

EFPIA Disclosure Methodological Note - 2021

Hungary

IPSEN Hungary

*European Federation of Pharmaceutical Industries and Associations (EFPIA) TRANSPARENCY
PROGRAM*

METHODOLOGICAL NOTE

Summarising the methodologies used by IPSEN in preparing the disclosures and identifying Transfers of Values (ToVs) to Health Care Professionals (HCP) and Health Care Organisation (HCO) in accordance with EFPIA Disclosure Code requirements, Ipsen Group considerations, and local considerations due to locally applicable laws and regulations.

The report covers the disclosure ToV from 1st of January 2021 to 31st of December 2021

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INTRODUCTION

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 an HCP to prescribe a medicine is one of the pillars of the healthcare system. In this context, the 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, IFPMA, and PhRMA Codes Disclosure Code (“Code on Disclosure of ToVs from Pharmaceutical Companies to HCPs and HCOs”) 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. Therefore, requires that each member company documents and disclose ToVs it makes, directly or indirectly, to or for the benefit of an HCP/HCO Recipient.

Ipsen, like EFPIA members, recognizes that:

- *Collaborative working between HCP/HCOs and commercial life sciences organizations has long been a positive driver for advancements in patient care and the progression of innovative medicine.*
- *This also 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.*

Therefore, based on the EFPIA Charter, Ipsen:

- *Across Europe, from 30 June 2016, is fully committed to ensure transparency is respected, resulting in being open about our activities and interactions by disclosing prescription-only*

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medicine related payments made to HCP/HCOs as described in Annex 1 of the EFPIA Disclosure Code.

- *Ipsen will also comply with the local applicable laws and regulations even in countries where deviations are allowed, but only to the extent necessary to comply with such national law or regulation.*

- *Will maintain the identity of the HCP/HCO depending on the local regulation and consent, where disclosures on an individual name basis are subject to appropriate consent; where such consent cannot be secured, related ToVs will be disclosure in aggregate.*

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TERMINOLOGY

Standard abbreviations or terms are presented in the table below.

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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

SCOPE OF DISCLOSURE

3.1 Definition

3.1.1 Definition of an HCP

General principle, Ipsen considers that disclosure must be made on the contracting entity. Ipsen fully follows EFPIA definition and the definition of AIPM Code of Conduct: natural persons having medical qualifications, participating in the recommendation, prescription, procurement, selling, distribution or administering of medicinal products and in the provision of health services, including, in particular, physicians, pharmacists, healthcare professionals, members of healthcare service provider staff or any other specialist working in health care. In the application of this Code, the definition of healthcare professionals includes the following: (i) any official or employee of a government, agency or other organisation (whether in the public or private sector) that may prescribe, purchase, recommend 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) wholesalers or distributors of Medicinal Products, and their employees.

EFPIA definition: “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/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 purpose of this Code, the definition of HCPs 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, recommend 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.”

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1. Definition of an HCO

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

- *Payments to Clinical Research Organisations (CROs) are excluded from the scope. However, ToV to HCPs/HCOs via CROs, within the ToV in scope are disclosed*

Healthcare Organisation/Provider (HCO): any legal person, entity, individual entrepreneur (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 Article 21) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more Healthcare Professionals provide services.

EFPIA definition: “any legal person/entity (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 (POs) within the scope of article 21) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.”

2. Definition of Transfer of Value (ToV)

Ipsen discloses both direct and indirect types of ToV such as defined in the Code.

- **Direct ToV:** *are payments made directly by Ipsen for the benefit of a Recipient*
- **Indirect ToV:** *Made by a third party (such as contractors, Clinical research organizations (CROs), agents, partners, affiliates (including foundations)) on behalf of Ipsen for the benefit of a Recipient, where the identity of such Member Company is known or can be identified by the Recipient that will benefit from the ToV. This also includes ToV between Ipsen and POs, however this is disclosed within a PO specific report.*

Reporting of Indirect Benefits provided through PCOs Contributions provided to Events through PCOs – that would therefore be the Beneficiaries of the Benefits – must be considered as Indirect Benefits. In consideration of legal issues that may arise in the reporting of Benefits through Distributors on behalf of a Member Company, reporting of such Benefits are not within scope of this Code. Contribution to costs related to Events paid through Third Parties to the benefit of individual HCPs that the Member Company knows, must be reported on an individually named basis, as Indirect Benefits to HCPs.

Scope of Medicinal Products

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Ipsen will collect, report and disclose all ToVs with HCPs/HCOs in relation to prescription-only medicine as described within the Code.

In line with the Hungarian requirements

EFPIA: *Excluded Disclosures. Without limitation, ToVs that (i) are solely related to over-the-counter medicines; (ii) are not listed in Section 23.05 of this article, such as Items of Medical Utility (governed by Article 17), meals (governed by Article 10, especially Section 10.05), Medical Samples (governed by Article 19); or (iii) are part of ordinary course purchases and sales of Medicinal Products by and between a Member Company and a HCP (such as a pharmacist) or a HCO do not fall within the scope of the disclosure obligation described above in “General Obligation”.*

3.3 Types of ToV

3.3.1 Donation and grants

Ipsen discloses ToVs related to donations and grants which 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 medical association or a patient organisation to support an independent medical education program; Scholarships, Fellowships; Awards.
- A **Research Grant** is funding to third-party registered research entities to conduct independent research that does not fall under the definition of company sponsored studies or Investigator-sponsored studies under the applicable Ipsen R&D policies.
- A **donation** is a charitable contribution to a non-profit third-party entity (charities) with charitable and philanthropic intent, without any expressed or implied benefit other than general goodwill.

For Benefits to HCOs, 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 12).

EFPIA: *Section 12.01. Donations and Grants (in cash or in kind or otherwise) to HCOs and/or POs are only allowed if: (i) they are made for the purpose of supporting healthcare, research or education; (ii) they are documented and kept on record by the donor/grantor; and (iii) they do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products.*

3.3.2 Contribution to costs of event

Ipsen discloses ToVs related to events at individual level, i.e., at HCP or HCO level in line with the Code. The ToVs disclosed under this section relate to either Third-Party organized events or Standalone Events organized by Ipsen:

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“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** category as outlined in EFPIA Disclosure Code Article 23.05, 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 4.4 for detailed calculation rules.

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

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iii. Travel and accommodation (must not be excessive/luxurious and must be in line with the objectives of the event) in accordance with the provisions of Article 10.

EFPIA: *Contribution to costs related to Events, through HCOs or third parties, including sponsorship to HCPs to attend Events, must be disclosed individually under the name of the Recipient: such costs may relate to: Registration fees; Sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event; and Travel and accommodation (to the extent governed by Article 10 of the EFPIA HCP Code). Since 30 June 2016, companies disclose transfers of value made to HCPs, such as consultancy and advisory boards, speaker fees, and sponsorship to attend meetings. This transformational step in the relationship between industry and health professionals is a result of the EFPIA Disclosure Requirements. (EFPIA FAQ Question 3)*

Additional notes for Sponsorships:

EFPIA: *Contributions provided to Events through Professional Congress Organiser (PCOs) – that would therefore be the Recipient of the ToVs – must be considered as indirect ToVs. When a Member Company contributes to the costs related to Events through PCOs, the following reporting approaches are considered compliant with EFPIA reporting requirements:*

All ToVs to an HCO (either as Recipient or as Beneficiary) are reported in the relevant category under the name of the HCO and ToVs through PCOs are reported:

- *either in the name of benefitting HCO (through include the name of Recipient PCO), if not included in direct ToVs to the HCO.*
- *or in the name of Recipient PCO (to the benefit of include the name of benefitting HCO)*

3.3.3 Fees for Service and Consultancy

Ipsen may contract with an HCP or an 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 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 principal 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:

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- 1 **Fees:** fees for services to HCPs/HCOs
Examples: Speaker fees (Speech given by an HCP (“Speaker”) in a meeting), fees for insights provided during an Advisory Board¹, 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: taxi.

C. Fees for Service and Consultancy.

Benefits resulting from or related to contracts between Member Companies and HCOs under which such HCOs 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 Benefits relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

Fees for Service and Consultancy.

Benefits 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 Benefits relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

EFPIA: *ToVs resulting from or related to contracts between Member Companies and HCOs under which such HCOs 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 ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.*

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.

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3.3.4 Research and Development (R&D):

Ipsen will disclose ToV to HCPs or HCOs as per the Code; 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

No further local specific requirements

EFPIA: *Payments made for research and development activities are disclosed in aggregate. For the purposes of the disclosure, these activities are defined as transfers of value to HCPs or HCOs related to the planning or conduct of:*

- *non-clinical studies (as defined in OECD Principles on Good Laboratory Practice).*

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- *clinical trials (as defined in Directive 2001/20/EC); or*
- *non-interventional studies (NIS) 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 18.01 of the EFPIA Code).*

Transfers of Value relating to NIS that are not within the definition of R&D ToVs under the EFPIA Disclosure Code must be reported on an individually named basis. For sake of clarity, activities not falling within the definition of R&D ToVs, including NIS that are not conducted to maintain a marketing authorization (in application and following definitions of the “Clinical Trials” Regulation 536/2014), will be disclosed under “consultancy/fee-for-services”.

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.

3.4 Transfer of value excluded from the scope

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, IFPMA, and PhRMA Codes setting amount thresholds for hospitality).

No further local specific requirements

EFPIA: *Without limitation, ToVs that (i) are solely related to over-the-counter medicines; (ii) are not listed in Section 23.05 of this article, such as Items of Medical Utility 29 (governed by Article 17), meals (governed by Article 10, especially Section 10.05), Medical Samples (governed by Article 19); or (iii) are part of ordinary course purchases and sales of Medicinal Products by and between a Member Company and a HCP (such as a pharmacist) or a HCO do not fall within the scope of the disclosure obligation described above in “General Obligation”.*

Meals and drinks are not disclosed, but a threshold has been applied in each country, limiting hospitality under a certain value. The Code does not require to be disclosed: inexpensive items of medical value;

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information and educational materials designed for patients; samples; and activities solely relating to over-the-counter medicines. [Q&A – Q7)

3.4.1 Specific consideration: Market Research

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.

In line with EFPIA Code.

No further local specific requirements

EFPIA: *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.”*

Section 15.04. Limited market research, such as one-off phone interviews or mail/e-mail/ internet questionnaires are excluded from the scope of this Article 15, provided that the HCP, HCO’s member or PO’s Representative is not consulted in a recurring manner (either with respect to the frequency of calls generally or of calls relating to the same research) and that the remuneration is minimal.

3.4.2 Specific consideration: Third parties’ interaction

In some parts of the world, Ipsen operates through partners and distributors. Therefore, 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.

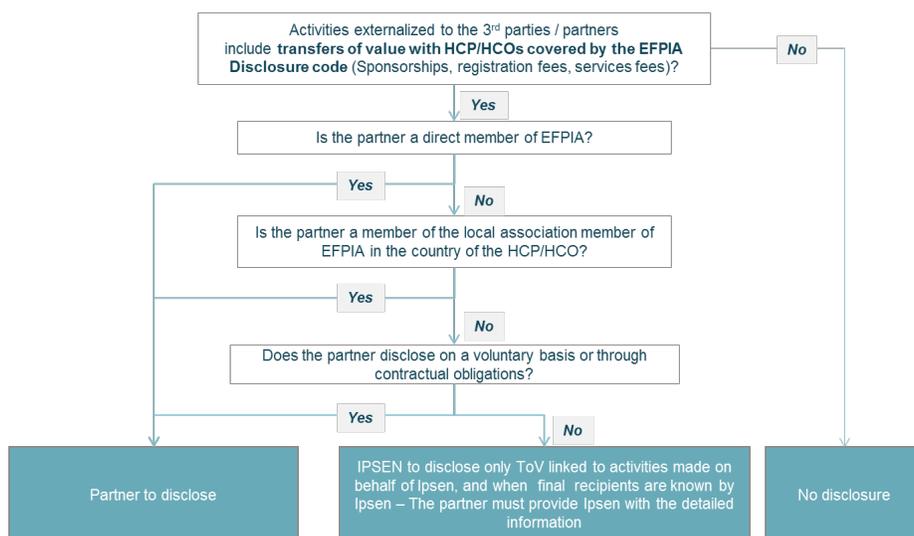
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No further local specific requirements

The following figure summarizes the approach followed.

Third parties interactions



EFPIA: *Third parties provide support to Member Companies in a variety of capacities, impacting more or less on the conduct of activities regulated by the EFPIA Codes. Such activities would be reported as indirect ToVs following provisions of the EFPIA Disclosure Code. When Member Companies provide support / sponsorship to PCOs involved in the organization of scientific Events, it is understood that the Member Companies' intention is to provide support to HCPs/HCOs at arm's length. Indirect ToVs are those made on behalf of a Member Company for the benefit of a Recipient, or ToVs through an intermediate and where the Member Company knows or can identify the HCP/ HCO that will benefit from the ToV*

3.5 ToVs related to Cross-border activities

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 principal 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.

No further local specific requirements

EFPIA: *In case of international Event for which a Member Company sponsors the attendance of a HCP, if any funding is provided to such HCP in accordance with the provisions of Article 13,*

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such funding is subject to the rules of the National Code where such HCP carries out his/her profession, as opposed to those in which the international Event takes place.

4 DISCLOSURE METHODOLOGY

4.1 Publication Date

Aligned with EFPIA Ipsen discloses all the relevant ToVs by 30th of June for the previous year according to 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.

The data will be on the public domain for 3 years and will be stored for minimum of 5 years. Ipsen will be able to modify or delete their disclosures at any time before or after the publication.

No further local specific requirements

***EFPIA:** Disclosures must be made by each Member Company within 6 months after the end of the relevant Reporting Period and the information disclosed must be required to remain in the public domain for a minimum of 3 years after the time such information is first disclosed unless, in each case, (i) a shorter period is required under applicable national laws or regulations, or (ii) the relevant data protection legal basis (e.g. the legitimate interest grounds, a legal duty or the Recipient's consent relating to a specific disclosure) is no longer applicable. The common reporting period for publication of ToVs to Recipients is set during the time interval from 20th to 30th June each year at the latest. Where a National Code provides a different time interval for its country, this must consistently apply to all disclosure obligations to Recipients.*

4.2 Form of disclosure

Ipsen will disclose the report using the guidance from section 23.04. The report is published in both local language and English.

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Disclosure must be made in Hungarian. Member Companies can make disclosures in English as well in addition to the mandatory disclosures in the local language.

4.3 Disclosure Platform

Ipsen disclosure reports will be publicly available on the local central platform provided by the local Transparency Disclosure Code within each other, or on Ipsen Corporate website. All the local reports disclosed by Ipsen are publicly available via the Corporate website: <https://www.ipsen.com/our-company-social-responsibility/>. In the 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.

In Hungary, member company disclosure reports are primarily displayed via the www.transzparencia.org website.

EFPIA: *Platform of Disclosure. Disclosures can be made in either of the following ways, provided that they are unrestricted and publicly available: on the relevant Member Company's website in accordance with the section "Applicable National Code"; or 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 must be made, so far as possible, using a structure set forth in Annex A for reference.*

4.4 Calculation rules

1 The general calculation including no-shows / cancellation fees and group expenses treatment

- The costs of "no-shows" (occurring when an 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 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 attended the meeting. The final invoice paid by Ipsen for this meeting is 100€.*

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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 » No further local specific requirements.

4.5 Currency

Ipsen will disclose the amounts in the report using the local 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.

5 COMPLIANCE WITH DATA PRIVACY

The collection and use of personal data are 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. 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.

In order for it to be valid, any consent from HCP must be:

- Freely given
- Specific
- Unambiguous

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- 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.

***EFPIA:** When deciding how a ToV must be disclosed, Member Companies should, wherever possible, identify and publish at the individual HCP (rather than HCO) level, if this can be achieved with accuracy, consistency and in compliance with applicable laws and regulations.*

5.1 Consent Management

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.

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.

In regard to partial consent where the Recipient has received multiple ToV in the same reporting period, however, does not agree to disclose one or more of those ToV, then Ipsen will disclose all of that Recipient's ToV within the aggregate amount. No further local specific requirements

***EFPIA:** Healthcare professionals and healthcare organisations will be informed by the company or companies they work with of the intent to disclose. In order for the disclosures to be made public, and if the company based its disclosure on consent, healthcare professionals need to give their consent for the*

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information to be made public. This usually will be managed through a clause in the contract between the healthcare professional/healthcare organisation and the company. [Q&A – Q14]

Where individual consent has been used as a basis for publication (rather than legitimate interest) and healthcare professionals do not grant consent to disclose payments, then the payments will be www.efpia.eu & disclosed on an aggregate basis. Each company will disclose the number of health professionals that did not grant consent and the total amount paid to them. [Q&A – Q18]

When a healthcare professional withdraws their consent for the information to be publicly disclosed, the data controller (the company) is obligated to remove the data related to payments made to that individual from the public domain. Instead, the data related to payments will be added to the aggregate total of payments made to health professionals that have not given consent to disclose and this aggregate figure will be published along with the number of healthcare professionals that did not give consent. [Q&A – Q19]

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6 DISPUTE MANAGEMENT

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.

No further local specific requirements