



Disclosure 2015

Methodological Note

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INTRODUCTION

The EFPIA Disclosure Code requires all European Federation of Pharmaceutical Industries And Associations (EFPIA) member companies such as scienceindustries in Switzerland to disclose transfers of value (TOV) such as support to attend medical education events, speaker fees and consultancy to healthcare professionals (HCPs) and healthcare organisations (HCOs).

Collaboration between healthcare professionals and Pharmaceutical Companies has long been a positive driver for advancements in patient care and progression of innovative medicine.

Healthcare professionals and organisations with whom they work provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and management experience. As the primary point of contact with patients, the medical profession can offer invaluable and expert knowledge on patient outcomes and the management of diseases.

To complement this, the pharmaceutical industry can provide a legitimate forum for the education of healthcare professionals and the exchange of knowledge among healthcare professionals and industry. This expert knowledge helps to adapt our products to better suit patients and thereby improve patient care overall.

We believe that healthcare professionals and organisations should be fairly compensated for the legitimate expertise and services they provide to us. At the same time, we acknowledge legitimate concerns that such transactions should be transparent.

The EFPIA Disclosure Code will protect the integrity of the industry-healthcare professional relationship, and represents a step towards fostering greater transparency and building greater trust between the pharmaceutical industry, the medical community and society across Europe.

This methodological note provides an overview of the main processes implemented at Sanofi to collect, reconcile and disclose those transfers of value.

WHAT ARE THE SCIENCEINDUSTRIES' PHARMA COOPERATION CODE REQUIREMENTS?

The EFPIA Disclosure Code and Pharma Cooperation Code of the Scienceindustries Switzerland (Business Association Chemistry Pharma Biotech) state that the transfers of value that are to be disclosed are:

- Research and development
- Donations and subsidies
- Events
- Services and consulting provided including expenses incurred

HOW WAS DISCLOSURE OF LOCAL LEVEL ORGANIZED?

Data were collected, reconciled and reported using a commercially available database which was customized to Sanofi's organizational requirements. This system is used by Sanofi to track payments within all EFPIA countries.

All direct TOVs were captured from our financial system and uploaded directly into the above mentioned database. Indirect TOVs were recorded outside of the database and then uploaded into the database.

All financial TOVs were reconciled against our financial system where all transparency relevant vendors are flagged to easily identify coding to correct categories of spend.

HOW IS THE DISCLOSURE OF CROSS-BORDER TRANSFERS OF VALUE ORGANIZED?

A "Cross-border transfer of value" was defined as a TOV made by any entity of an EFPIA Member Company based in a country which differed from the country where the HCP is practicing or where the HCO is incorporated.

A specific HCP/HCO Engagement process was implemented at Sanofi Group level (worldwide) to allow for collection of cross-border TOV.

To ensure compliance with the local requirements, any request for cross-border engagement had to be vetted by a validator of the HCP/HCO home country with specific attention to the rationale of the request, the fair market value (FMV) of the fees proposed and on respect of the country hospitality rules.

The following should be noted when considering the Disclosure Report 2015 with respect to these:

Sanofi has disclosed TOVs that were paid to Swiss HCOs and HCPs by International Affiliates during the period 1 January 2015 and 31 December 2015.

Where a Swiss HCP or HCO was contracted prior to 2015 by a Sanofi affiliate outside of Switzerland, but actually received their TOV in 2015, the 2015 Disclosure report includes these TOV's

Where a Swiss HCP or HCO was contracted by a Sanofi affiliate outside of Switzerland to provide a service in 2015 he/she would have received the benefit of the related expenses i.e. costs of flights, accommodation, and ground transportation in 2015. These TOVs will be disclosed in the Disclosure Report 2015. However, it should be noted there are instances where a Sanofi affiliate outside of Switzerland may not have paid the fee for service to a Swiss HCP or HCO for an engagement in 2015 until 2016. Therefore, it is possible that for an individual HCP or HCO there will only be related expenses listed that were paid to them in 2015 in the

Disclosure Report 2015, and the fee for service paid in 2016 will be listed in the Disclosure Report 2016.

SPECIFIC TRANSFERS OF VALUE

All transfers of value made by Sanofi to HCPs or HCOs in Switzerland between January 1st and December 31st, 2015 and corresponding to one of the categories described below, were captured in the system for Sanofi.

DONATIONS AND GRANTS TO HCO

Sanofi considered applications from HCOs and made donations and grants where it served to enhance patient care or academic research to enhance medical knowledge.

The following were not reported in this category:

- Grant, donations or other contributions to Patient Organisations and Patient Groups as these follow the EFPIA Code of practice governing industry relationships with patient organisations and are disclosed separately on the Sanofi's Corporate website available at <http://www.sanofi.ch//ch/de/layout.jsp?scat=89378C24-49F6-447A-A3A7-ED1A69EEDF83>
- Contributions to organizations to support an event which were disclosed in the "sponsorship agreements with HCOs or with Third-parties appointed by HCOs to manage an event" and "contribution to costs of events" (see below).

SPONSORSHIP AGREEMENTS WITH HCOs OR WITH THIRD-PARTIES APPOINTED BY HCO TO MANAGE AN EVENT

A Company event is defined as a gathering of HCPs organized by Sanofi. A Third-Party event is defined as a gathering of HCPs organized independently from Sanofi.

For a Third-party event, Sanofi may have entered in a "sponsorship agreement" with the organizer for different type of activities.

CONTRIBUTION TO COSTS OF EVENTS

A Third Party or Company event may have included the provision of hospitality to HCPs (regulations allowing). For the purpose of disclosure, this category includes any kind of scientific or educational events regardless of the number of participants.

Some Sanofi events are managed by third-parties (congress agencies, travel agencies, and congress organizers) on Sanofi’s behalf. The list of participants and related TOV for each participant are provided by these third-parties.

These contributions include:

- Registration fees
- Accomodation
- Travel

FEES FOR SERVICE AND CONSULTANCY

On a regular basis, Sanofi enters into compensation-for-service arrangements with various HCPs and HCOs to perform services or activities in medical or scientific-related domains for which Sanofi had legitimate needs and no internal capacity or knowledge. The services include involvement in scientific meetings (e.g. as speaker or chairman), boards and committees, training and medical education, and consulting. The purpose of and the rationale for those services rendered by HCPs and HCOs, as well as the expected deliverables, are clearly documented in a written agreement (contract) before the performance of the service.

The selection of HCPs and HCOs is based exclusively on objective criteria such as education, university degree, expertise and experience (e.g. number of publications, participation in clinical studies) in a particular therapeutic area.

The HCPs are compensated for the service based on their country of practice FMV determination.

RELATED EXPENSES AGREED IN THE FEE FOR SERVICE OR CONSULTANCY CONTRACT

Related expenses included in the fees for service or consultancy contract cover reasonable expenses linked to accommodation and travel costs (flight and ground transportation) incurred by the HCP in carrying out the service. No other expenses are allowed for reimbursement. In strict compliance with Sanofi’s and Swiss Pharma Cooperation Code’s hospitality rules, expenses are reimbursed only after verification of the documentation (e.g. original receipts or other supporting documents).

RESEARCH & DEVELOPMENT

Sanofi discloses in the aggregated R&D section, all R&D-related TOV to HCPs or HCOs related to the planning or conduct of the following:

- non-clinical studies (as defined in *OECD Principles on Good Laboratory Practice*)
- clinical trials (as defined in *EU Directive 2001/20/EC*)
- non-interventional studies that are prospective in nature and that require the collection of patient data specifically for the purpose of the non-interventional study
- retrospective non-interventional studies are included in the aggregated R&D category of non-interventional studies because Sanofi manages retrospective studies with the same quality processes and ethical rigor as prospective studies
- Investigator Sponsored Trials / Independent Investigator Trial (IST/IIT) are reported in the aggregated R&D disclosure as these studies belong to the above classification

Transfers of value related to the planning or conduct of studies mainly include: investigator fees, study nurse costs, pharmacy costs, hospital overheads, and technical committees fees.

HOW IS THE DISCLOSURE OF FINANCIAL DATA MANAGED?

WHICH ACTUAL DATES ARE USED FOR DISCLOSURE OF TOV?

For transfers of value, two different transfer dates were used:

- For direct payments, the date of transfer of value used is the “clearing date” from our financial systems which corresponds to the date of the wire transfer to the recipient’s bank account.
- For transfers of value linked to an event with different types and dates of expenses (congress registration, flight tickets, hotel bills, etc.), all these transfers of value are reported with the same date, i.e. the first day of the event;

Of note, all our payments are invoice-based (i.e. recipients have to submit an invoice to receive their service or sponsoring fee). If the recipient did not submit an invoice in 2015 for a service or sponsoring that took place in 2015, the payment is not disclosed in the 2015 disclosure report. Similarly, payments made in 2015 for services or sponsoring that took place in 2014 are included in the 2015 disclosure report.

HOW ARE CURRENCIES AND EXCHANGE RATES MANAGED?

- Transfers of value were always collected in the currency of the HCP/HCO, for Switzerland this will be Swiss Franc.
- When a Sanofi entity outside of Switzerland paid expenses to a Swiss based HCP/HCO (cross-border), the expenses were converted from the local currency into Euro, using the Sanofi Exchange Rate in force at that time.
- Amounts disclosed are those actually paid by Sanofi. They could be slightly different from amounts received by the HCP/HCO as they do not take into consideration any exchange fees or other fees applied by the recipient's bank.

HOW IS THE VAT MANAGED?

All the amounts disclosed as TOV include all taxes (e.g. VAT).

WHICH TRANSFERS OF VALUE ARE EXCLUDED FROM DISCLOSURE?

In full agreement with the EFPIA Disclosure Code, Sanofi is not disclosing the following:

- TOV that were solely related to over-the-counter medicines or medical devices
- Items of medical utility and of minimal nominal value
- Meals and drinks
- Medical samples
- TOV that were part of ordinary course purchases and sales of medicinal products
- Double-blind market research conducted according to Sanofi's global policy "Conduct of Market Research Projects" provided that the identity of the HCPs was not known to Sanofi
- TOV to HCPs who are (temporary or permanent) company employees or external contractors (whose principal activity was not practicing medicine)

OTHER SPECIFIC CONSIDERATIONS

WHICH UNIQUE IDENTIFIERS ARE USED TO ACCURATELY IDENTIFY HCPS?

The accurate and unique identification of each recipient (HCP or HCO) of a TOV is of paramount importance. Several internal and external IDs are used and translated into one unique disclosure ID per HCP/HCO to ensure an exact match between a TOV and a HCP/HCO.

MULTI-YEAR AGREEMENTS

Multi-year agreements cover a series of services or sponsored activities/events longer than one year. The associated TOV will be disclosed per calendar year as required by the EFPIA and Swiss Pharma Cooperation Code.

HOW IS THE HCP INFORMED CONSENT MANAGED?

COLLECTION OF INFORMED CONSENT

Sanofi has requested a written consent from all HCPs and HCOs related to disclosure of TOV in 2015. Consents have been requested during the first half of 2016 and HCPs and HCOs have been informed at the same time of the exact sums that were allocated to them. With a written consent, the data will be disclosed individually with mentioning the name, address and transfers of value of the HCP and HCO. If the consent has not been given, HCPs and HCOs data will be disclosed in the aggregated disclosure.

In agreement with the EFPIA Disclosure Code and in order not to distort the reality of the data published on an individual basis, Sanofi did not allow HCPs and HCOs to give partial consent to disclose only selected TOV.

HCPs and HCOs can withdraw their consent at any time with separate notice. If the consent is withdrawn, all transfer of value will be removed from the individual disclosure and will be disclosed in aggregate.

PERSONAL DATA PROTECTION

Sanofi is highly committed to protecting HCPs' and HCOs' personal data and upholding applicable data protection laws and regulations. Sanofi's legal departments ensures that specific provisions concerning the EFPIA Disclosure Code, the national disclosure code and personal data protection are included in Sanofi's standard contracts.

By signing a contract, the HCP and HCO consents to the processing of his/her personal data for the purpose of TOV disclosure. The process of collecting informed consents for individual disclosure is described above. The HCP and HCO is informed that he/she may request at any time to be provided with information on their personal data stored by Sanofi, and may demand correction or deletion of his/her data. HCPs and HCOs are also informed of their right to revoke their voluntary consent for individual disclosure at any time without any detrimental effect on their relationship with Sanofi.

HOW IS THE 2015 ANNUAL DISCLOSURE REPORT MANAGED?

- Date of publication: 30th June 2016
- Disclosure platform: www.sanofi.ch
- Disclosure language: English

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