

EFPIA Transparency

Inceptua Methodology

Note

Europe

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1. Introduction

Inceptua is committed to meet all global transparency requirements, including the EFPIA Code of Practice in Europe. The code places a requirement on pharmaceutical companies to publicly report payments (transfers of value) made to health care professionals (HCP), health care organisations (HCO), Patient Organisations (POs) and members of the public (MP).

The methodology note is a summary describing the methods used by Inceptua during the collection and publication of transfer of value (ToV). According to the instruction from EFPIA such a note shall be published together with the annual report of ToV.

The reason for publishing a methodology note is so external recipients of the annual report may fully benefit from an informed reading of the report by understanding how data has been collected. Inceptua follows the local trade association instructions for disclosing ToV provided in the local industry codes. However, there are some details which trade associations and EFPIA leave to the individual companies to decide on. This note is primarily intended to answer those questions.

The information in the methodology note corresponds to instructions provided to Inceptua employees involved in the collection and reporting of transfers of value.

2. Methodology

2.1 General

What is included in the annual report?

Transfers of value (ToV) made by the Inceptua group to Health Care Professionals (HCPs), Health Care Organisations (HCOs), POs or MP with their primary activity in Europe.

What is a Transfer of Value (ToV)?

A ToV can be salary, fee or remuneration for a service provided by the HCP, HCO, PO or members of the public to Inceptua. Expenses incurred during the execution of the service (e.g. travel and accommodation) are also considered ToV. Donations and sponsorships provided by Inceptua are also considered to be ToV.

Which ToV are not included in the Inceptua report?

Inceptua has decided to comply with the instructions provided by the local trade associations and EFPIA. ToV to recipients other than those mentioned in these instructions will not be reported in this report.

Who is the recipient of the ToV?

Inceptua will consider the recipient to be the contracting entity, which may be a HCP, [a legal entity owned by a HCP (which is then a HCO)] a HCO, a PO or MP. Hence the contracting party as stated on the legal contract executed between Inceptua and the counterpart will be reported as the recipient.

When are ToV disclosed?

ToV made by Inceptua during a calendar year are reported within six (6) months from the end of that calendar year. ToV are handled according to the cash basis principle, hence a specific ToV is registered when the payment is made. As a consequence, a fee for a service provided during 2020 and paid during 2021 will be registered on the 2021 ToV listing. If the exact date for a specific transfer cannot be obtained by the individuals registering the ToVs, the transfer is to be registered as close as possible to the actual payment date.

Where is a ToV disclosed?

ToV will be published at Inceptua external webpage (www.inceptua.com).

How is Inceptua handling contracts that span over several years?

Please see above under “When are Transfers of Value (ToV) disclosed”

Which currency is used?

Transfers of values are registered in EUR.

Is value added tax (VAT) included in the reported amounts?

- Fee for service (natural person providing services) – not applicable
- Fee for service (legal entity providing services) – fee excluding VAT disclosed
- Out of pocket expenses – the entire expense is disclosed (i.e. including VAT paid by the service provider)
- Travel and accommodation costs – cost including VAT is disclosed
- Registration fees (congresses) - cost including VAT is disclosed
- Other transfers of value (e.g. donations, grants and sponsorships) – the cost excluding

applicable VAT is disclosed

What about “no-shows”, e.g. if a HCP invited to a meeting does not attend and the transportation and accommodation has been paid?

If a HCP/HCO does not attend a meeting which has already been paid for, an actual transfer of value has not taken place. Hence such costs will not be registered/disclosed as a Transfer of Value.

How are the reported value of charitable product donations provided by Inceptua determined?

In such cases the local market value is used for reporting purposes.

2.2 Data Privacy and Consent

How is Inceptua handling HCPs and HCOs data?

Inceptua is committed to protect the personal rights of any individual whose Personal Data it processes. All processing of Personal Data subject to the provisions in the EU General Data Protection Regulation (GDPR) must fully comply with the GDPR. In order to fulfil these requirements Inceptua must ask the relevant recipients of ToV (i.e. HCPs and in some exceptional cases HCOs) for a signed informed consent to publicly disclose the ToV.

HCPs has the right to access the personal data that Inceptua processes concerning the HCP and to request that Inceptua rectifies any inaccurate personal data and under certain circumstances request erasure and/or restriction of processing of the personal data. HCPs has the right to object to processing and to receive the processed personal data in a structured, commonly used and machine-readable format and has the right to transmit those data to another controller.

How will Inceptua handle ToV subject to individual disclosure to a recipient who does not provide consent to disclosure of his/her name?

In order to contribute to the EFPIA Code Of Practice purpose, Inceptua aims at disclosing ToV on an individual basis (stating the name of the recipient) to the greatest extent possible when so required by the Code. There are, however, circumstances which require Inceptua to disclose ToV in aggregate. Under the European privacy legislation, HCPs may oppose to the disclosure of their personal data. If a HCP opposes to such disclosure Inceptua will report such ToV in aggregate (stating the ToV amount to a group of recipients without stating the name of the recipients).

How will Inceptua handle partial consents, i.e. if a HCP agrees to the disclosure of one ToV but opposes disclosure of other ToV?

If an individual provides partial consent (i.e. consent to disclosure of some transfers of value but not to others made during the same calendar year) Inceptua will treat all transfers of value to that individual in the same way and will report all transfers of value in aggregate in the annual report.

How will Inceptua handle different consent input from a recipient regarding a ToV, i.e. both consent provided and consent declined?

In the event that a recipient provides several different consent inputs regarding a given ToV, the latest received input will be considered when deciding on individual or aggregate disclosure of that ToV.

How will Inceptua handle Transfers of Value (ToV) which may pertain to commercially sensitive data or other information not suitable for disclosure?

If such data falls within the scope of the EFPIA Code Of Practice, Inceptua will report such ToV in aggregate.

2.3 Recipients

Which recipients are in scope for the disclosure in Europe?

HCPs, HCOs, POs, ORDMs, MPs with their primary practice in Europe.

What about academic institutions and similar organisations: should Transfers of Value (ToV) to such organisations included in the Inceptua report?

In general, Inceptua will not include ToV to academic institutions in the annual report. However, if the ToV benefits an identified/identifiable HCP or HCO, Inceptua will include the ToV. Hence a ToV made to a Faculty of Medicine at a university or to a University hospital should normally be included.

What about CROs, are ToV to them included in the Inceptua report?

No.

What about payments made from Inceptua to HCOs/HCPs through CRO's, are they included in the Inceptua report?

Yes, direct and indirect ToVs to HCPs and HCOs are included in the Inceptua report.

What about ToVs to a "Foundation", are they included in the Inceptua report?

This will be determined by Inceptua on a case-by-case basis. If the foundation is a legal entity through which HCPs/HCOs operate, then the ToV will be included in the report.

2.4 Fee of service and consultancy

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

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

Market research

Fees paid for participation in market research are reported only if the recipient is known to Inceptua.

What is included in the reported salary/fee?

Fees paid by Inceptua are registered as gross fees, including applicable taxes. Value added tax (VAT) and social security fees, if applicable, are however not included in the reported fees.

Related expenses

Inceptua pays for/reimburses consultants for reasonable and documented expenses regarding travel and accommodation necessary for providing the services to Inceptua. Such reimbursement will be considered as a related expense. Travel and accommodation costs are reported including VAT. Other expenses are normally not paid for/reimbursed by Inceptua. If another type of related expense (excluding travel, accommodation, meals and drinks) are incurred it will be paid for/reimbursed by Inceptua only if it was necessary in order to perform the service. If so, it will be reported in "Related expenses" in the annual report. Such expenses incurred during the performance of the services are

reimbursed to the service provider on submission of a receipt. The entire expense is reimbursed, including any VAT.

Meals and drinks

Meals and drinks are not to be reported according to EFPIA and hence will not be reported by Inceptua.

2.5 The report template

What is disclosed under “HCP”?

HCP is an abbreviation for Health Care Professionals. Transfers of value (i.e. fee for service and related expenses) to individuals included in this category are reported under HCP in the annual report.

What is disclosed under “HCO”?

HCO is an abbreviation for Health Care Organisations and include organisations which organises/include HCPs. A HCO is always a legal entity. Fees and related expenses invoiced from a HCO is reported under HCO in the annual report. Donations and sponsorships provided to HCOs are also reported under HCO in the annual report.

What is disclosed under “Other”?

ToVs that should be reported in aggregate according to the EFPIA Code Of Practice or ToVs which Inceptua, due to e.g. legal reasons, must disclose in aggregate, are reported under “Other”.

What is disclosed under R&D?

ToVs 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.

A number of activities are regarded as *related* to the planning and conduct of such studies. Inceptua includes e.g. ToV related to advisory boards (provided that the advisory board is clearly related to the planning of a study mentioned above), costs for providing study drugs and ToV to study staff for conducting the study.

Inceptua will include ToV related to Inceptua-sponsored studies as well as non-Inceptua-sponsored studies in the R&D category.

3. Contact information

Inquiries about Inceptua’s disclosure of ToVs to HCPs and HCOs to request further information or corrections by Inceptua should be directed to:

E-mail: medicalaffairs@inceptua.com