IPSEN [Greece]

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 Healthcare Professionals (HCP) and Healthcare Organisation (HCO) in accordance with EFPIA Code of Practice requirements, Ipsen Group considerations, and local considerations due to locally applicable laws and regulations.

The report covers the disclosure of ToVs from 1st of January 2025 to 31st of December 2025

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1 INTRODUCTION

Collaboration between pharmaceutical industry and healthcare professionals (HCPs) and healthcare organisations (HCOs) benefits patients. It is a relationship that has delivered new medicines and fosters the innovation that improves patients' lives. Ipsen is fully committed to complying with the codes and guidelines EFPIA and its member associations have adopted to ensure that these interactions meet the high standards of integrity that patients, society, governments and other stakeholders expect.
Bringing greater transparency to this already well-regulated and vital relationship, builds understanding of industry and HCPs/HCOs collaboration and, in the context of increasing societal expectations on transparency, addresses directly public concerns about interactions between the medical community and the pharmaceutical industry.
Therefore, Ipsen documents and discloses all 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 organisations 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 Code of Practice 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 payments made to HCP/HCOs as described in the EFPIA Code of Practice.

- 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. The legal basis for disclosure will vary as appropriate by country and may be 'legal obligation', 'legitimate interests' or 'consent', as applicable. Where disclosures on an individual name basis are subject to appropriate consent and such consent cannot be secured, related ToVs will be disclosed in aggregate.

2 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 Organisation
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	Patient Organisation
POM	Prescription Only Medicine (Rx)
SOP	Standard Operating Procedure
ToV	Transfer of Value

3 DEFINITIONS

3.1 Recipients

3.1.1 HCP

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

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."*

3.1.2 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

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."

3.2 Kind of ToVs

3.2.1 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.

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.*

3.2.2 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:

"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 organisation.

"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, i.e. Travel and accommodation, are disclosed, however not room rental or potential equipment.

In both cases, the hospitality levels are governed by local rules (resulting from local transposition of the EFPIA Code of Practice 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 Article 23.05 of the EFPIA Code of Practice, with HCOs or third parties (such as PCOs) appointed by HCOs to manage an event. In the latter case, the sponsorship is considered as 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 8.3 for detailed calculation rules.

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).*

3.2.3 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:

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 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: taxi.

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.*

3.2.4 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

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.

- 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

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).
• 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".

4 DISCLOSURE'S SCOPE

4.1 Products concerned

Ipsen will collect, report and disclose all ToVs with HCPs/HCOs in relation to prescription-only medicines as described within the Code and, will also include over-the-counter medicines related ToVs.

EFPIA: *Excluded Disclosures. Without limitation, ToVs that…(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".*

4.2 Company concerned

The report covers the disclosure of transfers of value to HCPs or HCOs that practice or are registered in a country where disclosure obligations of the EFPIA Code of Practice apply that are performed by Ipsen, its affiliates and acquired or merged companies irrespective of their location.

4.3 Excluded Transfers of value

As general principle, Ipsen fully follows EFPIA rules related to ToV excluded from the scope, apart from including over-the-counter medicine related ToVs within our disclosure. As stated in Part 3.2.2, the hospitality levels are governed by local rules (resulting from local transposition of the EFPIA Code of Practice setting amount thresholds for hospitality).

EFPIA: *Without limitation, ToVs that;… (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; information and educational materials designed for patients; samples; and activities solely relating to over-the-counter medicines. [Q&A – Q7)

4.3.1 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, where consent is required, 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), where consent is required, the ToV is disclosed at aggregate level.

In line with EFPIA Code.

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.*
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.

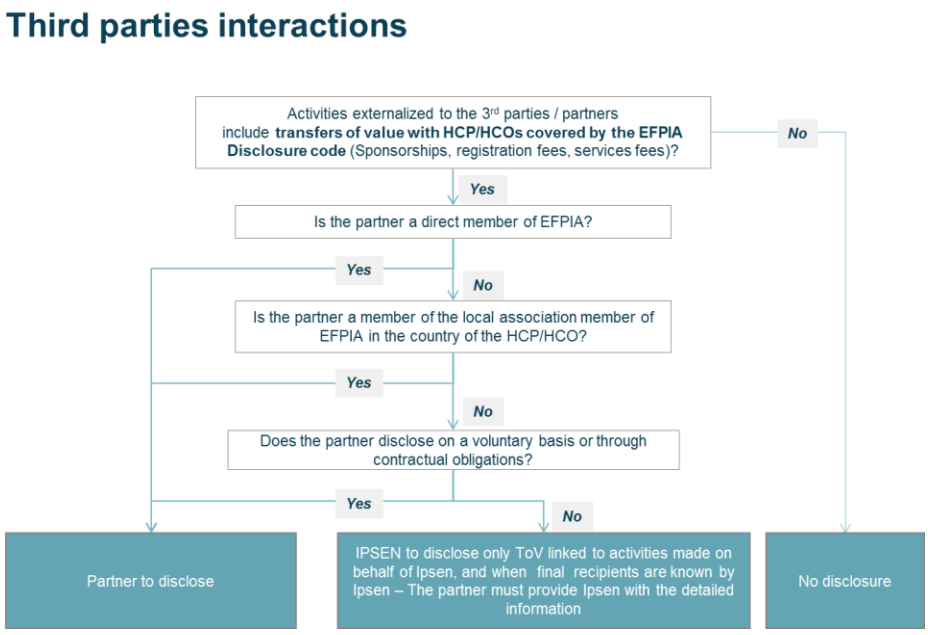
4.3.2 Specific consideration: Third parties' interaction

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, where applicable, for the processing and disclosure of the relevant ToV to HCP and HCO.

The following figure summarizes the approach followed.



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 organisation 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*

4.4 Transfers of Value Date

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.

4.5 Direct Transfers of Value

Ipsen discloses both direct and indirect types of ToV such as defined in the Code. Direct transfers of value are payments made directly by Ipsen for the benefit of a Recipient

4.6 Indirect Transfers of Value

Indirect transfers of value are payments made by a third party (such as contractors, Clinical Research Organisations (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.

4.7 Non-monetary Transfers of Value

For any significant non-monetary transfer of value a monetary value shall be assigned in line with applicable local market price, understood as as the amount a private party should generally have to pay in order to acquire a unit of a good, product, material, article, etc.

4.8 Transfers of Value in case of partial attendances or cancellation and refund

Ipsen shall disclose effective transfers of value. In relation to contribution to costs of event, when an HCP fails to attend a meeting they were supposed to no cost is disclosed under the name of the “no-shows”.

4.9 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.

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, 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.*

4.10 R&D

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.

Indirect payments through Clinical Research Organisation: as described in the 3.1.2 (a), a clinical research organisation 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.

4.11 Voluntary Disclosure

In addition to the disclosure scope set by EFPIA, Ipsen will also collect, report and disclose all ToVs with HCPs/HCOs in relation to over-the-counter medicines.

5 SPECIFIC CONSIDERATIONS

5.1 Country Unique Identifier

The disclosure template includes unique country identifier as a field of mandatory filling for each HCP and HCO. For each transfer of value Ipsen must be able to identify the Recipient. To this end, a unique identifier is assigned for each Recipient.

5.2 Self-incorporated HCP

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

5.3 Multi-year Agreements

As indicated in section 4.4 Transfer of Value Date, 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.

5.4 Country Specificities

5.5 Quality Checks

We use a combination of automated systems, standardized procedures and manual data entry through internal and external resources to collect relevant information and its subsequent publication. The information published reflects our good faith and best efforts to comply with the provisions of the EFPIA Code. In the event that, despite our best efforts to ensure a publication that accurately reflects the transfers of value performed, we failed to include correct and complete information, we will investigate and provide an appropriate response if the information is incorrect.

6 DATA PROTECTION LEGAL BASIS

The collection and use of personal data are subject to the European General Data Protection Regulation (GDPR) 2016/679. . This applies to processing personal data about individual HCPs in the context of disclosing ToV information. When processing this data Ipsen ensures that personal data is handled in line the relevant principles and obligations, including transparency, data minimization, accuracy, security, individual rights and lawfulness. We also ensure that any transfers of personal data from the EU to a third country outside of the EEA or to a country without an adequacy decision is subject to adequate safeguards, and approved contract terms, such as the EU standard contract clauses.

The legal basis (under Article 6 GDPR) for processing individual disclosure of ToV information linked to individual HCPs, varies by country. In some cases, such as in France, there is a legal obligation (French Public Health Code) that requires individual ToV disclosure. In other cases, certain countries rely on 'consent' and others rely on 'legitimate interests', as the legal basis for disclosure.

All HCPs whose data will be disclosed, are provided with information about how their personal data is managed by Ipsen and on what legal basis it will be disclosed, along with information about their individual rights and how to exercise those rights.
The HCPs have the right to access their personal data and, where the legal basis is legitimate interests, they can object to individual disclosure, or in the case of consent as the legal basis, they can withdraw their consent at any time. All HCPs have the right to seek correction of mistakes or in accuracies in their personal data, regardless of the legal basis.
The legal basis in Greece is consent. Details on how consent is managed the rationale for relying on legitimate interests, where applicable, is given the following sections.

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.*

6.1 Consent collection

Where the legal basis for ToV disclosure is 'consent', the following details apply.

Ipsen will inform healthcare professionals about how their personal data will be handled (in line with Article 13 or 14 of GDPR) and collect their consent to publish disclosure payment information at an individual level. We ensure that it is clear what the HCP is consenting to and that they are free to give or withhold that

consent. We will provide them with a method to withdraw their consent, should they change their mind later on.

Ipsen's recommended approach is to collect disclosure consent on a 'per-activity' basis, where applicable. 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, along with appropriate privacy information. In some countries where it is allowed by local transparency requirements, yearly disclosure consent is collected.

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 (and privacy information) is provided to the HCP and signed by the HCP prior to any disclosure.

Where individual consent has been used as a basis for publication 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 their consent for the information to be publicly disclosed then Ipsen is obliged to remove the individualised information about payments made to that HCP 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.

6.1.1 Partial 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.

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 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 8 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]

6.2 Legitimate Interests

Where the legal basis for ToV disclosures is 'legitimate interests', the following details will apply.

Ipsen will inform healthcare professionals about how their personal data will be handled (in line with Article 13 or 14 of GDPR) and will include an explanation of the applicable legitimate interests. The information provided will include information on the HCPs rights, and how to exercise them, including their right to object to the individual disclosure.

Ipsen has considered the balancing test related to legitimate interests, where this applies. This is summarised below.

6.2.1 The legitimate interests

The objective of ToV disclosure is to protect the integrity of relationships with HCPs and HCOs and this is an important aspect of fostering greater transparency and building greater trust between the pharmaceutical industry, the medical community and society across Europe. The legitimate interests for disclosing ToV relate to several parties, as follows:

- Ipsen's legitimate interests in meeting the requirements of the EFPIA Code of Practice which requires that each member company documents and discloses all ToVs it makes, directly or indirectly, to or for the benefit of HCPs, in order to protect the integrity of these relationships, foster greater transparency and build trust in the industry.
- The legitimate interest of local disclosure organizations to receive the data for publication, to help meet the overall objectives of ToV.
- The legitimate interests of HCPs, patients and the public, meeting a growing expectation that interactions between corporations and society are not only conducted with integrity but are also transparent, thus increasing trust.

6.2.2 Necessity of processing

The aim of TOV disclosure is to inform the public through transparency, so that every patient can be informed of the relationship between their HCP and the pharmaceutical sector and can take decisions based on this information. To achieve this, the information must be made public and should be linked to individually identified HCP, wherever possible. There are no less intrusive ways to achieve this objective.

6.2.3 Balance of interests

Nature of the data concerned

- The personal data processed is limited to the minimum data required for the purpose. No

"special category data" or data relating to criminal convictions, or data related to vulnerable data subjects is processed.
- The data relates to individuals in their professional rather than personal capacity and therefore generally carries less expectation of confidentiality or sensitivity.
- The ToV disclosure does not reveal the actual overall earnings of the HCPs and often represents a small fraction of the HCPs remuneration.
- ToV disclosure covers costs related to events (registration fees, travel and accommodation) and fees for service and consultancy agreements (fees and expenses). It does not include less relevant payments, such as for scientific research.

Reasonable expectations of the HCP

ToV disclosures are in the reasonable expectations of the HCPs for the following reasons:

- HCPs are fully informed about ToV requirements when engaged by Ipsen.
- Disclosure requirements are well understood in the industry and have been in place since 2012.
- Individuals will already be aware through their professional bodies and place of work the requirements and importance of transparency in the pharmaceutical industry.
- EPPIA has engaged with healthcare professional representative organisations on the issue and launched a social media platform to engage with individual HCPs. The practice of publishing TOV is thus very well known in the sector.

It is very unlikely that any HCP would not be aware of the publication of ToV.

Relationship between HCP and Ipsen

Ipsen has a professional relationship with the HCPs. There is no imbalance of power between Ipsen and the HCP, and the HCPs do not have to enter into any contract, activity or agreement with Ipsen if they choose not to. HCPs are not deprived of any right with significant consequences if they refuse TOV.

What is the impact on individuals

In principle, ToV disclosures are highly unlikely to result in any negative impact on the HCPs individual rights and freedoms, and safeguards are included in the process to ensure this, including:

- Limiting information to the minimum required to meet the objectives and limiting ToV to relevant types of expenditure and activity, e.g. excluding scientific research.
- ToV information will only be publicly available for a period of 3 years, and there are protocols to avoid data on the internet being indexed by search engines, limiting the risk of unintended uses of the data.
- Ipsen is also bound to comply with data protection obligations whilst handling the personal data involved, including meeting individual rights, such as the right to object, when processing is based on legitimate interests.

6.2.4 Right to Object

If an individual objects, Ipsen will consider the reasons for the objection on a case-by-case basis and balance that with Ipsen's grounds to continue with the individual disclosure. This is handled in line with the policy of the relevant Ipsen affiliate and, in principle, if the objection relates to potential significant harm to the HCP, the objection would be accepted and the HCPs data would be disclosed in aggregate.

7 FORM OF DISCLOSURE

7.1 Date of Publication

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

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.

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.*

7.2 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.

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.*

7.3 Disclosure Language

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

8 DISCLOSURE FINANCIAL DATA

8.1 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.

8.2 VAT Included or Excluded

Countries can disclose the « net amount » or the « gross amount »

8.3 Calculation rules

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

- 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€.
       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.

9 ADDITIONAL INFORMATION

9.1 Dispute management

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.