

METHODOLOGICAL NOTE

on the EFPIA disclosure of transfers of value to healthcare professionals, healthcare organisations and patient organisations

Country: Romania

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1 Introduction

Interactions between pharmaceutical companies and healthcare professionals and healthcare organisations 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 organisations in accordance with the:

- EFPIA Code on Disclosure of Transfers of Value From Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations (EFPIA Disclosure Code)
- ARPIM code related to the disclosure of ToVs from pharmaceutical companies and healthcare professionals and healthcare organisations
- Law no. 95/2006 on health care reform, republished, with subsequent amendments and completions
- Order of Ministry of Health no. 194/2015 on the approval of the Norms for the evaluation and approval of advertising for medicines for human use

For more information on the above mentioned codes please visit <http://transparency.efpia.eu>, <https://arpim.ro/codul-de-etica/> or <https://www.anm.ro/medicamente-de-uz-uman/publicitate/legislatie-specifica-publicitate/>.

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 Romania SRL 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). Due to the fact that Omedicamed Unipessoal products are in the Vifor Pharma Romania portfolio, the ToV related to pathology target for Omedicamed Unipessoal products are disclosed in the Transparency Report.

The report includes transfers of value to healthcare professionals and healthcare organisations based in Romania. Transfers of value to healthcare professionals and healthcare organisations 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 prescription-only medicinal products exclusively for human use.

3.2 Recipients

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

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 organisations).

Patient Organization ("PO"): non-for-profit legal person/entity (including the umbrella organization to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in Europe.

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)

	<ul style="list-style-type: none"> - 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>
ToV to PO	<ul style="list-style-type: none"> - For support: <ul style="list-style-type: none"> – the monetary value of financial support and of invoiced costs. – the non-monetary benefit that the PO receives when the non-financial support cannot be assigned to a meaningful monetary value. - For contracted services: the total amount paid per PO over the Reporting Period.
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 and must be reported on an individually named basis. ToVs related to research & development are disclosed in aggregate form.</p> <p><i>*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 (Section 15.02 of the EFPIA HCP Code).</i></p>

4 Disclosure Scope

4.1 Excluded Transfers of Value

The following ToVs are not included in Vifor Pharma'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 beverage, medical samples
- Fees charged by logistics agencies assisting in organising 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/PO. 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 2021.

- The ToV date is generally defined as the payment date. ToVs for which relevant data becomes available only after the cutoff date on 31.03.2022 will be included in the following disclosure report (e.g. if invoice has not been received 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 not received by the Recipient as a result of partial attendance or cancellation are excluded from disclosure.

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 Romania, including ToVs made by foreign affiliates and ToVs related to events taking place outside Romania.

4.6 Further Considerations

- ToVs to Contract Research Organizations/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 local regulations, ToVs disclosure (including personal data) is mandatory and the explicit consent of the HCP or HCO/PO is not required.

5.1 Consent Collection

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

Consent is generally obtained for each TOV as part of the written contract between Vifor Pharma and the Recipient. Pharma companies are encouraged (by ARPIM) to include in the agreements with HCO and HCP/PO a clause related to the obligation of Vifor Pharma to report the ToV..

Before the publication of the disclosure report, Recipients receive a statement with the details of ToVs to be disclosed. This gives the Recipient the opportunity to verify and review the information to ensure it is accurate.

5.2 Management of Requests

Recipients may also contact Vifor Pharma at office.romania@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, until 31.03.2022 and within six months after the end of the calendar year for Research and Development ToVs. 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 published on the external central platform: <https://sponsorizari.anm.ro/afisare-2021/sponsori>. Vifor Pharma provides a link to the central platform on its website.

6.3 Language

The disclosure report is available in Romanian.

7 Financial Considerations

7.1 Tax Aspects

For direct ToVs Vifor Pharm discloses ToV at gross value (not VAT included in case of service agreements; VAT included in case of sponsorship agreements). Where income tax or equivalent is withheld by Vifor Pharma on amounts earned by the Recipients, the ToV will include these amounts. For indirect ToVs Vifor Pharma discloses the ToV at grossvalue (not VAT included in case of service agreements; VAT included in case of sponsorship agreements) (i.e. including or excluding tax) depending 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

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).

8 Country-Specific Considerations

8.1 Unique Identifier

Vifor Pharma uses the Personal Numeric Code (CNP) for HCPs and Fiscal Identification Code (CIF) for HCO/POs to ensure that there is no doubt as to the identity of the benefitting Recipient.