

Idorsia Pharmaceuticals UK Ltd

ABPI Disclosure: United Kingdom

Methodology Note Applicable to Transfers of Value

Patient Organisations & Members of the Public (including patients and journalists)

Disclosure Period: Calendar year 2023

INTRODUCTION

In order to ensure confidence in the pharmaceutical industry, transparency surrounding the industry's relationship with healthcare providers (HCPs), other relevant decision makers (ORDMs), healthcare organisations (HCOs), patient organisations and other members of the public (including patients and journalists) is fundamental. Therefore, the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice 2019 places a requirement on all pharmaceutical companies to publicly disclose certain transfers of value (ToV) made directly or indirectly to HCPs, ORDMs, HCOs and Patient Organisations located in Europe on an annual basis. The Association of the British Pharmaceutical Industry (ABPI) Code of Practice 2021 has incorporated these requirements for pharmaceutical companies in the UK.

The ABPI Code of Practice 2021 also requires companies to publicly disclose certain details relating to patient organisations that have been provided with donations, grants, sponsorships or that have provided contracted services. Furthermore, a public disclosure must also be made for certain contracted services and expenses paid to members of the public.

Idorsia Pharmaceuticals UK Ltd (Idorsia UK) is committed to transparency regarding our business operations and relationships with HCPs, ORDMs, HCOs, patient organisations and members of the public (including patients and journalists). Sharing information about these relationships will improve the public's confidence and understanding that these relationships are for the purpose of better patient management.

The Idorsia UK's 2023 ToV disclosure report for HCPs, ORDMs and HCOs is disclosed on the ABPI Disclosure UK database. This report provides details relating to HCPs, ORDMs, HCOs that have been provided contracted service fees and expenses, collaborative working, grants, donations, event sponsorship, event registration fees, event travel and accommodation.

The Idorsia UK's 2023 ToV disclosures for Patient Organisations and members of the public (including patients and journalists) can be found on the Idorsia UK company website.

The purpose of this methodological note is to serve as accompanying documentation to Idorsia UK's 2023 ToV disclosure report for patient organisations and members of the public (including patients and journalists). This document will allow external recipients to benefit from an informed reading of the report by understanding how the data has been collected and is reported. According to the instruction from the ABPI Code of Practice 2021, this note is published together with the annual report of ToVs.

DEFINITIONS

Idorsia UK has adopted the definitions below as per the relevant Clauses of the ABPI Code of Practice 2021.

HEALTHCARE PROFESSIONAL (HCP, Clause 1.9)

Includes any member of the medical, dental, pharmacy or nursing profession and any other

person who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine.

Transfers of Value made to Allied HCPs, including Psychologists will also be disclosed in the Idorsia UK report.

The Idorsia UK report will be based and dependant on reference data stored in Idorsia systems.

HEALTHCARE ORGANISATION (HCO, Clause 1.8)

Either a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more health professionals or other relevant decision makers provide services.

If a healthcare organisation consists of only one health professional or other relevant decision maker, then it would be subject to the requirements in the Code regarding individual health professionals.

OTHER RELEVANT DECISION MAKER (ORDM, Clause 1.13)

An individual with an National Health Service (NHS) role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who is not a health professional.

PATIENT ORGANISATION (Clause 1.15)

An organisation mainly comprising of patients and/or caregivers or any user organisation such as a disability organisation, carer or relative organisation and consumer organisation that represents and/or supports the needs of patients and/or caregivers.

EVENTS (Clause 1.7)

Includes all professional, promotional, scientific and educational meetings, congresses, conferences, symposia, and other similar events organised or sponsored by or on behalf of a company.

This includes, but is not limited to:

- advisory board meetings
- visits to research or manufacturing facilities
- planning, training or investigator meetings for clinical trials and non-interventional studies

COLLABORATIVE WORKING (Clause 1.3)

A pharmaceutical company working with other organisations to deliver initiatives which either enhance patient care or are for the benefit of patients or alternatively benefit the NHS and, as a minimum, maintain patient care.

DONATION AND GRANTS (Clause 1.5)

Providing funds, benefits-in-kind or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient organisation, institution and the like to provide goods or services to the benefit of the pharmaceutical company in return.

Donations and grants to individuals are prohibited.

Donations are physical items, services or benefits-in-kind which may be offered or requested.

Grants are the provision of funds.

RESEARCH AND DEVELOPMENT (Clause 1.20)

For the purpose of disclosure, research and development transfers of value are transfers of value to HCPs or HCOs related to the planning or conduct of:

- non-clinical studies (as defined in the OECD Principles on Good Laboratory Practice)
- clinical trials (as defined in Regulation 536/2014)
- 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 health professionals specifically for the study

Costs that are subsidiary to these activities are included in a single aggregate amount.

TRANSFER OF VALUE (TOV, Clause 1.25)

A direct and indirect TOV, whether in cash, in-kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of medicines.

A direct TOVs is one made directly by a company for the benefit of a recipient.

An indirect TOV is those made on behalf of a company for the benefit of a recipient or through an intermediate and where the company knows or can identify the recipient that will benefit from the ToV.

REPORTING OF TRANSFERS OF VALUE

Direct transfers of value will be disclosed in the ToV period during which payments are paid irrespective of the contract date, contract duration or event date.

Indirect ToVs will be disclosed with the date provided to Idorsia UK by the intermediary. In the event that the payment date is not provided by the intermediary, then the event date is used.

TRANSFER OF VALUE CATEGORIES

The following types of ToVs have been disclosed under the following category types.

CATEGORY	DESCRIPTION
Financial support - Grants	This includes: <ul style="list-style-type: none"> - Charitable contributions - Educational grants (e.g., fellowships, courses provided by a patient organisation where Idorsia does not select the individual HCPs participating) - Sponsoring of speakers/faculty which by nature of purpose and funding are classified under educational grants
Financial support – Sponsorship of Meetings	This includes: <ul style="list-style-type: none"> - Placement of a brand logo in a conference programme or invitation communication in exchange for supporting the programme - Funding an event in return for a display booth - Funding an event in exchange for advertising space - Satellite symposia at a congress - Any other activity qualified as “Corporate Sponsorship” - Sponsoring of speaker/faculty and sponsoring courses provided by a Patient Organisation which are qualified as “Corporate Sponsorship”
Financial support – Other Sponsorships	Patient organisations (including individuals representing patient organisations) to attend events/meetings
Non-financial support - Donations	Physical items, benefits-in-kind or services freely given for the purpose of supporting the patient organisation. This includes educational materials provided to patient organisations for the purpose of disease area training.
Contracted Services - Fees	Fees received in consideration for consultancy services and/or ToVs resulting from or related to a contract between Idorsia UK Ltd and the patient organisations or member of the public under which provide any type of services to Idorsia Ltd. This includes: <ul style="list-style-type: none"> - Speaker engagements - Advisory Boards - Study-related engagements - Medical writing - Data analysis - Development of education materials - General consulting / advising - Speaker training if linked to a speaker engagement
Contracted Services - Expenses	Travel (e.g. flight, train, taxi, car hires, tolls, mileage reimbursement, parking) Accommodation
Non-monetary benefit for Patient Organisation	Non-financial and/or indirect support (donation) cannot be assigned a meaningful monetary value. This includes employee hours or company facilities offered to support the patient organisation

EXCLUDED TOVs

The following are not included as TOVs for the purposes of disclosure:

- HCP, HCO and ORDM contracted service fees and expenses, collaborative working, grants, donations, event sponsorship, event registration fees, event travel and accommodation are reported separately on the ABPI Disclosure UK database
- Hospitality costs, i.e. subsistence provided to health professionals (meals and drinks), unless an integral and inseparable part of the cost of an event, e.g. sponsorship of a third-party HCO event
- Items for HCPs/ORDMS or HCOs and patient educational materials
- Logistical costs related to Idorsia UK Ltd. organised meetings/events

OTHER CONSIDERATIONS

MULTI-YEAR CONTRACTS

Idorsia UK discloses the details of the payment on the date the ToV was made and not for the full value of the contract.

CROSS-BORDER ENGAGEMENTS

Transfers of value paid from other Idorsia legal entities in other countries to patient organisations and members of the public (including patients and journalists) from the UK, will be disclosed within the UK report. The disclosure report includes ToVs made to patient organisations and members of the public (including patients and journalists) in the United Kingdom. This includes all ToVs (direct and indirect) made by any Idorsia affiliates in the European countries included in the EFPIA disclosure code. For non EFPIA countries, Idorsia UK will make its best effort to collect and disclose direct transfers of value made by Idorsia affiliates.

Transfers of value paid to other EFPIA country patient organisations will be disclosed on the Idorsia Pharmaceuticals Ltd company website.

TRACKING AND COLLATION OF DISCLOSURES

Idorsia UK maintains all ToV data made to patient organisations and members of the public (including patients and journalists) on a single spreadsheet. This data is based on relevant contracts, agreements, data privacy consent responses, other Idorsia affiliate ToV information, agency submitted ToV information and invoice and payment dates stored on various finance platforms.

CURRENCY

All disclosures will be displayed in pound sterling (GBP). Where payments were made in a currency other than GBP, the disclosed value will be the exact equivalent value in GBP calculated using the exchange rate on the date on which the payment was made.

The pound sterling totals will be calculated using the exchange rate on the date of payment. Readers should understand that the total amounts disclosed in pound sterling could therefore vary slightly from the exact amount paid in the local currency; variations will be

greater if there have been significant movements in exchange rate during the reporting period.

TREATMENT OF VAT AND OTHER TAX ASPECTS

Idorsia UK reports transfers of value as net (i.e. without value added tax or withholding tax unless the collection of net values is not possible through Idorsia's financial systems). There are no other tax considerations.

INDIRECT PAYMENTS

Idorsia UK may contract with agencies (such as an advertising, marketing, or PR agency) that make transfers of value to patient organisations and members of the public (including patients and journalists). The end recipient (patient organisations and members of the public, including patients and journalists) may not appear within Idorsia UK's accounting tool. Idorsia UK makes the best effort to ensure that these transfers are value made on our behalf are captured and reported as if they were made directly by requesting information from our agencies.

DATA PRIVACY

In accordance with applicable laws, rules, regulations and requirements relating to the privacy and security of Personal Data (as defined in the EU Data Protection Directive 95/46/EC or any replacement legislation), Idorsia UK will not disclose personal data relating to members of the public (including patients and journalists). Idorsia UK has declared the total spend as part of an aggregate figure within each relevant disclosure category, alongside the total number of recipients disclosed in aggregate.

PUBLICATION

Idorsia UK will submit and publish transparency disclosure reports in line with country timelines as defined by the trade association or government.

This disclosure report covers all payments made to UK patient organisations and members of the public (including patients and journalists) between 1st January 2023 to 31st December 2023.

The Idorsia Pharmaceuticals UK Ltd ToV disclosure report will remain publicly available for a period of 3 years.

MANAGEMENT OF TOV RECIPIENT QUERIES

Queries and clarification requests made by patient organisations are managed through Idorsia UK.