

EFPIA Transparency

Sobi Methodology Note

2020 Transfers of Value (reported 2021)

Bulgaria

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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 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 Swedish Orphan Biovitrum - Branch Bulgaria, ("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 Health Care Professionals (HCPs) and Health Care Organisations (HCOs) with their primary practice in the reportable affiliate.

What is a Transfer of Value (ToV)?

A ToV can be salary, 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. Donations and sponsorships provided by Sobi 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?

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.

When are ToVs disclosed?

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 is made. As a consequence, a fee for a service provided during 2020 and paid during 2021 will be registered on the 2021 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.

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). A specific ToV will be disclosed in the country report where the HCP has his/her primary practice or where the HCO is registered.

Where are R&D ToVs disclosed?

A majority of R&D ToV 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.

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 to HCP s and HCOs.

How is Sobi handling contracts that span over several years?

Please see above under “When are Transfers of Value (ToV) disclosed”

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 has used 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 utilized annual average rates from x-rates.com.

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

All ToVs are reported with VAT.

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/HCO does not attend a meeting which has already been paid for, an actual transfer of value has not taken place. Hence such costs will not be registered/disclosed as a Transfer of Value.

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

In such cases the local market value is used for reporting purposes.

How is Sobi reporting ToV for acquired companies under the reporting period?

Sobi reports ToV (in cash or kind) that occurred after the completion dates of the acquisitions done during 2019.

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. 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 publically disclose the ToV.

HCPs has the right to access the personal data that Sobi processes concerning the HCP and to request that Sobi rectifies any inaccurate personal data and under certain circumstances request erasure and/or restriction of processing of the personal data. HCPs has the right to object to processing and to receive the processed personal data in a structured, commonly used and machine-readable format and has the right to transmit those data to another controller.

How will Sobi handle ToVs subject to individual disclosure to a recipient who does not provide consent to disclosure of his/her name?

In order to contribute to the EFPIA Code Of Practice purpose, 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 to the disclosure of their personal data. If a HCP opposes to 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.

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 EFPIA Code Of Practice, Sobi will report such ToV in aggregate.

2.3 Recipients

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 in the annual report. However, if the ToV benefits an identified/identifiable HCP or HCO, Sobi will include the ToV. Hence a ToV made to a Faculty of Medicine at a university or to a University hospital should normally 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, 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.

2.4 Fee of service and consultancy

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

- Speakers' fees;
- Speaker training;
- Medical writing;
- Data analysis;
- Development of educational materials;
- General consulting / advising.

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 salary/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 hence will not be reported by Sobi.

2.5 The report template

What is disclosed under “HCP”?

HCP is an abbreviation for Health Care 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 Health Care Organisations and include organisations which organises/include HCPs. A HCO is always a legal entity. Fees and related expenses invoiced from a HCO is reported under HCO in the annual report. Donations and sponsorships provided to HCOs are also reported under HCO in the annual report.

What is disclosed under “Other”?

ToVs that should be reported in aggregate according to the EFPIA Code Of Practice or ToVs which Sobi, due to e.g. legal reasons, must disclose in aggregate, are reported under “Other”.

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 in the R&D category.

3. Contact information

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

E-mail: transparency@sobi.com