



*Eu*Disclose

**EFPIA Disclosure
Country Methodological
Note - Serbia**

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).

INOVIA (Association of Innovative Drug Manufacturers in Serbia) Disclosure code is fully aligned with EFPIA Disclosure Code.

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 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.

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 differed from the country where the HCP is practicing or where the HCO is incorporated.

WHICH TRANSFERS OF VALUE ARE DISCLOSED?

All transfers of value which occurred between January 1st and December 31st, 2019 (see section on "Actual Dates of transfer") and corresponding to one of the categories described below.

DONATIONS AND GRANTS TO HCO

"Donations and Grants to HCOs" covered all financial contributions to HCOs 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.

The following were not reported in this category: Donations of medicines and vaccines for humanitarian purposes made in response to a request by a non-profit or charitable organization; 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 Corporate website available at http://en.sanofi.com/csr/approach/stakeholders/patient_associations/patient_associations.aspx; 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.

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 and state of the art, benefiting the care of their patients.

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 - for different type of activities:

- Company satellite symposium during which scientific lectures are delivered;
- Booth rental where individualized scientific information is provided to HCP at their request;
- Sponsorship of speakers or faculty (where Sanofi did not interfere in the selection of speakers, who are solely selected by the Event Organizing Committee);
- Sponsorship of Educational/Training courses (where Sanofi did not have any say in the selection of participants);
- Advertisement space (e.g. paper, electronic, banner, or any other format).

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 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) if it was not rented from HCO.

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

Sanofi discloses in the Aggregated R&D section, all R&D-related transfers of value 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.

Transfers of value related to the planning or conduct of studies mainly include: investigators fees, study nurses' costs, pharmacy costs and hospital overheads.

Ethics Committee fees as mandatory fees were not disclosed.

HOW IS THE DISCLOSURE OF FINANCIAL DATA MANAGED?

WHICH ACTUAL DATES ARE USED FOR DISCLOSURE OF TOV?

Depending on the type (direct or indirect) and the nature (in cash or in kind) of 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 (payment term is usually between 30 and 45 days after the invoice is booked by the Accounting Department);

- 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 1st day of the event;

HOW ARE CURRENCIES AND EXCHANGE RATES MANAGED?

- Local transfers of value are always paid and collected in the currency of the HCP/HCO's country;
- International (cross-border) transfers of value paid by legal entities of sanofi group other than local affiliate 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 using the official Company monthly exchange rates.

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

HOW IS THE VAT AND WITHHOLDING TAXES MANAGED?

All the amounts disclosed as transfers of value for direct payments to the HCO are inclusive of VAT additions.

Disclosed direct and indirect payments to the HCP do not include withholding taxes (net values are disclosed).

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).

RECIPIENT VERSUS BENEFICIARY

The term "recipient" means any natural person (HCP) or legal entity (HCO) which receives a transfer of value. In case of direct transfer of value 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 who ultimately benefits from the transfer of value. In some cases, the beneficiary of a transfer of value, if different from the recipient, is not known to Sanofi.

If recipient is different from beneficiary, transfer of value to the beneficiary is disclosed as follows:

- payment of service fees and/or expenses to an HCO or other third party (the recipient) for indirect TOV to an HCP are reported as transfers of value to the HCP in question (the beneficiary);
- payment of sponsorship or service fees to a third party (the recipient) that represents, or acts on behalf of an HCO, are reported as transfers of value to the HCO in question (the beneficiary).

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. Since in Serbia 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 2019 pushed all of his/her reportable transfers of value into the aggregate reporting category for 2019.

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 tries to convince the HCP of the benefit of contributing to the transparency concerning transfer of value, but Sanofi ultimately respects their choice to refuse disclosure at their individual level.

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.

HCP have been advised in the contract template that they may revoke their consent at any time and also demand that incorrect data be corrected, deleted or removed, as well as to request to be provided with further information on their personal data processed by sending a written notice to local Sanofi affiliate.

HOW IS THE 2019 ANNUAL DISCLOSURE REPORT MANAGED?

- 2019 annual disclosure report and Country Methodological notes will be published on 30th June 2020 on www.sanofi.com in English and Serbian language.

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

HCPs may withdraw their consent at any time by writing or calling to the Sanofi Affiliate (contact below) and requesting that their personal information is not individually disclosed.

In such cases, after authentication of the HCP, the Sanofi Affiliate will ensure that all transfers of value made by Sanofi to that particular HCP were disclosed in aggregate. Required modification will be taken into account within 28 days.

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

For any enquiry please contact **SANOFI - AVENTIS D.O.O.**

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