IPSEN

EFPIA TRANSPARENCY PROGRAM

METHODOLOGICAL NOTE

REVISION HISTORY

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Contents

1 PREAMBLE

Healthcare professionals (HCPs) and organisations (HCOs) with whom they work provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and management experience.
These interactions between pharmaceutical companies and HCPs – either directly or through HCOs – have a profound and positive influence on the quality of patient treatments and the value of future research.
At the same time, the integrity of the decisions of a HCP to prescribe a medicine is one of the pillars of the healthcare system.

The pharmaceutical industry is being proactive, based on its commitment to this relationship.
In this context, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and its member associations have adopted codes and guidelines to ensure that these interactions meet the high standards of integrity that patients, Society, governments and other stakeholders expect.

The EFPIA Disclosure Code ("Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations") was created to protect the integrity of these relationships, and represents a step towards fostering greater transparency and building greater trust between the pharmaceutical industry, the medical community and society across Europe.
The EFPIA Disclosure Code, adopted on June 24, 2013, requires that each member company documents and disclose Transfers of Value (ToV) it makes, directly or indirectly, to or for the benefit of a HCP/HCO Recipient. The first Reporting Period was the calendar year 2015 (disclosure in 2016).

Ipsen, like EFPIA members, recognizes that:

- Collaborative working between HCPs and commercial life sciences organizations has long been a positive driver for advancements in patient care and the progression of innovative medicine.

- Both parties regularly join together, during early scientific research, clinical trials and medical education in the interests of delivering and advancing high quality patient care. What's more, as the primary point of contact with patients, the medical profession can offer invaluable and expert knowledge on patient outcomes and the management diseases.

- This plays a big part in informing the pharmaceutical industry's efforts to improve patient care and treatment options – and is essential in improving health outcomes. A healthy working relationship between the pharmaceutical industry and HCPs/HCOs is in the best interest of patients.

Ipsen believes that:

- Bringing greater transparency to this, already well regulated, vital relationship is about strengthening the basis for trustful collaboration. Industry is being proactive, based on its commitment to this relationship.

- Society has increasingly high expectations for transparency, none more so than in healthcare. We want to ensure we meet those expectations going forward.

Therefore, based on the EFPIA Charter, Ipsen commits to:

- Across Europe, by 30 June 2016, disclose payments made to health professionals and organizations, such as consultancy, advisory boards, speaker fees and sponsorship to attend professional meetings.

- Work with individuals, healthcare systems, professional and representative bodies, to manage this transition effectively and ensure individual disclosure with health professionals giving their consent to disclose.

Moreover, in Belgium, national legislation (see Belgian Royal Decree dated 14/06/2017 for execution of the 'Sunshine Act'), requires Ipsen to document and publicly disclose direct or indirect transfers of value made to healthcare professionals, healthcare organisations, patient organizations and other parties as applicable by the precited law.

DISCLAIMER NOTE:

The disclosure report for transfer of values of 2019, submitted end of May 2020 to the betransparent.be platform, contains data extracted on 5th March 2020.

2 PURPOSE

Pursuant to Section 3.05. of the EFPIA Disclosure Code, *"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".*

The present document constitutes this required **methodological note**, and describes the EFPIA Disclosure Code requirements, Ipsen Group considerations, and local considerations due to locally applicable laws and regulations.
The EFPIA Disclosure Code and EFPIA FAQ document to which this note refers to are given in appendix.

This note applies to **Belgium & Luxemburg**

2.1 Terminology

Standard abbreviations or terms are presented in the table below.

ACRONYMS AND ABBREVIATIONS	
EFPIA	European Federation of Pharmaceutical Industries and Associations
ESS	External Sponsored Study
GTM	Global Transparency Manager
HCO	HealthCare Organization
HCP	HealthCare Professional
LTM	Local Transparency Manager
OTC	Medicines which can be delivered without prescription and never reimbursed
OTX	Medicines which can be delivered without prescription, but which are reimbursed if prescribed
PO	Patients Organization
POM	Prescription Only Medicine (RX)
SOP	Standard Operating Procedure
ToV	Transfer of Value

3 SCOPE OF THE DISCLOSURE

3.1 Recipients

3.1.1 HCP

a) EFPIA definition

Pursuant to Schedule 1 Definition of terms used in the EFPIA HCP/HCO Disclosure Code, a "Healthcare Professional" 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: 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 any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes all other employees of a Member Company and a wholesaler or distributor of medicinal products."*

b) Ipsen Group considerations

As general principle, Ipsen considers that disclosure has to be made on the contracting entity. Ipsen fully follows EFPIA definition.

c) Local considerations

Same as (b) plus taking into account the stipulations in the Belgian national legislation (Belgian Royal Decree dated 14/06/2017 for execution of the 'Sunshine Act').

3.1.2 HCO

a) EFPIA definition

Pursuant to Schedule 1 Definition of terms used in the EFPIA HCP/HCO Disclosure Code, an "Healthcare Organization" constitutes *"Any legal person that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organizations within the scope of the EFPIA PO Code) whose business address, place of incorporation or primary place of operation is in Europe or through which one or more HCPs provide services."*

Based on the EFPIA FAQ Question Definitions -1, *"A CRO is not a HCO. A clinical research organization (CRO) is an organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis. However, Member Companies may make Transfers of Value to HCPs / HCOs through CROs – such indirect payments are within the scope of the Code".*

b) Ipsen Group considerations

As general principle, Ipsen considers that disclosure has to be made on the contracting entity. Ipsen fully follows EFPIA definition.

Additional notes: As specified in the Disclosure Code:

- Payments to Clinical Research Organizations are excluded from the scope. However, ToV to HCPs/HCOs via CROs, within the ToV in scope (see 3.3) are disclosed (See 3.3.5).

c) Local considerations

Same as (b) plus taking into account the stipulations in the Belgian national legislation (Belgian Royal Decree dated 14/06/2017 for execution of the 'Sunshine Act').

3.1.3 Specific case: Company owned by an HCP

a. EFPIA requirements

According to EFPIA FAQ Question 3.01 - 10, *"The Fee for Service paid to a legal entity owned by a physician should be disclosed under the name of the legal entity (considered an HCO), as this is the Recipient of the payment. Similarly, payments to a clinic, when disclosed on an individual basis, will be disclosed in the name of the clinic.*
The Code requires that Member Companies will make individual disclosures in the name of the person / legal entity that receives the Transfer of Value (i.e. the Recipient)."

EFPIA FAQ Question definitions - 6 confirms that *"Under the Code, a self-incorporated HCP (where he/she is the only employee of the corporation) would be considered a HCO".*

b. Ipsen Group considerations

As general principle, Ipsen considers that disclosure has to be made on the contracting entity. If the contracting entity is a company owned by a HCP (company owned by an HCP in order to practice medicine or to provide medical education services), the amount is disclosed as a ToV made to the appropriate HCO.

c. Local considerations

Same as (b) plus for Belgium taking into account the stipulations in the Belgian national legislation (Belgian Royal Decree dated 14/06/2017 for execution of the 'Sunshine Act') that the disclosure should be nominative according to set ruling (see betransparent.be guidance documentation).

3.2 Medicinal products and applicability of the Code

a) EFPIA definition

Pursuant to Schedule 1 Definition of terms used in the EFPIA HCP/HCO Disclosure Code, *"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."*

According to EFPIA FAQ Question 1.02 - 2, *"The Code aims at disclosing monetary values attached to activities that are self-regulated by the EFPIA HCP Code, which governs activities relating to prescription-only medicines (POM).*
The code excludes Transfers of Value solely related to OTC products with respect to each country's regulation on the legal status of a medicine".

b) Ipsen Group considerations

At Ipsen, for consistency purposes, it has been decided to collect and report the ToV related to all Ipsen products.

c) Local considerations

Same as (b) plus for Belgium taking into account the stipulations in the Belgian national legislation (Belgian Royal Decree dated 14/06/2017 for execution of the 'Sunshine Act').

Transfers of value

3.2.1 Definition of Transfers of value

a. EFPIA requirements

Pursuant to Schedule 1 of the 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."*

b. Ipsen Group considerations

Ipsen discloses both direct and indirect types of ToV such as defined in the Code.
When ToV are made through an intermediary ("Third party"), necessary arrangements have been made with third parties to ensure the obligations are fulfilled (Third parties representing Ipsen or acting on behalf of Ipsen, provide Ipsen with a detailed tracker of the ToV made to HCPs and HCOs).

c. Local considerations

Saame as (b) plus for Belgium taking into account the stipulations in the Belgian national legislation (Belgian Royal Decree dated 14/06/2017 for execution of the 'Sunshine Act'). In the rare event that fees for services and consultancy payments dates were not falling in the same calendar/reporting year as the dates of payments/reimbursements of expenses for service and consultancy (including travel & accommodation), both categories of fees paid were grouped together with the actual payment date for reimbursement of expenses for service and consultancy (including travel and accommodation) in one reporting year, instead of split per actual payment date.

3.2.2 Donations and grants

a) EFPIA requirements

Pursuant to section 3.01. of the Disclosure Code*, "Individual Disclosure"* Member Companies must disclose under *"Donations and grants"* category any *"Donations and Grants to HCOs that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organizations or associations that are comprised of HCPs and/or that provide healthcare (governed by Article 11 of the HCP Code)."*

b) Ipsen Group considerations

In this section, Ipsen discloses ToVs related to donations and grants at individual level, i.e., at HCO level.

A **Grant** or a **Donation** is a payment made to a third party without consideration or any kind of return in exchange of such payment for an **educational, scientific or a charitable** purpose:

- An **Educational Grant** is funding provided to an HCO to support a bona fide, independent educational program, such as medical science or public health policy. The primary purpose of the support is the provision of legitimate educational program.
- A **Scientific Grant** can take the form of funding to third party entities for the purpose of the advancement of medical or scientific knowledge.
- A **donation** is a charitable contribution to a third party entity (charities) with charitable and philantropic intent, without any expressed or implied benefit other than general goodwill.

Grants can include some research-related grants, including external sponsored studies.

c) Local considerations

Same as b) plus for Belgium taking into account the stipulations in the Belgian national legislation (Belgian Royal Decree dated 14/06/2017 for execution of the 'Sunshine Act').

3.2.3 Contribution to costs of event

a) EFPIA requirements

Pursuant to section 3.01.of the Disclosure Code *"Individual Disclosure"* Member Companies must disclose under *"Contribution to costs of events"* category any *"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: The total amount of Registration Fees paid in a given year to a HCO should be disclosed on an individual basis under "Contribution to costs related to Events". The total amount of Registration Fees paid in a given year to a HCP who is the clearly identifiable Recipient should be disclosed on an individual basis under "Contribution to costs related to Events".

ii. Sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event: "Sponsorship Agreements" are formalized in contracts that describe the purpose of the sponsorship and the related Transfers of Value. If the contract includes "Registration fees" and "Travel and Accommodation", such Transfers of Value should, in principle, be disclosed separately in the relevant categories.

iii. Travel and accommodation (to the extent governed by Article 10 of the EFPIA HCP Code)."

Additional notes for Sponsorships:

- *"Indirect sponsorship of HCPs through HCOs should be disclosed under payment to HCOs as this is the Recipient of the Transfer of Value. Such disclosures would be disclosed under the category "Contribution to Costs related to Events / Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an event". (EFPIA FAQ Question 3.01-7)*
- *"Where the intermediary is a professional conference organiser (PCO), Member Company should declare the Transfers of Value in the appropriate category in the name of the sponsored HCO. This is because in such case, the Member Company provides the sponsorship through the PCO, but with the intention to sponsor the HCO" (EFPIA FAQ Question 1.01-2)*

b) Ipsen Group considerations

In this section Ipsen discloses ToVs related to events at individual level, i.e., at HCP or HCO level.

The ToVs disclosed under this section relate to either Third-Party organized events or Standalone Events organized by Ipsen:

- "Third-party events", organised by an independent third party, such as a learning Society, HCP association etc. An international scientific congress is an example of third-party events.
    - **HCPs Sponsorship:** Ipsen may sponsor HCPs to attend congresses or events to enhance their medical and/or scientific knowledge, and their use of medicines.

In this context, the sponsorship covers **congress registration**, **travel**, **accommodation** and meals. The HCP does not receive any compensation, as no service is provided from the HCP (*See categories 1. and 3. below*).

- **Congress Sponsorship:** Ipsen may also **sponsor a third-party event** (congress for example), in exchange for services such as a slot for an Ipsen satellite symposium (educational activity independently organized by Ipsen and held within the congress, the admission of employees to the Congress) or a booth (*See category 2. below*). The ToVs related to sponsorships are always made to an organization.

- "Ipsen Standalone meetings". These are events initiated by Ipsen to provide information on an Ipsen medicinal product, therapeutic area, treatment options, etc. or as a response to address a legitimate need for scientific information. Hospitality can be provided to HCPs that participate in such meetings. Logistical costs are not disclosed.

In both cases, the hospitality levels are governed by local rules (resulting from local transposition of the EFPIA HCP Code, setting amount thresholds for hospitalities).

The report section *"Contribution to costs of events"* is composed of three (3) categories:

1 **Registration fees**: participants' admission fees to third-party events, are included in sponsorship of HCPs.

2 **Sponsorship agreements** with HCOs or third parties (such as PCOs) appointed by HCOs to manage an event. In the latter case, the sponsorship is considered an indirect ToV to an HCO.
Examples of ToV disclosed: Rental of booth space, satellite symposia slot at a congress (Ipsen controlled event at third-party event).

3 **Travel and accommodation** provided to HCPs as part of HCPs sponsorships at Third-party events or related to HCPs participation at Ipsen stand-alone meetings.
Examples of ToV disclosed: Flight tickets, train tickets, taxi, hotel nights.
For mass group transport (e.g., a bus / coach) organised for an event, the cost is allocated to each individual HCP having benefited from the "Travel and accommodation".
Refer to Part 5.2 for detailed calculation rules.

c) Local considerations

Same as b) plus for Belgium taking into account the stipulations in the Belgian national legislation (Belgian Royal Decree dated 14/06/2017 for execution of the 'Sunshine Act').and the circular letter number 622 from the Belgian Federal Agency (www.fagg.be)

3.2.4 Fees for Service and Consultancy

a) EFPIA requirements

Pursuant to section 3.01. of the Disclosure Code *"Individual Disclosure"* Member Companies must disclose under *"Fees for Service and Consultancy"* category any *"Transfers of Value resulting from or related to contracts between Member Companies and HCPs, institutions, organizations or associations of HCPs under which such institutions, organizations 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."*

b) Ipsen Group considerations

Ipsen may contract with a HCP or a HCO in exchange of services provided by the HCP/HCO based on scientific/medical expertise, reputation, knowledge and experience in a particular therapeutic area. Ipsen enters into contractual arrangements with an HCP or an HCO only where there is a legitimate business or scientific need which cannot be satisfied by internal or other available sources. The services provided are insights, presentations or other consulting services.
Participation in consultancy agreements requires an investment of time and expertise from the HCP, over and above their principle practice. Therefore it is appropriate that they are paid for their time and reimbursed for expenses such as travel. Remuneration must be part of a written agreement, be strictly related and proportional to the services rendered, be in line with fair market value and comply with relevant Code of Practice, regulations and laws.

In this section Ipsen discloses services at individual level, i.e., at HCP or HCO level, the fees and related expenses, in two separate ToV categories:

1 **Fees:** fees for services to HCPs/HCOs
Examples: Speaker fees (Speech given by a HCP ("Speaker") in a meeting), fees for insights provided during an Advisory Board[1], fees for consultancy .

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. Such ToVs are disclosed in this category.
Examples: Flight tickets, train tickets, taxi, hotel nights.

1 An **Advisory Board** is a group of external experts convened by a company to get their professional advice and insights on a specific topic for which the expertise and knowledge are not available within the company. Advisors (experts in their areas) can be healthcare professionals (HCP), payers, patients, representatives of patient associations, patient advisors and non-HCP specialists, e.g. Market Access specialists.
Covering scientific and / or healthcare-related issues, Advisory Boards help us to better understand the external environment, therapeutic area, data and use of products approved or in development, clinical and medical asset strategies, or unmet medical needs.

c) Local considerations

Same as (b) plus for Belgium taking into account the stipulations in the Belgian national legislation (Belgian Royal Decree dated 14/06/2017 for execution of the 'Sunshine Act').and with the circular letter number 622 from the Belgian Federal Agency (www.fagg.be) and with the local fair market values.

3.2.5 R&D

a) EFPIA requirements

Pursuant to section 3.04. of the Disclosure Code *"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."*

Pursuant to Schedule 1 Definition of terms used in the EFPIA HCP/HCO Disclosure Cod**e** *"Research and Development Transfers of Value"* related to *"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)."

Moreover, as stated in the EFPIA Q&A Batch 1 Q58, *"Not every research activity that Member Companies undertake is done for a regulatory purpose. Studies that are not intended for submission to regulatory authorities do not fall within the "Research and Development Transfers of Value" disclosure category and should be disclosed in the relevant category on an individual basis".*

b) Ipsen Group considerations

ToV to HCPs or HCOs related to the planning or conduct of:

- Non-clinical studies
- Clinical trials
- 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

Definitions:

Non-clinical studies *(Source: OECD Principles on Good Laboratory Practice)*: 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.

Clinical trials *(Source: OECD Principles on Good Laboratory Practice)*: Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmaco-dynamic 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.

Non-interventional studies *(Source: OECD Principles on Good Laboratory Practice)*: Studies where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorization. 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.

Examples of R&D ToV that are disclosed in this section (if the related study falls into the EFPIA definition of R&D):

- Collaboration Agreement
- Clinical Study Agreement
- Consulting Agreement - Services Agreement
- Speaker Agreement
- Advisory Board
- Investigator meeting
- Ancillary services patient care
- Ethics committee fees

Specific cases

1 Ancillary services provided in hospitals (i.e. hospital services provided by non-medical staff) can be related to patient care provided during a trial, or can be non-patient related (e.g. data building). The latter is often outsourced to specialised organisations. Ancillary services directly related to patient care in a trial fall within the scope of the Code and are therefore disclosed on an aggregate basis. Ancillary services that are not directly related to patient care in a trial are considered business-to-business transactions that are not subject to the Code's disclosure requirements.

2 Indirect payments through Clinical Research Organization: as described in the 3.1.2 (a), a clinical research organization is not considered a HCO.
Therefore, the fees paid to CROs for the services they provide to Ipsen are not included in the scope of the disclosure.
However, the indirect ToV through CROs that ultimately benefit HCPs/HCOs are disclosed in R&D section.
The contracts with the CROs have been adapted to include provisions related to the CROs' obligation to provide Ipsen with detailed information related to indirect ToV that benefit HCP/HCO.

c) Local considerations

Same as (b) plus for Belgium taking into account the stipulations in the Belgian national legislation (Belgian Royal Decree dated 14/06/2017 for execution of the 'Sunshine Act').

3.2.6 Transfers of value excluded from the scope

a) EFPIA requirements

Pursuant to the Section 1.02. of the Code, "*Without limitation, Transfers of Value that […] (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*".

Moreover, *"Member Companies are not obliged to disclose any logistical costs e.g. hire of Member Companies facility associated with a stand-alone event."* (EFPIA FAQ Question 3.01 - 13).

Notes:

- *"For the avoidance of doubt, under the EFPIA Code, "****meals and drinks****" do not need to be disclosed as such Transfers of Value are regulated by the new provisions in the EFPIA HCP Code. National laws and regulations may have additional obligations"(*EFPIA FAQ Question 3.01 - 11)
- *"As the* ***medical samples*** *are excluded from the disclosure obligations, the same principle should apply to* ***investigational compounds*** *and* ***biological sample*** *for study.*
- *The investigational compounds and biological sample are subject to provisions under the Clinical Trials Directive, and their use will submitted to Clinical Trials approval processes"* (EFPIA FAQ Question 1.02 - 4).

b) Ipsen Group considerations

As general principle, Ipsen fully follows EFPIA rules related to ToV excluded from the scope.
As stated in Part 3.3.3, the hospitality levels are governed by local rules (resulting from local transposition of the EFPIA HCP Code, setting amount thresholds for hospitality).

c) Local considerations

Meals & drinks:
The local threshold for hospitality for Mdeon (www.Mdeon.be) approved events are € 40 for lunch and € 80 for dinner. According the Belgian Federal Agency (www.fagg.be) circular letter 622, the maximum amount for meals & drinks are € 20 per hour scientific meeting per HCP, with a maximum of € 40 for a lunch and € 80 for a dinner.
Samples:
A maximum of 8 medical samples per year per HCP and per product & dosage (smallest pack-size) can be delivered to the HCP in accordance to Belgian local legislation.

3.2.7 Specific consideration #1: Market research

a) EFPIA requirements

Pursuant to Section 1.01. of the Disclosure Code *"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."*

According to EFPIA FAQ Question 3.01 - 12 *"The Code does not require disclosure of the Transfers of Value made to market research companies when the identity of the HCPs/HCOs participating in the market research studies is not known.*
As a rule, one of the basic tenets of market research is the right of the respondents to remain anonymous, which is also enshrined in market research definitions and relevant codes of conduct worldwide. However, where the Member Company knows the identity of the HCP/HCO participating in activities defined as market research the Member Company should disclose it in the "Fees for Service and Consultancy" category. In such exceptional cases, it is expected that the Member Company will secure the consent to disclosure through contract."

b) Ipsen Group considerations

A market research is the process of gathering and analysing information related to a specific market, in a systematic and objective manner. The purpose of any market research project is to achieve an increased understanding of the subject matter.
Most of the time, market research is covered by contracting arrangements between Ipsen and external vendors; personal information of respondents is then kept fully confidential by the vendor.

In case of ToV related to market research, three situations can occur:

- If the names of the respondent HCPs are not known, the ToV is not disclosed.
- If the names of the HCPs are known and their disclosure consent (see Part 4) has been obtained, the ToV is disclosed at individual level;
- If the names of the HCPs are known and their disclosure consent has not been obtained (refusal of the HCPs), the ToV is disclosed at aggregate level.

c) Local considerations

Same as b) plus for Belgium taking into account the stipulations in the Belgian national legislation (Belgian Royal Decree dated 14/06/2017 for execution of the 'Sunshine Act').

3.2.8 Specific consideration #2: Third parties interactions

a) EFPIA requirements

Pursuant to Section 1.01 of the Disclosure Code "*General Obligation"*, *"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."*

According to EFPIA FAQ 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 arrangements, as appropriate."*

b) Ipsen Group considerations

In some parts of the world, Ipsen operates through partners and distributors.
In this context, Ipsen considers that if the Partner is a member of the EFPIA, or a member of the local association member of EFPIA in the country of the HCP/HCO, and/or if the country where the Partner operates has adopted a legislation providing for transparency of interactions between the pharmaceutical industry and HCPs and HCOs, the Partner is responsible for documenting and disclosing ToV made to HCPs and HCOs, in accordance with the local code of conduct or legislation, and in compliance with applicable personal data law protection.

When the partner is not a member of the EFPIA or when the recipient comes from a country where the partner is not a member of the local association member of EFPIA, two cases can occur:

- The partner discloses on a voluntary basis or through contractual obligations: These ToV are then excluded from the Ipsen Transparency reports;
- The partner does not disclose: Ipsen discloses only the ToV linked to activities included in the scope of the EFPIA, made on behalf of Ipsen, and when final recipients / costs are known by Ipsen. In these cases, the partner commits to assist Ipsen in fulfilling its obligations under the Code by collecting the required information and consents for the processing and disclosure of the relevant ToV to HCP and HCO.

The following figure summarizes the approach followed.

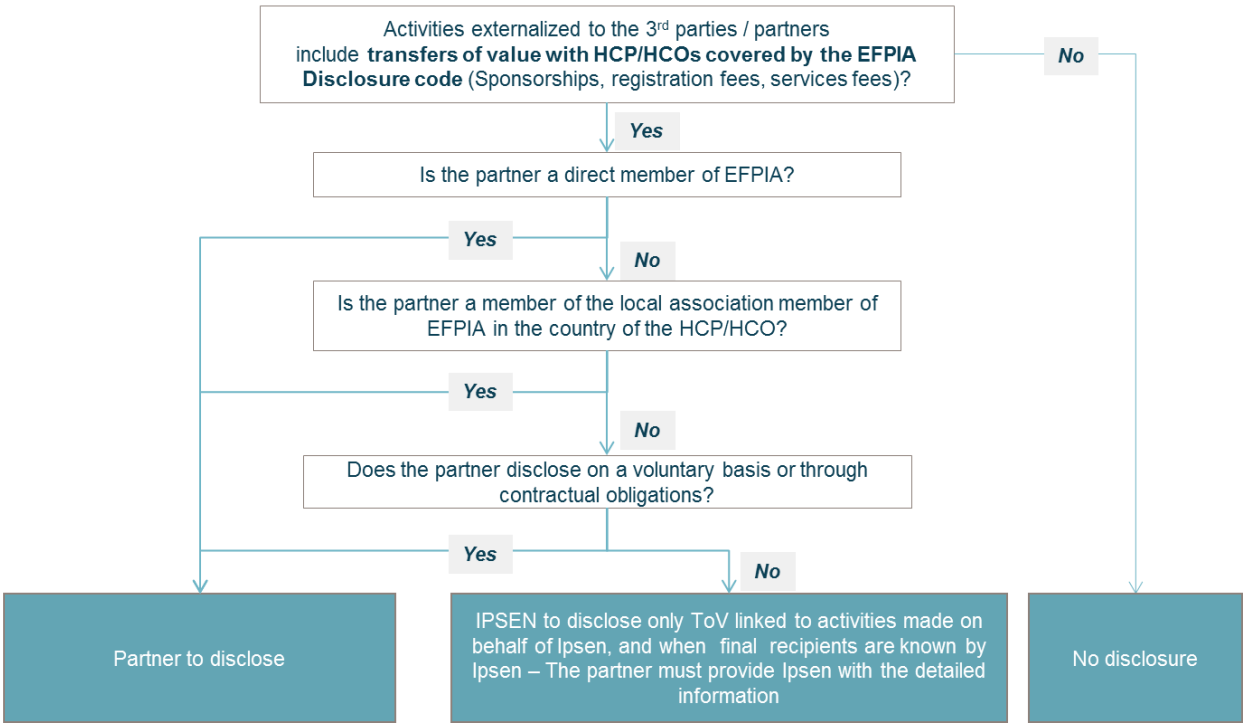

Figure 1 – Third parties' interactions

c) Local considerations

Same as (b) plus for Belgium taking into account the stipulations in the Belgian national legislation (Belgian Royal Decree dated 14/06/2017 for execution of the 'Sunshine Act').

3.3 Transfers of value related to cross-border activities

a) EFPIA requirements

According to EFPIA FAQ Question 2.05 – 3, "*Transfers of Value to a HCP / HCO whose practice, professional address or place of incorporation is in Europe, **are required to be disclosed in the country where the Recipient has its principal practice**, pursuant to the national code of the country where the Recipient's principle practice is located, whether the Transfers of Value occur in or outside that country. The Code requires transparency of Transfers of Value based on the country of primary/principal practice, which will ensure that the searching patient or other interested stakeholder can easily find this information. The physical address where the HCP practices or HCO is located should be used as the reference when determining in which country the data should be disclosed".*

b) Ipsen Group considerations

At Ipsen, a **"cross-border" activity** is defined as an activity initiated either by an Ipsen affiliate with a Recipient coming from one or several countries, or by a Corporate department.
To comply with the EFPIA Code which requires disclosure in the country where the recipient has its principle practice (HCP) or where it is registered (HCO), whether the ToV occurs in or outside of that country, the cross-border activities management process has been refined in order to capture all expenses from any Ipsen entity to HCPs/HCOs within the scope of EFPIA requirements.

Examples of ToV related to cross-border activities (based on EFPIA FAQ Question 2.05 – 3):

1. Ipsen's US headquarters sponsoring a HCP whose practice is in Sweden for an activity in Germany has reported the ToV centrally and this ToV is disclosed under the name of the Recipient HCP, in Sweden (following the applicable laws, regulations and the national code in Sweden).
2. Ipsen France sponsoring a HCO located in Italy to provide expertise, has reported the ToV centrally and this ToV is disclosed in the name of the Recipient HCO in Italy (following the application of Italian laws, regulations and national codes in Italy).
3. Ipsen HQ sponsoring a US expert for participation in an advisory board in Argentina is not required to disclose that Transfer of Value under the EFPIA Code. However, disclosure is required in the US under the "Sunshine Act".

c) Local considerations

Same as (b) + Cross Borders initiators are responsible for involving the relevant local transparence / Ethics & Compliance contact to ensure compliance with local requirements. If the HCP/HCO is a **Belgian person/organization**, the values of expenses, and technical key information gathered, must be in line with the Belgian stipulations in the Belgian national legislation (Belgian Royal Decree dated 14/06/2017 for execution of the 'Sunshine Act').

4 CONSENT MANAGEMENT

4.1.1 Background on data privacy requirements

The collection and use of personal data is subject to the European General Data Protection Regulation (GDPR) 2016/679 (URL link), which relates to the processing of personal data. It applies to physical persons (HCPs) and exceptionally, in the case of Austria, Luxembourg and Switzerland to HCOs as well.
The Regulation is directly applicable in each country and harmonizes national data protection legislations.
The Regulation requires that personal data needs to be adequate, relevant, and limited to what is necessary in relation to the purposes for which they are processed d. Data controllers (such as Ipsen) need to ensure that the data is accurate, up-to-date and must keep it secure.
Where the publication of data is deemed to be in the public interest, this can outweigh the individual's right to privacy and form a legitimate basis for publication. This approach is being adopted in countries such as France, the Netherlands, Denmark, and Slovakia.

Data subjects (HCPs and HCOs, where applicable) have the right to access their data and to object to its disclosure.
The Regulation requires that adequate safeguards are put in place for any transfer of personal data to countries outside the EEA not ensuring an adequate level of protection.

Individuals need to be informed on the fact that their personal data are processed by Ipsen, and in certain cases, the individual's consent is necessary for the processing or publishing of their personal data (e.g. when you disclose payment information of HCPs or when advertisement is sent to individuals). Giving complete information and obtaining valid consent is at the same time an opportunity for that data processors to show that they are processing personal data fairly.
To be valid, any consent from HCP must be:

- Freely given
- Specific
- Unambiguous
- The result of an informed decision.

Where individual consent has been used as a basis for publication (rather than public interest) then HCPs still has the right to refuse to disclose their data and has still the right to seek correction of mistakes or deletion of their data.

4.1.2 Consent Collection

a) EFPIA requirements

Pursuant to Section 4.01 of the Disclosure Code "*Enforcement through Member Associations - When making a Transfer of Value to an HCP / HCO, and in their written contracts with HCPs / HCOs,*

Member 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."

b) Ipsen Group considerations

European Data Protection Regulation requires companies to seek health professionals' consent to publish disclosure payment information.

For consent to be valid, it must be informed: the Recipient must receive all the information on the requirements and objectives of the EFPIA disclosure code, the protection status of his personal data and what the consequence is if the consent is refused.
At Ipsen's level, the recommended approach is to collect the disclosure consent activity per activity. The Ipsen affiliates can use either the corporate consent template or a local consent clause approved by the local association. In these cases, the Consent form must be added into each activity contract.
In some countries where it is allowed by local transparency requirements, yearly disclosure consent is collected, and reflects an informed consent.

In the case of HCP attending an event with no contracting engagements with Ipsen, the personal data collecting & processing provision may be included in the invitation letters and/or the presence sheet, and a disclosure consent form is signed by the HCP prior to the disclosure.

c) Local considerations

b) plus National legislation in Belgium (see Belgian Royal Decree dated 14/06/2017 for execution of the 'Sunshine Act') requires Ipsen nv to document and publicly disclose direct or indirect transfers of value, whether in cash, in kind or otherwise provided. According to the legally set time-frame and after the end of the relevant reporting period, disclosures are being made annually, according to the legally set web-based route in Belgium (betransparent.be platform). This information is given as part of the Ipsen approved contract templates such as Speaker Service Agreement; Consultancy or Advisory Board agreement.

4.1.3 Disclosure consent refusal & revocation

a) EFPIA requirements

According to the EFPIA FAQ Question 2.02 - 1, *"The relevant data privacy and other (local) laws will apply to such cases. Member Companies will need to assess the implications of such revocation on a case-by-case basis and are encouraged to seek independent legal advice. If a Recipient's consent is revoked, Member Companies need to be clear as to when such revocation is effective and amend their individual disclosures at such time. However, depending on any (local) legal implications of revocation, companies must retain data relating to specific transactions and report such Transfers of Value on an aggregate basis, in line with applicable national law and regulations".*

b) Ipsen Group considerations

Where individual consent has been used as a basis for publication (rather than public interest) and HCPs do not grant consent to disclose payments, then the payments are disclosed on an aggregate basis. Ipsen discloses the number of recipients that did not grant consent and the total amount paid to them.

When a recipient withdraws its consent for the information to be publicly disclosed then Ipsen is obligated to remove payments made to that individual from the public domain. Instead the payments are added to the aggregate total of payments made to health professionals that have not given consent to disclose and this aggregate figure is published along with the number of healthcare professionals that did not give consent.

If the revocation occurred prior to the disclosure, the relevant actions and systems updates have been taken into account, to make sure the information related to all ToVs of the reporting period are disclosed on an aggregate manner.
If the revocation occurs after the disclosure, Ipsen will amend the report accordingly.
In any cases, the date of the effective revocation is tracked and archived internally.

If a HCP or HCO doesn't give or revokes its consent, it should not work for its disadvantage, meaning it can continue to work with Ipsen. The recipient's refusal does not impact the collaboration between HCP/HCO and Ipsen.

c) Local considerations

Same as (b) except that according to the stipulations in the Belgian national legislation (Belgian Royal Decree dated 14/06/2017 for execution of the 'Sunshine Act'), for Belgian HCPs/HCOs transparency has become legally binding, as from 1st January 2017 onwards. So even in the case that prior to the publication of the Belgian Royal Decree, recipients had not given their consent, Ipsen nv has become legally bound to nevertheless report the ToVs over the full calendar year – retroactively overcoming prior given non-consent.

4.1.4 Partial consent

(a) EFPIA requirements

According to the EFPIA FAQ Question 3.02 - 2, *"Member Companies are encouraged to include a consent notice in their contracts that would prevent, wherever possible, Recipients from "cherry picking" which Transfers of Value they consent to be disclosed.*
If notwithstanding the Member Company's efforts, a Recipient gives only partial consent to any aspect of disclosure (i.e. the Recipient does not allow for disclosure of all categories or of all Transfers), all Transfers of Value of the Member Company made to that Recipient should be declared in the aggregate disclosure (not in the individual disclosure category), subject to applicable laws.

Partial disclosure under the individual disclosure category would be misleading with respect to the nature and scale of the interaction between the Member Company and the Recipient, and would as such not fulfil the intent of the Code."

(b) Ipsen Group considerations

Consistent with EFPIA position on this topic, at Ipsen, the rule is the following: If a Recipient has received a number of ToV from Ipsen within the same reporting period, and decides not to agree to disclosure of one or more of those ToV, then Ipsen discloses all of that individual's ToV in its aggregate amount.

(a) Local considerations

Same as (b) except that according to the stipulations in the Belgian national legislation (Belgian Royal Decree dated 14/06/2017 for execution of the 'Sunshine Act'), for Belgian HCPs/HCOs transparency has become legally binding, as from 1st January 2017 onwards. So even in the case that prior to the publication of the Belgian Royal Decree, recipients had only given their partial consent, Ipsen nv has become legally bound to nevertheless report all ToVs over the full calendar year.

5 DISCLOSURE METHODOLOGY

5.1 Publication Date

a) EFPIA requirements

According to EFPIA FAQ Question 2.01 - 1, *"Member Companies are required to disclose Transfers of Value as and when they are made. They would therefore be expected to disclose Transfers of Value in a given year within 6 months after the end of the relevant reporting period. Thus payments made in 2015 will have to be disclosed by 30 June 2016.*
It is expected that Member Companies will apply the relevant company accounting principles. However, the principles applied shall not allow Transfers of Value not to be disclosed, for instance by changing the principles from one year to the next.
Member Companies are expected to provide information on how their disclosures are managed in their Methodological Note, where they can also provide additional clarification on Transfers of Value recognition."

b) Ipsen Group considerations

Ipsen discloses before the 30th of June all relevant ToVs of the previous year according to the following rules:

- ToV from the 1st of January to the 31st of December of the previous year (reporting period)
- The type of date taken into account for the ToV varies depending on the following situations:
    - For **direct ToV linked to an event**:
        - When the information is collected from the financial system (direct payments): Date of the payment
        - When the information is manually collected: Date of the event (or the 1st day of a congress)
    - For **direct ToV not linked to an event** (fees for consultancy for example): Date of the invoice reception or date of the payment
    - For **indirect ToV linked to an event**: Date of the event (or the 1st day of an event)
    - For **indirect ToV not linked to an event** (fees for consultancy for example): Date of the invoice reception or date of the payment

However, different rules apply for specific cases:

- For ToV related to the Clinical Operations department (non –interventional studies, Phase II, III, IV trials), the issue date of the invoice is considered.

In the case of multi-year contract, the date of the payment is considered. If several payments occur within several reporting periods, each disclosure will contain payments done during the appropriate reporting period.

c) Local considerations

Same as (b) plus for Belgium taking into account the stipulations in the Belgian national legislation (Belgian Royal Decree dated 14/06/2017 for execution of the 'Sunshine Act'): *for instance, Transfers of Value made in 2017 to Belgian HCPs/HCOs required uploading of the report by end of May 2020 for public disclosure at the betransparent.be platform by July 2020.*
For Luxembourg, disclosure is required by 30 June 2020.

5.2 Calculation rules

a) EFPIA requirements

Pursuant to Section 3.01 of the Disclosure Code *"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 itemized disclosure shall be made available upon request to the relevant Recipient, and/or the relevant authorities."*

According to EFPIA FAQ Question 1.01 - 1, "*The disclosure obligation pertains to Transfers of Value made by Member Companies, not to the resulting income / benefit to the HCP/HCO."*

b) Ipsen Group considerations

<u>The general calculation including no-shows / cancellation fees and group expenses treatment</u>

- The costs of "no-shows" (occurring when a HCP fails to attend a meeting they were supposed to) - Two situations can occur:
  1. Ipsen booked and paid in advance for a forecasted number of HCPs/HCOs
     - Calculated Amount = (Actual cost / Forecasted number of attendees, including Ipsen staff and non-HCP attendees)
     - Disclosure: Calculated Amount, disclosed on actual attendees
     - *Example: Ipsen has paid in advance 100 € for 8 HCPs and 2 Ipsen staff.*
       Only 6 of the 8 HCPs have actually attended the meeting.
       For each of these 6 actual HCPs attendees, the calculated amount (100 € / (8+2) = 10 €) is disclosed.
       No cost is disclosed under the name of the "no-shows", nor on the Ipsen staff.
  2. Ipsen paid fees according to the number of attendees
     - Calculated Amount = (Actual cost / Actual number of attendees, including Ipsen staff and non-HCP attendees)
     - Disclosure: Calculated Amount, disclosed on actual attendees.
     - *Example: A meeting is organized with 11 HCPs and 2 Ipsen staff.*
       Only 8 of the 11 HCPs have actually attended the meeting.
       The final invoice paid by Ipsen for this meeting is 100 €.

For each of the 8 actual HCPs attendees, the calculated amount (100 € / (8+2) = 10 €) is disclosed.
No cost is disclosed under the name of the "no-shows", nor on the Ipsen staff.

- Cancellation fees (penalty for annulling a confirmed arrangement or order) are not disclosed.

The treatment of VAT and other taxes

- Countries can disclose the « net amount » or the « gross amount » (see local considerations).

The final benefit versus ToV (linked above to the question 1.01 -1) HCPs / HCOs

- *Please refer to 5.2 a).*

c) Local considerations

Same as (b) + for Belgium since stipulations in the Belgian national legislation (Belgian Royal Decree dated 14/06/2017 for execution of the 'Sunshine Act'), all amounts are to be quoted in € excluding VAT.

5.3 Currency

a) EFPIA requirements

According to the Question 19. of the EFPIA FAQ Batch 1, *"EFPIA Member Associations will decide on the currency to be used for the relevant disclosures. It is likely to be the local currency (i.e. the currency of the country where the Recipient has his/her principal activity) or the Euro.*
Where Transfers of Value are made in a different currency than the currency in which the disclosure is made, Member Companies should describe in their Methodological Notes how currency conversions are handled".

b) Ipsen Group considerations

The currency of the disclosed amounts in the report is the currency of the country where the disclosure is made, even if the payment of the ToV has been done in a different currency.
In the case where ToV have been made in a different currency, the Ipsen Transparency systems have calculated the disclosed amount in local currency, based on the daily exchange rate effective on the date of the ToV.

c) Local considerations

Belgian & Luxemburg disclosure is done in EUR (€) currency.

6 FORM OF DISCLOSURE

6.1 Language of disclosure

a) EFPIA requirements

Pursuant to Section 2.06 of the Disclosure Code *"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)."*

b) Ipsen Group considerations

The report is published in both local language and English.

c) Local considerations

The report will be published in Dutch and French for Belgium, French for Luxemburg.

6.2 Disclosure platform

a) EFPIA requirements

According to the Section 2.04 of the Code: "*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."

Moreover, EFPIA FAQ Question 2.05 adds "*If a Member Company is not resident or does not have a subsidiary or an affiliate in the country where the Recipient has their principal practice, the Member Company should disclose such Transfer of Value in a manner consistent with the national code of the country where the Recipient has their practice*."

b) Ipsen Group considerations

Ipsen is making the disclosure report available on the platform or website as required by the local Transparency Disclosure Code, whether it is the company's website or a central platform.
In addition to the disclosure on local platform or local website, all the local reports disclosed by Ipsen are also publicly available via the Corporate website: www.ipsen.com
In the particular case where the local transparency code requires that the disclosure report is made available in on company's website and Ipsen has no direct presence in this country, therefore no local website, the disclosure of the ToVs to the HCPs/HCOs will be made available on the Corporate Ipsen website only.

c) Local considerations

1. The disclosure report for Belgium will be made available in the legally set platform betransparent.be
2. The disclosure report for Luxemburg will be made available in the dedicated page of the Ipsen Corporate website: www.ipsen.com and cross-referenced as requested by the Association Pharmaceutique Luxembourgeoise.

7 DISPUTE MANAGEMENT

a) EFPIA requirements

Pursuant to Section 3.01 of the Disclosure Code *"Individual Disclosure", "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."*

Pursuant to Section 2.06 of the Disclosure Code *"Privacy law & regulations", "There is no prescribed process for Member Companies to follow for handling HCP or HCO enquiries, nor are they obliged under the Code to validate data with HCPs or HCOs before disclosure. However, as a matter of good practice, companies are advised to put in place procedures for handling enquiries and for making HCPs / HCOs aware of the content of upcoming disclosures."*

According to EFPIA FAQ Question Preamble - 2, "*A Member Company should bear in mind the obligation under Section 3.01 to be able to demonstrate that its disclosures were accurate at the time they were made in the event of a complaint and be able to respond to requests to the relevant Recipient or the relevant authorities."*

b) Ipsen Group considerations

Pursuant to Directive 95 46/EC, data subjects (HCP and HCO) have the following rights:
"The data subject's right of access to data […] the right to obtain from the controller:
(a) without constraint at reasonable intervals and without excessive delay or expense:
confirmation as to whether or not data relating to him are being processed and information at least as to the purposes of the processing, the categories of data concerned, and the recipients or categories of recipients to whom the data are disclosed;
communication to him in an intelligible form of the data undergoing processing and of any available information as to their source;
knowledge of the logic involved in any automatic processing of data concerning him at least in the case of the automated decisions referred to in Article 15(1);
(b) as appropriate the rectification, erasure or blocking of data the processing of which does not comply with the provisions of this Directive, in particular because of the incomplete or inaccurate nature of the data;
(c) notification to third parties to whom the data have been disclosed of any rectification, erasure or blocking carried out in compliance with (b), unless this proves impossible or involves a disproportionate effort.

The data subject's right to object: […] (a) object at any time on compelling legitimate grounds relating to his particular situation to the processing of data relating to him, save where otherwise provided by national legislation. Where there is a justified objection, the processing instigated by the controller may no longer involve those data;
(b) to object, on request and free of charge, to the processing of personal data relating to him which the controller anticipates being processed for the purposes of direct marketing, or

to be informed before personal data are disclosed for the first time to third parties or used on their behalf for the purposes of direct marketing, and to be expressly offered the right to object free of charge to such disclosures or uses."

In order to be compliant with the data privacy regulation, Ipsen has implemented a responsive dispute process. Each question or claim is centralized and followed up. After a thorough analysis of the inquiry, all applicants will receive a response via a letter signed by Ipsen.
Objectives of the process are to:

- Answer to HCP/HCO claims and questions within a reasonable timeframe with respect to local regulation,
- Have an organized arbitration in case of litigation (Ipsen local Transparency Committee, consisting of the Local Transparency Manager (LTM), the Sub-Certifier(s) and the General Manager),
- Ensure an update of the Transparency report, taking into account legal constraint in less than 2 months.

The dispute process is available to all HCP/HCO only through the "Dispute letter template" that is downloadable from the Ipsen website. Before providing any information in response to a question, Ipsen will ask for identity evidence of the applicant.

c) Local considerations

- Queries received from HCPs or HCOs will be answered as soon as possible and no later than within 2 months following the receipt of the query. Queries can be sent to transparency.belux@ipsen.com.
- However, the platform 'betransparent.be' is being managed by the body officially appointed through local Belgian legislation. If needed, a dispute letter/template can be found on the Ipsen Corporate website: www.ipsen.com and sent to: transparency.belux@ipsen.com

8 APPENDICES

8.1 EFPIA Disclosure Code

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

Adopted by the EFPIA Statutory General Assembly of 24 June 2013, and requiring implementation in national codes by 31 December 2013

FINAL EDITED VERSION
Following General Assembly Approval

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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]

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[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.

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 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.

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 it 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]

[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.

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 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

Model of a Standardised Template
For reference

Insert template

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).

8.2 EFPIA Disclosure Code FAQ

EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations

(EFPIA HCP/HCO DISCLOSURE CODE)

Frequently Asked Questions – FAQ

It is understood that unless there is a strong legal mandatory requirement, no deviations from the EFPIA HCP/HCP Disclosure Code should be envisaged by the Member Associations, which were required to transpose the Code in full by 31 December 2013.

These FAQs provides clarification and interpretation of the EFPIA Code provisions. They are provided as guidance and in addition relevant national association codes and related guidance have to be considered.

It is recommended that companies carefully consider the content of their Methodological Notes to ensure they address some of the complex situations that cannot always be addressed in FAQs. Companies are also advised that, where there are doubts, the reasonable solution is to disclose unless the Transfer of Value is clearly out of scope. *Companies would not be criticized for over-disclosure, but are likely to be in breach of national codes for under-disclosure.*

This document replaces previous drafts and editions
Where the question is from previous drafts released, the batch or list and question number has been added for ease of reference (e.g. Batch/List x, Q.x).

Points of Clarification and Definitions

Transposition Expectation

The EFPIA Codes set out the minimum standards, which must apply to all countries with an EFPIA Member Association. The Member Associations are required to transpose the EFPIA Codes in their national codes, in line with applicable laws and regulations.

The Member Associations are expected:

- Where possible, to transpose the EFPIA Code in full (without deviations);
- Deviations from the EFPIA Code should not go beyond mandatory national laws & regulations;

Issues that will arise at the time of disclosure – i.e. potential implementation issues – should not be a barrier, to the transposition of the Code. Such issues, e.g. protection of personal data ("privacy" regulations), may be dealt with during the implementation phase. The Member Company (who owns the data) will be responsible to gain consent of the Recipient of a Transfer of Value, and will make its own decision on how it will comply with the Code.

However, with a view to simplifying the process of collecting consent from individual HCPs (and in some case, HCOs), EFPIA will support Member Associations in countries where consent issues may constitute a major hurdle to the implementation of the EFPIA Code in full.

Template

At its 18 December 2013 meeting, the Board acknowledged the value of making the Disclosure Template mandatory, which will therefore be referenced as "The Template". Deviations would only be acceptable where legal requirements justify that the EFPIA Code is not transposed in full, and therefore, in a given country, a single template shall apply.

For good understanding, the Template is made in a manner, which shows how the publications should be made. Nevertheless, other templates could be imposed by the relevant national authorities/codes, for instance for uploading data onto central platform.

The Template in place has been latest updated on 11 December 2013 (rev1).

Research and Development

Where questions arise relating to potential Research and Development activities, companies should first consider if the activity fulfils the definition of Research and Development, set out below:

- If the answer is yes, then the disclosure should be on an aggregate basis, as set out in Section 3.04, under the category "Research and Development Transfers of Value".
- If the answer is no, then the Member Company should declare, as required, on an individual basis as set out in Section 3.01.

The Disclosure Code defines "**Research and Development Transfers of Value**" as 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*).

Definitions in the relevant legal and regulatory instruments

i. Non-clinical studies as defined in the OECD Principles on Good Laboratory Practice

The OECD Principles on Good Laboratory Practice (as latest revised in 1997) define non-clinical studies as follows (Section I – 2. Definitions of Terms; section 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 complete reference, see www.oecd.org

ii. Clinical trials (as defined in Directive 2001/20/EC)

The EU Directive 2001/20/EC (Article 2(a)) defines clinical trials as:
any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmaco-dynamic 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.

For complete reference, see http://eur-lex.europa.eu

iii. Non-interventional studies

The EU Directive 2001/20/EC (Article 2(c)) defines non-interventional trials as:
study(ies) 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 studies are subject to the provisions of the EFPIA HCP Code (Section 15.01).

Privacy law & regulations

Article 7 of Directive 95/46 EC on "Data Protection" states that Member States shall provide that personal data may be processed only if:

a) the data subject has unambiguously given his consent, or
b) processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract, or

c) processing is necessary for compliance with a legal obligation to which the controller is subject, or
d) processing is necessary in order to protect the vital interests of the data subject, or
e) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller or in a third party to whom the data are disclosed, or
f) processing is necessary for the purposes of the legitimate interests pursued by the controller or by the third party or parties to whom the data are disclosed, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection.

In application of these provisions, Member States have laid out the conditions for disclosure of personal data. Therefore, Member Companies are referred to national laws (including jurisprudence) in place, and will organise their disclosures in line with these laws and regulations.

As a general rule, each Member Company will therefore need to obtain the consent of each HCP (or HCO when privacy regulation also apply to organisations) to disclose their personal data. Where Transfers of Value to an HCP (or HCO, as applicable) occur in the context of a contract, the contract provides a ready mechanism to obtain the data subject's consent to the processing of his/her personal data. As a matter of good practice, companies should create and retain evidence showing that the consent was indeed given.

A company (as a data controller) may have legitimate interest in disclosing data – for instance: to promote confidence in its relationships with HCPs. This legitimate interest must be outweighed by the data subject's interests. The legal basis is significantly strengthened when a data controller can say that consent had been obtained.

There is no prescribed process for Member Companies to follow for handling HCP or HCO enquiries, nor are they obliged under the Code to validate data with HCPs or HCOs before disclosure. However, as a matter of good practice, companies are advised to put in place procedures for handling enquiries and for making HCPs / HCOs aware of the content of upcoming disclosures.

The Executive Committee has asked EFPIA to provide additional support to Member Associations and local operations in countries where consent issues may constitute a major hurdle to implementation of the EFPIA in full. EFPIA will intensify its efforts throughout 2015 towards resolution of outstanding hurdles.

Competition & regulation

The Code was drafted with the support of legal counsel, taking into account the relevant competition law considerations. This support gives EFPIA sufficient comfort as to conformity of the Code with applicable EU legislation.

In some countries, self-regulation is submitted to prior authorisation of Competition Authorities. For instance, in Germany, the Bundeskartellamt has approved the FSA Code. This gives additional comfort about the appropriateness of the EFPIA Code.

Cross Border Payments

Disclosures of Transfers of Value should be made pursuant to the national code of the country of the Recipient's Principal Practice (i.e. its business address, place of incorporation or primary place of operation in Europe – "Principal Practice").

The objective of the EFPIA Disclosure Code is to require transparency of Transfers of Value to ensure that this information can easily be found by the searching patient or other interested stakeholder. The address where the HCP practices or HCO is located should be used as the reference when determining in which country the data should be disclosed.

Therefore, Transfers of Value that fall within the scope of the EFPIA HCP/HCO Disclosure Code should be disclosed in the country where the Recipient has their Principle Practice in Europe, whether the Transfer of Value occurs in or outside of that country.

Each Member Company will clarify in its Methodological Note how cross-border Transfers of Value are being disclosed.

Deviations and Variations

In principle, Member Associations are asked to transpose the Code in full and in a manner consistent with applicable laws and other applicable legal requirements. Member Associations are required to inform EFPIA of reasons why national disclosure requirements differ from those required under the EFPIA Code. Such differences shall be clearly and conspicuously so identified.

Unless there are strong legal mandatory requirements, it is expected that Member Associations will transpose the Code in full i.e. without deviations. In each country, Member Companies will be required to comply with the disclosure requirements applicable in that country.

With support of an independent consultant (ICE Ltd), EFPIA has conducted an in depth comparative analysis of all national codes versus the Code. Follow-up actions have been discussed and reviewed with the relevant Member Associations. The table below summarises the outstanding issues reported to the Board / Executive Committee.

DISCLOSURE CODE TRANSPOSITION STATUS – Actions Required

Latest update: 09 December 2014

Comment	Countries
TRANSPOSITION COMPLETED (21)	Austria, Belgium, Bulgaria, Croatia, Cyprus, Estonia, Germany, Greece, Hungary, Italy, Lithuania, Malta, Poland, Russia, Serbia, Slovenia, Spain, Sweden, Switzerland, Turkey, UK.
Outstanding issues with **CENTRAL PLATFORMS** (2) - being finalized	Ireland, Slovakia
Outstanding issues with **TEMPLATE** (3)	Ireland, Slovakia, Ukraine
DEFINITION OF HCP (2)	Czech Republic, Finland
LEGISLATION IN PLACE (8) – assessing how to close the gaps	Denmark, France, Latvia*, the Netherlands, Norway, Portugal, Romania*, Slovakia

Country	* Outstanding issues
Latvia	Legislation being past (no direct sponsorship to HCPs to attend Congress)
Romania	Legislations passed in February 2014, but outstanding implementation measures, making law inoperable – ARPIM's Code shall apply

Source: ICE Ltd

Member Associations are finalising/ fine-tuning transposition of the EFPIA Disclosure Code: variations and deviations have been identified, and follow-up actions are being completed with a view to ensuring consistency among countries, as appropriate. However, it has become clear that additional issues, clarifications, etc. will become apparent as companies move through implementation and these will be addressed as they come up – attempting to resolve all details (that are often company-specific) upfront will unduly delay/ increase complexity.

For good understanding:

- A VARIATION is a provision in a national code that is stricter than the provision in the Code – in such cases, the Code is transposed in full, but includes stricter standards (such as: an extended scope (for instance to include all OTC) or additional discloser categories).
- When, because of mandatory national regulations Member Associations cannot transpose the Code in full, the "gaps" are considered DEVIATIONS under Article 4.02 of the Code. EFPIA is preparing detailed reports for those countries where there are such DEVIATIONS, and will ensure they are kept to a minimum.

FREQUENTLY ASKED QUESTIONS
Submitted by the Membership
Questions follow the order of the Code Sections & Articles

PREAMBLE

Question Preamble - 1 *(Batch 1 Q.3 re-worded – previously List 1 Q 1):* **What efforts has EFPIA taken to ensure that transparency can be achieved without sacrificing the legitimate privacy interests of healthcare professionals?**
See also the "Point of Clarification & Definitions" on Privacy Law & Regulations", and questions 1 & 2 of the Section 3.02

Answer: When **transposing** the EFPIA Disclosure Code into national codes, each Member Association should obtain the necessary legal advice as to applicable laws and regulations in its country.

EFPIA has engaged (and will continue to engage) with scientific and medical societies at the European level with a view to ensuring full understanding of the industry's standards. Member Associations are expected to engage in similar discussions at the national level. In some countries, this has/may lead to co-creation of disclosure platforms with HCPs/HCOs *(see also section 2.04)*.

Question Preamble - 2 *(Batch 1 Q.1 – previously List 2 Q 29)*: **Will there be a formal process for HCP or HCO enquiries? How long will companies have to respond to HCP or HCO requests to confirm or validate data?**

Answer: It is strongly recommended that Member Companies' undertakings in their relationships with HCPs/HCOs are clearly set out in a written contract with the HCP/HCO. This recommendation is reflected in a footnote to Section 4.01 of the EFPIA Disclosure Code, as follows:

> *When making a Transfer of Value to an HCP/HCO, and in their written contracts with HCPs/HCOs, Member 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.*

A Member Company should bear in mind the obligation under Section 3.01 to be able to demonstrate that its disclosures were accurate at the time they were made in the event of a complaint and be able to respond to requests to the relevant Recipient or the relevant authorities.

Question Preamble - 3 *(Batch 1 Q.2 - previously List 2 Q 31)*: **Have any criteria or conditions been established for the types of events that would require Member Companies to restate or amend their disclosure reports? Where is the data expected to be amended: only in publicly viewable reports or also in the source systems / reporting databases**?

Answer: When a Member Company is aware of inaccuracies in its public disclosure, it must, as a matter of principle, correct that information. The company will decide if amendments to its source

systems or reporting databases are required. This may depend on the type and significance of the inaccuracy.

Question Preamble - 4: *(Batch 1 Q.61 – previously List 2 Q 30)* **To ensure consistency among Member Companies, will EFPIA or EFPIA's Member Associations provide HCP and HCO master data lists (including unique identifiers, names, addresses, etc.)?**

Answer: No. EFPIA will not be developing a unique database of HCPs / HCOs.

Member Associations at the national level may develop such databases; however, Member Associations are under no obligation to do so. Member Associations may also recommend the use of the existing databases or otherwise provide additional clarification.

In any event, Member Companies have to ensure that each Recipient is identified in such a way that there is no doubt as to the identity of the HCP/HCO benefiting from the Transfer of Value. Therefore, it is expected that each Member Company will develop its own *unique identifiers*.

APPLICABILITY OF THE CODE

Question Applicability - 1 *(Batch 2 Q 32 – previously List 2 Q 32):* **How should Member Companies involved in a co-promotion agreement disclose any Transfers of Value made under the agreement? Should disclosure align with the % split of cost-sharing set out in the agreement?**

Answer: Each Member Company involved in the co-promotion agreement will disclose their own Transfers of Value. The co-promotion agreement is not relevant in this case.

Question Applicability - 2 *(Batch 2 Q.2 – previously List 1 Q 3):* **What should companies do if they believe that disclosure requirements may pertain to commercially sensitive or other information not suitable for being disclosed by Member Companies? Will EFPIA provide additional guidance with respect to such situations?**

Answer: The Methodology Note that each Member Company will add to its disclosures is designed to ensure it is clear how data has been managed such that companies do not have to publish what would be seen as commercially sensitive, in compliance with relevant laws and regulations.

The content of the Methodology Note is the exclusive responsibility of each Member Company, and EFPIA will not provide additional guidance.

Question Applicability - 3 *(Batch 1 Q.7 – previously List 1 Q 4):* **Once a Member Association has transposed and adopted a local version of the Code, should Member Companies follow the national code (rather than the EFPIA Code) in each country in which they operate, even if a particular country has not transposed all of the EFPIA requirements?**

Answer: It is a condition of EFPIA membership that Member Associations adopt **all** EFPIA Codes **in full**, and that Member Companies comply with the national codes (even in those countries where they are not a direct member of the relevant Member Association). EFPIA has the right to exclude

any member – corporate or association – that does not meet its obligations under the EFPIA Codes or otherwise jeopardise achieving the goals pursued by EFPIA.

Where a Member Company operates in a jurisdiction where a Member Association has transposed the EFPIA Code into its national code by the relevant deadline but with a deviation agreed by EFPIA, such Member Company will be required to comply with the Member Association's Code.

Where a Member Company operates in a jurisdiction where a Member Association has **failed** to transpose the EFPIA Code into its national code by the relevant deadline, such Member Company will be required to comply with the EFPIA Code **directly** in the country concerned – i.e. the EFPIA Code would then have "direct effect" in such country *(see Applicability, § 6)*.

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 *(see Applicability, § 7)*.

As a general rule, it is consider 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 arrangements, as appropriate.

ARTICLES

Article 1: Disclosure Obligation

Section 1.01: General Obligation

Question 1.01 - 1 *(Batch 1 Q.9 – previously List 1 Q 5)*: **Does the reporting obligation apply to value/cost of Transfers of Value made by a Member Company, or should the disclosure focus on the income / benefit that the Transfer of Value constitutes for a HCP/HCO?**

Answer: The disclosure obligation pertains to Transfers of Value made by Member Companies, not to the resulting income / benefit to the HCP/HCO.

Question 1.01 - 2 *(Batch 2 Q.21 – previously List 2 Q 33):* **When Transfers of Value are made through an intermediary, are Member Company required to disclose them on an individual basis? Will such disclosure require consents of the intermediary as well as of the HCP / HCO who is the ultimate beneficiary?**
See also questions 3 & 6 of Section 2.05

Answer: As a rule, Transfers of Value and payments should be disclosed on an individual basis, with aggregate disclosure being permitted as an exception.

Where an intermediary (third party) represents or acts on behalf of a Member Company, it must ensure that its respective obligations are fulfilled. It is recommended that the Member Company makes the necessary arrangements with the third parties, in a written contract, as to how its obligations under the EFPIA Codes will be fulfilled.

> For reference: The EFPIA HCP Code states: "*Member Companies shall also be responsible for the obligations imposed under any relevant Applicable Code even if they commission other parties (e.g., contracted sales forces, consultants, market research companies, advertising agencies) to design, implement or engage in activities covered by the Applicable Code on their*

behalves. In addition, Member Companies shall take reasonable steps to ensure that any other parties that they commission to design, implement or engage in activities covered by the Applicable Code but that do not act on behalf of the Member Company (e.g., joint ventures, licensees) comply with Applicable Codes."

Where the intermediary is a professional conference organiser (PCO), Member Company should declare the Transfers of Value in the appropriate category in the name of the sponsored HCO. This is because in such case, the Member Company provides the sponsorship through the PCO, but with the intention to sponsor the HCO.

Question 1.01 - 3 *(previously List 3 Q 55)*: **How should Member Companies represented by (independent) distributors handle Transfers of Value through such distributors?**
See also questions 2 of Section 1.01

Answer: If this distributor is involved in the promotion of medicines on behalf of a Member Company in an EFPIA country, then its activities are reportable by the Member Company in that country. As such, the Member Company must ensure, via contracts or other means that the distributor complies with the relevant local code.

Section 1.02: Excluded Disclosures

Question 1.02 - 1 *(previously List 3 Q 48):* **Why are specific Transfers of Value exempted from the disclosure obligation?**

Answer: The disclosure categories are determined in Article 3 of the Code. They cover interactions between pharmaceutical companies and HCPs/HCOs, except those categories for which limitations are included in the HCP Code, i.e.: activities relating solely to OTCs; samples; meals and drinks (that are subject to specific prescriptions and to thresholds set in the national codes); and informational & educational materials and items of medical utility.

Question 1.02 - 2 *(Batch 2 Q.4 – previously List 1 Q 6):* **Where companies have Non-Medical, Over-the-Counter (OTC), Diagnostics and other Healthcare Divisions, what should they declare under the Code?**

Answer: The Code aims at disclosing monetary values attached to activities that are self-regulated by the EFPIA HCP Code, which governs activities relating to prescription-only medicines (POM).

The "legal status" (POM, OTC, etc.) of a medicine is defined in the pharmaceutical regulation, and may differ from one country to the other.

In principle, the Disclosure Code is linked to POM. The Code excludes Transfers of Value that:

- are solely related to over-the-counter medicines;
- are not listed in Article 3 of the Disclosure Code (e.g. informational or educational materials and items of medical utility; meals and drinks; medical samples);
- are part of ordinary course purchases and sales of medicinal products.

Transfers of Value relating to a group of products that includes a POM (e.g. combination products/diagnostics and medicinal products) should be reported in total following the disclosure requirements of the Code.

Member Companies should include additional clarification on how such situations have been managed, in their Methodological Note.

Question 1.02 - 3 *(Batch 2 Q 34 – previously List 2 Q 34)*: **Section 1.02 of the Code states that Transfers of Value that are solely related to over-the-counter medicines (OTCs) are excluded from the disclosure obligations under the Code.**
Does that mean that any Transfers of Value to HCPs / HCOs related to OTCs that can also be prescribed need to be disclosed?

Answer: Transfers of Value that are solely related to over-the-counter medicines are excluded from reporting.

However, when a Member Company promotes an over-the-counter medicine with a prescriber, with the intention to generate prescription, then the Member Company should consider disclosing the Transfers of Value attached to this activity. Member Companies should include additional clarification on how such situations have been managed, in their Methodological Note.

Question 1.02 - 4 (Section 1.02): **Shall the investigational compounds and biological sample for a study have to be disclosed?**

Answer: As the medical samples are excluded from the disclosure obligations, the same principle should apply to investigationnal compounds and biological sample for study.
The investigationnal compounds and biological sample are subject to provisions under the Clinical Trials Directive, and their use will submitted to Clinical Trials approval processes.

Article 2: Form of Disclosure

Section 2.01: Annual Disclosure Cycle

Question 2.01 - 1 *(previously Batch 2/ List 2 Q35, and List 3 Q 71):* **How should expenses concerning congresses be disclosed when dates of expenses differ from a date when a congress takes place (e.g. advance payments, payments upon reservation to travel agencies and payments for air flights)?**

Answer: Member Companies are required to disclose Transfers of Value as and when they are made. They would therefore be expected to disclose Transfers of Value in a given year within 6 months after the end of the relevant reporting period. *Thus payments made in 2015 will have to be disclosed by 30 June 2016.*

It is expected that Member Companies will apply the relevant company accounting principles. However, the principles applied shall not allow Transfers of Value not to be disclosed, for instance by changing the principles from one year to the next.

Member Companies are expected to provide information on how their disclosures are managed in their Methodological Note, where they can also provide additional clarification on Transfers of Value recognition.

Section 2.02: Time of Disclosure

Question 2.02 - 1 *(Batch 1 Q.11 – previously List 2 Q 36)*: **What are the obligations of a Member Company when a Recipient's consent is revoked? Is it sufficient to stop disclosing the relevant information on an individual basis going forward or are Member Companies required to amend / restate historical reports that have already been published? Are Member Companies required to remove all such information from all source systems, reporting databases, etc.?**

Answer: The relevant data privacy and other (local) laws will apply to such cases. Member Companies will need to assess the implications of such revocation on a case-by-case basis and are encouraged to seek independent legal advice.

However, depending on any (local) legal implications of revocation, companies must retain data relating to specific transactions and report such Transfers of Value on an aggregate basis, in line with applicable national law and regulations.

Section 2.04: Platform of Disclosure

Question 2.04 - 1 *(Batch 2 Q 37 – previously List 2 Q 37):* **Methodological Note – where a central disclosure platform is in place, should the Member Companies be obliged to publish their Methodological Notes the same central platform or will it be sufficient if their Methodological Note are published on their own company website?**

Answer: It would be logical that the Methodological Notes can be accessed along the data they are supposed to clarify. How this is technically achieved will be decided at national level, as part of the "rules" applicable to the central platform.

Since the Methodological Notes are meant to explain how companies have constructed their data, it is obvious that companies take responsibility for the content of their methodological notes.

Section 2.05: Applicable National Code

Question 2.05 - 1 *(previously List 3 Q 66):* **Is the Member Company required to disclose in accordance to local regulations on one site, and in accordance with EFPIA recommendations on another site?**

Answer: Member Companies can make their disclosures either on a relevant website of the Member Company, or on a central platform. Member Companies will not be requested to duplicate disclosures. However, the information shall be accessible in the countries where the Recipients have their principal practice.

It may be helpful for Member Companies to make clear, on their own websites, where their disclosures can be accessed if they are not on the company's website where the Recipients have their principal practice (e.g. central platform, government website, the company's head offices website or another website of the company). Whatever the option the Member Companies all its Transfers of Value to a given Recipient shall be found in the same place.

Question 2.05 - 2 *(Batch 1 previously Q.56 – previously List 2 Q 38):* **Should disclosures pursuant to the Code also be made in respect of secondary (that is, not the principal) practice or professional address?**

See also questions 2 of Section 1.01 & 6 of Section 2.05

Answer: The Code requires disclosure in the country where the Recipient has its Principal Practice. All Transfers of Value to a given Recipient will be disclosed in the country where this Principal Practice is located.

As a principle, no disclosure would be required in the secondary (or other) country of practice of a given Recipient, unless this would significantly enhance transparency (for example, where the Principal Practice is in the country that is not within EFPIA's jurisdiction). Member Companies will provide additional clarification in their Methodology Notes if required.

Question 2.05 - 3 *(Batch 1 Q.15 – previously List 1 Q 8):* **When a consultant is used in another country, where should this be disclosed?**

Answer: Transfers of Value to a HCP / HCO whose practice, professional address or place of incorporation is in Europe, are required to be disclosed in the country where the **Recipient has its principal practice**, pursuant to the national code of the country where the Recipient's principle practice is located, whether the Transfers of Value occur in or outside that country.

The Code requires transparency of Transfers of Value based on the country of primary/principal practice, which will ensure that the searching patient or other interested stakeholder can easily find this information. The physical address where the HCP practices or HCO is located should be used as the reference when determining in which country the data should be disclosed.

Each Member Company will clarify in its Methodological Note how cross-border Transfers of Value are being disclosed.

Examples:

- A Member Company's US headquarters sponsoring a HCP whose practice is in Sweden for an activity in Germany will be required to disclose the Transfer of Value under the name of the Recipient HCP in Sweden (following the applicable laws, regulations and the national code in Sweden).
- An Italian Member Company sponsoring a HCO located in Italy to provide expertise to a hospital in Tunisia will be required to disclose the Transfer of Value in the name of the Recipient HCO in Italy (following the application of Italian laws, regulations and national codes in Italy).
- A Spanish Member Company sponsoring a US expert for participation in an advisory board in Argentina is not required to disclose that Transfer of Value under the EFPIA Code. However, disclosure may be required in other jurisdictions, including in the US under the "Sunshine Act".

Question 2.05 - 4 *(Batch 1 Q.14 – previously List 1 Q 7):* **Which legal entities are required to make disclosures? Are disclosures by the parent company sufficient or are local affiliates required to make their own disclosures? Can affiliates of the same company in one country each disclose part of the Transfers of Value?**

Answer: The EFPIA Code states that each Member Company will decide how to organise its disclosures, either at a central or local level, unless the national code fixes the platform of disclosure. However, disclosure should conform to the national code requirements and relevant disclosures should be publicly accessible in the country where **the Recipient has their practice.**

If a Member Company is not resident or does not have a subsidiary or an affiliate in the country where the Recipient has their principal practice, the Member Company should disclose such Transfer

of Value in a manner consistent with the national code of the country where the **Recipient has their practice**.

When a Member Company has separate organisations within the same country, it will decide on the most appropriate legal entity for such disclosures. All Transfers of Value to a given Recipient should be disclosed in "one place" – disclosure in the country where the Recipient has their practice must cover all Transfers of Value made to the same HCP/HCO, irrespective of where they occurred (i.e. whether in or outside of the country where the Recipient has its practice).

Regardless of the approach used (i.e. disclosure on the parent company's website or at an affiliate level), disclosures must be made in compliance with the national code applicable in the country where the Recipient has its practice, in line with applicable national laws and regulations.

In the event that several parts of the same Member Company generate payments in the same country to the same HCPs, these payments should be disclosed on the same website, and cannot be split, on the basis of a different part of the company engaging.

Moreover, disclosures have to take into account local arrangements and this is particularly relevant if the Member Association requires disclosure by means of a central platform.

Question 2.05 - 5 *(Batch 2 Q.8 – previously List 1 Q 9):* **A US affiliate of a company that is an EFPIA direct member makes a Transfer of Value to a (Spanish) HCP. Is it understood that this Transfer of Value has to be captured according to the (Spanish) Code, and the (Spanish) affiliate, if any – not the US one – would be responsible for reporting the Transfer of Value? Which entity would be sanctioned?**

Answer: Disclosures shall be made pursuant to the national code of the country where the Recipient has its principal practice. Unless the platform for disclosure is fixed in the national code or imposed by national law, the Member Company will decide whether the disclosure will be made on the companies head office website or each affiliates website. But it must be possible for the public to easily find and access the disclosed information in the country where the Recipient has its principal practice.

In case the Member Company is found in breach of the applicable code, the Member Association of the country where the Recipient has its principal practice – in this instance Spain – would sanction the Spanish company as this is within their jurisdiction.

For example, in the UK it is a clearly established principle that the UK Company is responsible under the ABPI Code for the activities of overseas companies in the UK.

Question 2.05 - 6 *(Batch 1 Q.16 –previously List 1 Q 10):* **Are non-European companies – e.g. a US company – required to disclosure Transfers of value to HCPs/HCOs in Europe?**

Answer: Any company that is a corporate member of EFPIA is required to comply with the EFPIA Codes. The Code requires, for example, that Transfers of Value made by the US part of a Member Company to HCPs/HCOs with their practice in one of the 33 countries covered by EFPIA should be disclosed.

The EFPIA Code applies to all EFPIA members as defined under the section "Applicability of The Code", which covers:

- Corporate Member Companies;
- Members of EFPIA Specialised Groups: (i) European Bio-pharmaceutical Enterprises
- (EBE); and (ii) Vaccines Europe (VE); and

- Member Companies of Member Associations that are not directly members of EFPIA.

For EFPIA direct membership (i.e. corporate members), separate entities belonging to the same multinational company – which could be the parent company (e.g. the headquarters, the principle office, or the controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organization – are deemed to constitute a single company, and as such all these entities are required to comply with the EFPIA Codes.

Question 2.05 - 7 *(previously List 3 Q 69):* **Are payments made to a European-based HCO from outside Europe required to be disclosed? If so, which exchange rate should be used?**
See also questions 2 of Section 1.01 & 3 of Section 2.05

Answer: Yes, Transfers of Value to HCOs, even when made from outside Europe, will require disclosure in line with the national code of the country of incorporation in Europe. *The 33 countries covered by the Code are listed in the footnote on page 4 of the Code.*

Member Companies are expected to provide information on the treatment of currency aspects in their Methodological Note.

Section 2.07: Documentation and Retention of Records

Question 2.07 - 1 *(Batch 1 Q.20 – previously List 2 Q 39)*: **What qualifies as "relevant records" that Member Companies should maintain? Does this refer to all source system transactions, reporting databases, etc. relating to individual HCPs and HCOs? Does this also include hard copies of supporting documents, such as contracts, receipts, reports, etc.?**

Answer: The definition of "relevant records" depends on the nature of a Transfer of Value. In the event of a enquiry / inquiry / complaint, a Member Company should be able to demonstrate that its disclosures were accurate at the time they were made and has to be able to respond to requests of the relevant Recipient or authorities under Section 3.01 in line with applicable law and regulations, including data protection laws (including in regard of retention of information / documents).

The requirements of the Code are in addition to any other document retention obligations that a Member Company may have.

Article 3: Individual and aggregate Disclosure

Section 3.01: Individual Disclosure

Question 3.01 - 1 *(Batch 1 Q.33 – previously List 1 Q 11)*: **What does the phrase "clearly identifiable Recipient" mean?**

Answer: Member Companies have to ensure that each Recipient is identified in such a way that there cannot be any doubt about the identity of the HCP/HCO receiving the Transfer of Value.

Question 3.01 - 2 *(Batch 1 Q.24 – previously List 1 Q 13):* **How should "related expenses" agreed to in a Fee for Service or Consultancy contract be treated?**

Answer: As a general rule, "related expenses" agreed to in a "Fees for Service" or "Consultancy" contract should be disclosed in the relevant category – i.e. the amount of the fee will be shown separately from the related expenses agreed in the Fee for Service or the consultancy contract *(see Schedule 2 Model Template, page 13 of the Code)*.

Where a service agreement / consultancy agreement is in place, incidental expenses would be, for example, the travel and accommodation cost associated with the activity and as such do not constitute part of the Fees being paid to the contracted party. When such expenses are not material (e.g. of limited value), Member Companies may not have registered them separately from the Fees. If disaggregation of expenses registered in the companies' accounts is not appropriate or easily achievable, Member Companies should explain the treatment of the "related expenses" in their Methodology Notes.

Question 3.01 - 3 *(Batch 1 Q.25 – previously List 1 Q 14):* **If services are performed in connection with a third-party congress, should the related expenses be disclosed under "Contribution to costs related to Events" or "Fees for Service and Consultancy"?**

Answer: In this example, services are performed (either by a HCP/HCO): therefore these should be declared under the "Fee for Service" category.

Question 3.01 - 4 *(Batch 1 Q.26 – previously List 1 Q 15):* **How should the hire of booths or stand space be disclosed?**

Answer: In general, the hire of booths or stand space are regulated by "Sponsorship Agreements" with HCOs or with Third Parties that manage an event.

When organised by Third Parties, the sponsorship would be considered an indirect Transfer of Value. Disclosure should be made in the country where the HCO is registered.

Member Companies are advised to include a provision relating to the consent to disclose in their "Sponsorship Agreements".

Question 3.01 - 5 *(Batch 1 Q.42 – previously List 1 Q 16):* **What Transfers of Value should be reported under "Registration Fees" paid to HCOs?**

Answer: The total amount of Registration Fees paid in a given year to a HCO should be disclosed on an individual basis (in the name of the HCO) under "Contribution to costs related to Events".

Question 3.01 - 6 *(Batch 1 Q.43 – previously List 1 Q 17):* **What Transfers of Value should be reported under "Registration Fees" paid to a HCP?**

Answer: The total amount of Registration Fees paid in a given year to a HCP who is the clearly identifiable Recipient should be disclosed on an individual basis (in his / her name) under "Contribution to costs related to Events".

Question 3.01 - 7 (Section 3.01) *(Batch 1 Q.35 – previously List 2 Q 40)*: **How should indirect sponsorship of HCPs through HCOs be disclosed?**

Answer: Indirect sponsorship of HCPs through HCOs should be disclosed under payment to HCOs as this is the Recipient of the Transfer of Value. Such disclosures would be disclosed under the

category "Contribution to Costs related to Events / Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an event".

Question 3.01 - 8 *(Batch 1 Q.44 – previously List 1 Q 18):* **What types of items should be reported under "Sponsorship Agreements" with HCOs or with Third Parties Appointed by a HCO to Manage an Event"?**

Answer: "Sponsorship Agreements" are formalised in contracts that describe the purpose of the sponsorship and the related Transfers of Value. If the contract includes "Registration fees" and "Travel and Accommodation", such Transfers of Value should be disclosed separately in the relevant categories in the name of the HCO.

Examples of activities that should as a minimum be covered under "Sponsorship Agreements":

- Rental of booths at an "Event";
- Advertisement space (in paper, electronic or other format);
- Satellite symposia at a congress;
- Sponsoring of speakers/faculty;
- If part of a package, drinks or meals provided by the organisers (included in the "Sponsorship Agreement");
- Courses provided by a HCO (where the Member Company does not select the individual HCPs participating).

Member Companies may provide additional clarification on the nature of the Transfers of Value included in this category in their Methodology Notes.

Question 3.01 - 9 *(Batch 1 Q.48 – previously List 1 Q 19):* **What types of items should be reported under "Fees for Service and Consultancy" to a HCP/HCO, directly or through a third party?**

Answer: As good practice, Member Companies will formalise such collaboration in a contract describing the purpose of Transfers of Value.

Examples of Transfers of Value that could be covered under Fee for Service and Consultancy agreements:

- Speakers' fees;
- Speaker training;
- Medical writing;
- Data analysis;
- Development of education materials;
- General consulting / advising.

The payment received by the contracting entity – which may be a HCP, a legal entity owned by a HCP (which is then a HCO) or a HCO – will be disclosed as a Transfer of Value made to that entity.

Member Companies may provide additional clarification on the nature of the Transfers of Value in their Methodology Notes.

Question 3.01 - 10 *(Batch 1 Q.21 – previously List 2 Q 41)*: **When a Fee for Services is provided to a legal entity that is owned by a physician should this be disclosed as a Transfer of Value to an HCP or an HCO? Similarly, how should a payment to a clinic where a physician is employed be disclosed?**

Answer: Disclosure is made on the Recipient's name. The Fee for Service paid to a legal entity owned by a physician should be disclosed under the name of the legal entity (considered an HCO under the Code), as this is the Recipient of the payment. Similarly, payments to a clinic, when disclosed on an individual basis, will be disclosed in the name of the clinic.

The Code requires that Member Companies will make individual disclosures in the name of the person / legal entity that receives the Transfer of Value (i.e. the Recipient).

Question 3.01 - 11 *(Batch 1 Q.28 – previously List 2 Q 42)*: **What should be disclosed under "Travel and Accommodation"?**

Answer: All expenses related to "Travel and Accommodation", such as costs of flights, trains, car hire, tolls, parking fees, taxis and hotel accommodation should be disclosed.

The Code does not require disaggregating Transfers of Value to a group of HCPs. For instance, where mass group transport (e.g. a bus / coach) is organised for an event, the cost can be disclosed on an aggregate basis and does not need to be apportioned / allocated to each individual HCP having benefitted from the "Travel and Accommodation".

Each Member Company will clarify what it includes under the "Travel and Accommodation" category in its Methodology Note.

For the avoidance of doubt, under the EFPIA Code, "meals and drinks" do not need to be disclosed as such Transfers of Value are regulated by the new provisions in the EFPIA HCP Code. National laws and regulations may have additionnal obligations.

> For reference:
> The EFPIA HCP Code requires *"each Member Association to set a monetary threshold in its national code by 31 December 2013, failing which EFPIA will set such threshold. Where the monetary value of "meals and drinks" does not exceed the applicable threshold, these will not need to be disclosed. Where Member Companies would provide or offer "meals and drinks" exceeding the applicable threshold, they would not be compliant with the EFPIA HCP Code."*

Question 3.01 - 12 *(Batch 2 Q.14 – previously List 2 Q 43)*: **In market research studies the identity of the respondents is usually not known and such research is often performed through market research companies. However, Member Companies usually know how many HCPs will participate and how much they get paid. In such case, should Member Companies disclose related Transfers of Value in aggregate?**

Answer: The Code does not require disclosure of the Transfers of Value made to market research companies when the identity of the HCPs/HCOs participating in the market research studies is not known.

As a rule, one of the basic tenets of market research is the right of the respondents to remain anonymous, which is also enshrined in market research definitions and relevant codes of conduct worldwide. However, where the Member Company knows the identity of the HCP/HCO participating in activities defined as market research the Member Company should disclose it in the "Fees for Service and Consultancy" category. In such exceptional cases, it is expected that the Member Company will secure the consent to disclosure through contract.

Question 3.01 - 13 *(Batch 2 Q.15 – previously List 2 Q 44)*: **Should a Member Company disclose the costs relating to 'stand alone' half-day meetings dedicated to therapeutic education or general scientific meetings – where the Member Company would cover the cost for the facility, lunch and lecturers? If so, under which category will these costs be reported?**

Answer: "Stand alone" events are within the scope of the Code. Transfers of Value relating to such events will be disclosed in the relevant categories (as will be the case: "Events", "Fee for Service and Consultancy", R&D Transfers of Value).

Member Companies are not obliged to disclose any logistical costs e.g. hire of Member Companies facility associated with a stand-alone event. However, Transfers of Value to participants to such events must be disclosed. *For instance, Transfers of Value for non-investigators HCPs during an investigator meeting are disclosable.*

Question 3.01 - 14 *(previously List 3 Q 61)*: **How should Transfers of Value be disclosed when a vendor is organising an event, with sponsorship of a Member Company, on behalf of more than one HCO?**
See also questions 8 & 9 of Schedule 1

Answer: If the Member Company knows which Transfers of Value each HCO has received, it should report the Transfers to the relevant HCO.

Where it would not be possible to allocate the Transfers of Value to each HCO involved in the event, it would be reasonable to consider that the HCOs have similar levels of involvement. In such case, the Transfers of Value would be divided by the number of HCOs, which would each be reported as having received their equal share of the Transfers of Value.

Information on how this is managed should be considered in the Methodological Note.

Question 3.01 - 15 *(previously List 3 Q 54):* **How should Member Companies handle the more intangible Transfers of Value relating to medical publications support which could be "in kind" transfers of value or indirect support?**

Answer: This answer need to be review by the drafting group.

Question 3.01 - 16 *(Batch 2 Q.13 – previously List 2 Q 45)*: **A HCP may ask companies to assume the translation costs into different languages of a piece he / she authored. A healthcare professional may also ask for financial support for editing or publishing such materials in a scientific journal.**
Are companies required to disclose the Transfers of Value associated to those collaboration?

Answer: It is reminded that under the new Article 9 of the EFPIA HCP Code does not permit to provide support that offset routine business practices of the Recipient. If the cost referred to in the question constitute costs relating to routine business practice such support shall not be provided, and doing so would constitute a breach of the HCP Code.

The answer to the question will therefore depend on the specifics of the situation:

- If the request was associated with an activity where there was already a service agreement in place or there was a contractual relationship between the HCP and the company, then this support would, in principle, not be considered as off-setting costs relating to routine business

practices of the HCP. In this case, this service should be included in the contract / agreement in place and disclosed accordingly, under "Fee for Service and Consultancy".
- If the request was not associated with any agreement or contractual relationship, then care should be taken to ensure, first and foremost, that the requirements of the HCP Code are complied with.

Question 3.01 - 17 *(Batch 1 Q.45 – previously List 2 Q 46)* **Indirect Payments (example): We have recently engaged a university to provide some services. We knew that the individual employee at the university who would be involved in the provision of those services was a specific doctor, but understand that none of the payment for those services will be provided to the doctor, who would simply be performing the work as part of his role and paid his normal salary.**
Is it consistent with EFPIA's interpretations to view this as a payment made to the HCO and not an indirect payment to the HCP in question?

Answer: Yes. In the example as described, the Recipient of the payment will be the HCO, and the payment should be disclosed as "Fee for Service and Consultancy" paid to an HCO

Question 3.01 - 18 *(previously List 3 Q 53):* **If an adverse event is cited within the context of a market research study, and the adverse event contains the HCP's contact details (in case of follow-up on the adverse event by the company's drug safety team or the regulator), is it required to disclose Transfers of Value to the respondent HCP taking part in the market research study?**

Answer: No, since at the point of deciding the Transfer of Value, the company would not know the HCPs participating in the market research study, but would only learn after an adverse event occurred.

If in a market research investigation a HCP mentions an adverse event related to a product of the company sponsoring the survey that has occurred in a specific patient or group of patients, the market research agency would have to pass a report onto the company's Drug Safety Department, even if the HCP has already reported the adverse event himself.

In order to comply with this pharmaco-vigilance obligation, market research agencies ask the HCPs if they are willing to renounce confidentiality only for the purpose of reporting the adverse event, in such a way that the sponsoring company is able to contact the HCP(s) if additional information is required. This would not be linked in any way to the responses given during the survey. As this is a necessary exception to comply with the pharmaco-vigilance legislation, the Transfers of Value would not need to be disclosed.

Question 3.01 - 19 *(previously List 3 Q 62)*: **How should the Transfers of Value to HCPs / HCOs that participate in a Steering Committee supporting the organisation of an international event be disclosed?**

Answer: Unless the activity is within scope of the R&D Transfers of Value (in which case it will be part of the aggregate disclosure), the Transfers of Value are to be disclosed in the name of the Recipient HCP/HCO.

If the HCO is paid "in lump" for organising a meeting of experts the Transfers of Value attached will be disclosed in the name of the HCO organising the international event. However, if members of the Steering Committee receive direct compensation for their support, the Transfers of Value will be disclosed individually, in the name of the individual HCP / HCO, as will be the case.

Question 3.01 - 20 *(previously List 3 Q 60)*: **In which category should independent investigator trials (IIT) / investigator sponsored trials (IST) be disclosed?**

Answer: Independent Investigator Trials (ITT) / Investigator Sponsored Trials (IST) are, by definition, studies which are not initiated by a Member Companies, but they can benefit from Member Companies support, which may be financial or non-financial, direct or indirect. As such any Transfer of Value provided for these activities are disclosable under the Code and should be disclosed in the "Donations & Grants" category to the Recipient HCO.

Attention is drawn to the requirements of the HCP Code Article 11 whereby donations and grants to individual HCPs are not permitted.

Question 3.01 - 21 *(previously List 3 Q 64):* **How should investigator meetings be disclosed when both HCOs/HCPs and non-HCOs/HCPs are present?**

Answer: Transfers of Value to investigator meetings are disclosable under the Code. The Member Company would be expected to disclose the total amount of the Transfer, since the EFPIA Code does not require Tranfers to be disaggregated.

Where the investigator meeting would fall under the definition of R&D Transfers of Value, it will be part of the aggregate disclosure under this category.

If it does not fall within that definition, the Transfers of Value will be disclosed in the relevant disclosure categories, in the name of Recipient HCOs/HCPs.

Section 3.02: Aggregate Diclosure

Question 3.02 - 1 *(Batch 1 Q.23 – previously List 1 Q 20):* **What must a Member Company do if it does not obtain a consent from a HCP (or a HCO, where applicable) for disclosure on an individual basis?**
See also "Points of Clarification" on "Privacy Law & Regulations", and question 2 of Section 3.02

Answer: Member Companies should make their best efforts to obtain the consents necessary to disclosure of Transfers of Value at the individual level, with aggregate disclosure being permitted in exceptional circumstances only.

Where Transfers of Value occur in the context of a contract, the contract provides an opportunity to obtain the HCP's /HCO's consent to the processing of his/her/its personal data for the purpose of meeting the Member Company's obligations under the Code. It is recommended that Member Companies (data controllers) create and retain evidence showing that such consent has been requested / obtained.

The following footnote will be added to Section 4.01 of the EFPIA Code:
"*When making a Transfer of Value to a HCP/HCO, and in their written contracts with HCPs/HCOs, Member Companies are encouraged to include provisions relating to the Recipients' consent to disclose Transfers of Value in accordance with the provisions of the Code. In addition, Member Companies are encouraged to renegotiate existing contracts at their earliest convenience to include such consent to disclose.*"

Where Member Companies would be required by national laws and regulations to obtain the consent of the Recipient for individual disclosure and the Recipient does not consent to such disclosure following Member Companies repeated efforts, the relevant Transfer of Value may be disclosed on an aggregate basis. The Member Companies are also required to indicate the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed (respectively under the HCPs and HCOs disclosures). *See also the Template, page 13 of the Code*

Question 3.02 - 2 *(previously List 3 Q 50):* **How should disclosure be managed where the Recipient gives partial consent? For example, where consent is given for the consultancy fees to be disclosed, but not associated payments for travel & accommodation, what would be the disclosure requirement?**
See also "Points of Clarification" on "Privacy Law & Regulations", and question 1 of Section 3.02

Answer: Member Companies are encouraged to include a consent notice in their contracts that would prevent, wherever possible, Recipients from "cherry picking" which Transfers of Value they consent to be disclosed.

If notwithstanding the Member Company's efforts a Recipient gives only partial consent to any aspect of disclosure (i.e. the Recipient does not allow for disclosure of all categories or of all Transfers), all Transfers of Value of the Member Company made to that Recipient should be declared in the aggregate disclosure (not in the individual disclosure category), subject to applicable laws.

Partial disclosure under the individual disclosure category would be misleading with respect to the nature and scale of the interaction between the Member Company and the Recipient, and would as such not fulfil the intent of the Code.

Information on how this is managed should be considered in the Methodological Note.

Question 3.02 - 3 *(Batch 1 Q.22 – previously List 1 Q 21):* **What circumstances can constitute "legal reasons" preventing disclosure on an individual basis for purposes of Section 3.02?**

Answer: This can happen, for example where disclosures on an individual basis are not permitted by local personal data protection laws unless the Recipient's consent has been obtained.

The EU Data Protection Directive (Directive 95/46/EC) has been transposed into national legislation in all EU Member States. National requirements regarding the processing of personal data and obtaining the consent to disclosure from the data subject differ significantly from jurisdiction to jurisdicton.

Member Companies must comply with applicable personal data protection and other laws, which may impose certain limitations on their ability to make disclosures on an individual basis. A company (as a data controller) may have legitimate interest in disclosing data, for instance, to promote confidence in its relationship with HCPs. The data subject's interests must outweigh this legitimate interest. The legal basis is significantly strengthened when a data controller can show the required consent had been obtained.

Data privacy requirements must in each case be checked at the national level (i.e. the jurisdiction of the Recipient) by the Member Company prior to disclosure.

For good understanding, transposition of the EFPIA Code into Member Associations' codes is not prevented by unresolved consent issues. However, Member Associations are encouraged to support

local operations with resolving consent issues, for instance through reaching out to HCPs/HCOs to promote the merits of transparency for all stakeholders and for the patients indeed.

***Question 3.02 - 4*: Which amounts / percentages does the Member Company have to publicise in case of aggregate disclosure of Transfers of Value to non-consenting Recipients?**

Answer: The Member Company has to disclose:

- the aggregate amount attributable to Transfers of Value to Recipients that did not consent to individual disclosure;
- the number of Recipients included in the aggregate disclosure;
- the percentage of HCPs (respectively HCOs) that did not consent out of the total number HCPs (respectively HCOs).

Section 3.04: Research and Development Transfers of Value

Question 3.04 - 1 *(previously List 3 Q 52):* **Why shall Transfers of Value connected to R&D as defined in the Code be disclosed in aggregate?**

Answer: At the request of CCSG, this answer is submitted to legal counsel opinion.

Section 3.05: Methodology

Question 3.05 - 1 *(previously List 3 Q 70):* **Is VAT associated with Transfers of Value to be excluded or included?**

Answer: Member Companies are expected to provide information on the treatment of VAT and other tax aspects in their Methodological Note.

Section 4.03: Disclosure Requirements Different from this Code

Question 4.03 - 1 *(Batch 1 Q.6 – previously List 1 Q 22):* **Should the existing national codes be modified to cover the same scope of disclosures as the Code? When local law does not cover the same spectrum of disclosures as the Code, would disclosures pursuant to local law be deemed sufficient?**

Answer: Member Associations are asked to transpose the Code in full and in a manner consistent with applicable laws and other applicable legal requirements. Member Associations are required to inform EFPIA of reasons why national disclosure requirements differ from those required under the EFPIA Code. Such differences shall be clearly and conspicuously so identified.

Unless there are strong legal mandatory requirements, it is expected that Member Associations will transpose the Code in full i.e. without deviations. However, where national codes impose additional requirements in line with national laws and regulations, such variations from the EFPIA Code are admissible. This may be the case when national laws are in place. In each country, Member Companies will be required to comply with the disclosure requirements applicable in that country, whether imposed by law or by self-regulation.

Based on a detailed "gaps" analysis between legal requirements versus the EFPIA Code, efforts will be made to close these gaps with a view to ensuring consistent reporting around Europe.

Question 4.03 - 2 (Section 4.03) *(Batch 1 Q.5 reworded – previously List 1 Q 23):* **Would disclosure in line with national requirements be considered sufficient if the national provisions do not require as many provisions as the Code?**

Answer: Yes, when the EFPIA Code provision is in conflict with applicable national law or regulation, in which case the deviation is allowed.

SCHEDULE 1 - DEFINITIONS

Question Definitions - 1 *(Batch 1 Q.54 – previously List 2 Q 47)*: **Is a clinical research organization (CRO) a HCO?**

Answer: A CRO is not a HCO. A clinical research organization (CRO) is an organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis. However, Member Companies may make Transfers of Value to HCPs / HCOs through CROs – such indirect payments are within the scope of the Code.

As a rule, each Member Company will decide on the inclusion of Transfers of Value to CROs into the different categories of disclosure.

If activities contracted to CROs fall within the scope of the definition of R&D Transfers of Value, they will be part of the aggregate disclosure under that category. Otherwise, they will be reported under the relevant category.

In their written contracts with CROs, Member Companies are encouraged to include provisions relating to the CROs' consent to disclose Transfers of Value that will ultimately benefit HCPs/HCOs in accordance with the provisions of the Code. In addition, companies are encouraged to renegotiate existing contracts at their earliest convenience to include such consent to disclosure.

In the Methodology Note, the Member Company are encouraged to provide additional clarification on the nature of the Transfers of Value included.

Question Definitions - 2 *(Batch 2 Q 24 – previously List 1 Q 24):* **Does EFPIA plan to provide Member Companies with a list of all specialties and professional designations that fall into the definition of a "HCP"?**

Answer: No. The EFPIA HCP Code defines HCPs as any 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 or administer a medicinal product. *See also the EFPIA HCP Code (Scope - § 4)*

The Member Associations have transposed the EFPIA HCP Code into their national codes. In principle, these codes will include the list of specialities and professional designations that fall into the definition of an HCP, also reflecting healthcare practice in the country – for instance, nurses can prescribe medicines in some countries but are not allowed to do so in other countries.

Question Definitions - 3 *(Batch 1 Q.51 – previously List 1 Q 25):* **How is a "Foundation" defined for the purposes of the "HCO" definition?**

Answer: A "Foundation" is one of the legal forms in which HCPs/HCOs may operate and organise relationships with Member Companies.

Member Companies will need to determine on a case-by-case basis whether a particular Foundation falls within the definition of a HCO under the Code, taking into account factors such as the foundation's characteristics, members, bylaws and purpose.

Where Member Companies engage, provide a Transfer of Value etc. to a Foundation, due diligence would be to ensure all such support, engagements and the like are appropriately documented in a writing (preferably a contract), that may also include a clause consenting the individual disclosure of the Transfer of Value.

Question Definitions - 4 *(Batch 1 Q.52 – previously List 1 Q 26):* **Are research organisations (such as INSERM in France) considered HCOs for purposes of the Code?**

Answer: INSERM is a Medical Research Organisation and as such would be classified as a HCO.

As with any Transfer of Value, the purpose and intent of any payment made to INSERM, or similar organisations, should be considered to establish if such payments are in scope of the Code. If they are, they should then be disclosed under the appropriate category for a HCO.

Where Member Companies engage, provide a Transfer of Value to a research organisation, due diligence would be to ensure all such support, engagements and the like are appropriately documented in a writing (preferably a contract), that may also include a clause consenting the individual disclosure of the Transfer of Value.

Question Definitions - 5 *(Batch 1 Q.53 – previously List 1 Q 27):* **Should Transfers of Value to universities or teaching institutions be disclosed under the Code?**

Answer: As a general matter, the Code does not provide for the disclosure of interactions between Member Companies and teaching institutions (such as support of or involvement in a management programme). However, where such support or involvement ultimately benefits a HCP, then such Transfer of Value should be disclosed under the Code identifying the Recipient, in this instance the teaching institution, of such Transfer of Value.

As such, Transfers of Value to a Faculty of Medicine at a university or to a University Hospital should be disclosed under the relevant category. Collaboration with such entities will be company-specific and each Member Company should organise its disclosures accordingly and provide additional information in its Methodology Note.

Where Member Companies engage, provide a Transfer of Value etc. to a university or a teaching institution, due diligence would be to ensure all such support, engagements and the like are appropriately documented in a writing (preferably a contract), that may also include a clause consenting the individual disclosure of the Transfer of Value.

Question Definitions - 6 *(Batch 2 Q.22 – previously List 1 Q 28):* **Under the Code, would a self-incorporated HCP (where he/she is the only employee of the corporation) be considered a HCO?**

Answer: Yes. HCO is defined as "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".

Question Definitions - 7 *(previously List 3 Q 57):* **Why do the retrospective non-interventional studies fall under the individual disclosure category?**

Answer: Following the definition of R&D Transfers of Value in Schedule 1 in the EFPIA Code approved in June 2013, retrospective non-interventional studies do not fall within the scope of the definition of R&D Transfers of Value. Only the non-interventional studies that are prospective in nature will be included in the aggregate disclosure of Research & Development Transfers of Value.

Transfers of Value relating to retrospective non-interventional studies, that shall comply with the provisions of Article 15 the EFPIA HCP Code, shall be disclosed under the name of the individual Recipient.

Comment: This interpretation has been confirmed at the General Assembly of 6 June 2014, following Board decision.

Question Definitions - 8 *(previously List 3 Q 56):* **How should Member Companies disclose Transfers of Value through contracted third parties, which may include e.g. Clinical Research Organisations (CROs), Professional Congress Organisers (PCOs), travel agencies?**

Answer: Member Companies would be expected to collect details from third parties to disclose following the disclosure requirements of the Code (category of disclosure, individual or aggregate). Individual disclosure, where applicable, should be under the name of the HCO on whose behalf the third party is operating.

The process followed to collect the information should be described in the Methodological Note.

Question Definitions - 9 *(previously List 3 Q 58):* **How should Member Companies disclose Transfers of Value attached to services provided by commercial entities (such as events providers, publishers or general suppliers) who may engage with HCPs on behalf of the Member Company to obtain HCP services?**
See also questions 2 of Applicability of the Code & 2 of Section 2.04

Answer: Services provided by commercial entities or materials prepared by internal staff do not, as such, constitute a Transfer of Value to on HCP/HCO. However, the Member Company's contract with the commercial entity expects that HCP/HCO services will be obtained, then related Transfers of Value should be disclosed in accordance with the Code.

Question Definitions - 10 *(previously List 3 Q 65):* **If a company sponsors an event / activity through a third party without indicating the particular HCPs by name who should be invited, should the indirect Transfers of Value be disclosed or are they only to be disclosed when a HCP receives the transfers at the instruction of the Member Company?**

Answer: If a company sponsors a third party event (e.g. a medical congress) and in return has the possibility for image promotion activities (e.g. a booth etc.), this must be disclosed under the category "Sponsorship" naming the Recipient (the HCO).

The same applies if the Recipient HCO uses some of the received sponsorship to invite HCPs or to hire HCPs as speakers for that congress.

However, if it is part of the sponsoring contract that the organization must use some of the sponsorship to invite a given list of HCPs to that congress, this should be split-up and disclosed individually under the name of each HCP.

Following the same principle, where a Member Company provides a third party organisation conducting market research on its behalf with a specified list of named HCPs to use for recruitment purposes, and the Member Company is made aware of which HCPs have agreed to participate in the market research, it would make sense that the Member Company discloses it in the "Fees for Services and Consultancy" category.

SCHEDULE 2 – STANDARDISED TEMPLATE

Question Template - 1 *(previously List 1 Q 12):* **What is meant by the "unique identifier"?**

Answer: For the purpose of the disclosure in the Template, Member Associations are strongly recommended to provide guidance on the most appropriate "professional code" in their country that Member Companies should use as unique identifiers.

In the Model Template (see Schedule 2), it has been suggested that such *unique identifier* would include:

- the Full Name;
- for a HCP: the City of Principal Practice;
- for a HCO: the City where Registered;
- the Country of Principal Practice;
- the physical address of the Principal Practice; and
- (where applicable) the Unique Country Local Identifier (e.g. a professional code)

Whether such full details can be publically disclosed may depend on applicable personal data protection laws and regulations.

For sake of clarity, EFPIA will not develop unique identifiers for HCPs / HCOs in Europe.

Question Template - 2 *(previously List 3 Q 64)*: **What text is the Member Company expected to put in the last section of the Template under "R&D – aggregate disclosure"?**

Answer: As is reflected in the Template, the Code requires Member Companies to disclose the total amount of R&D Transfers of Value to HCPs / HCOs per year (reporting period) in aggregate.
