

## **HRA Pharma Global Methodological Note**

**on disclosure of Transfer of Values to Health Care Professionals and Health Care Organisations following the « EFPIA Code on Disclosure of Transfers of Value » in date 2014.**

**Version 2 – June 2017**

## 1. Introduction

Through its adhesion to the European Bio-Pharmaceutical Enterprises (EBE) and under the EFPIA Disclosure Code adopted on June 24, 2013, HRA Pharma has committed to bringing greater transparency regarding relationships the Company has with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs).

This document is intended to summarize the methodological information relevant for the interpretation of the information disclosed by HRA Pharma as required in Section 3.01 of the EFPIA HCP/HCO Disclosure Code.

## 2. Abbreviations

|                               |   |
|-------------------------------|---|
| CRO                           | Contract Research Organisation  |
| EBE                           | European Bio-pharmaceutical Enterprises   |
| EFPIA                         | 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 |
| HCO                           | Health Care Organisation  |
| HCP                           | Health Care Professional  |
| HCP Code                      | EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals                        |
| PO Code                       | EFPIA Code of practice on relationships between pharmaceutical industry and patient organisations                                     |
| ToV                           | Transfers of Value  |

## 3. Definitions

### 3.1. Recipients of ToV

#### 3.1.1. Health Care Professional (HCP)

Pursuant to Schedule 1 Definition of terms used in the EFPIA HCP/HCO Disclosure Code, a HCP constitutes:

*“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.”

### **3.1.2. Health Care Organisation (HCO)**

Pursuant to Schedule 1 Definition of terms used in the EFPIA HCP/HCO Disclosure Code, a HCO constitutes:

*“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.”*

#### Notes:

- This definition includes: hospitals, healthcare institutions or clinics, medical or learned societies, associations of healthcare professionals, universities, and ethic committees.

### **3.2. Transfers of Value (ToV)**

Pursuant to Schedule 1 Definitions of terms used in the EFPIA HCP/HCO Disclosure Code, ToV are:

*“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.”*

### **3.3. Events**

Pursuant to Schedule 1 Definitions of terms used in the EFPIA HCP/HCO Disclosure Code, events can be defined as:

*“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).”*

## **4. Scope of the Disclosure**

### **4.1. Categories of ToV according to the EFPIA Disclosure Code**

#### 4.1.1. Donations and Grants to HCOs

Pursuant to section 3.01 of the EFPIA HCP/HCO Disclosure Code, it should be disclosed under the category “Donations and Grants” any:

*“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)”.*

##### Notes:

- A grant or a donation is a payment made to HCOs without consideration or any kind of return in exchange of such payment for an educational, scientific or a charitable purpose. Grants can include research-related grants.

#### 4.1.2. Contribution to costs of Events

Pursuant to section 3.01 of the EFPIA HCP/HCO Disclosure Code, it should be disclosed under the category “Contribution to costs of events” any:

*“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).”*

The category “Contribution to costs of events” is composed of three sub-categories:

1. Sponsorship agreements with HCOs/ third parties appointed by an HCO, to manage an Event  
Example of ToV disclosed: rental of booths or stand space
2. Registration fees and related expenses agreed in the fee for service or consultancy contract
3. Travel and accommodation  
Example of ToV disclosed: flight tickets, train tickets, taxi, hotel nights. For group transport organized for an event, the global cost has been divided by the number of HCPs having benefit from the transport.

##### Notes:

- Indirect sponsorship of HCPs through HCOs are disclosed under payment to HCOs as this is the Recipient of the ToV. Such ToVs would be disclosed under the category “Contribution to Costs related to Events/Sponsorship agreements with HCOs/third parties appointed to manage an event”. (EFPIA Code - Answering Your Questions, Question 3.01-7)
- “Where the intermediary is a professional conference organizer (PCO), Member Company should declare the ToV in the appropriate category in the name of the sponsored HCO. In such case, the Member Company provides the sponsorship through the PCO, but with the intention to sponsor the HCO” (EFPIA Code - Answering Your Questions, Question 1.01-2)

#### 4.1.3. Fees for Service and Consultancy

Pursuant to section 3.01 of the EFPIA HCP/HCO Disclosure Code,

*“ToV 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 ToV relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.”*

The category “Fees for service and consultancy” is therefore composed of two sub-categories and should be reported for HCPs/HCOs:

1. **Fees:** fees for services to HCPs/HCOs  
Example of ToV disclosed: speakers’ fees, general consulting/advising
2. **Related expenses:** where a service agreement is in place, other expenses may occur which do not constitute part of the fees but relate to the provision of this service and are reimbursed to the HCP/HCO. Ex. Flight tickets, taxi, hotel nights

#### 4.1.4. Research and Development

Pursuant to section 3.04 of the EFPIA HCP/HCO Disclosure Code,

*“Research and Development ToV 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 ToV” category”.*

Moreover, pursuant to Schedule 1 Definition of terms used in the EFPIA HCP/HCO Disclosure Code, Research and Development ToVs correspond to:

*“ToV 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).”*

#### Notes:

- Examples of ToV disclosed in this category: Investigator’s meeting, Advisory Boards, Speaker agreement, Collaboration agreement, Clinical study agreement, Ethics committee fees
- A Clinical Research Organisation (CRO) is not considered as a HCO. Therefore the fees paid to CROs of Data Management/ Monitoring/ Medical writing for the services they provided to HRA Pharma are not included in the scope of the disclosure except when indirect ToV would ultimately benefit HCPs/HCOs; in this latter case ToVs are disclosed in the R&D category.

#### 4.2. ToV excluded from the scope

Pursuant to the Section 1.02 of the EFPIA HCP/HCO Disclosure Code,

*“Without limitation, ToV 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.”*

#### Notes:

##### 1) Market research studies:

According to EFPIA Code - Answering Your Questions, Question 3.01-12, ToV made to market research companies are not in the scope of disclosure except in cases where HRA Pharma knows the identity of the HCP/HCO participating in the activities;

##### 2) Partners and distributors interactions:

According to EFPIA Code - Answering Your Questions, Question Applicability-3, *“As a general rule, it is considered that where third parties represent or act on behalf of a Member Company, the respective obligations should be “transferred” to the third party. This will be reflected in the contractual agreements, as appropriate”*.

In some countries HRA Pharma operates through local distributors. In these countries HRA Pharma considers that if the local distributor is a member of the EFPIA, or a member of the local association of the EFPIA in the country and/or if the country where the local distributor operates has adopted a specific legislation, it is the responsibility of the local distributor to document and disclose ToV made to HCPs/HCOs.

## **5. Consent management**

According to European data protection, regulation (EU Directive 95/46), HCPs consent should be obtained before publishing disclosure payment information.

As the consent for disclosure of ToV has not been collected from all HCPs/HCOs, ToVs cannot currently be totally disclosed on an individual basis for legal reasons, taking into consideration the European and local data privacy legislation. HRA Pharma has initiated an internal process that would enable collection of the consent and publishing of the nominative data when applicable in the coming years.

Therefore, for the reporting period of 2016, HRA Pharma will publish the disclosed ToVs in both aggregated and nominative form.

## **6. Calculation rules and form for disclosure**

### **6.1. Currency**

The currency used in the reports is the currency of the relevant country of the HCP/HCO even if the payment has been done in a different country.

In the case where ToV have been made in a different currency, HRA Pharma has calculated the amount in the local currency based on the daily exchange rate effective on the date of payment of the ToV.

## **6.2. VAT and other taxes**

The data collected and disclosed includes VAT.

## **6.3. Language of disclosure**

The reports are published in the local languages and in English when available except for Switzerland and Italy, where the English language is acceptable for the purpose of disclosure.

## **6.4. Disclosure platform and date of disclosure of ToV**

HRA Pharma is publishing the disclosure reports on the HRA Pharma Corporate website except in cases where local transparency codes require the reports to be published on other specific platforms. In that case, links to relevant websites have been included on the dedicated page “Transparency” of the HRA corporate website. For the purpose of the disclosure HRA Pharma used the EFPIA excel templates except for countries where different templates are accepted.

This report discloses all ToV when date of payment falls within the year 2016. This information will remain available on the HRA Pharma Corporate website for a period of 3 years after the date of publication.