FORUM OF INTERNATIONAL RESEARCH & DEVELOPMENT PHARMACEUTICAL COMPANIES, EIG

efpia
European Federation of Pharmaceutical Industries and Associations

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

(Disclosure code)

Adopted by the General Assembly of Forum International Research and Development Pharmaceutical Companies, EIG on 21 November 2013

as amended on 4 July 2014, 5 December 2014 and May 27 2016

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IMPLEMENTATION OF CODE PROVISIONS

The Forum of International Research and Development Pharmaceutical Companies, EIG (hereinafter: Forum) is introducing appropriate procedures to assure that companies, members of the Forum, operate in accordance with the European code (as adopted by the European Federation of Pharmaceutical Industries and Associations (hereinafter: EFPIA)) and the appropriate national code (Code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organisations: Disclosure code)) thereby assuring transparency of payments and transfers of value and resolving possible complaints regarding their in-appropriacy.

INTRODUCTION

Healthcare professionals (HCP) and healthcare organisations (HCO) 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 between healthcare professionals and industry.

The Forum emphasizes that interactions between the pharmaceutical industry and healthcare professionals have a profoundly 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. The Forum recognizes 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. Beside integrity in the cooperation between corporations and society, complete transparency of such processes is an ever increasing requirement. Following the adoption of 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", the Forum believes that it is critical to the future success of the pharmaceutical industry to respond to society's heightened expectations. The Forum has therefore decided that its existing regulations, such as the 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 public disclosure of the nature and scale of interactions between the industry and healthcare professionals and organisations. The Forum 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.

The Forum also believes that the interest of patients and other stakeholders in the transparency of these interactions is completely justified. The Forum recognizes that disclosure can raise data privacy concerns and seeks to work with healthcare professionals to ensure that these concerns are addressed. The Forum 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 Disclosure code sets out disclosures of payments and other transfers of value to healthcare professionals, whether directly or indirectly via healthcare organisations or made by third parties (such as contractors, agents, partner or subsidiaries (including foundations)). When deciding how a transfer of value should be disclosed, companies are encouraged to publish data at the level of 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 payments and other 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 the Forum in a manner consistent with applicable competition and data protection laws and regulations and all other applicable legal requirements.

SCOPE OF IMPLEMENTATION OF CODE PROVISIONS

This Code governs disclosures regarding payments and transfers of value pertaining to certain interactions with HCPs and HCOs. The purpose of this Code is its application to regulate the transparency of interactions with HCPs and HCOs within the same scope of the current HCP and PO codes. This Code applies to all Forum member companies.

PROVISIONS OF THE CODE

1. DISCLOSURE OBLIGATION

1.1. **General obligation.** Subject to the terms of this Code, each Member Company shall document and disclose payments and transfers of value it makes, directly or indirectly, to or for the benefit of a Recipient, as described in more detail in Article 3.

1.2. **Consent of Recipient.** Each Member is obliged to acquire consent for disclosure of information from each clearly identifiable HCP prior to such disclosure of payments and other transfers of value. When concluding a contract, which includes transfer of value to a HCP, members are encouraged to include in the contract provisions relating to HCP's consent to disclose transfers of value in accordance with the provisions of this Code. The same applies to the existing contracts, for which the members are encouraged to include such consent for disclosure at their earliest convenience.

1.3. **Excluded Disclosures.** The following transfers of value are not subject to disclosure: (i) transfers that are solely related to over-the-counter medicines; (ii) which are not listed in Article 3 hereof, that is informational and educational materials and items of medical utility (Art. 2.9. HCP Code); meals and drinks at the events (Art. 2.11. HCP Code with special reference to point 5) and medical samples (Art. 11. HCP Code) (iii) and which are part of the ordinary course of purchases and sales of medicinal products by and between a Member Company and an HCP (such as a pharmacist) or an HCO.

1.4. **Appendices.** Each of the attached Annexes forms part of this Code.

Definitions of capitalised terms are included in Appendix 1 to ensure consistent understanding of such terms.

A standardised template for disclosure of transfers of value is enclosed in Appendix 2.

2. FORM OF DISCLOSURE

2.1. **Annual disclosure cycle.** Data on payments and transfers of value 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, whereby the relevant data shall be published in the first half of 2016.

2.2. **Time of disclosures.** 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 2.4, 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 has been revoked.

2.3. **Template.** Subject to Section 2.4., for consistency purposes, disclosures will be made using standardised template set forth in Appendix 2.

2.4. **Platform of disclosures.** Disclosures shall be made on the website of the relevant member company pursuant to Section 2.5., provided access to the website is not limited.

2.5. **Applicable national code.** Disclosures shall be made pursuant to the national code of the country where the Recipient has its place of main practice or registered headquarters. If the Forum Member is not resident or does not have a subsidiary or an affiliate in the country where the Recipient has its place of main practice, the Forum Member shall disclose such Transfer of Value in a manner consistent with the national code to which it is subject.

2.6. **Language of disclosures.** Disclosures shall be made in Slovenian language. Member Companies are encouraged to make disclosures in English in addition to the mandatory disclosures in the Slovenian 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 10 years after the end of the relevant Reporting Period.

3. INDIVIDUAL AND AGGREGATE DISCLOSURE

3.1. **Individual disclosure.** Except as expressly provided by this Code, payments and 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. Reasonable costs of travel, accommodation and registration shall be presented in a transparent manner, as set out below. Such payments and Transfers of Value may be aggregated on a category-by-category basis, provided that itemised disclosure shall be made available upon request to the relevant Recipient and/or the relevant authorities.

3.1.1. For **Transfers of Value to an HCO**, an amount related to any of the categories set

forth below shall be disclosed:

3.1.1.1. Donations and grants for education. Donations and Grants for education 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 6 of the HCP Code).

3.1.1.2. Contribution to costs related to Events. Contribution to costs related to Events, including direct sponsorship to attend Events for HCP or via HCO, such as:

i. Registration fees;

ii. Sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event; and

iii. Costs of travel and accommodation (to the extent governed by Article 2.11. of the HCP Code).

3.1.1.3. 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, if such services (or other financing) (x) are provided with the intent of supporting healthcare or research and (y) do not constitute an inducement to recommend, prescribe, purchase, supply or sell specific medicinal products (pursuant to Articles 7. and 8. of the HCP Code). 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. For **Transfers of Value to an HCP,** an amount related to any of the categories set forth below shall be disclosed:

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

i. Registration fees; and

ii. Costs of travel and accommodation (to the extent governed by Article 2.11. of the HCP Code).

3.1.2.2. 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, including agreed and/or contractually set costs related to remuneration for services) (Pursuant to Articles 7 and 8 of the HCP Code). 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.** For Transfers of Value where certain information, which can be otherwise reasonably allocated to one of the categories set forth in Section 3.1, 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.

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 required to be disclosed once. To the extent possible, such disclosure shall be carried out pursuant to Section 3.1.2.

3.4. **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.

3.5. **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 3.1. The note 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.

4. SANCTIONS

If the Forum finds out or is informed a violation of the Disclosure Code, it shall request the violating company to immediately cease the violation and sign a statement that it shall not repeat it. Sanctions must be proportionate to the nature of the violation, have a deterrent effect and take into account repeated violations of the same type or patterns of various violations. Sanctions are set out in the Working Procedure of the Committee for supervision of the provisions of ethical codes. Generally the most effective sanction is the combination of notifying all the Forum members and financial fine for the violating company, however, the Forum may impose any other effective sanction to enforce the implementation of the Code. The Forum must also study all the applicable legal or financial requirements that could influence the nature of sanctions.

5. RESPONSIBILITY

5.1. Scope of responsibility

Responsibility for disclosure of payments and other transfers of value from pharmaceutical companies to HCP and HCO shall apply for disclosure as a whole: for categories of transfers, Recipients, for public disclosure and observation of deadlines.

5.2. Responsible persons

Responsibility for assuring compliance with the present Code shall be borne by all Forum members. Compliance with the provisions hereof shall also be the responsibility of authorised representatives of Forum members.

The Forum shall assure that the Disclosure Code and other codes and relevant information is readily available at least by means of publishing on the Forum website.

6. SUPERVISION

Committee for supervision of the provisions of ethical codes (Committee) as a Forum body assesses information regarding disclosure of payments and other transfers of value from pharmaceutical companies to HCP and HCO and provides guidelines regarding the same. The Committee shall decide by a procedure equal to that applied in the establishment of violations of the HCP Code.

7. COMPLAINTS

Complaints regarding violations of these rules shall be submitted to the Committee within 30 days of violation.

8. AMENDMENTS

Amendments or adjustments of the Disclosure Code may be instituted on the basis of an opinion of the majority of Forum members.

8.1. The Code may be amended several times per year:

8.1.1. upon amendment of the EFPIA Code on the transfer of value from pharmaceutical companies to HCP and HCO.

8.1.2. upon a request submitted to the Forum Board by a member company (or several thereof), which shall be submitted for approval to the Forum General Assembly.

8.2. Adoption shall require the majority of present votes at a General Assembly.

9. ENFORCEMENT

This code entered into force on 21 November 2013 when approved by Forum`s General Assembly.

Appendix 1:

Definition of terms used in the Disclosure code

Donations and grants

- Donations and Grants, collectively, means donations and in kind within the scope of Article 6 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 2.11. of the HCP Code).

Healthcare organisations (HCO)

- All single entrepreneurs and 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) or (ii) through which one or more HCPs provide services.

Healthcare professionals (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 the Republic of Slovenia.

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 person employed in the Republic of Slovenia whose primary occupation is that of a practising HCP, but excludes (x) all other persons employed in the Republic of Slovenia and (y) a wholesaler or distributor of medicinal products.

HCP Code

- Forum Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals, adopted by the Forum General Assembly on 20 January 2012, as may be amended, supplemented or modified from time to time.

Medicinal Products

- The term "Medicinal Products" as used in the present Code and HCP 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 the sense of Directive 2001/83/EC.

Member Companies

- Collectively, "members" (as defined in the HCP Code) of the Forum, 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, committed to compliance with the present Code.

PO Code

- Forum Code of Practice on Relationships between Pharmaceutical Industry and Patient Organisations, adopted by the General Assembly on 20 January 2012, 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 the Republic of Slovenia, or are employed in such HCO.

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 (Article 9 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 patented 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 by third parties (such as contractors, agents, partner or subsidiaries (including foundations)) in the name of a Member for the benefit of a Recipient, whereby the Member Company knows or can identify the Recipient.

Appendix 2:

Disclosure template (see appended Excel sheet)

Appendix 2 - TEMPLATE

		Full Name	Principal Practice Address or Registered Seat of Institution	Donations and Grants to HCOs *(Art. 3..1.1.1)*	Contribution to costs of Events *(Art. 3.1.1.2 & 3.1.2.1)*			Fee for service and consultancy *(Art. 3.1.1.3 & 3.1.2.2)*			**TOTAL** *OPTIONAL*
					Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accomodation	Fees	Related expenses agreed in the fee for service or consultancy contract, including travel&accomodation related to the contract		
INDIVIDUAL	HCPs	***INDIVIDUAL NAMED DISCLOSURE - one line per HCP*** *(i.e. all transfers of value during a year for an individual HCP will be summed up; itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)*									
		Dr A		N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	
		Dr B		N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	
		etc.		N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	
		OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons									
		Aggregate amount attributable to transfers of value to such Recipients *- Art. 3.2*		N/A	N/A	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*	N/A	*Optional*
		Number of Recipients *(named list, where appropriate) - Art. 3.2*		N/A	N/A	*number*	*number*	*number*	*number*	N/A	*Optional*
		% of the number of Recepients included in the aggregate disclosure in the the number Recepients disclosed *- Art. 3.2*		N/A	N/A	%	%	%	%	N/A	N/A
	HCOs	***INDIVIDUAL NAMED DISCLOSURE - one line per HCO*** *(i.e. all transfers of value during a year for an individual HCO will be summed up; itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)*									
		HCO 1		*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	*Optional*
		HCO 2		*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	*Optional*
		etc.		*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	*Optional*
		OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons									
		Aggregate amount attributable to transfers of value to such Recipients *- Art. 3.2*		*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	N/A	*Optional*
		Number of Recipients included in the aggregate disclosure *- Art. 3.2*		*number*	*number*	*number*	*number*	*number*	*number*	N/A	*Optional*
		% of the number of Recepients included in the aggregate disclosure in the the number Recepients disclosed *- Art. 3.2*		%	%	%	%	%	%	N/A	N/A
R & D		***AGGREGATE DISCLOSURE***									
		Transfers of Value re Research & Development as defined (Art. 3.4)								*TOTAL AMOUNT*	*OPTIONAL*

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Unambiguous identification of each HCP/HCO, as appropriate, including:

- name and surname,
- principal practice address,
- registered seat of institutio

MEMBERS OF THE FORUM OF INTERNATIONAL RESEARCH AND DEVELOPMENT PHARMACEUTICAL COMPANIES:

- Abbvie
- Amgen
- Astellas
- AstraZeneca
- Bayer
- Biogen Idec
- Boehringer Ingelheim
- Celgene
- Eli Lilly
- GlaxoSmithKline
- Janssen
- Lundbeck
- Merck Sharp & Dohme
- Novartis
- Novo Nordisk
- Pfizer
- Roche
- Sanofi-Aventis
- Servier