EFPIA / INFARMA
Disclosure Report

Methodological Note

SANOFI POLAND

June 2018

SANOFI

EuDisclose

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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 Poland (as an affiliate of Sanofi ,EFPIA –Member company) to collect, reconcile and disclose those transfers of value.

WHAT ARE THE EFPIA 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.).

HOW WAS DISCLOSURE AT A CENTRAL AND LOCAL LEVEL ORGANIZED?

Within Sanofi, a specific Transparency organization was implemented both at Region Europe and local affiliate level.

The local Sanofi team was mainly in charge of:

- Adaptation of central tools and systems to local specificities
- Informed Consent and Data privacy management
- Data collection, data quality and completeness verifications
- Disclosure report

Data were collected, reconciled, and reported using a database which was customized to Sanofi organizational requirements.

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

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

A "Cross-border transfer of value" was defined as a transfer of value made by any entity of an EFPIA Member Company based in a country which differs 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 transfers of value:

- 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 of the fees proposed and on respect of the country hospitality rules.

Where a Polish HCP was contracted by an International Affiliate to provide a service in 2017 he/she would have received the benefit of the related expenses i.e. costs of flights, accommodation, and ground transportation in 2017, these TOVs will be disclosed in the Disclosure Report 2017. However, it should be noted these are instances where an International Affiliate may not have paid the fee for service to a Polish HCP for an engagement in 2017 until 2018. Therefore,

it is possible that for an individual HCP there will only be related expenses listed that were paid to them in 2017 in the Disclosure Report 2017, and the fee for service paid in 2018 will be listed in the Disclosure Report 2018.

WHICH TRANSFERS OF VALUE ARE DISCLOSED?

All transfers of value which occurred between January 1st and December 31st, 2017 and corresponding to one of the categories described above, were captured in the local database.

In this report following business entities of the Sanofi Group are concerned:

- Sanofi
- Genzyme (Sanofi Genzyme)
- Zentiva
- Sanofi-Aventis R&D

The following were not reported in this category:

- Grant, donations or other contributions to Patient Organizations and Patient Groups as these follow the EFPIA Code of practice governing industry relationships with patient organizations and are disclosed separately on the Sanofi's Poland website available at https://www.sanofi.pl

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.

Examples of events include: congresses, conferences, symposia, conventions and educational meetings. The main objectives of these events are the dissemination of disease and product knowledge and to stimulate scientific exchange between HCPs. These events keep the HCP's knowledge current, benefiting the care of their patients.

Benefits provided by the Company directly to health organizations and also benefits to entity acting on behalf of Company are subject for disclosure

For example, when the event is organized by a company engaged in the organization of conferences, and the initiator and organizer of the content is, for example. scientific society. In the absence of support from the logistics company, scientific society would have to carry out the above activities. The existence of intermediary in the transfer of benefits (not just financial) for final beneficiary does not exempt from the obligation to make public information about the scope and value of collaboration with health organizations.

If all or part of the benefit will be indirectly pass to health professionals, a health care organization should get their consent to disclosure personal data. If it is not possible to indicate the individual value of invitations for individual representatives of the medical professions in the subject of sponsorship for the organization of health care, the solution is individual agreement with the representatives of the medical profession in terms of their participation in the event.

If an event has been held during 2017, but the costs have been paid in 2018, the TOV will be recorded in Sanofi's 2018 Disclosure Report.

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 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 Polish fair market value (FMV) determination.

Related expenses included in the fees for service or consultancy contract cover reasonable expenses linked to accommodation, travel costs (flight and ground transportation) and meals 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).

All benefits transferred to the representative of the medical profession must be made available in the Disclosure Report on the benefits for the medical profession. Thus, if a representative of the medical profession does not agree to the publication, the data will go to the pooled data of the medical professions. The same principle is applies to medical professionals who are partners in civil partnerships.

In case of ToVs for HTA consulting companies , the ToVs are disclosed when the owner of HTA company is an practicing HCP or the company employs practicing HCP to provide services contracted by Sanofi.

The following should be noted when considering the Disclosure Report 2017 with respect to these:

- Sanofi requested the individual HCPs consent to disclose the TOV in the contract – consent was collected on a per event basis.
- Sanofi has recorded date of TOV as the date the payment was processed and released by Sanofi for payment to the HCP.
- It should be noted that where services were provided in 2017 but Sanofi did not receive an invoice or completed fee and expense form in 2017, or it was received in 2017 but which was not actually paid in 2017, the TOV will not appear in the 2017 Disclosure Report. Where the invoice will be paid in 2018, the TOV will be recorded in Sanofis 2018 Disclosure Report.
- Benefits were identified in the amount in which they represented the cost to the Company, not revenue for the Beneficiary

RESEARCH AND DEVELOPMENT

All the benefits associated with the expenditure incurred by the organizations of health care or medical professions in research and development, including clinical trials, events related to the activities of research and development, non-interventional studies, the activities of the committees monitoring data related to clinical trials, clinical studies initiated by independent researchers are disclosed, including, as a total amount with no breakdown by health organizations and medical practitioners.

HOW IS THE DISCLOSURE OF FINANCIAL DATA MANAGED?

HOW ARE CURRENCIES AND EXCHANGE RATES MANAGED?

- Local transfers of value are always paid and collected in the PLN for the Polish HCP/HCO's
- International (cross-border) transfers of value are sometimes paid in a currency different from the HCP/HCO's country currency. In those cases, the amount of the transfer of value is converted to the PLN using the official Company monthly exchange rates.

HOW IS THE VAT MANAGED?

All the amounts disclosed as transfers of value for direct payments are inclusive of all taxes additions (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:

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

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 transfer of value 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 transfer of value and a HCP/HCO. Identification is on the basis PESEL (personal identity number) or NIP (Tax ID number) but the ID is not disclosed.

HOW IS THE HCP INFORMED CONSENT MANAGED?

COLLECTION OF INFORMED CONSENT FOR SERVICE AGREEMENT

Specific provisions concerning the EFPIA Disclosure Code, the national disclosure code and personal data protection are included in Sanofi's standard contracts. For Poland where HCPs have an option to choose between individual and aggregate disclosure, a consent form was included for the HCP to either (i) agree to the individual disclosure of all transfers of value, or to (ii) refuse the individual disclosure, in which case the amounts were reported on an aggregate basis.

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. Any refusal by a given HCP of individual disclosure in a single contract in 2017 pushed all of his/her reportable transfers of value into the aggregate reporting category for 2017.

Sanofi respects the right of every HCP to agree or not with the individual disclosure as long as it is not a formal legal requirement in the country of origin of the HCP. A Sanofi representative prior to contracting with an HCP highlights the value of contributing to the transparency concerning transfer of value, but Sanofi ultimately respects their choice to refuse disclosure at their individual level.

Upon demand of a medical professional – i.e. in the event of consent withdrawal – their personal data shall be removed from the disclosed Form without delay and no later than 14 days from submitting such a demand.

In the event of consent withdrawal by a medical professional, the Sanofi obligation to disclose the transfer of value continues to apply, but in this case it is disclosed in an aggregate manner (without disclosing the beneficiary's identity).

PERSONAL DATA PROTECTION

Sanofi is highly committed to protecting HCP's personal data and upholding applicable data protection laws and regulations and therefore discharged its aforementioned obligations only with HCP's prior consent and knowledge. The informed consent in the contract explained which types of personal data will be collected, stored and published. By signing this informed consent, the HCP consents to the processing of his/her personal data in accordance with the procedures set out in the informed consent and for the only purpose of transfers of value disclosure. The HCPs is informed that he/she may request at any time to be provided with information on their personal data stored by Sanofi, and demand that incorrect data be corrected or deleted. HCPs are also informed of their right to revoke their voluntary consent at any time without any detrimental effect on their relationship with Sanofi.

HOW IS THE HCP PRE-DISCLOSURE NOTIFICATION MANAGED?

All along 2017, our Company contracts informed HCPs that, prior to publishing transfers of value information, the HCP will be presented, in semester 1, 2018, with an overview of his/her individual line items and the total amount that Sanofi plans to disclose for 2017. This allows the HCP to verify and if necessary correct any data which may be of material importance for the HCP to comply with his/her own personal obligations of revenues and tax declarations.

To comply with such pre-disclosure information, a web portal (https://www.sanofikodeks.pl) is accessible to all HCPs with at least one transfer of value during the 2017 calendar year. Access to this web portal was granted to HCPs on a voluntary basis after registration and careful authentication.

All HCP have been informed of the possibility to review their services on the portal. They have been received an individual access codes to the portal.

HOW IS THE 2017 ANNUAL DISCLOSURE REPORT MANAGED?

- Date of publication: The report will be available from 29th June 2018
- Disclosure platform: in the pdf file on the website (https://www.sanofikodeks.pl)
- Disclosure language: The report will be in Polish and English

LOCAL CONTACT

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GLOSSARY

CRO	[*Contract Research Organization*]
EFPIA	[*European Federation of Pharmaceutical Industries and Associations*]
FMV	[*Fair Market Value*]
HCO	[*Healthcare Organization*]
HCP	[*Healthcare Professional*]
R&D	[*Research & Development*]
TOV	[*Transfer of Value*]
VAT	[*Value-Added Tax*]