



Sanofi Bulgaria EOOD

Methodological Note

INTRODUCTION

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 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.

On the other hand, 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.

Sanofi believes 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 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”).

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 is intended to assist the reader to identify the type of declarable made to a HCPs or HCOs, and to understand how the ToV were collected and verified for disclosure by Sanofi in Bulgaria.

WHAT ARE THE ARPHARM DISCLOSURE CODE REQUIREMENTS?

The Association of research-based Pharmaceutical Manufacturers in Bulgaria (“ARPharM”) has transposed the EFPIA Disclosure Code requirements in its own “Code for disclosure of transfers of value by pharmaceutical companies to healthcare professionals and healthcare organizations” (“Code”) (adopted November 2013, in force since 1st of January 2014).

The following definitions are determined in the Code:

ToV: The direct and indirect provision of value in cash, in kind or otherwise, made for promotional purposes or otherwise, in connection with development (“R&D”) and marketing of prescription-only medicinal products for human use.

Direct ToVs: the transfer made directly by the Company in favour of the recipient.

Indirect ToVs: Made on behalf of the Company in favour of the recipient or through an intermediary, in which case the Company knows or can identify the HCP or the HCO that will benefit from it.

Recipient: Any HCP or HCO, as applicable, in each case, with main practice, practice address or place of registration in Europe.

HCP: Any of the following: medical doctors, doctors of dental medicine, master pharmacists, nurses, midwives, medical laboratory technicians, paramedics and doctor's assistants, assistant-pharmacists or any other person who in the course of his/her professional activity could prescribe, purchase, supply or administer medicinal products and whose main practice, practice address or place of registration is in Europe.

For the avoidance of doubt, the definition of a HCP includes:

1. any officer or employee of a government agency or other organization (public or private), which have the right to prescribe, purchase, supply, recommend or administer medicinal products
2. any employee of the Company whose main activity is the medical practitioner,
but excluding
3. any other employees of the Company and
4. a wholesaler and distributor of pharmaceutical products.

HCO: Any healthcare organization, or medical or scientific organization or association (regardless of its legal or organization form), such as a hospital under the Act for hospitals, or foundation, university or other educational institution, or professional or scientific society (with the exception of patient organizations), whose registered office, place of incorporation or primary place of business in Europe, or in which one or more HCPs provide services.

The Code defines the following categories of ToVs to HCO or HCP to be disclosed:

- Donations and Grants;
- Contribution to costs related to Events:

Sponsorship agreements with HCOs/third parties appointed by the HCO to manage an Event;

Registration fees;

Travel and accommodation;

- Fees for Service and Consultancy:

Fees;



Related expenses agreed in the fee for service or consultancy contract;

- ToVs for research and development.

HOW WAS DISCLOSURE OF LOCAL TRANSFERS OF VALUE ORGANIZED?

Data were collected, reconciled, and reported using a commercially available database which was customized to Sanofi organizational requirements. This system is used by Sanofi to track payments within all EFPIA countries.

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

All financial ToVs were reconciled against our financial system where all transparency relevant vendors are flagged to easily identify coding to correct categories of spend.

HOW WAS DISCLOSURE OF CROSS-BORDERS TRANSFERS OF VALUE ORGANIZED?

A “Cross-border transfer of value” is defined as a ToV 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.

Sanofi has disclosed ToVs that were paid to Bulgarian HCO/HCP by other affiliates within Sanofi Group during the reporting period.

WHICH UNIQUE IDENTIFIERS ARE USED TO ACCURATELY IDENTIFY HCPS AND HCOS?

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

For data protection considerations, the unique country identifiers of HCPs which were publically available are reported in the disclosure report. For HCPs without respective unique country identifier a local unique internal code was created to facilitate reporting.

WHICH TRANSFERS OF VALUE ARE DISCLOSED?

Sanofi has disclosed TOVs that were paid to recipients practicing or incorporated in Bulgaria by Sanofi Bulgaria EOOD and by other Sanofi International Affiliates based in a country which differed from Bulgaria, occurred between January 1st and December 31st, 2016.

DONATIONS AND GRANTS TO HCO

Sanofi considered applications from HCOs and made donations and grants to enhance patient care or academic research to enhance medical knowledge.

CONTRIBUTION TO COSTS OF EVENTS PAID TO HCOS OR TO THIRD PARTIES MANAGING EVENTS ON THEIR BEHALF

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.

During the course of 2016 Sanofi has supported a number of events organized by HCOs for which Sanofi has concluded sponsorship agreements.

When ToVs for sponsorship were made to a third party that represents, or acts on behalf of an HCO, are reported as ToV to the HCO in question.

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.

Sanofi has paid hospitality costs (registration fees, travel and accommodation) related to events directly to third-parties (congress agencies, travel agencies, and congress organizers) for the benefit of individual HCPs. Where a ToV is made to an individual HCP indirectly via a HCO such ToV is disclosed only once on HCP basis depending on his/her consent.

FEEES FOR SERVICE AND CONSULTANCY

In 2016 Sanofi entered into service/consultancy agreements 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.

When ToVs for fees for service and consultancy were made to a Third party that represents, or acts on behalf of an HCO, are reported as ToV to the HCO in question.

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 and travel costs (flight and ground transportation) related to the carry out of the service.

ToVs for related expenses are reported to the HCP/HCO with whom the service/consultancy agreements has been concluded.

RESEARCH & DEVELOPMENT

R&D-related transfers of value are reported in aggregate and include ToVs to HCPs or HCOs related to the planning or conduct of the following:

- Direct and indirect payments to interventional and non-interventional studies;
- Investigator sponsored trials

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.

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

It should be noted that for direct payments related to events that took place in 2016 which were not made in 2016, the TOVs will not appear in the 2016 Disclosure Report but in the one for 2017.

- 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 - the 1st day of the event;

It should be noted that payments related to transfers of value made in 2016 for events, services or sponsoring that took place in 2015 are excluded from the 2016 disclosure report.

MULTI-YEAR AGREEMENTS

TOVs related to multi-year agreements are reported based on the date of payment described above.

CURRENCIES AND EXCHANGE RATES

- Local transfers of value are paid and collected in Bulgarian levs.
- When a Bulgarian HCP received payments in other currency, the expenses were converted into Bulgarian lev using the official exchange rate issued by the Bulgarian National Bank on the date of payment.

HOW ARE THE VAT AND OTHER FINANCIAL ASPECTS MANAGED?

All the amounts disclosed as ToV for direct and indirect payments are exclusive of all taxes additions (e.g. VAT) and deductions (e.g. withholding taxes, social securities).

OTHER SPECIFIC CONSIDERATIONS

ToVs to HCOs were disclosed as documented in the written agreement (contract) concluded between the parties.

In the event of any doubt over whether any specific ToVs related to over-the-counter medicines need to be published; Sanofi has assumed in the interests of transparency that such ToVs should be published. For this reason some ToVs related to promotional activities of over-the-counter medicines to HCPs are disclosed, as well as those activities related to products with mixed registration status.

INFORMED CONSENT

Sanofi has obtained informed consent for disclosure of personal data from each individual HCP prior to the first engagement in 2016. Individual disclosure of the HCP personal data is made only if a voluntary written consent to such disclosure was expressed. In all other cases, the data was aggregated to allow Sanofi to disclose summary statistics without disclosing any personal data of the HCP.

It is Sanofi's policy that partial consent (the disclosure of some but not all ToVs) is not permitted. In such case Sanofi has disclosed on aggregate base.

HCP can revoke his/her consent at any time with a separate notice to Sanofi.

Once published the information disclosed including any personal data shall remain in the public domain for a minimum of 3 years after the time such information is first disclosed. Should the recipient revoke his/her consent after the date of publication of the report, his/her personal data will not appear on individual base in the report for the next reporting period.

Consents were not requested from HCOs since it is not a requirement in the data protection legislation in Republic of Bulgaria.

DISCLOSURE PLATFORM, FREQUENCY AND TIMING

This 2016 Sanofi Bulgaria EOOD disclosure report has been officially published in Bulgarian language on 30.06.2017 at www.sanofi.bg.

This data will remain published for three years from the date of publication.

Updates of already published ToVs will only be made in case discrepancies are detected after the date of publication.

CONTACTS

For any further information please contact: bg-transparency@sanofi.com

CONCLUSION

As a conclusion, Sanofi and HCPs collaborated over the course of 2016 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.