IPSEN

Innovative Pharmaceutical Initiative
TRANSPARENCY PROGRAM

METHODOLOGICAL NOTE - CROATIA

Contents

1 PREAMBLE 4
2 PURPOSE 6
2.1 Terminology 6
3 SCOPE OF THE DISCLOSURE 7
3.1 Recipients 7
3.1.1 HCP 7
3.1.2 HCO 8
3.1.3 Specific case: Company owned by an HCP 9
3.2 Medicinal products and applicability of the Code 10
3.3 Transfers of value 11
3.3.1 Definition of Transfers of value 11
3.3.2 Donations and grants 12
3.3.3 Contribution to costs of event 13
3.3.4 Fees for Service and Consultancy 15
3.3.5 R&D 17
3.3.6 Transfers of value excluded from the scope 20
3.3.7 Specific consideration #1: Market research 21
3.3.8 Specific consideration #2: Third parties interactions 22
3.4 Transfers of value related to cross-border activities 24
4 CONSENT MANAGEMENT 25
4.1.1 Background on data privacy requirements 25
4.1.2 Consent Collection 25
4.1.3 Disclosure consent refusal & revocation 26
4.1.4 Partial consent 28
5 DISCLOSURE METHODOLOGY 29
5.1 Publication Date 29
5.2 Calculation rules 31
5.3 Currency 33
6 FORM OF DISCLOSURE 34
6.1 Language of disclosure 34
6.2 Disclosure platform 35
7 DISPUTE MANAGEMENT 36
END OF DOCUMENT 37

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 (Croatian association Innovative Pharmaceutical Initiative) 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 is 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.

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 are given in the appendix.

This note applies to **CROATIA.**

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 above.

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"*.

(a) 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:

- Patient Organizations (PO) are not included in the definition of HCO– Patients Organizations being covered by the "EFPIA PO Code". (http://transparency.efpia.eu/uploads/Modules/Documents/code_po2011.pdf).
- 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).

(b) Local considerations

Same as above

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 above

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 above

3.3 Transfers of value

3.3.1 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

Same as above

3.3.2 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.

(c) Local considerations

Same as above

3.3.3 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 above

3.3.4 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 for 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 above

3.3.5 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"* relate 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 above

3.3.6 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).

(a) 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).

(b) Local considerations

Pursuant to Article 11.2 of local Association Code of conduct of innovative pharmaceutical companies: "*Costs of meals during the Event shall be paid: up to maximum amount of HRK 500,00 / person / meal; and this form of Hospitality must be limited to refreshments and/or meals during the Event. In case of International Events, the maximum value of meals set in the country where the respective Event takes place (i.e. the "host country") shall prevail.*"

3.3.7 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 HCP), the ToV is disclosed at aggregate level.

(c) Local considerations

Same as above

3.3.8 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.

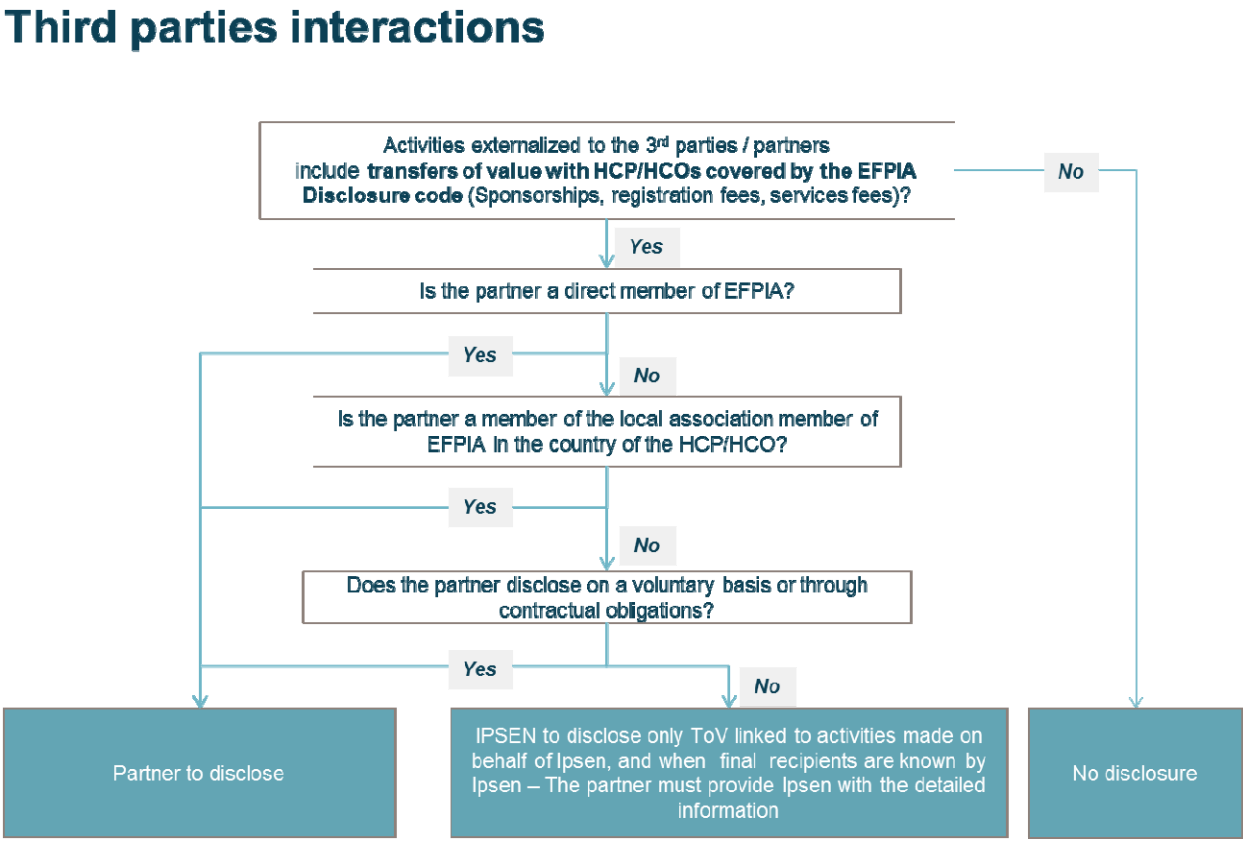

Figure 1 – Third parties interactions

(c) Local considerations

Same as above

3.4 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):

- 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).
- 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).
- 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 above

4 CONSENT MANAGEMENT

4.1.1 Background on data privacy requirements

The collection and use of personal data is subject to **EU Directive 95/46** (*URL link*), which relates to the processing of personal data. It applies to physical persons (HCPs) and exceptionally, in the case of Austria, Italy, Luxembourg and Switzerland to HCOs as well.
The Directive is transposed in to data protection legislation in each country.
The Directive stipulates that the personal data needs to be adequate, relevant, and not excessive. Data controllers (such as Ipsen) need to ensure that the data is accurate, up-to-date and 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, Belgium and Slovakia.

Data subjects (HCPs and HCOs, where applicable) have the right to access their data and to object to its disclosure.
The Directive also indicates that there should be no transfer of data outside European area without adequate safeguards.

Gaining an individual's consent to process and publish their personal data is an alternative way that data processors can show that they are handling data fairly.
In order for it 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 will retain the right to refuse to disclose their information and will retain their right under the law to seek correction of mistakes or deletion of their information.

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.

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 HCPs 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 to 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 above

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 above

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 above

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

1 <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.

2 The treatment of VAT and other taxes

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

(c) Local considerations

Same as above

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

The disclosed amounts are reported in Croatian Kuna.

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 is published in English
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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: *http://www.ipsen.com/en/*
In the particular case where the local transparency Code requires that the disclosure report is made available on the 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) Ipsen Group considerations

The disclosure report for Croatia is available on Ipsen Corporate website.

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),
- 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 evidence of identity of the applicant.

(c) Local considerations

Same as above

END OF DOCUMENT