

METHODOLOGICAL NOTE

on the EFPIA disclosure of transfers of value to healthcare professionals and organizations

Country: Bulgaria

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Version: 01; this document replaces previous drafts and versions

1 Introduction

Interactions between pharmaceutical companies and healthcare professionals and healthcare organizations are indispensable for the exchange of knowledge and the improvement of patient care. Vifor Pharma 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 Pharma complies with the obligation to identify, collate and disclose transfers of value to healthcare professionals and healthcare organizations in accordance with the:

- EFPIA Code on Disclosure of Transfers of Value From Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations (EFPIA Disclosure Code)
- AEPPharm: Consolidated Code of Ethics of the Research-based Pharmaceutical Industry in Bulgaria

For more information on the above mentioned codes please visit <http://transparency.efpia.eu> or <http://arpharm.org/index.php?id=914>.

2 Document Purpose and Scope

This Methodological Note summarizes the recognition methodologies and business decisions as well as country specific considerations applied by Vifor Pharma when preparing its disclosure report. The report includes transfers of value by all Vifor Pharma Group companies (Vifor Pharma, Vifor Fresenius Medical Care Renal Pharma, and Relypsa). Transfers of Values made by OM Pharma from 1 January to 30 September 2020 are disclosed in the report, and are excluded from 1 October 2020 following the divestment.

The report includes transfers of value to healthcare professionals and healthcare organizations based in Bulgaria.

Transfers of value to healthcare professionals and healthcare organizations based in other countries are disclosed separately. For information on the methodologies applied in preparing these disclosure reports, please consult the respective methodological note on the global website of the Vifor Pharma Group (<https://www.viforpharma.com/responsibility/integrity/transparency>).

3 Definitions

3.1 Transfers of Value (ToVs)

Direct and indirect Transfers of Value ("ToVs"), whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of medicinal products exclusively for human use.

3.2 Recipients

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

A Healthcare Professional (“HCP”) is defined as 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 or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product.

A Healthcare Organization (“HCO”) is any legal person that is a healthcare, medical or scientific association or organization such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organizations).

3.3 Reporting Categories

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

Donations and grants to HCOs	<ul style="list-style-type: none"> - Charitable contributions - Donations for the purpose of supporting healthcare or research - Educational grants (e.g. independent educational programs) - Research grants (if not falling under the definition of Research and Development*)
Contribution to costs of events – sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event	<ul style="list-style-type: none"> - Funding an event in exchange for the placement of a brand logo in a conference program or invitation communication - Funding an event in return for a display booth or projection area at the event - Satellite symposia at a congress - Funding or support of HCO website in return for space to publish educational or promotional content or link to Vifor website - Other advertisement space (in paper, electronic or other format) <p>Note: Catering costs are included in the disclosed ToV if they form part of the sponsorship package.</p>
Contribution to costs of events – registration fees	<ul style="list-style-type: none"> - Registration fees paid for HCPs/HCOs to attend third-party educational event <p>Note: Vifor Pharma does not charge registration fees for its own events. Logistical costs e.g. hire of facilities associated with Vifor Pharma stand-alone events are not disclosed.</p>
Contribution to costs of events – travel and accommodation	<ul style="list-style-type: none"> - Travel (e.g. flight, train, taxi, mileage reimbursement, parking) - Accommodation <p>Note: Travel and accommodation costs related to services or research & development activities are not covered in this category.</p>
Fees for services and consultancy	<ul style="list-style-type: none"> - Speaker engagements - Advisory boards and other consulting engagements - Data analysis, medical writing and development of educational materials - Market research (if identity of participant is known) - Other research-related services (if not falling under the definition of Research and Development*)
Related expenses agreed in the fee for service or consultancy contract (including travel and accommodation relevant to the contract)	<ul style="list-style-type: none"> - Travel (e.g. flight, train, taxi, mileage reimbursement, parking) - Accommodation <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>
Research and development	<ul style="list-style-type: none"> - Fee for investigator activities related to research and development - Funding of investigator initiated research - Activities contracted to CROs, where indirect ToVs are made to HCPs/HCOs

	<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 & development are disclosed in aggregate form.</p> <p>*Research and Development ToVs: <i>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 (Section 15.02 of the EFPIA HCP Code).</i></p>
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4 Disclosure Scope

4.1 Excluded Transfers of Value

The following ToVs are not included in Vifor Pharma's disclosure report:

- ToVs excluded from the scope of the EFPIA Disclosure Code, such as informational and educational materials, items of medical utility, food and beverage, medical samples
- Fees charged by logistics agencies assisting in organizing travel and 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

4.2 Direct and Indirect Transfers of Value

Vifor Pharma discloses direct and indirect ToVs.

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

Indirect ToVs are defined as those made on behalf of Vifor Pharma for the benefit of a Recipient or made through an intermediary (e.g. meeting organizer) and where Vifor Pharma 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 organizer)
- ToVs to individual HCPs through a third party are disclosed under the HCP (e.g. travel arrangements made through a travel agency)
- ToVs to individual HCPs through an HCO are disclosed under the HCO, where the contracting party and account holder is the HCO (e.g. HCP rendering services on behalf of an HCO)
- ToVs to self-incorporated HCPs are either disclosed under the individual HCP or the HCP's company (i.e. HCO) depending on the underlying contract

4.3 Transfers of Value Date

The disclosure report includes all ToV whose date falls within the year 2020.

- The ToV date is generally defined as the activity date.
- ToVs for which relevant data becomes available only after the cutoff date on 31.01.2021, will be included in the following disclosure report (e.g. if invoice has not been received or if cross-border activities have not been communicated on time).
- For multi-year contracts or contracts covering multiple ToVs, each individual ToV is disclosed according to the methodology described above.

4.4 Partial Attendance or Cancellation

ToVs made to Recipients despite cancellation or partial attendance, such as cancellation fees, are included in the disclosure report.

4.5 Cross-border Activities

ToVs are disclosed in the country where the Recipient has his/her primary practice, principal professional address or its place of incorporation.

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

4.6 Further Considerations

- ToVs to Contract Research Organizations/Clinical Research Organizations (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.

5.1 Consent Collection

Vifor Pharma advocates transparency and encourages Recipients to grant consent to full disclosure.

Consent is obtained on a Recipient level at the time of the first relevant activity and is valid for the full calendar year and consecutive calendar years till (i) the Recipient decides to withdraw consent or (ii) the end of a period of three consecutive years without any interactions between Vifor Pharma and the Recipient involving a transfer of value made to the Recipient by Vifor Pharma.

Vifor Pharma 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

5.2 Management of Requests and Consent Withdrawals

Consent is voluntary and can be withdrawn at any time in writing to Vifor Pharma at transparency@viforpharma.com.

Recipients may also contact Vifor Pharma at GroupDPO@viforpharma.com to request further information about, or corrections to, the published data. Subject to Vifor Pharma's internal review and approval, changes resulting from disputes will be published from time to time.

6 Disclosure Form

6.1 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.

6.2 Platform

The disclosure report is unrestricted and publicly accessible on the global website of the Vifor Pharma Group (<https://www.vifor-pharma.com/responsibility/integrity/transparency>).

6.3 Language

The disclosure report is available in Bulgarian.

7 Financial Considerations

7.1 Tax Aspects

Whether Vifor Pharma discloses the ToV at gross or net value (i.e. including or excluding tax) depends on the underlying invoice.

7.2 Currency Aspects

ToVs are disclosed in the local currency of the Recipients' country of primary practice or incorporation. ToVs in foreign currencies are converted into local currency.

- ToVs by Vifor Pharma are converted on the day of documenting the effective payments in the electronic system using actual exchange rates in agreement with the accounting policy of Vifor Pharma
- ToV by foreign affiliates (i.e. cross-border ToVs) are converted when preparing the disclosure report using average yearly exchange rates indicated by Vifor Pharma Group

7.3 Calculation Rules

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

ToVs to multiple Recipients (e.g. group transportation, sponsorship of event organized 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).