EFPIA Disclosure
Core Methodological Note

Version 1

SANOFI

TABLE OF CONTENTS

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 organisations (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 organisations 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 organisations 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)
- 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.).

WHICH TRANSFERS OF VALUE ARE DISCLOSED?

All transfers of value which occurred between January 1st and December 31st, 2015 (see section on "Actual Dates of transfer") and corresponding to one of the categories described below are disclosed.

The report concerns the following Sanofi Group entities:

- *Sanofi*
- *Genzyme (sanofi Genzyme)*
- *Zentiva*
- *Sanofi-Pasteur*
- *Sanofi-Aventis R&D*

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 Organisations and Patient Groups as these follow the EFPIA Code of practice governing industry relationships with patient organisations 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).

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

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:

- clinical trials (as defined in *EU Directive 2001/20/EC*);
- non-interventional studies 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, hospital overheads, and technical Committees fees.

Investigator Sponsored Trials / Independent Investigator Trial (IST/IIT) are reported in the aggregated R&D disclosure as these studies belong to the above classification.

INDIVIDUAL DISCLOSURE

Other activities managed by R&D were included in the HCP or HCO individual disclosure (after collection of the individual's consent) as these are not specifically related to the planning or conduct of studies:

- Expert committee not linked to a study: e.g.; advisory board for drug submission, regulatory strategy, pharmacovigilance cases analysis, etc.
- Medical lecture or presentation on pathology, disease, product mechanism of action
- Diverse reports related to area such as: partnering, innovation, comparative analysis
- Diverse grants or donations: research Grants and other educational donations.

MEDICAL & SCIENTIFIC PUBLICATIONS

Support related to medical & scientific publications may include medical writing and editing, graphic support, submission and publication fees.

This support was not considered as a transfer of value to the authors, for the following reasons:

- Publishing results of clinical studies is a societal obligation and may require the provision of editorial support to investigators at their request. Timely dissemination of the study does ensure that HCPs treat their patients in accordance with the best and most complete available evidence.
- Publication of study results benefit the whole scientific community and ultimately the patients and go well beyond the interests of the individual authors and Sanofi.
- Sanofi requires that any funding for editorial support along with the sponsorship of the study is fully disclosed in the manuscript for all to read and interpret. The disclosure of any conflict of interest by all authors (including any Sanofi-employed authors) is also required by all medical & scientific journals.

HOW IS THE DISCLOSURE OF FINANCIAL DATA MANAGED?

WHICH ACTUAL DATES ARE USED FOR DISCLOSURE OF TOV?

Depending on the type (direct or indirect) of transfers of value, two different transfer dates were used:

- The transfer date for direct TOVs is the actual date of the transfer.
- The transfer date for TOVs related to various events (conference participation fees, flight tickets, accommodation, etc.) is the date of the first day of the event.

HOW IS THE VAT MANAGED?

TOVs to HCPs are disclosed as net amounts.

Disclosed TOVs to HCOs reflect the amounts agreed in the contracts and on invoices submitted to Sanofi by HCOs.

WHICH TRANSFERS OF VALUE ARE EXCLUDED FROM DISCLOSURE?

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

- 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. Sanofi uses an ID number or company registration number to identify HCPs and HCOs in Estonia.

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 most cases, the beneficiary of a transfer of value, if different from the recipient, is not known to Sanofi.

In the following cases the transferred value is linked to the beneficiary rather than the recipient:

- 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. The associated transfers of value will be disclosed per calendar 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

In Estonia, where HCPs have an option to choose between individual and aggregate disclosure, a consent form was included to standard contracts 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.

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. To revoke his/her consent the HCP needs to send applicable e-mail to avalikustamine@sanofi.com.

HOW IS THE HCP PRE-DISCLOSURE NOTIFICATION MANAGED?

All along 2015, our Company contracts informed HCPs that, prior to publishing transfers of value information, the HCP will be presented, with an overview of his/her individual line items and the total amount that Sanofi plans to disclose for 2015. This would allow 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 was accessible to all HCPs with at least one transfer of value during the 2015 calendar year. Access to this web portal was granted to HCPs on a voluntary basis after registration and careful authentication.

HOW IS THE 2015 ANNUAL DISCLOSURE REPORT MANAGED?

Data of TOVs for the previous year are published in the Estonian language on the Sanofi website www.sanofi.ee on 1 June.

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

If an HCP wants to withdraw their consent to individualised disclosure or make corrections after the data have been disclosed, he or she has to send a relevant request in writing to Sanofi by e-mail: avalikustamine@sanofi.com. Changes will be made to published reports on a periodic basis.

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 2015:

- 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 2015 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?

If you have questions on the disclosure procedure or the report, please e-mail your questions to avalikustamine@sanofi.com.

GLOSSARY

CRO	Contract Research Organization
CSU	Clinical Study unit
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