



Methodological Note

Disclosure of Transfers of Value to Healthcare Professionals and Healthcare Organizations

Sanofi-Aventis Ukraine LLC

Reporting year 2017

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INTRODUCTION

The European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code requires all EFPIA member companies to disclose transfers of value (TOVs) to healthcare professionals (HCPs) and healthcare organizations (HCOs).

Sanofi-Aventis Ukraine LLC (Sanofi Ukraine) is a member of the Association of Pharmaceutical Research and Development (APRAD) – the organization that represents the research-based pharmaceutical industry operating in Ukraine and is a member of EFPIA.

Sanofi Ukraine follows the national code, namely APRAD Code of Pharmaceutical Marketing Practices which has duly transposed the EFPIA requirements to disclosure of TOVs to HCPs and HCOs.

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

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.

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.

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 EFPIA and APRAD Disclosure Codes 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 is intended to assist the reader to firstly identify the type of declarable TOVs made to HCPs or HCOs, and secondly, to understand how the TOVs were collected and verified for disclosure by Sanofi Ukraine.

WHAT ARE THE EFPIA & APRAD DISCLOSURE CODE REQUIREMENTS?

EFPIA Disclosure Code requires that the European affiliates of EFPIA member companies collect and disclose TOVs made to European HCPs and HCOs wherever they might come from (inside or outside the country).

Transfers of value can 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 TOV (examples of indirect TOVs 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.).

DEFINITIONS

“Healthcare professional (HCP)” means any member of the regulatory authorities, medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product.

“Healthcare organization (HCO)” means any legal person irrespective of the legal or organizational form or its separate unit, aims at health care of patients and/or provision of medical services to the public based on appropriate licenses and professional activities of medical (pharmaceutical) workers. In addition, HCO includes: medical or scientific associations, learned society (except for patient organizations), medical teaching institutions, healthcare foundations and other medical institution whose business address, place of incorporation or primary place of operation is in Europe.

“Research and development transfers of value” means transfers of value to healthcare professionals or healthcare organizations related to the planning or conduct of (i) pre-clinical studies; (ii) clinical trials; or (iii) post-registration observation (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, healthcare professionals specifically for the study.

“Transfers of value (TOVs)” means direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only pharmaceutical products exclusively for human use. Direct transfers of value are those made directly by a pharmaceutical company for the benefit of a recipient. Indirect transfers of value are those made on behalf of a pharmaceutical company for the benefit of a recipient, or transfers of value made through an intermediate and where the pharmaceutical company knows or can identify.

“Events” means all promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) organized or sponsored by or on behalf of Sanofi.

HOW IS THE DISCLOSURE OF LOCAL TRANSFERS OF VALUE ORGANIZED?

Data were collected, reconciled, and reported using a local information system (Enterprise Resource Planning system – ERP) customized to Sanofi’s organizational requirements and internal financial system giving access to payment database related to the reporting period (2017).

TOVs were captured directly in the financial systems for all direct payments to HCPs and HCOs, and benefits to HCOs related to services agreements with third parties appointed by HCOs to manage events and indirect payments to HCPs related to registration fees, travel, and hospitality etc.

TOVs for indirect payments to HCPs and HCOs were recorded and consolidated outside of the systems based on the relevant financial reports of the authorized logistic agency, intercompany transactions, contracts with intermediary companies, information collected by Medical Department, and further integrated into the final report file.

WHICH TRANSFERS OF VALUE ARE DISCLOSED?

TOVs which occurred between January 1, 2017 and December 31, 2017 and are corresponding to one of the categories described below were further disclosed.

DONATIONS AND GRANTS TO HCO

Donations and other charitable contributions to HCOs covered all financial contributions to support:

- medical or scientific research;
- medical or scientific education;
- healthcare programs to achieve better health outcomes and patient care (e.g., disease screening);

- scholarships and fellowships;
- other types of activity as long as it promotes healthy behavior with a healthcare related objective;
- product donations for humanitarian purposes made in response to requests by hospitals.

The following were not reported in this category:

- donations or other contributions to patient organizations and patient groups.

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 objective of these events is to disseminate disease and product knowledge and to stimulate scientific exchange between HCPs. These events keep the HCP's knowledge current and state of the art, benefiting the care of their patients.

For a Third Party event, Sanofi Ukraine enters into agreements with HCO being the organizer of the event itself or with a third party (technical partner) being the event manager appointed by the hosting HCO. TOVs in the context of such agreements being effective in 2017 were reflected in this category.

CONTRIBUTION TO COSTS OF EVENTS

The 2017 Disclosure Report includes direct and indirect TOVs associated with HCPs' participation in the international events organized by Sanofi Global Office or Third Parties.

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 TOVs per each participant are provided by these third parties (as stipulated in their Service Agreement).

A Third Party or Company event in most cases included the provision of hospitality to HCPs (regulations allowing).

For international events wherein the HCPs' participation was managed centrally by a logistic agency on behalf of Sanofi Global Office, the participation package costs (usually including registration fee, accommodation, logistic fee and hospitality) were borne directly by Sanofi Global Office and further reallocated to Sanofi Ukraine affiliate. Sanofi Ukraine received a consolidated report for intercompany re-invoicing with the amounts related to the events that took place during the reporting year. This report contained the details of expenses for each event, so that it was possible to allocate the amounts to a certain category of TOV (registration fee, travel and accommodation) per each participating HCP.

However, there were instances when it was impossible to segregate and personalize the indicated amounts by type of expenses (e.g., the amount was indicated as a total amount of participation package within the international event). In such cases TOVs were still considered to be subject for disclosure for HCPs in the aggregated amount covered in the category “*Related expenses agreed in the fee for service and consultancy contract including travel and accommodation relevant to the contract*”.

FEES FOR SERVICE AND CONSULTANCY

On a regular basis, Sanofi enters into compensation-for-service arrangements with various HCPs 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, as well as the expected deliverables, are clearly documented in a written agreement (contract) before the performance of the service.

The selection of HCPs 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.

HCPs are compensated for the service based on the fair market value (FMV) determination in their country of practice.

RELATED EXPENSES AGREED IN THE FEE FOR SERVICE OR CONSULTANCY CONTRACT

Related expenses included in the fee for service or consultancy contract cover reasonable expenses linked to accommodation, travel costs (flight, ground transportation, visa) and meals incurred by HCP in carrying out the service. No other expenses are allowed for reimbursement.

RESEARCH & DEVELOPMENT

Sanofi Ukraine disclosed all TOVs associated with R&D activities in the aggregated R&D section; all R&D-related TOVs to HCPs or HCOs are related to the planning or conduct of the following:

- clinical trials;
- post-registration observation (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, healthcare professionals specifically for the study.

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

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

Within Sanofi Group in case of cross border TOVs to HCP, whether HCP is engaged outside of or inside the country of his/her principal practice, related TOVs are to be disclosed in the report of the country of his/her principal practice.

A specific HCP/HCO engagement process was implemented at Sanofi Group level (worldwide) to allow for collection of cross-border transfers of value:

- a commercially available web-based solution (system) and customized to our organization was deployed in the whole company. This platform was accessible 24/7 to worldwide users;
- 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.

The following should be noted when considering the Disclosure Report 2017 by Sanofi Ukraine.

Sanofi Ukraine disclosed TOVs that were transferred to the Ukrainian HCPs (direct and indirect) by Sanofi affiliates abroad during the period from January 01, 2017 to December 31, 2017.

Where a Ukraine based HCP was contracted by any Sanofi international affiliate to provide a service in 2017 he/she received fee for service and consultancy as well as the benefit of the related expenses (i.e. costs of flights, accommodation, and ground transportation) in 2017. These TOVs were included in the 2017 Disclosure Report.

HOW IS THE DISCLOSURE OF FINANCIAL DATA MANAGED?

WHICH ACTUAL DATES ARE USED FOR DISCLOSURE OF TRANSFER OF VALUE?

Depending on the type (direct or indirect) and the nature (in cash or in kind) of TOVs, two different transfer dates were used:

- for direct payments, the date of TOV used is the “clearing date” from the internal financial systems which corresponds to the date of the wire transfer to the recipient’s bank account;
- for TOVs linked to an event with different types and dates of expenses (congress registration, flight tickets, hotel bills, etc.), all these TOVs were reported at the date of their transfer to third parties together with accruing and paying taxes (e.g., for tickets purchased by the travel agency, TOV is reported with the same date or date after for such payment to the travel agency).

HOW ARE CURRENCIES AND EXCHANGE RATES MANAGED?

Local TOVs are always done in the local currency of the HCP/HCO's country (UAH).

International (cross-border) TOVs as well as intercompany reallocations related to international events were done in a currency different from the HCP/HCO's country currency (e.g., EURO, USD). Such amounts of TOVs were converted into the local currency of HCP/HCO's country using the company average comparable currency rate.

Of note, amounts disclosed are those paid by Sanofi. These amounts could slightly differ from amounts received by the HCP/HCO depending on bank exchange rate and/or transfer fees.

HOW IS VALUE ADDED TAX AND OTHER TAXES MANAGED?

The amounts disclosed as TOVs for indirect payments are inclusive of VAT, where applicable.

Related taxes (mostly personal income tax, military tax and unified social tax) accrued and paid by Sanofi Ukraine in relation to the amounts of TOVs to HCPs were not disclosed, as the purpose of this disclosure was other than tax reporting or tax transparency.

WHICH TRANSFERS OF VALUE ARE EXCLUDED FROM DISCLOSURE?

According to the APRAD Disclosure Code, the following is excluded from the disclosure obligations:

- TOVs solely related to over-the-counter pharmaceutical products
- items of medical utility;
- meals and drinks;
- samples;
- TOVs that are part of ordinary course purchases and sales of pharmaceutical products by and between a pharmaceutical company and a healthcare professional or a healthcare organization.

**It should be noted that due to technical peculiarities it was impossible to exclude a part of non-declarable TOVs, hence, the 2017 Disclosure Report still includes:*

- *meals (where applicable) as an inseparable part of hospitality according to the relevant HCP service and consultancy contracts or within the event participation package – covered in the category “Related expenses agreed in the fee for service and consultancy contracts”;*
- *TOVs related to over-the-counter pharmaceutical products.*

OTHER SPECIFIC CONSIDERATIONS

WHICH UNIQUE IDENTIFIERS ARE USED TO ACCURATELY IDENTIFY HCPS?

The accurate and unique identification of each recipient (HCP or HCO) of 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 TOV and HCP/HCO.

For data protection considerations, only those country-required publically available IDs are reported in the disclosure report.

RECIPIENT VERSUS BENEFICIARY

The term “recipient” means any natural person (HCP) or legal entity (HCO) which receives TOV. In case of direct TOV following a service agreement, the recipient is the entity which is mentioned in the service agreement and to which the payment is due after the service has been delivered (holder of the bank account on which the money is transferred).

The term “beneficiary” means the natural person or legal entity who ultimately benefits from the transfer of value. In most cases, the beneficiary of TOV, if different from the recipient, is not known to Sanofi.

In the 2017 Disclosure Report the following principle was followed:

- payment to a third party (the recipient) that represented or acted under an agreement with and in the interest of HCO, was reported as TOV to HCO (the beneficiary).

HOW IS THE HCP INFORMED CONSENT MANAGED?

COLLECTION OF INFORMED CONSENT FOR SERVICE AGREEMENT

Sanofi Ukraine’s legal department ensured that specific provisions concerning the EFPIA Disclosure Code, the APRAD disclosure code and personal data protection rules are included in Sanofi’s standard contracts. In 2017 upon signing a yearly frame service agreement HCPs had an option to choose between individual and aggregate disclosure. A consent form, as a part of the agreement, makes HCP either (i) agree to the individual disclosure of all TOVs, or (ii) refuse the individual disclosure, in which case the amounts were reported on an aggregate basis.

In accordance 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 & choose” which transfers he/she wishes to disclose. Any refusal to individual disclosure given by

HCP in the frame service and consultancy contract for 2017 pushed all of his/her reportable TOVs 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 HCP. A Sanofi representative prior to contracting with an HCP tries to convince the HCP of the benefit of contributing to the transparency concerning TOV, but Sanofi ultimately respects their choice to refuse individual disclosure.

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 agrees that his/her personal data will be processed in accordance with the procedures set out in the informed consent and for the only purpose of TOV disclosure. The HCP 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.

OTHER COUNTRY INFORMATION

The following points should be taken into account in the context of the 2017 Disclosure Report:

- International (cross-border) TOVs as well as intercompany reallocations related to international events were done in a currency different from the HCP/HCO's country currency (e.g., EURO, USD). Such amounts of TOVs were converted into the local currency of HCP/HCO's country using company average comparable currency rate.
- HCPs' principal practice addresses are disclosed based on the recent available information provided by HCPs to Sanofi. If the address of principal practice was not clearly defined by HCP, and only the name of the place of work (institution) was provided instead, the legal address of this institution available in open sources was taken and mentioned in this report.

HOW IS THE 2017 ANNUAL DISCLOSURE REPORT MANAGED?

- Publication date: June 27, 2018
- Publication platform: www.sanofi.ua
- Language of publication: Ukrainian

WHAT IS THE PROCESS IN CASE OF POST-DISCLOSURE REQUEST FOR MODIFICATION?

In case of HCP's written request for individual disclosure consent withdrawal (the consent given upon signing the 2017 frame service or consultancy contract), all related TOVs will be removed from the individual and transferred to the aggregated disclosure, and the report will be further republished.

CONCLUSION

This Methodological Note describes the main Sanofi processes and methods used to prepare this annual disclosure report on TOVs to HCP/HCO.

Sanofi believes that these principles and methods resulted in a disclosure report that is a fair and complete reflection of TOVs from Sanofi to HCP/HCO in 2017.

As a conclusion, Sanofi Ukraine and HCPs collaborated over the course of 2017 in a wide range of activities from clinical research to sharing best clinical practice and exchanging information on how our new medicines fit into the patient's treatment pathway. Working together for patients is a partnership which benefits patients, HCPs and healthcare system.

WHO SHOULD BE CONTACTED IN CASE OF ANY QUESTION ON THIS REPORT?

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