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

**Approved by the AIFP General Meeting on 21 November 2013, last revision on 23rd May 2014**

## PREAMBLE

Healthcare professionals and healthcare organisations 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. 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.

The European Federation of Pharmaceutical Industries and Associations (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 members (including AIFP), 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*".

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 AIFP in a manner consistent with applicable competition and data protection laws and regulations and all other applicable legal requirements of the Czech Republic.

## 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, meals and drinks, samples; 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.

## 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 data privacy or other laws or regulations, or (ii) the Recipient's consent relating to a specific disclosure, if required by applicable 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 the structure set forth in Schedule 2, reflecting the requirements of this Code.

Section 2.04. *Platform of Disclosure.* Disclosures shall be made on the central platform provided by AIFP.

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 a

competent 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 this code.

Section 2.06. *Language of Disclosure.* Disclosures shall be made in Czech and 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, that is in line with timelines for maintaining of the relevant records related to the advertisement set by the Law on Advertisement.

## 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.

    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.

    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.

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
## SURVEILLANCE OVER THE COMPLIANCE WITH THE CODE

Section 4.01. For the purpose of the surveillance over the compliance with the Code and decision making on a possible breach of the Code, procedural and sanction provisions of the AIFP Code of Conduct are applicable. The AIFP Ethics Committee is a supervisory authority.

## Schedule 1

## Definition of terms used in the AIFP CODE ON DISCLOSURE OF TRANSFERS OF VALUE FROM PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

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

**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 15.02 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 generic or branded 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.

Definitions and terms not defined by this code shall have the same meaning as assigned to them by the AIFP Code of Conduct.

## Schedule 2

## Model of a Standardised Template
***For reference***

*Include the Template*