

# Lenis/Medicopharmacia Transparency Reporting Methodological Note

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## 1. Introduction

This methodological note is intended to help readers understand how the Transfers of Value (ToVs) from Lenis farmacevtika d.o.o. and its Affiliates (collectively referred as Lenis) to Healthcare Professionals (HCPs), Healthcare Organisations (HCOs) and Patient Organisations (POs) (collectively referred to as Reportable Recipients) have been collated and reported. This note covers all Lenis' affiliates countries.

A glossary has been included at the end of this methodological note containing an alphabetical list of the main terms used within this note and their definitions.

Lenis began its transparency reporting project independently in 2023, in addition to reporting made in previous years to its principals/partners who are EFPIA members.

EFPIA or the „European Federation of Pharmaceutical Industries and Associations“ is the body that represents the pharmaceutical industry in Europe containing collection of ethical rules for the Promotion of Medicinal Products to HCPs and the interactions with Reportable Recipients. The requirements for Disclosure of ToVs made to Reportable Recipients is part of the EFPIA Code.

Although Lenis and its Affiliates are not part of EFPIA, Lenis decided to voluntarily report ToV independently to promote transparency in pharmaceutical industry. A healthy working relationship between the pharmaceutical industry and HCPs/HCOs is in the best interest of patients and the EFPIA Disclosure was created to protect the integrity of these relationships.

## 2. Definition of Transfers of Value

Transfer of Value (ToV) is a financial support and/or significant indirect/non-financial support provided by Lenis to an HCP, HCO or PO.

ToVs may arise from the following broad types of activity (there are others):

- a. **Fee for service** - Lenis may contract with an HCP or an HCO in exchange for services provided by the HCP/HCO based on scientific/medical expertise, reputation, knowledge and experience in a particular therapeutic area. Lenis enters into contractual arrangements with an HCP or an HCO only where there is a legitimate business or scientific need which cannot be satisfied by internal or other available sources. The services provided may be insights, presentations or other consulting services. Patients and POs via their representatives also may give Lenis independent advice and contribute via their personal experience where the knowledge cannot be obtained within Lenis. Also, some Non-for-Profit Organisations (NGOs) that do not identify as „Patient Organisations“ support specific projects which directly support the needs of patients within the scope of Lenis's therapeutic areas and may be under these circumstances considered qualified as a reportable ToV. Lenis may pay a honorarium to each participant and/or pay their travelling expenses to the place where the meeting is being held. If a Patient is representing a PO in an official capacity, remuneration should be paid to the Patient organisations and not to the Patient. The same principle applies for representatives of other NGOs.

**Related expenses** - where a service agreement is in place, other expenses may occur which do not constitute part of the fees but relate to the provision of this service and are paid for the HCP, for e.g. travel or lodging.

Contractual arrangements lasting several years – disclosure of the individual payments will be based on the date of receipt of the respective invoices. Details depend on the contract with the consultant (e.g. what services are agreed for which time period, which amounts are foreseen for these services, etc.)

- b. **Meetings** - Lenis organizes meetings for HCPs on different topics such as education in a specific therapy area or other scientific events. The knowledge and expertise of HCPs or POs are often needed to help conduct these events. Lenis may arrange meetings focusing on disease awareness. The knowledge and expertise from Patients and POs are often needed to help conduct these events. Lenis may pay honoraria and/or travelling and lodging expenses to the consultants, Patients and Patient Organisation representatives participating in these events. The same principle applies to Non-for-Profit Organisations (NGOs) that do not identify as „Patient Organisations“, however they support specific projects which directly support the needs of patients within the scope of Lenis’s therapeutic areas.
- c. **Individual support** – Lenis may support one or more HCPs or members of POs, including representatives of NGOs supporting needs of patients to attend a scientific conference or congress which might include paying the HCPs’ conference fees and/or their travelling and lodging expenses. Lenis may support one or more HCOs who will propose which HCPs to send to a conference. In this case, as Lenis knows which HCPs received the ToVs, Lenis will therefore report the ToVs against the relevant HCPs.
- d. **Sponsorship** - Lenis may also sponsor a third-party event (congress for example) in exchange for corporate benefits at an event such as booth space, hosting of a symposium, stands, advertising on programmes or banners and similar. The ToVs related to sponsorships are always made to an organization.
- e. **Grants and Donations** – Lenis may make grants or donations for an educational, scientific or a charitable purpose, to enhance patient care or for the purpose of supporting research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return. Lenis may also make donation/grant for conference attendance where it may support one or more HCOs who will choose which HCPs to send to a conference. In this case, Lenis does not know which HCPs received the ToVs and will therefore report the ToVs against the relevant HCOs.
- f. **Patient screening and linkage to care (SLTC)** – Lenis may provide funding to organizations that provide SLTC to meet public health needs by raising awareness and closing the gaps between disease prevalence, diagnosis and treatment. SLTC initiatives are important for identifying infected individuals, engaging them in care and linking them to appropriate health resources.
- g. Note that food and drink is not reportable under the **EFPIA Code** so Lenis does not report it.

### 3. Definition and management of Cross-Border Spend

Some ToVs to Reportable Recipients are made by Lenis or on behalf of Lenis, that is not the “home country” (country of principal practice) of the Reportable Recipient receiving the ToVs. For example, Lenis from Slovenia can pay sponsorship to a HCO, which is a tax resident of Serbia, or make ToVs to a Macedonian HCP, or an events agency working for Lenis’s Head Office might make ToVs to several HCPs from different countries. This is called **Cross-Border Spend**.

Any ToVs made by, or on behalf of, Lenis or any of its Affiliates to Reportable Recipients within different countries, including Cross-Border Spend, are captured as described under “How Transfers of Value are captured and recorded by Lenis”.

### 4. Which Recipients of Transfers of Value are reported by Lenis

Lenis defines all Reportable Recipients as defined under the EFPIA Code.

Where HCPs have set up separate legal entities through which they deliver their services, Lenis discloses the ToV under the names of the HCPs themselves wherever clearly identifiable; otherwise, the ToV is disclosed under the name of the legal entity, being treated as an HCO.

Where Lenis has made a ToV to a department or association within an HCO, that ToV is disclosed under the name of the HCO, not the department/association.

Where Patient is representing a PO in an official capacity, ToV is disclosed under the name of the PO.

Non-for-Profit Organisations (NGOs) that do not identify as „Patient Organisations“ may receive funding from Lenis to support specific projects which directly support the needs of patients within the scope of Lenis’s therapeutic areas and may be under these circumstances considered qualified as a reportable ToV.

For all countries for which Lenis reports, the reporting template used is in English, except for the countries where local regulations require reporting in local language and/or inclusion of additional fields (e.g. specific unique identifier for HCPs and/or HCOs).

Professional Congress Organisers (PCO) are not reportable recipients. ToV made to PCOs are disclosed under the end recipients (HCOs or HCPs) if they are clearly identifiable and the exact values transferred to them are made available by the PCOs.

### 5. How Transfers of Value are captured and recorded by Lenis

#### 5.1. Direct Spend

Lenis makes some ToVs directly to Reportable Recipients; these transfers are referred to as **Direct Spend**. Direct Spend typically covers items such as fees for services and associated travelling expenses.

Lenis uses a template Excel spreadsheet to capture ToVs to Reportable Recipients. The template Excel spreadsheet provides data in the same standardised format.

## 5.2. Indirect Spend

ToVs made to Reportable Recipients by **Third Party Vendors** on behalf of Lenis are called **Indirect Spend**. Indirect Spend typically covers travel and accommodation at meetings and conferences and may also include honoraria payments.

Lenis uses a template Excel spreadsheet also to capture ToV made through Third Party Vendors to Reportable Recipients. The template Excel spreadsheet provides data in the same standardised format, which are then treated in the same way as for Direct Spend as described above.

## 5.3. ToV Dates

The date recorded against each ToV determines the ToV reporting period.

For short-term activities (e.g. congresses, fee for service and similar) the ToV date recorded by Lenis is the event date and in case of multiple days events, the first day of the event or start of activity (e.g. honoraria payments for professional opinion).

For long-term activities (multi-year contracts), each individual payment determines the reporting period.

## 5.4. Treatment of Tax

TOV is shown in gross amounts (including VAT, when charged), as these are amounts paid for or on behalf of HCP.

When the ToV is taxed as Other income in accordance with the provisions of the Income Tax Act, the calculated income tax and contributions are not included in the report.

## 5.5. Currency Management

Each ToV is transferred to the Reporting Excel spreadsheet in its original currency, although some ToVs may have been made in a currency other than the local currency. For the final yearly report the amounts are converted to EUR according to the median yearly rate of Bank of Slovenia for every local currency.

## 6. How Lenis manages Consent

As required by **Data Privacy** legislation Lenis has sought **Consent** from Reportable Recipients for individual disclosure of their ToVs in the **Report**. Such Consent has been obtained either on an engagement-by-engagement basis, or by reporting period, based on Lenis Affiliate business processes.

If an HCP is the Sole proprietor he/she has been considered as an HCP and therefore the provided ToVs are disclosed following the consent management procedure. However, if the HCP works through his/her separated legal entity, in that case it will be disclosed under HCO.

Lenis does not do “partial disclosure”, i.e. an HCP can only consent to all reporting of ToVs. Either all ToVs made to a Reportable Recipient in a reporting period are disclosed individually, or they are disclosed in aggregate.

ToVs are disclosed in aggregate section of the Report if:

- a. the Recipient does not consent to disclosure;
- b. the Recipient only grants consent to some, not to all ToV;
- c. no response from the Recipient is received on time.

## 7. How Lenis avoids reporting duplicate transactions

Lenis has put in place several steps to ensure that ToVs are reported only once. The key step is that Lenis Affiliate that makes the ToV is responsible for capturing and reviewing the ToV.

Lenis' Project Manager is responsible for second review of Reportable Recipient ToVs in the Reporting Excel spreadsheet and taking reasonable steps to identify and resolve any potential duplicates or mistakes.

Where Lenis works with other pharmaceutical companies (principals, sub-distributors), each company reports the ToVs relating to the activities that they funded. For jointly organised events, the companies agree in advance which ToVs will be reported by which company. This mechanism avoids duplicate reporting for joint activities.

Where Lenis has a sponsoring agreement with several HCOs it will generally publish details ToV on an individual basis in accordance with the EFPIA Disclosure Code & local legislation. If an individual ToV can be allocated pro rata to the relevant organisations, these shares will be published under the name of the respective organisation. If such an allocation is not possible, Lenis will assume that each organisation receives an equal share and will publish this accordingly.

## 8. How Lenis checks the accuracy of reports

In addition to the steps above to prevent duplicate ToVs, some of the activities undertaken as part of this review may include:

- a. Identifying inconsistencies in the Report output, such as travelling expenses associated with services with no fees for services, or travelling expenses related to Sponsorship of events without any associated registration fee costs;
- b. Sample checking ToVs back to source documentation, such as signed contracts or supplier invoices.

Such activities as those described above give Lenis reasonable assurance that the ToVs it reports are as accurate and complete as possible.

## 9. Publication of reports

Each initiator of activity that includes ToV to Reportable Recipients is responsible for producing ToV reports for their activities during the year. At the end of the year Lenis's Project Manager is responsible for combining the data to the final Report and publishing it appropriately. Before publishing the Report is reviewed by the Business Compliance Officer or their deputy.

The joint Report for all countries where Lenis performs ToV to Reportable Recipients is published on Lenis's website. Transfers of value made to HCPs and HCOs are recorded throughout the year and publicly disclosed by 30 June of the following year.

Reportable Recipients may notify Lenis of any errors in reporting or withdraw their Consent at any time.

In countries where Lenis has no Affiliate but where ToVs have been made to Reportable Recipients, final reporting is managed centrally by Lenis.

In countries where Lenis has no Affiliate and a local sub-Distributor makes ToVs to Reportable Recipients, sub-Distributors are responsible for reporting according to local legislation if this is stated in the Distribution Agreement and when the sub-Distributor is the end-payor of such costs.

The Report will be available for a period of three years.

Any queries regarding Lenis's reporting should be addressed to [gdpr@lenis.si](mailto:gdpr@lenis.si).

## 10. Glossary

This glossary includes the technical definitions of all terms used within this methodological note, including relevant abbreviations.

<b>Term</b>	<b>Meaning</b>
Consent	<p>Consent refers to the Reportable Recipient agreeing to Lenis's use and disclosure of that Reportable Recipient's personal data for Data Privacy purposes.</p> <p>To be valid, Consent must be given freely and must be informed.</p> <p>For Consent to be 'informed', Lenis must tell the Reportable Recipient in advance of Consent being given: (i) what personal data of that Reportable Recipient Lenis wants to collect; and (ii) how Lenis intends to use that personal data.</p> <p>Consent can be withdrawn by the relevant Reportable Recipient at any time by giving notice to Lenis.</p>
Cross-Border Spend	<p>Any payment made by one Lenis group company to a payee (Reportable Recipient) who is reportable by another Lenis Affiliate (e.g. a payment made by the Slovenian Headquarter to a Macedonian HCP is reportable by Lenis Macedonia).</p>
Data Privacy / Data Protection	<p>The laws relating to processing of personal data (information relating to an identifiable person), including General Data Protection Regulation (GDPR) and national legislation implementing the same.</p>
Direct Spend	<p>Direct spend means all Transfers of Value to a Reportable Recipient made directly by Lenis. In other words, all sums paid by Lenis directly to a Reportable Recipient. See also Indirect Spend.</p>
Disclosure Code	<p>See EFPIA Code.</p>
EFPIA	<p>EFPIA or the 'European Federation of Pharmaceutical Industries and Associations' is the body that represents the pharmaceutical industry in Europe.</p>
EFPIA Code	<p>The EFPIA Code constitutes the collection of ethical rules agreed by EFPIA members for the Promotion of Medicinal Products to HCPs and the interactions with HCPs, HCOs and POs, with the intent of guaranteeing that these activities are conducted while respecting the most stringent ethical principles of professionalism and responsibility. This Code applies to all types of communication and interaction (traditional and digital).</p>

The requirements for Disclosure of ToVs made to HCPs, HCOs and POs is part of the EFPIA Code.

Although Lenis and its Affiliates are not part of EFPIA, Lenis decided to report ToV independently in order to promote transparency in pharmaceutical industry.

HCO – healthcare organisation	An HCO is any legal entity that is a healthcare, medical or scientific association or organization such as a hospital, clinic or association through which one or more HCPs provide services.
HCP - healthcare professionals	HCP defines any 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 or administer a medicinal product.
Indirect Spend	ToVs made to Reportable Recipients by <b>Third Party Vendors</b> on behalf of Lenis.
Patients	Patients who are persons with personal experience of living with a disease. They may or may not have technical knowledge in R&D or regulatory processes, but their main role is to contribute with their subjective disease and treatment experience.
PO - Patient Organizations	<p>A PO is a non-for-profit legal person/entity (including the umbrella organisation to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers.</p> <p>Some Non-for-Profit Organisations (NGOs) that do not identify as „Patient Organisations“ may receive funding from Lenis to support specific projects which directly support the needs of patients within the scope of Lenis’s therapeutic areas and may be under these circumstances considered qualified as a reportable ToV.</p>
PO Representative - Patient Organisation Representatives	A PO Representatives are persons who are mandated to represent and express the collective views of a patient organisation on a specific issue or disease area.
SLTC – Screening and Linkage to Care	Lenis may provide funding to organizations that provide SLTC to meet public health needs by raising awareness and closing the gaps between disease prevalence, diagnosis and treatment. SLTC initiatives are important for identifying infected individuals, engaging them in care and linking them to appropriate health resources.

Reportable Receptient	Means any HCPs/HCOs/POs in relation to whom Lenis is disclosing the Transfers of Value that it makes.
Reportable Spend	All Transfers of Value made by any Lenis or by any third party on behalf of Lenis, to any Reportable Recipient.
Transfer of Value (ToV)	Transfer of Value means a direct or indirect benefit (whether money or money's worth) given to a Reportable Recipient (HCP, HCO or PO) by Lenis.
ToV Report	The local report of ToVs to Reportable Recipients.