Transparency

Sobi Methodology Note

2025 Transfers of Value (reported 2026)

Country name:
Germany

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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 AB (publ) is therefore committed to meet all global transparency requirements, including the EFPIA Code of Practice in Europe. The code places a requirement on pharmaceutical companies to publicly report payments (transfers of value) made to health care professionals (HCP), health care organisations (HCO) and Patient Organisations.

The methodology note is a summary describing the methods used by affiliates within Swedish Orphan Biovitrum AB, ("Sobi") during the collection and publication of ToVs to HCPs and HCOs. According to the instructions 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.

Definitions

Recipients

Who is the recipient of the ToV?
Sobi will consider the recipient to be the contracting entity, which may be a HCP, a legal entity owned by a HCP (which is then a HCO) or a HCO. Hence the contracting party as stated on the legal contract executed between Sobi and the counterpart will be reported as the recipient.

What is a Transfer of Value (ToV)?

A ToV can be a fee or remuneration for a service provided by the HCP or HCO to Sobi. Expenses incurred during the execution of the service (e.g. travel and accommodation) are also considered ToV if required by the applicable local rules. Donations and sponsorships provided by Sobi are also considered to be ToV.

What about CROs, are ToVs to them included in the Sobi report?
No.

What about payments made from Sobi to HCOs/HCPs through CROs, are they included in the Sobi report?
Yes, all 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.

Kind of ToVs

Transfers of value (ToV) made by the Sobi group ("Sobi") to Health Care Professionals (HCPs) and Health Care Organisations (HCOs) with their primary practice in the reportable country.

Disclosure's Scope

Products concerned

Type of products included in the disclosure report: Prescribed Only Medicines.

Company concerned

Sobi affiliate in the reporting country

Excluded ToVs

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.

ToVs date

ToVs made by Sobi during a calendar year are reported within six (6) months from the end of that 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 generally be registered on 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.

Direct ToVs

This term refers to ToVs given **directly** to a HCP or HCO without intermediaries.

Examples of Direct ToVs, which Sobi reports:

- Consulting fees (including advisory services)
- Speaker fees
- Sponsored attendance at scientific events (travel,hotel)
- Research funding
- Sponsorship

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.

Non-monetary ToVs

This term describes a ToVs that are **not in the form of direct cash payments;** rather, it involves goods, services, or benefits given to a HCP or HCO.

Examples of non-monetary ToVs Sobi reports subject to the applicable local requirements:

- Items of value intended to benefit patients (e.g., promotional items, medical devices, samples)
- Provision of meals or hospitality (e.g., sponsored dinners or refreshments)
- Travel and accommodation expenses paid or arranged by the company
- Sponsorship of education or training events
- Grants or donations in kind (e.g., equipment, software)

ToVs in case of partial attendances or cancellation and refund

i. **Partial Attendance at Events or Meetings**

If a recipient attends only part of a sponsored event, ToVs typically will be reported **proportionally** based on the actual value received. Example: if hospitality, travel, or accommodation was provided but the attendee only attended a portion of the event, SOBI shall adjust the reported value to reflect the actual usage or benefit.

ii. **Cancellations**

- If an event or service is cancelled beforehand and costs are incurred, **no ToV is reported**.
- If a HCP cancels their attendance last minute and costs are incurred, the cost **will be reported as ToV against the HCP**.

iii. **Refunds**

- The reported ToV should be adjusted accordingly to reflect the net value transferred. In practice, this means the ToV data is updated or corrected in disclosure reports to show the reduced or nullified value after refunds.

Cross-border activities

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 HCPs, HCOs, outside of their country. The ToVs are required to be disclosed in the country where the Recipient has its practice, professional address or place of incorporation, pursuant to the transparency regulations of the country, whether the ToV occurs in or outside that country.

R&D

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.

Voluntary disclosure

SOBI is committed to full transparency in line with the EFPIA Code's Disclosure provisions, which require disclosure of all ToVs made to HCPs, HCOs. SOBI is not currently a member of EFPIA. SOBI complies with mandatory reporting requirements in local countries when it is binding by local law or through membership of the local member association. Sobi discloses voluntary in other countries

where Sobi has a local affiliate and there is no legal requirement or Sobi is not a member of the local industry association. This commitment to voluntary disclosure ensures ongoing transparency and fosters trust in interactions with HCPs, HCOs, reflecting SOBI's dedication to ethical collaboration and regulatory compliance.

Specific considerations

Country unique identifier

Refers to the distinctive number assigned to a HCP or HCO within a specific country and is used to ensure that transactions are reported under the correct recipient, where required. Sobi will provide the "Country Unique Identifier" for HCPs/HCOs as required by local regulations.

Self-incorporated HCP

Refers to a healthcare professional who operates as a legal business entity (e.g., a personal company, consulting firm, or professional corporation) rather than as an individual employed by a hospital or organization. W

Multi-year agreements

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

Country specificities

Companies operating across Europe must apply the specific rules and thresholds established by the national association in each country where the activity or the recipient is located.

Quality Checks

Sobi perform internal data quality checks on the information before disclosure and the disclosure statement is certified at the affiliate level.

Data protection legal basis

Consent collection

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. In order to fulfil these requirements Sobi must ask the relevant recipients of ToV (i.e. HCPs and in some exceptional cases HCOs) for a signed informed consent to publicly disclose the ToV.

How will Sobi handle ToVs subject to individual disclosure to a recipient for whom individual level disclosure is not legally possible?
Sobi aims at disclosing ToVs on an individual basis (stating the name of the recipient) to the greatest extent possible when so required by the Code. There are, however, circumstances which require Sobi to disclose ToVs in aggregate. Under the European privacy legislation, HCPs may oppose the disclosure of their personal data. If an HCP opposes such disclosure Sobi will report such ToVs in aggregate (stating the ToV amount to a group of recipients without stating the name of the recipients). Such aggregate disclosures will be reported under "Other" in the report template.

How will Sobi handle partial consents, i.e. if a HCP agrees to the disclosure of one ToV but opposes disclosure of other ToVs?
If an individual provides partial consent (i.e. consent to disclosure of some transfers of value but not to others made during the same calendar year) Sobi will treat all transfers of value to that individual in the same way and will report all transfers of value in aggregate under "Other" in the annual report.

How will Sobi handle different consent input from a recipient regarding a ToV, i.e. both consent provided and consent declined?
In the event that a recipient provides several different consent inputs regarding a given ToV, the latest received input will be considered when deciding on individual or aggregate disclosure of that ToV.

Form of disclosure

Date of publication

When do we publish the ToV?
Sobi will publish ToV reports by 30th of June in the following calendar year for the previous calendar year, unless local laws or binding industry codes require otherwise (in which case Sobi shall comply such).

Disclosure platform

Where (i.e. in which country) is a ToV disclosed?
Sobi will produce one report per country which Each report will be published locally according to the instructions provided by each member association (i.e. local trade association) and applicable laws as well as on the Sobi external webpage (www.sobi.com).

Disclosure language

What languages do we use when we disclose ToV?
We always disclose in English language and if required, we also disclose in local language.

Disclosure financial data

Currency

Which currency is used?
Transfers of values are initially registered in the currency paid by Sobi. If the locally reported currency is not the same as that in which Sobi initially paid, Sobi use the monthly average exchange rates found at Swedish Central Bank (Riksbank.se). Averages are calculated on published observations for the daily fixing rates. For currencies not published at the Swedish Central Bank, we utilize annual average rates from x-rates.com.

VAT included or excluded

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

- Fee for service (natural person providing services) – not applicable
- 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
- Other transfers of value (e.g. donations, grants and sponsorships) – the cost excluding applicable VAT is disclosed

Calculation rules

Transfers of value during the reporting period are totaled per disclosure template segment, either individually or in aggregate. Only payments made within the calendar year are included (refer to notes on ToV date and ToV across years). ToVs are reported in a single currency (see note on Currency).