholders expect.

In order to continue to be successful, self-regulation needs to respond to the evolving demands of the society. In particular, there is a growing expectation that interactions between corporations and society are not only conducted with integrity but are also transparent. Following the EU Commission initiative on Ethics & Transparency in the pharmaceutical sector, a multi-stakeholders' platform – including, among others, EFPIA – has adopted a "List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector" (the "**Guiding Principles**").

In line with these "Guiding Principles", EFPIA believes that it is critical to the future success of the pharmaceutical industry to respond to society's heightened expectations. EFPIA has therefore decided that its existing Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (the "**HCP Code**") and Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations (the "**PO Code**") should be supplemented by requirements for detailed disclosure regarding the nature and scale of the interactions between the industry and healthcare professionals and organisations. EFPIA hopes that, by taking this step, it can enable public scrutiny and understanding of these relationships and thus contribute to the confidence of stakeholders in the pharmaceutical industry.

EFPIA believes that the interest of patients and other stakeholders in the transparency of these interactions is compelling. EFPIA recognises that disclosure can raise data privacy concerns and seeks to work with healthcare professionals to ensure that these concerns are addressed. EFPIA nonetheless believes that transparency can be achieved without sacrificing the legitimate privacy interests of healthcare professionals and legislation should not therefore impose excessive restrictions on disclosure by the industry.

The following Code provides for disclosures of transfers of value to healthcare professionals, whether directly or indirectly. When deciding how a transfer of value should

be disclosed, companies should, wherever possible, identify and publish at the individual healthcare professional (rather than healthcare organisation) level, as long as this can be achieved with accuracy, consistency and compliance with applicable law.

The following code imposes obligations to disclose transfers of value to healthcare professionals and healthcare organisations commencing with reporting in 2016 in respect of transfers of value for the calendar year 2015. The provisions of this Code shall be implemented by EFPIA's member associations in a manner consistent with applicable competition and data protection laws and regulations and all other applicable legal requirements.

APPLICABILITY OF THIS CODE

This Code governs disclosures regarding certain interactions with HCPs and HCOs. It is intended that this Code shall apply to interactions with HCPs and HCOs to the same extent as the existing HCP Code and PO Code[1]. Therefore, this Code applies to Member Companies, including:

- Full members: research-based pharmaceutical companies, developing and manufacturing medicinal products in Europe for human use – *called corporate members*;
- Affiliate members: companies specialising in particular fields of pharmaceutical research and/or development or in new technologies of particular interest to the pharmaceutical industry – *called* "*affiliate corporate members*";
- Research-based pharmaceutical companies operating in a particular segment of the pharmaceutical market that join a *specialised group within EFPIA*: (i) European Bio-pharmaceutical Enterprises (EBE); and (ii) Vaccines Europe (VE).

Separate entities belonging to the same multinational company – which could be the parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation – shall be deemed to constitute a single company, and is as such committed to compliance with the EFPIA Codes.

"**Europe**", as used in this Code, refers to, collectively, those countries for which there is an EFPIA Member Association.[2]

This Code sets out the minimum standards which EFPIA considers must apply to all EFPIA Member Associations in all member states. All EFPIA Member Associations will be required to transpose this Code into their national codes in full, except where its provisions are in conflict with applicable national laws or regulations, in which case

[1] This Code is not intended to apply to Transfers of Value the disclosure of which is already provided for under, or that are otherwise regulated by, the PO Code.

[2] Those countries currently include the following 33 countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and the United Kingdom.

deviations are allowed, but only to the extent necessary to comply with such national law or regulation.

Where an EFPIA Member Association has determined that this Code cannot be implemented in full due to national law or regulation, such EFPIA Member Association will not be in breach of its obligations under this Code if the deviation from this Code is no broader than necessary to comply with such national law or regulation and if it clearly documents the legal issues limiting full implementation. It is understood that if there is an inconsistency between this Code and the applicable law or regulation to which a Member Company is subject which would make adherence to this Code not reasonably possible, the Member Company must comply with such law or regulation and such lack of adherence shall not constitute a breach of this Code.

Member Companies shall be bound by the relevant EFPIA Member Association's code in each country in Europe in which they operate (whether directly or through its relevant subsidiary). If an EFPIA Member Association where a Member Company operates fails to transpose this Code into its national code by the relevant deadline, such Member Company will be required to comply with this Code. If a Member Company is not a member of the EFPIA Member Association in any given country in Europe, it agrees, as a consequence of its membership in EFPIA (either directly or through its relevant subsidiary), to be bound by that EFPIA Member Association's code (including any applicable sanctions that may be imposed under such code).

Non-member associations and companies that decide to voluntarily implement this Code shall require that each of their respective members, affiliates and subsidiaries, as applicable, comply with all of the provisions of this Code.

ARTICLE 1
DISCLOSURE OBLIGATION

Section 1.01. *General Obligation.* Subject to the terms of this Code, each Member Company shall document and disclose Transfers of Value it makes, directly or indirectly, to or for the benefit of a Recipient, as described in more detail in Article 3.

Section 1.02. *Excluded Disclosures*. Without limitation, 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 items of medical utility *(governed by Article 9 of the EFPIA HCP Code),* meals and drinks *(governed by Article 10, especially Section 10.05 of the EFPIA HCP Code)*, medical samples *(governed by Article 16 of the HCP Code)*; or (iii) are part of ordinary course purchases and sales of Medicinal Products by and between a Member Company and an HCP (such as a pharmacist) or an HCO do not fall within the scope of the disclosure obligation described in Section 1.01.

Section 1.03. *Schedules.* Each of the attached Schedules forms part of this Code. Definitions of capitalised terms are included in Schedule 1 to ensure consistent understanding of such terms.

ARTICLE 2
FORM OF DISCLOSURE

Section 2.01. *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.

Section 2.02. *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 be required to remain in the public domain for a minimum of 3 years after the time such information is first disclosed in accordance with Section 2.04, unless, in each case, (i) a shorter period is required under applicable national data privacy or other laws or regulations, or (ii) the Recipient's consent relating to a specific disclosure, if required by applicable national law or regulation, has been revoked.

Section 2.03. *Template.* Subject to Section 2.04(ii), for consistency purposes, disclosures pursuant to this Code will be made using a structure set forth in Schedule 2 for reference, reflecting the requirements of this Code. Deviations from this Schedule should only be acceptable where legal requirements justify that this Code is not transposed in full – therefore, within a given country, only one template shall apply.

Section 2.04. *Platform of Disclosure.* Disclosures can be made in either of the following ways, provided that they are unrestricted and publicly available:

(i) on the relevant Member Company's website in accordance with Section 2.05; or

(ii) on a central platform, such as one provided by the relevant government, regulatory or professional authority or body or a Member Association, provided that disclosures made on a central platform developed at the initiative of Member Associations shall be made, so far as possible, using a structure set forth in Schedule 2 for reference.

Section 2.05. *Applicable National Code*. Disclosures shall be made pursuant to the national code of the country where the Recipient has its physical address. If a Member Company is not resident or does not have a subsidiary or an affiliate in the country where the Recipient has its physical address, the Member Company shall disclose such Transfer of Value in a manner consistent with the national code to which the Recipient is subject.

Section 2.06. *Language of Disclosure.* Disclosures shall be made in the language(s) prescribed in the national code by the relevant Member Association. Member Companies are encouraged to make disclosures in English in addition to the mandatory disclosures in the local language (if other than English).

Section 2.07. *Documentation and Retention of Records*. Each Member Company shall document all Transfers of Value required to be disclosed pursuant to Section 1.01 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, unless a shorter period is required under applicable national data privacy or other laws or regulations.

ARTICLE 3
INDIVIDUAL AND AGGREGATE DISCLOSURE

Section 3.01. *Individual Disclosure.* Except as expressly provided by this 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, the amounts attributable to Transfers of Value to such Recipient in each Reporting Period which can be reasonably allocated to one of the categories set out below. Such Transfers of Value may be aggregated on a category-by-category basis, provided that itemised disclosure shall be made available upon request to (i) the relevant Recipient, and/or (ii) the relevant authorities.

1. *For Transfers of Value to an HCO, an amount related to any of the categories set forth below*:

    a. Donations and Grants. Donations and Grants to HCOs that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organisations or associations that are comprised of HCPs and/or that provide healthcare (*governed by Article 11 of the HCP Code*).

    b. Contribution to costs related to Events. Contribution to costs related to Events, through HCOs or third parties, including sponsorship to HCPs to attend Events, such as:

        i. Registration fees;
        ii. Sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event; and
        iii. Travel and accommodation (*to the extent governed by Article 10 of the EFPIA HCP Code*).

    c. Fees for Service and Consultancy. Transfers of Value resulting from or related to contracts between Member Companies and institutions, organisations or associations of HCPs under which such institutions, organisations or associations 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.

2. *For Transfers of Value to an HCP*:

    a. Contribution to costs related to Events. Contribution to costs related to Events, such as:

        i. Registration fees; and
        ii. Travel and accommodation (*to the extent governed by Article 10 of the EFPIA HCP Code*).

    b. Fees for Service and Consultancy. Transfers of Value resulting from or related to contracts between Member Companies and HCPs under which such 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.

Section 3.02. *Aggregate Disclosure.* For Transfers of Value where certain information, which can be otherwise reasonably allocated to one of the categories set forth in Section 3.01, cannot be disclosed on an individual basis for legal reasons, a Member Company shall disclose the amounts attributable to such Transfers of Value in each Reporting Period on an aggregate basis. Such aggregate disclosure shall identify, for each category, (i) the number of Recipients covered by such disclosure, on an absolute basis and as a percentage of all Recipients, and (ii) the aggregate amount attributable to Transfers of Value to such Recipients.

Section 3.03. *Non Duplication.* Where a Transfer of Value required to be disclosed pursuant to Section 3.01 or 3.02 is made to an individual HCP indirectly via an HCO, such Transfer of Value shall only be required to be disclosed once. To the extent possible, such disclosure shall be made on an individual HCP named basis pursuant to Section 3.01(2).

Section 3.04. *Research and Development Transfers of Value.* Research and Development Transfers of Value in each Reporting Period shall be disclosed by each Member Company on an aggregate basis. Costs related to events that are clearly related to activities covered in this section can be included in the aggregate amount under the "Research and Development Transfers of Value" category.

Section 3.05. *Methodology.* Each Member Company shall publish a note summarising the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category described in Section 3.01. The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Transfers of Value for purposes of this Code, as applicable.

ARTICLE 4
ENFORCEMENT

Section 4.01. *Enforcement through Member Associations.* Each Member Association shall adopt Implementation and Procedure Rules (as set forth in more detail in Schedule 3), which will be binding upon its members, and set forth the framework for the implementation of this Code, the processing of complaints and the enforcement of sanctions in a manner consistent with applicable data protection, competition and other applicable laws and regulations.[3]

Section 4.02. *Transposition in Member Associations' Codes.* Each Member Association shall transpose the provisions of this Code into its national code by 31 December 2013. This Code sets out the minimum standards applicable to Member

[3] When making a Transfer of Value to a HCP/HCO, and in their written contracts with HCPs/HCOs, companies are encouraged to include provisions relating to the Recipients' consent to disclose Transfers of Value in accordance with the provisions of the EFPIA HCP/HCO Disclosure Code. In addition, companies are encouraged to renegotiate existing contracts at their earliest convenience to include such consent to disclosure.

Associations, except where it is in conflict with applicable national law or regulation, in which case deviations are allowed, but only to the extent necessary to comply with such national law or regulation. Any provisions contained in national codes that embody higher standards than those of this Code shall not be deemed to constitute deviations from this Code.

Section 4.03. *Disclosure Requirements Different from this Code.* Any proposal to transpose this Code into a national code, or to amend any provision transposing this Code, that requires disclosures different from those required under this Code, shall be clearly and conspicuously so identified in the relevant Member Association's consultative process and any materials relating to such proposal. In such case, the EFPIA General Assembly shall be asked to confirm consistency with this Code, following an EFPIA Board decision after consultation with the EFPIA Codes Committee. Member Companies abiding by such Member Associations' codes as confirmed by the EFPIA General Assembly shall not be considered to have failed to meet their obligations under this Code.

If the applicable national law or regulation, the relevant national code or other industry self-regulation prescribes equivalent or more stringent disclosure requirements, the relevant Member Company shall comply with such equivalent or more stringent requirements in a manner as consistent as possible with the substantive disclosure requirements of this Code.

Section 4.04. *Sanctions.* Each Member Association should include in its code provisions governing the imposition of sanctions for violations of its code. Sanctions should be proportionate to the nature of the infringement, have a deterrent effect and take account of repeated offences of a similar nature or patterns of different offences. A combination of publication and fines will generally be considered to be the most effective sanction; however, each Member Association may use any other appropriate sanction to enforce its code. Each Member Association should consider any applicable legal, regulatory or fiscal requirements which would affect the nature or extent of sanctions which may be imposed. Where publication or fines are not permitted due to applicable legal, regulatory or fiscal requirements, Member Associations should impose the best alternative effective sanction.

Section 4.05. *Reporting*. The EFPIA Codes Committee shall produce at least annually reports summarising:

(i) the transposition by Member Associations of this Code into their national codes (such report to be produced by 31 March 2014, which date is three months after the deadline for the transposition of this Code by Member Associations and prior to the 2014 General Assembly so as to allow sufficient time to remedy inadequate or incomplete transposition by any Member Association); and

(ii) once this Code has been transposed into national codes and disclosures are made for the first time in 2016 (no later than 30 June 2016), activities related to this Code (first such report to be produced in September 2016).

ARTICLE 5
AMENDMENTS TO, AND GUIDANCE REGARDING COMPLIANCE WITH, THE CODE

Section 5.01. *Code Compliance.* The EFPIA Codes Committee shall assist Member Associations to comply with their obligations under this Code. The key tasks of the Committee are set forth in Schedule 3 attached to this Code.

Section 5.02. *Amendments to the Code.* The EFPIA Codes Committee shall regularly review this Code and any guidance issued regarding compliance with this Code.

Any proposed amendments to the Code will be submitted for the EFPIA Board decision and the EFPIA General Assembly ratification. Proposed amendments to this Code shall be reviewed by the Codes Committee following consultation with the EFPIA membership and the relevant EFPIA committees.

Schedule 1

Definition of terms used in the EFPIA HCP/HCO Disclosure Code

Donations and Grants
Donations and Grants, collectively, means those donations and grants (either cash or benefits in kind) within the scope of Article 11 of the HCP Code.

Events
All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) (each, an "**Event**") organised or sponsored by or on behalf of a company. (*Article 10 of the HCP Code*).

HCO
Any legal person (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations within the scope of the EFPIA PO Code) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.

HCP
Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.

HCP Code
EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals, adopted by the EFPIA Board on 5 July 2007 and ratified by the EFPIA Statutory General Assembly on 19 June 2008, amended on 14 June 2011, and as further amended on 24 June 2013, and as may be amended, supplemented or modified from time to time.

Medicinal Products
Medicinal Products as used in the EFPIA HCP/HCO Disclosure Code has the meaning set forth in Article 1 of the Directive 2001/83/EC, including: medicinal products, immunological medicinal products, radiopharmaceuticals, medicinal products derived from human blood or human plasma, for which a marketing authorisation has been delivered in application of Directive 2001/83/EC.

Member Associations
Collectively, the national Member Associations or their constituent members, as the context may require, and bound by the EFPIA codes of practice, including the EFPIA HCP Code, the EFPIA PO Code and the EFPIA HCP/HCO Disclosure Code.

Member Companies
Collectively, “corporate members” (as defined in the HCP Code) of EFPIA, their respective parent companies, if different, subsidiary companies (irrespective of whether a subsidiary is a company or such other form of enterprise or organisation) and any companies affiliated with corporate members or their subsidiaries
Separate entities belonging to the same multinational company – which could be the parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation – shall be deemed to constitute a single company, and is as such committed to compliance with the EFPIA Codes.

PO Code
EFPIA Code of Practice on Relationships between Pharmaceutical Industry and Patient Organisations, adopted in 2007 and as amended by the General Assembly on 14 June 2011, and as may be amended, supplemented or modified from time to time.

Recipient
Any HCP or HCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Europe.

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 *OECD Principles on Good Laboratory Practice*); (ii) clinical trials (as defined in Directive 2001/20/EC); or (iii) 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 (*Section 15.01 of the HCP Code*).

Transfers of Value
Direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only Medicinal Products 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, or transfers of value made through an intermediate and where the Member Company knows or can identify the HCP/HCO that will benefit from the Transfer of Value.

Schedule 2

Standardised Template

Insert template as updated on 11 December 2013 v1

Schedule 3

IMPLEMENTATION AND PROCEDURE RULES

The Implementation and Procedure Rules set out below establish the framework for the implementation of the European Federation of Pharmaceutical Industries and Associations ("**EFPIA**") Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (the "**Code**"), the processing of complaints and the enforcement of sanctions ordered by Member Associations.

SECTION 1. Member Association Implementation

Each Member Association is required to:

a. establish national procedures to receive and process complaints, to determine sanctions to be ordered and to publish appropriate details regarding the same including, at a minimum, a national body of the Member Association that is designated to handle complaints and consists of a non-industry chairman and, besides any industry members, membership from other stakeholders;
b. ensure that its national code, together with its administrative procedures and other relevant information, are easily accessible through, at a minimum, publication of its national code on its website; and
c. prepare, and provide to the EFPIA Codes Committee an annual report summarizing the work undertaken by it in connection with the implementation, development and enforcement of its national code during the applicable year.

SECTION 2. EFPIA Codes Committee Implementation and Key Tasks

The EFPIA Codes Committee shall assist Member Associations to comply with their obligations under Section 1 above:

a. The EFPIA Codes Committee will be composed of all the national code secretaries, who will elect a chair among their peers, assisted by one person from the EFPIA staff.
b. As a key part of its role of assisting Member Associations in their national code compliance activities, the EFPIA Codes Committee shall monitor the adoption of national codes. The EFPIA Codes Committee will not participate in the adjudication of any individual complaint under any national code.
c. In order to promote the Code and to encourage best practice among Member Associations, the EFPIA Codes Committee will, at least annually, invite Member Associations and company representatives to participate in a meeting at which the participants will be encouraged to share their respective relevant experiences relating to the Code. Any conclusions from the meeting shall be summarised in the Annual Codes Report (referred to under (e) of this Section 2 below) and, if appropriate, be presented to the EFPIA Board.
d. The EFPIA Codes Committee shall publish an Annual Code Report which will summarise the work and operations which have taken place in connection with the implementation, development and enforcement of the various national codes during the applicable year, based on the country reports provided by the Member Associations pursuant to Section 1(c) above.
e. On an annual basis, the EFPIA Codes Committee shall: (i) advise the EFPIA Board of its work and operations and the work and operations of the Member Associations, as summarised in the Member Association's annual reports; and (ii) review with the EFPIA Board any additional recommendations to improve the

Code with a view towards increasing transparency and openness within the pharmaceutical industry and among Member Associations and companies.

SECTION 3. Reception of Complaints

Complaints may be lodged either with a Member Association or with EFPIA. Adjudication of complaints shall be a matter solely for the Member Associations.

Complaints received by EFPIA shall be processed as follows:

a. EFPIA will forward any complaints it receives (without considering their admissibility or commenting upon them) to the relevant Member Association(s).
b. EFPIA will send an acknowledgement of receipt to the complainant, indicating the relevant Member Association(s) to which the complaint has been sent for processing and adjudication.
c. In addition, upon receipt by EFPIA of multiple external complaints (i.e. several complaints on the same or similar matter(s) lodged from outside the industry against several subsidiaries of any company), EFPIA will communicate these complaints to the Member Association either of the parent company or of the European subsidiary designated by the parent company.

SECTION 4. Processing of Complaints and Sanctions by Member Associations

a. Member Associations shall ensure that industry and non-industry complaints are processed in the same manner, without regard to who made the complaint.
b. Complaints will be processed at the national level using the procedures established by the relevant Member Association(s) pursuant to Section 1(a) above. Each Member Association's national body shall take decisions and order any sanctions on the basis of the national code in force in its country.
c. Where a complaint fails to establish a prima facie case for a violation of the applicable national code, such complaint shall be dismissed with respect to that national code. Member Associations may also provide that any complaint which pursues an entirely or predominantly commercial interest shall be dismissed.
d. Each Member Association should establish effective procedures for appeals against the initial decisions made by its national body at the national level.
e. Member Associations shall ensure, to the extent permissible, that any final decision taken in an individual case shall be published in its entirety or, where only selected details are published, including a level of detail that takes into account the seriousness and/or persistence of the breach as follows:
    (i) in cases of a serious/repeated breach, the company name(s) should be published together with details of the case;
    (ii) in cases of a minor breach, or where there is no breach, publication of the details of the case may exclude the company name(s).
f. Member Associations or national disciplinary bodies are encouraged to publish summaries in English of cases that have precedential value and are of international interest (keeping in mind that cases resulting in the finding of a breach as well as those where no breach is found to have occurred may each have such value and/or interest).

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.)