

**EFPIA Transparency**

**Sobi Methodology Note**

**Belgium**

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## 1. Introduction

Transparency is fundamental to ensure a positive working relationship between the pharmaceutical industry and healthcare providers, relationships that best serve the interests of patients. Swedish Orphan Biovitrum (Belgium) BV is therefore committed to meet all global transparency requirements, including the EFPIA Code of Practice in Europe and the Belgian Royal Decree of 14 June 2017 implementing the Sunshine Act. The code places a requirement on pharmaceutical companies to publicly report payments (transfers of value) made to healthcare professionals (HCP), healthcare organisations (HCO) and Patient Organisations (PO).

The methodology note is a summary describing the methods used by Swedish Orphan Biovitrum (Belgium) BV, ("Sobi") during the collection and publication of ToVs to HCPs and HCOs. According to the instruction from EFPIA such a note shall be published together with the annual report of transfers of value (ToV).

The reason for publishing a methodology note is so external recipients of the annual report may fully benefit from an informed reading of the report by understanding how data has been collected. Sobi follows the local trade association instructions for disclosing ToVs provided in the local industry codes. However, there are some details which trade associations and EFPIA leave to the individual companies to decide on. This note is primarily intended to answer those questions.

The information in the methodology note corresponds to instructions provided to Sobi employees involved in the collection and reporting of transfers of value.

## 2. Methodology

### 2.1 General

*What is included in the annual report?*

Transfers of value (ToV) made by the Sobi group ("Sobi") to Healthcare Professionals (HCPs), legal entities owned by HCPs (which is then a HCO), Healthcare Organisations (HCOs) and Patient Organisations (POs) with their primary practice/residence in Belgium.

*What is a Transfer of Value (ToV)?*

A ToV can be a fee or remuneration for a service provided by the HCP, HCO or PO to Sobi. Expenses incurred during the execution of the service (e.g. travel and accommodation) are also considered ToV. Contributions to the costs of participating in scientific events (registration fees, travel and accommodation expenses) granted to healthcare professionals, healthcare organizations or patient organizations, as well as grants and sponsorships provided by Sobi to HCOs or POs are also considered to be ToV.

*Which ToVs are not included in the Sobi report?*

Sobi has decided to comply with the instructions provided by the local trade associations and EFPIA. ToVs to recipients other than those mentioned in these instructions will not be reported in this report.

#### *Who is the recipient of the ToV?*

All ToVs will be disclosed on an individual basis (in the name of the beneficiary who received the fee/benefit directly or indirectly or who performed the service). ToV are reported according to the “Final beneficiary principle” (independent of who has been paid). In some cases the HCO requests to report the ToV on the name of the HCO (e.g. UZ Leuven requires this). This will be indicated in the relevant ToV paragraph in the agreements with the HCO.

The ToVs are aggregated by category so that one total amount per category per beneficiary per calendar year is displayed in the transparency register.

#### *Indirect ToVs*

Refers to ToVs given to HCPs or HCOs by a third party. In the event that Sobi is aware that ToVs granted to a third party have been passed on to identified healthcare professionals or healthcare organizations, we will publish the details of each of those ToVs under the name of the relevant HCP or HCO.

#### *When are ToVs disclosed?*

ToVs made by Sobi during a calendar year are reported before 31 May of the next calendar year. ToVs are handled according to the cash basis principle, hence a specific ToV is registered when the payment or benefit is effected. As a consequence, a fee for a service provided during 2025 and paid during 2026 will be registered in the 2026 ToV listing. If the exact date for a specific transfer cannot be obtained by the individuals registering the ToVs, the transfer is to be registered as close as possible to the actual payment date. For multi-year contracts with HCPs, HCOs or POs, we report the ToVs whenever a financial transaction occurred during the reporting year in relation to such multi-year contracts.

#### *Where (i.e. in which country) is a ToV disclosed?*

Sobi will produce one report per country which is in scope of the EFPIA Code of Practice. Each report will be published locally according to the instructions provided by each EFPIA member association (i.e. local trade association) as well as on the Sobi external webpage ([www.sobi.com](http://www.sobi.com)). A specific ToV will be disclosed in the country report where the HCP has his/her primary practice or where the HCO/PO is registered.

#### *Where are R&D ToVs disclosed?*

A majority of R&D ToVs will be paid by the Swedish parent company, Swedish Orphan Biovitrum AB, to recipients in many European countries. Sobi will disclose such aggregate ToV in the country where the recipient has its primary practice. Hence R&D ToV to a Belgian recipient will be reported in Belgium.

#### *How will Sobi act in the countries where the Sobi subsidiary is not a member of the EFPIA member association?*

The parent company, Swedish Orphan Biovitrum AB [publ] is a member of the Swedish EFPIA member association and according to corporate decision all Sobi companies are obligated to follow the EFPIA code and disclose ToVs made to European HCPs and HCOs.

#### *How is Sobi handling contracts that span over several years?*

If Sobi has a contractual arrangement with an HCP, HCO, or relevant third party that span multiple calendar years., Sobi will report the transfer of value paid in the relevant reporting year.

*Which currency is used?*

For transactions handled by Sobi by the Swedish parent company, Swedish Orphan Biovitrum AB: Transfers of values are initially registered in the currency paid by Sobi. If the locally reported currency (euro) is not the same as that in which Sobi initially paid, Sobi use the monthly average exchange rates found at Swedish Central Bank (Riksbanken.se). Averages are calculated on published observations for the daily fixing rates. For currencies not published at the Swedish Central Bank, we utilized annual average rates from [x-rates.com](http://x-rates.com)

For transactions handled by Sobi Belgium the actual exchange rate of the bank at the time of payment is used whenever a payment is done in another currency than euro.

*Is value added tax (VAT) included in the reported amounts?*

- Fee for service (natural person providing services) – fee excluding VAT disclosed
- Fee for service (legal entity providing services) – fee excluding VAT disclosed
- Out of pocket expenses – the entire expense is disclosed (i.e. including VAT paid by the service provider)
- Travel and accommodation costs – cost including VAT is disclosed
- Registration fees (congresses) - cost including VAT is disclosed except if amount excluding VAT is mentioned on the registration page of the congress
- Other transfers of value (e.g. grants and sponsorships) – the cost excluding applicable VAT is disclosed

*What about “no-shows”, e.g. if a HCP invited to a meeting does not attend and the transportation and accommodation has been paid?*

If a HCP does not attend a meeting which has already been paid for, the ToVs that are non-recuperable will be disclosed under the name of the HCP. Only in case the HCP cancels due to health reasons or due to matters outside their control (e.g. cancelled/delayed flight/train due to strike or other reason), no ToVs will be disclosed by Sobi.

*How are the reported value of charitable product donations provided by Sobi determined?*

These are not reported as ToV.

*How do we report for cross-border activities?*

For cross-border engagements under the Global Transparency Program, each Sobi Affiliate shall be responsible for appropriately recording ToV when engaging Recipient outside of their country. The ToVs are required to be disclosed in the country where the Recipient has its primary practice, professional address or place of incorporation, pursuant to the transparency regulations of the country, whether the ToV occurs in or outside that country.

## **2.2 Data Privacy and Consent**

*How is Sobi handling HCPs and HCOs data?*

Sobi is committed to protect the personal rights of any individual whose Personal Data it processes. All processing of Personal Data subject to the provisions in the EU General Data Protection Regulation (GDPR) must fully comply with the GDPR. The Sunshine Act imposes the legal obligation to process HCPs personal data. It is not required to obtain the HCPs' consent. However, all beneficiaries are informed through the signed agreement.

HCPs have the right to access the personal data that Sobi processes concerning the HCP and to request that Sobi rectifies any inaccurate data.

*How will Sobi handle Transfers of Value (ToV) which may pertain to commercially sensitive data or other information not suitable for disclosure?*

If such data falls within the scope of the relevant local industry requirements, Sobi will report such ToV in aggregate.

## 2.3 Recipients

*Which recipients are in scope for the disclosure in Belgium?*

HCPs, HCOs and POs with their primary practice/residence in Belgium.

*What about academic institutions and similar organisations: should Transfers of Value (ToV) to such organisations included in the Sobi report?*

In general, Sobi will not include ToVs to academic institutions (excluding HCOs) in the annual report. However, if Sobi is informed by the academic institution that the ToV is intended to be transferred onwards to an identified/identifiable HCP or HCO, Sobi will include the ToV. Hence a ToV made to a university hospital should be included.

*What about CROs, are ToVs to them included in the Sobi report?*

No.

*What about payments made from Sobi to HCOs/HCPs through CRO's, are they included in the Sobi report?*

Yes, direct and indirect ToVs to HCPs and HCOs are included in the Sobi report.

*What about ToVs to a "Foundation", are they included in the Sobi report?*

This will be determined by Sobi on a case-by-case basis. If the foundation is a legal entity through which HCPs/HCOs operate, then the ToV will be included in the report.

## 2.4 Fee for service and consultancy

*Examples of Transfers of Value that could be covered under Fee for Service and Consultancy agreements*

- Speakers' fees;
- Consulting fees (including advisory services);
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*Market research*

Fees paid for participation in market research are reported only if the recipient is known to Sobi.

*What is included in the reported remuneration/fee?*

Fees paid by Sobi are registered as gross fees, including applicable taxes. Value added tax (VAT) and social security fees, if applicable, are however not included in the reported fees.

### *Related expenses*

Sobi pays for/reimburses consultants for reasonable and documented expenses regarding travel and accommodation necessary for providing the services to Sobi. Such reimbursement will be considered as a related expense. Travel and accommodation costs are reported including VAT. Other expenses are normally not paid for/reimbursed by Sobi. If another type of related expense (excluding travel, accommodation, meals and drinks) are incurred it will be paid for/reimbursed by Sobi only if it was necessary in order to perform the service. If so, it will be reported in "Related expenses" in the annual report. Such expenses incurred during the performance of the services are reimbursed to the service provider on submission of a receipt. The entire expense is reimbursed, including any VAT.

### *Meals and drinks*

Meals and drinks are not to be reported according to EFPIA and the Sunshine Act and hence will not be reported by Sobi.

## **2.5 The report template**

### *What is disclosed under "HCP"?*

HCP is an abbreviation for Healthcare Professionals. Transfers of value (i.e. fee for service and related expenses) to individuals included in this category are reported under HCP in the annual report.

### *What is disclosed under "HCO"?*

HCO is an abbreviation for Healthcare Organisations and include organisations which organises/include HCPs. A HCO is always a legal entity. Service fees and related expenses invoiced from a HCO are reported as detailed in paragraph 2.1 under "*Who is the recipient of the ToV?*". Grants and sponsorships provided to HCOs are always reported under HCO in the annual report.

### *What is disclosed under "PO"?*

PO is an abbreviation for Patient Organisations and include organisations which organises/include patients and patient advocates. The scope of the organization's activities is limited solely to representing patient interests, Fees and related expenses invoiced from a PO is reported under PO in the annual report. Grants and sponsorships provided to POs are also reported under PO in the annual report.

### *What is disclosed under R&D?*

ToVs related to the planning or conduct of (i) non-clinical studies (as defined in *OECD Principles on Good Laboratory Practice*; (ii) clinical trials (as defined in Directive 2001/20/EC); or (iii) non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of HCPs specifically for the study.

A number of activities are regarded as *related* to the planning and conduct of such studies. Sobi includes e.g. ToVs related to advisory boards (provided that the advisory board is clearly related to the planning of a study mentioned above), costs for providing study drugs and ToV to study staff for conducting the study.

Sobi will include ToVs related to Sobi-sponsored studies as well as non-Sobi-sponsored studies that are financially supported by Sobi in the R&D category.

### **3. Contact information**

Inquiries about Sobi's disclosure of ToVs to HCPs, HCOs and POs to request further information or corrections by Sobi should be directed to:

E-mail: [transparency\\_benelux@sobi.com](mailto:transparency_benelux@sobi.com)