

METHODOLOGICAL NOTE

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

Country: United Kingdom

Last Update: 20.03.2018

Version: 02, this document replaces previous drafts and versions

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 Group 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 Group 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)
- Association of British Pharmaceutical Industry's Code of Practice (ABPI Code)

For more information on the above mentioned codes please visit <http://transparency.efpia.eu> or <http://www.abpi.org.uk/ethics/ethical-responsibility/disclosure-uk/>

2 Document Purpose and Scope

This Methodological Note summarizes the recognition methodologies and business decisions as well as country specific considerations applied by Vifor Fresenius Medical Care Renal Pharma UK Ltd. ("VFMCRP UK") when preparing its disclosure report. The report includes transfers of value by VFMCRP to healthcare professionals and healthcare organisations based in the United Kingdom.

Transfers of value to healthcare professionals and healthcare organisations based in other countries as well as transfers of value by Vifor Pharma UK Ltd. 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 (<http://www.vifor-pharma.com/en/about-vifor-pharma/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 the United Kingdom.

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).

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 Vifora 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 activities (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</i></p>

	<i>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>
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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 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. 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 2017.

- The ToV date is generally defined as the event date. For ToVs related to donations and grants as well as research & development the ToV date is defined as the payment date.
- ToVs for which relevant data becomes available only after the cutoff date on 31.12.2017 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 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 the United Kingdom including ToVs made by foreign affiliates and ToVs related to events taking place outside of the United Kingdom

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 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 generally obtained for each ToV as part of the written contract between Vifor Pharma and the Recipient.

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. To withdraw consent or to request further information about, or corrections to, the published data, Recipients may contact Vifor Pharma at [mailto:info_VFMCRPUK@viforpharma.com].

Updates to the disclosure report are conducted on a regular basis to reflect data updates or consent withdrawal after disclosure submission.

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 published on the external central platform <https://www.abpi.org.uk/ethics/ethical-responsibility/disclosure-uk/>. Vifor Pharma provides a link to the central platform on its website.

6.3 Language

The disclosure report is available in English.

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).

8 Document History

Version	Effective Date	Summary of Changes
01	22.06.2016	New methodological note template
02	28.03.2018	Revision of content and structure of all sections