SANOFI

EuDisclose

Disclosure 2018

Methodological Note

Italy

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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 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

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.

Sanofi's Transparency approach was a combination between central coordination and local accountability.

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.

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, called NAYA (BMI SYSTEM) and customized to our organization was deployed in the whole Company. This platform was accessible 7/24 to worldwide users.
- To ensure compliance with the local requirements, any request for cross-border engagement had to be vetted and approved by a validator (Transparency Officer) 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 the respect of the country hospitality rules.

HOW IS THE DISCLOSURE OF LOCAL TRANSFERS OF VALUE ORGANIZED?

Data were captured from various sources

- The main source was Sanofi's financial system (SAP): all direct payments were automatically uploaded by Sanofi Global in the "NAYA Aggregate Spend platform" via an automatic connector without any manual processing.

- Non-SAP payments and indirect payments were manually entered into NAYA Aggregate Spend platform either via mass uploads of formatted Excel files or directly entered case-by-case into the platform.

HOW IS THE DISCLOSURE OF THE CONSENT TO LOCAL TRANSFER OF VALUE ORGANIZED?

The disclosure of the data takes place thanks to the consent provided by the HCP on the appropriate form (MRD form for events and consultancy - Farmindustria module for participation in conferences).

The disclosure of the consent, is given by the HCP on those forms.

In case of the HCP does not provide the consent, the data will be, however, disclosed in aggregate.

The HCP who has been invited to a congress and has given his consent to the disclosure but who does not attend (no show) the event is an exception.

In this particular case Sanofi has already payed the hospitality and the congress registration fee so this expenses, despite the consent given by the HCP, won't be declared in the EFPIA report as individual data but as aggregate.

WHICH TRANSFERS OF VALUE ARE DISCLOSED?

All transfers of value which occurred between January 1st and December 31st, 2018

(see section on "Actual Dates of transfer") and corresponding to one of the categories described below, were captured in the "NAYA Aggregate Spend Platform" and further disclosed.

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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 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://www.sanofi.it/l/it/it/layout.jsp?scat=891ADEAC-8670-4A6A-AB28-28CE49F9E341

- 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 courses performed during the congress (where Sanofi did not have any say in the selection of participants).
- Sponsorship for the attendance (hospitality + registration) for pre-defined group of HCPs (where Sanofi did not have any say in the selection of HCPs completely managed by the HCO).
- 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. 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 a Country specific fair market value (FMV) determination.

Related expenses agreed in the fee for service or consultancy contract

FEE FOR SERVICE AND 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 ORGANIZATION

Sanofi's R&D transfers of value could come from different R&D entities:

- Sanofi's Corporate R&D entities: located in France, USA, Germany, China, and Japan. These Corporate R&D entities were responsible of transfers of value made either directly or indirectly through international Contract Research organizations (CROs).
- Sanofi's Clinical Study Units (CSUs) located in most of Europeans countries. All transfers of value made to HCPs or HCOs were locally extracted from the financial tools. For multi-country CSUs, cross-border transfers of value were reallocated to the HCP/HCO home country.

AGGREGATED DISCLOSURE

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, hospital overheads, and Ethical Committees fees.

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.

The EFPIA Code excludes the following transfers of value from disclosure: All costs related to fixed costs for the management of clinical trials by local CROs

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 60-90 days after the invoice is booked by the Accounting Department).
- For indirect payments, the date of transfer of value used is the “date” reported into the excel file prepared by the Agency which corresponds to the date of the wire transfer to the recipient’s bank account (payment term is usually 60-90 days after the invoice is booked by the Agency).
- 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; all 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 2018 for a service or sponsoring that took place in 2017/2018, the payment is not disclosed in the 2018 disclosure report.
- Payments made in 2018 for services or sponsoring that took place in finaly 2017 are included in the 2018 disclosure report.

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 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 in the NAYA “Aggregate Spend” platform to the HCP/HCO’s country currency 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 MANAGED?

All the amounts disclosed as transfers of value for HCOs’ and HCPs’ direct and indirect payments are inclusive of all taxes additions (e.g. VAT if applicable) and deductions (e.g. withholding taxes).

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)

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.

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 legal entity () 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). Due to Italian ECM rule the recipient usually is the agency which organizes the congress for a Medical or Scientific Association

The term “beneficiary” means any natural person (HCP) or legal entity (HCO) which ultimately benefits from the transfer of value. Due to Italian ECM rule the beneficiary usually is the Medical or Scientific Association owner of the event.

According to the definition of ‘recipient’ and ‘beneficiary’ all transfer of value were managed as follow:

- payment of service fees and/or expenses referred to the agency activities (the recipient) are not reported into the disclosure report),

- payment of service fees and/or expenses to an HCP managed by the agency 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)

MULTI-YEAR AGREEMENTS

Multi-year agreements cover a series of services or sponsored activities/events across multiple years with HCPs or HCO. The associated transfers of value will be disclosed per calendar year (the amount reported is corresponding to the total value of invoices paid during the specific year) as required by the EFPIA and local disclosure code.

The HCP’s consent for personal data processing and individual disclosure of transfers of value for multi-year agreements was obtained: once for the entire duration of the agreement

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. For countries where HCPs have an option to choose between individual and aggregate disclosure, a consent form was gathered 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 2018 pushed all of his/her reportable transfers of value into the aggregate reporting category for 2018.

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.

The NAYA database is reported to the French data protection authority (CNIL) as the servers and data controllers are based in France, as well as to other European country data protection authorities when locally required.

HOW IS THE 2018 ANNUAL DISCLOSURE REPORT MANAGED?

- Date of publication 30 June 2019
- Disclosure platform www.sanofi.it
- Disclosure language English

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

From the report publication date the updates will be done in case of exercise of the right by the interested person according to the general data protection regulation law (REG.EU. 2016-69)

• CONCLUSION

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

Sanofi believes that these principles and methods resulted in a disclosure report that is a fair and complete reflection of the transfer of value from Sanofi to HCP/HCO in 2018:

- All internal steps and quality controls were put in place to ensure the exhaustiveness and accuracy of all the different required categories of transfers of value
- Careful consideration was taken to ensure a proper allocation of transfer of value to the proper recipient or beneficiary as applicable
- A pre-disclosure notification was made available to HCPs for correcting possible errors
- The respect of the HCP's consent for disclosure at their individual, as well as the respect of all relevant Personal Data Protection regulations were carefully implemented
- The R&D aggregated category only included transfers of value linked to pre-clinical, clinical and non-interventional studies. All other R&D transfers of value were individually disclosed, HCP/HCO consent allowing.

As a conclusion, Sanofi and HCPs collaborated over the course of 2018 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. We believe that this disclosure report puts these data in context, ensures that patients and society understand and can have confidence in the relationship between Sanofi and its medicines they rely on and the professionals that prescribe these. Working together for patients is a partnership which benefits patients, HCPs and healthcare systems.

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

Indirizzo mail: *Informazioni.medicoscientifiche @sanofi.com*

GLOSSARY

CRO	Contract Research Organization
CSU	Clinical Study unit
EFPIA	European Federation of Pharmaceutical Industries And Associations
ERP	Enterprise Resource Planning (i.e. SAP)
FMV	Fair Market Value
HCO	Healthcare Organization
HCP	Healthcare Professional
MN	Methodological Note
MSA	Medical & Scientific Association
PA/ PG / PO	Patient Association / Patient Group / Patient Organization
PCO	Professional Congress Organizer
R&D	Research & Development
T&E	Travel & Expenses
TOV	Transfer of Value
VAT	Value-Added Tax