



Disclosure
Methodological Note
For
Sanofi Aventis Latvia SIA
As Sanofi

INTRODUCTION

The EFPIA Disclosure Code requires all European Federation of Pharmaceutical Industries and Associations (EFPIA) member companies to disclose transfers of value (TOV) such as support to attend medical education events, speaker fees and consultancy to healthcare professionals (HCPs) and healthcare organizations (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 organizations 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 organizations 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 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 EFPIA AND LOCAL SIFFA / LPMA DISCLOSURE CODE REQUIREMENTS?

The EFPIA Disclosure Code requires that European affiliates of EFPIA-Member Companies collect and disclose transfers of value made to European HCPs and HCOs wherever they might come from (inside or outside the country).

Transfers of value could be:

- in-cash (e.g. fees for service and consultancy to HCP or HCO; sponsorships, grants, donations or other contributions to HCOs)
- in-kind (e.g. hospitality provided during events or related to the conduct of the service and consultancy);
- direct: those made directly by a EFPIA Member Company for the benefit of a recipient

- indirect: those made on behalf of an EFPIA Member Company for the benefit of a recipient, or transfers of value made through an intermediate (i.e. Third-party) and where the EFPIA Member Company knows or can identify the HCP/HCO that will benefit from the Transfer of Value (examples of indirect TOV are those made by Congress Management Agencies inviting HCPs on an EFPIA Member Company's behalf, CROs responsible for investigator fees management on behalf of an EFPIA Member Company's, etc.).

SIFFA (Latvian Association of International Research-based Pharmaceutical Manufacturers) and LPMA (Latvian Generic Medicines Association) have adopted codes and guidelines to EFPIA Discloser Code requirements in Latvia.

DEFINITION

The term 'healthcare professional' (HCP) is any natural person that is a representative of the medical, dental, pharmacy or nursing profession or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply or dispense a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe..

The term 'healthcare organization' (HCO) is any legal entity that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other educational institution or training group (except for patient organisations) or through which one or more HCPs provide services.

The term 'transfers of value' (TOV) is direct or indirect transfers of value, whether in cash or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of generic or original prescription-only medicinal products for human use.

HOW WAS DISCLOSURE AT LOCAL LEVEL ORGANIZED?

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

TOVs were captured directly in the system for all direct payments. TOVs for indirect payments were recorded outside of the system and then uploaded.

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 WAS THE DISCLOSURE OF CROSS-BORDER TRANSFERS OF VALUE ORGANIZED?

Sanofi has disclosed TOVs that were paid to Latvian HCOs or HCPs by International Affiliates during the period 1 January 2018 and 31 December 2018.

Where a Latvian HCP was contracted prior to 2018 by an International Affiliate, but actually received their TOV in 2018, the 2018 Disclosure report includes these TOV's.

Where a Latvian HCP was contracted by an International Affiliate to provide a service in 2018, HCP would have received the benefit of the related expenses i.e. costs of flights, accommodation, and ground transportation in 2018. These TOVs will be disclosed in the Disclosure Report 2018. However, it should be noted there are instances where an International Affiliate may not have paid the fee for service to a Latvian HCP for an engagement in 2018 until 2019. Therefore, it is possible that for an individual HCP there will only be related expenses listed that were paid to them in 2018 in the Disclosure Report 2018, and the fee for service paid in 2019 will be listed in the Disclosure Report 2019.

WHICH TRANSFERS OF VALUE ARE DISCLOSED?

All transfers of value by legal entities of Sanofi Group in Latvia (Sanofi, Sanofi Genzyme, Sanofi-Pasteur S.A., Sanofi-Aventis R&D) which occurred between January 1st and December 31st, 2018 and corresponding to one of the categories described below, were captured in the system for Sanofi and further disclosed. All transfers for Zentiva entity between January 1st and May 31st are disclosed.

DONATIONS AND GRANTS TO HCO

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

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 – being a congress organizer appointed by the hosting HCO, or the HCO itself.

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 (product or non-product-related events, congresses, conferences, symposia, advisory board meetings, consulting meetings, training meetings, round table discussion, etc.) regardless of the number of participants.

Most Sanofi events are managed by third-parties (congress agencies, travel agencies, and congress organizers) on Sanofi's behalf. The list of participants and related transfers of value for

each participant are provided by these third-parties (as stipulated in their Service Agreement). The EFPIA Code excludes the following transfers of value from disclosure:

- No-shows and last-minute cancellations as no characterized benefit was provided to the HCP
- Meeting room rental (as a stand-alone cost)
- Mass group transportation (e.g. coach rental).

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 fair market value (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, 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 EFPIA's hospitality rules, expenses are reimbursed only after verification of the documentation (e.g. original receipts or other supporting documents).

RESEARCH & DEVELOPMENT (R&D)

R&D transfers of value are required to be reported on an aggregate basis and include:

- Direct and Indirect payments for Clinical Studies, including:
 - Interventional studies
 - Non-interventional and observational studiesInvestigator sponsored trials (ISS).

HOW IS THE DISCLOSURE OF FINANCIAL DATA MANAGED?

WHICH ACTUAL DATES ARE USED FOR DISCLOSURE OF TOV?

The discloser of transfers of value for 2018 includes all payments done during 2018 and transfers of value related to events held in 2018. Event costs have been allocated to the starting date of the event even though the actual transaction date would have been different.

HOW ARE CURRENCIES AND EXCHANGE RATES MANAGED?

Transfers of value are disclosed in euro (EUR).

When Latvian HCP or HCO have received payments in other currency, the expenses were converted into EUR using the exchange rate in force at that time.

HOW IS THE VAT MANAGED?

The TOV reported is the total, including VAT where applied.

WHICH TRANSFERS OF VALUE ARE EXCLUDED FROM DISCLOSURE?

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

- Transfers of value 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
- Transfers of value 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
- Transfers of value to HCPs who were (temporary or permanent) Company employees or external contractors (whose principal activity was not practicing medicine).

HOW IS THE HCP INFORMED CONSENT MANAGED?

COLLECTION OF INFORMED CONSENT FOR SERVICE AGREEMENT

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.

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 to give partial consent, that is "to pick & chose" which transfers he/she wishes to disclose.

CONTACTS

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