

# Vifor Methodological Note

## June 2024

This Methodological Note describes the methods used by Vifor in Ireland to meet its obligations and the requirements for disclosing payments and Transfers of Value (TOV) to Healthcare Professionals (HCPs), Other Relevant Decision Makers (ORDMs) and Healthcare Organisations (HCOs) as outlined in the EFPIA HCP/HCO Code of Practice and reflected in the Irish Pharmaceutical Healthcare Association (IPHA) Code of Practice.

Transfers of Value made to Patient Organisations and the Public, Including Patients and Journalists will continue to be disclosed separately on the Vifor website <https://www.csl.com/we-are-csl/our-businesses-and-products/disclosures#Vifor>

<b>Country:</b>	Ireland
<b>Last Update:</b>	June 2024

## Table of Content

<b>1</b>	<b>Introduction</b>	<b>3</b>
<b>2</b>	<b>Document Purpose and Scope</b>	<b>3</b>
<b>3</b>	<b>Definitions</b>	<b>3</b>
	TRANSFER OF VALUE (TOV)	3
	RECIPIENTS	3
	REPORTING CATEGORIES	4
<b>4</b>	<b>Disclosure Scope</b>	<b>5</b>
	EXCLUDED TRANSFER OF VALUE	5
	DIRECT AND INDIRECT TRANSFER OF VALUE	5
	TRANSFER OF VALUE DATE	5
	CROSS-BORDER ACTIVITES	6
	FURTHER CONSIDERATIONS	6
<b>5</b>	<b>Consent Management</b>	<b>6</b>
	CONSENT COLLECTION	6
	MANAGEMENT OF REQUESTS AND CONSENT WITHDRAWALS	6
<b>6</b>	<b>Disclosure Form</b>	<b>7</b>
	TIME OF PUBLICATION	7
	PLATFORM	7
<b>7</b>	<b>Financial Consideration</b>	<b>7</b>
	TAX ASPECTS	7
	CURRENCY ASPECTS	7
	CALCULATION RULES	7
<b>8</b>	<b>Country-Specific Consideration</b>	<b>7</b>
	UNIQUE IDENTIFIER	7

## 1 Introduction

Interactions between pharmaceutical companies and healthcare professionals (HCPs) and healthcare organisations (HCOs) are indispensable for the exchange of knowledge and the improvement of patient care. Vifor is fully committed to ensuring that these interactions meet the high standards of integrity and transparency expected by patients, governments, society and other stakeholders. Vifor complies with the obligation to identify, collate and disclose transfers of value to healthcare professionals and healthcare organisations in accordance with the EFPIA Code on Disclosure and IPHA Code. For more information on the above Codes please visit <https://www.efpia.eu/relationships-code/disclosure-of-payments/> or <https://www.ipha.ie/>.

## 2 Document Purpose and Scope

This Methodological Note summarises the methodologies and business decisions as well as country specific considerations applied by Vifor when preparing its disclosure report. The report includes transfers of value by all Vifor Group companies (Vifor and Vifor Fresenius Medical Care Renal Pharma) to healthcare professionals and healthcare organisations based in Ireland.

Transfers of value to healthcare professionals and healthcare organisations based in other countries are disclosed separately and can be found on the global website for CSL (<https://www.csl.com/we-are-csl/our-businesses-and-products/disclosures>)

For information on the methodologies applied in preparing these disclosure reports, please consult the respective methodological note on the global website of the Vifor Group (<https://www.csl.com/we-are-csl/our-businesses-and-products/disclosures>)

## 3 Definitions

### TRANSFER OF VALUE (TOV)

Direct and indirect Transfers of Value (TOVs), whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only medicinal products exclusively for human use.

### RECIPIENTS

Any healthcare professional and healthcare organisation whose primary practice, principal professional address or place of incorporation is in Ireland .

- **Healthcare Professional (HCP)** is defined as 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.
- **Healthcare Organisation (HCO)** is 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 healthcare professionals or other relevant decision makers provide services.

## REPORTING CATEGORIES

Vifor applies the EFPIA Disclosure Code’s reporting categories definitions. The following table provides examples (list not exhaustive) of the specific activities reported under each category.

<p><b>Donations and grants to HCOs</b></p>	<ul style="list-style-type: none"> <li>- Charitable contributions</li> <li>- Donations for the purpose of supporting healthcare or research</li> <li>- Educational grants (e.g., independent educational programs)</li> <li>- Research grants (if not falling under the definition of Research and Development*)</li> </ul>
<p><b>Contribution to costs of events – sponsorship agreements with HCOs or with third parties appointed by a HCO to manage an Event</b></p>	<ul style="list-style-type: none"> <li>- Funding an event in exchange for the placement of a brand logo in a conference program or invitation communication</li> <li>- Funding an event in return for a display booth or projection area at the event</li> <li>- Satellite symposia at a congress</li> <li>- Funding or support of HCO website in return for space to publish educational or promotional content or link to Vifor website</li> <li>- Other advertisement space (in paper, electronic or another format)</li> </ul> <p>Note: Catering costs are only included in the disclosed TOV if they form part of the sponsorship package.</p>
<p><b>Contribution to costs of events – registration fees</b></p>	<ul style="list-style-type: none"> <li>- Registration fees paid for HCPs/HCOs to attend third-party educational events</li> </ul> <p>Note: Vifor does not charge registration fees for its own events. Logistical costs e.g., hire of facilities associated with Vifor stand-alone events are not disclosed.</p>
<p><b>Contribution to costs of events – travel and accommodation</b></p>	<ul style="list-style-type: none"> <li>- Travel (e.g., flight, train, taxi, mileage reimbursement, parking)</li> <li>- Accommodation</li> </ul> <p>Note: Travel and accommodation costs related to services or research &amp; development activities are not covered in this category.</p>
<p><b>Contracted Services - Fees</b></p>	<ul style="list-style-type: none"> <li>- Speaker engagements</li> <li>- Advisory boards and other consulting engagements</li> <li>- Data analysis, medical writing and development of educational materials</li> <li>- Other research-related services (if not falling under the definition of Research and Development*)</li> </ul>
<p><b>Contracted Services - expenses</b></p>	<ul style="list-style-type: none"> <li>- Travel (e.g. flight, train, taxi, mileage reimbursement and parking)</li> <li>- Accommodation</li> </ul> <p>Note: Where expenses are immaterial or cannot be disaggregated from the service fee without unreasonable effort they are disclosed under “Fees for Services and Consultancy” category.</p>
<p><b>Research and development</b></p>	<ul style="list-style-type: none"> <li>- Fee for investigator activities related to research and development</li> <li>- Funding of investigator-initiated research</li> <li>- Activities contracted to CROs, where indirect TOVs are made to HCPs/HCOs</li> </ul> <p>Note: TOVs related to research activities which do not fall under the definition of Research and Development* (e.g. retrospective non-interventional studies) are not covered in this category. TOVs related to research &amp; development are disclosed in aggregate form.</p>

	<p>*Research and Development TOVs: TOVs to HCPs/HCOs related to the planning and conduct of (i) non-clinical studies (as defined in the OECD Principles of GLP), (ii) clinical trials (as defined in Directive 2001/20/EC), or (iii) non-interventional studies that are <u>prospective</u> in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study (Clause 24.6 SI of the ABPI Code).</p>
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## 4 Disclosure Scope

### EXCLUDED TRANSFER OF VALUE

The following TOVs are not included in Vifor’s disclosure report:

- TOVs solely related to over-the-counter medicines
- TOVs excluded from the scope of the EFPIA Disclosure Code, such as informational and educational materials, items of medical utility, food and beverages, medical samples.
- Third party fees relating to logistical assistance in relation to organising travel or events/meetings
- TOVs which are part of the ordinary course of purchase and sale of medicinal products, such as discounts, price reductions and other trading devices.

### DIRECT AND INDIRECT TRANSFER OF VALUE

Vifor discloses direct and indirect TOVs.

Direct TOVs are defined as those made directly by Vifor to the benefitting Recipient.

Indirect TOVs are defined as those made on behalf of Vifor for the benefit of a Recipient or made through an intermediary (e.g., meeting organiser) and where Vifor knows or can identify the benefitting Recipient.

In general, TOVs are reported at the level of the first identifiable Recipient which falls under the definition of an HCP/HCO. Each TOV is only disclosed once to avoid duplication.

- TOVs to HCOs through a third party are disclosed under the HCO (e.g., sponsorship provided to a medical association through an event organiser),
- TOVs to individual HCPs through a third party are disclosed under the HCP (e.g., travel arrangements made through a travel agency),
- TOVs to self-incorporated HCPs are disclosed under the individual HCP,
- TOV to a patient via a third party or organisation would be disclosed against the patient.

### TRANSFER OF VALUE DATE

This disclosure report includes all TOVs disclosed had a payment made between 1st January 2023 and 31st December 2023. These payments do include some activities conducted in 2022 where payment was made in 2023.

## **CROSS-BORDER ACTIVITIES**

TOVs are disclosed in the country where the Recipient has their primary practice, principal professional address or its place of incorporation.

The disclosure report includes all TOVs to Recipients based in Ireland, including TOVs made by foreign affiliates and TOVs related to events taking place outside of Ireland.

## **FURTHER CONSIDERATIONS**

TOVs to Contract Research Organisations/Clinical Research Organisations (CRO), are not included in the disclosure report unless (i) the CRO is comprised of HCPs or linked to a HCO and therefore falls under the definition of an HCO, or (ii) the TOV constitutes an indirect TOV through the CRO to the benefit of a HCP/HCO.

## **5 Consent Management**

In compliance with applicable data privacy regulations, the disclosure of personal data is dependent on the explicit consent of the HCP concerned.

### **CONSENT COLLECTION**

Vifor advocates transparency and encourages Recipients to grant consent to full disclosure. Vifor request consent once per calendar year, not for each activity and for HCPs this has been given at the same time as contracts signed for the initial annual activity undertaken with Vifor.

Vifor discloses the TOV in the aggregate section of the disclosure report if:

- the Recipient dissents to the disclosure of the data,
- the Recipient only grants partial consent,
- no response from the Recipient is received on time.

Vifor have taken the decision to move to legitimate interest, this will take effect in 2024.

### **MANAGEMENT OF REQUESTS AND CONSENT WITHDRAWALS**

Consent is voluntary and can be withdrawn at any time in writing to [VPUKCompliance@viforpharma.com](mailto:VPUKCompliance@viforpharma.com).

Recipients may also contact Vifor at [VPUKCompliance@viforpharma.com](mailto:VPUKCompliance@viforpharma.com) to request further information about, or corrections to, the published data. Subject to Vifor's internal review and approval, changes resulting from disputes will be published from time to time.

## 6 Disclosure Form

### TIME OF PUBLICATION

TOVs are disclosed on an annual basis and within six months after the end of the calendar year. The disclosure report remains in the public domain for a minimum of three years, unless required otherwise for legal reasons.

### PLATFORM

The disclosure report can be accessed via <https://www.csl.com/we-are-csl/our-businesses-and-products/disclosures>

## 7 Financial Consideration

### TAX ASPECTS

In general, VAT is excluded from the TOVs in this report.

Two exceptions from the above rule exist:

- For indirect payments related to events, VAT is typically not recoverable for Vifor and the company's systems do not capture VAT separately. In this instance the reported TOV will include VAT.
- The same applies to actual cross-border spend captured for which no VAT is readily identifiable. In this instance, reported TOV will include VAT.

### CURRENCY ASPECTS

- TOVs are disclosed in the local currency of the recipients' country of primary practice or incorporation.
- TOVs paid in foreign currencies are converted to the local currency using the average yearly exchange rate indicated by Vifor.

### CALCULATION RULES

TOVs are valued at the cost amount for Vifor and not the Recipient's revenue.

TOVs to multiple Recipients (e.g., group transportation, sponsorship of event organised by more than one HCO) are whenever possible disaggregated. Where an exact disaggregation is not possible, the TOV is divided by the total number of Recipients (including non-HCPs/HCOs).

## 8 Country-Specific Consideration

### UNIQUE IDENTIFIER

Vifor uses the IQVIA's OneKey database for HCPs and HCOs so that in as far as possible, a single searchable record is published for each individual and organisation.