

EFPIA Transparency / ABPI public reporting of transfers of value

Sobi Methodology Note

2016 Transfers of Value (reported 2017)

UK

1. Background

A new disclosure code was approved by European Federation of Pharmaceutical Industries and Associations, EFPIA, in June 2014 which has or will be implemented in Europe by all EFPIA member associations. The code places a requirement on pharmaceutical companies to publicly report payments (transfers of value, ToV) made to health care professionals (HCP), other relevant decision-makers (ORDM) and health care organisations (HCO). The second reporting is to be published 2017 based on ToVs made 2016.

The methodology note is a summary describing the methods used by [Swedish Orphan Biovitrum AB, (“Sobi”)] during the collection and publication of transfers of value (ToV) 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.

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. Furthermore, the EFPIA disclosure code together with the FAQ provided by EFPIA are used as guidelines for how disclosure should be conducted. 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.

Considering that disclosure of ToVs shall be made for the second time in 2017, some specifics regarding the collection and processing of data may not have been considered at the outset. This document has been revised during 2016 in order to capture new questions and corresponding answers. Hence there might be some inconsistencies pertaining to the collection and processing of ToVs during this first year of collection.

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), Other Relevant Decision-Makers (ORDM) and Health Care Organisations (HCOs) with their primary practice in the UK.

What is a Transfer of Value (ToV)?

A ToV can be salary, fee or remuneration for a service provided by the HCP, Other Relevant Decision-Makers (ORDM) 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 to HCOs 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 transfer of value?

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

When are Transfers of Value (ToV) disclosed?

ToV 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 2015 and paid during 2016 will be registered on the 2016 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 disclosure code. 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 or ORDM has his/her primary practice or where the HCO is registered.

Where are R&D transfer of value (ToV) 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. Hence R&D ToV to a UK recipient will be reported in the UK

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

Since the parent company, Swedish Orphan Biovitrum AB, is a member of LIF (the Swedish EFPIA member association) all its subsidiaries will be indirectly bound by the local EFPIA member association with regard to EFPIA disclosure requirements.

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 GBP is not the same as that in which Sobi initially paid, Sobi has used the annual 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, those found at XE.com will be used. These rates are mid-market rates as of 2016-12-31 17:00 UTC.

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

What about “no-shows”, e.g. if a HCP/ORDM 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.

2.2 Individual vs aggregate disclosure

How are data disclosed, individually or in aggregate?

In order to contribute to the EFPIA disclosure code 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 EFPIA disclosure code. There are, however, circumstances which require Sobi to disclose 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 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 EFPIA disclosure code, Sobi will report such ToV in aggregate.

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

Under the European privacy legislation, HCPs/ORDMs may oppose to the disclosure of their personal data. If a HCP opposes to such disclosure Sobi will report such ToVs in aggregate.

How will Sobi handle partial consents, i.e. if a HCP/ORDM 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.

2.3 Recipients

Which recipients are in scope for the disclosure in UK?

HCPs, Other Relevant Decision Makers (ORDMs), and HCOs with their primary practice in UK.

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 and other commercial agencies, 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&ORDM”?

HCP is an abbreviation for Health Care Professionals. ORDM is an abbreviation for Other Relevant Decision Makers, as defined by the ABPI Code of Practice. Transfers of value (i.e.

fee for service and related expenses) to individuals included in these categories are reported under HCP&ORDM 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 disclosure code 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.