



# **Disclosure 2017**

## **Methodological Note for SANOFI Group, Czech Republic**

## INTRODUCTION

The EFPIA Disclosure Code (DC) requires all 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). Locally, these requirements are implemented by the Association of the Innovative Pharmaceutical Industry (AIFP).

Collaborative working between HCPs and commercial life sciences organizations has long been a positive driver for advancements in patient care and progression of innovative medicine.

HCPs and HCOs with whom we work to provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical experience. What's more, 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 HCPs and the exchange of knowledge among HCPs and industry. This expert knowledge helps to adapt our products to better suit patients and thereby improve patient care overall.

We believe that HCPs and HCOs should be fairly compensated for the legitimate expertise and services they provide to the industry. At the same time, we acknowledge concerns that such transactions should be transparent.

The EFPIA Disclosure Code will protect the integrity of the relationship between the industry and healthcare professionals, and represent 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 TOV made to a HCP or HCO, and secondly to understand how the TOV was collected and verified for disclosure by Sanofi in the Czech Republic (CZ).

With the exception of Research & Development, the 2017 Disclosure Report for Sanofi in the CZ covers the support provided by any of legal or organizational entities covered by the Sanofi Group umbrella (hereinafter as "Sanofi") by means of monetary payments and/or other transfers of value made to HCPs and HCOs.

Expenses related to Clinical Studies conducted by Sanofi in the CZ as well as other expenses related to research and development (R&D) are by definition disclosed in aggregate in the 2017 report.

## WHAT ARE THE AIFP DC REQUIREMENTS?

The AIFP has translated the requirements of the EFPIA Disclosure Code in the AIFP Code on Disclosure which states that the transfers of value which are declarable are:

1. For Transfers of Value to an HCO, an amount related to any of the categories set forth below:
  - a. Donations and Grants;
  - b. Contribution to costs related to Events, such as:
    - i. Registration fees;

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ii. Sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event; and

iii. Travel and accommodation.

c. Fees for Service and Consultancy.

### 2. For Transfers of Value to an HCP:

a. Contribution to costs related to Events, such as:

i. Registration fees;

ii. Sponsorship agreements;

ii. Travel and accommodation expenses.

b. Fees for Service and Consultancy

In accordance with the EFPIA DC, Sanofi does not disclose TOV related to:

- a. Non-prescription drugs, food supplements, or health-care devices;
- b. The provision of meals, drinks and refreshments;
- c. Medicinal product samples;
- d. Ordinary trading contracts and sales of medicinal products between Sanofi and HCPs or HCOs;
- e. Market surveys, in which Sanofi does not know the identity of participating HCPs;
- f. HCPs who were employees of the company or its external HCP collaborators (whose activity did not extend to health-care provision).

## DEFINITIONS

The term 'healthcare professional' (HCP) includes persons who in the course of their professional activities may prescribe or dispense a medicine, i.e. members of the medical, dental and pharmacy professions.

The term 'healthcare organization' (HCO) means either a healthcare, medical or scientific association as well as other non-profit healthcare organizations, patient organizations etc., or organization such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe or an organization through which one or more health professionals or other relevant decision makers provide services.

The term 'transfer of value' (TOV) means a direct or indirect transfer of value, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines. A direct transfer of value is one made directly by a company for the benefit of a recipient. An indirect transfer of value is one made on behalf of a company for the benefit of a recipient or through an intermediate and where the company knows or can identify the recipient that will benefit from the transfer of value.

In the Czech Republic, the term 'Sanofi' is represented by following legal entities generating TOV as subjects for Disclosure:

- sanofi-aventis, s.r.o., inclusive of Sanofi, Sanofi Pasteur, and Sanofi Genzyme organizational units;
- Zentiva, k.s.;
- Zentiva Group, a.s.

## HOW WAS THE 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 TOV were reconciled against the financial system where all transparency relevant vendors are flagged to easily identify coding to correct categories of spend.

## HOW WAS THE DISCLOSURE OF CROSS-BORDER TRANSFERS OF VALUE ORGANIZED?

The following should be noted when considering the Disclosure Report 2017 with respect to these:

Sanofi has disclosed TOVs that were paid to CZ HCOs and HCPs by International Affiliates during the period 1 January 2017 and 31 December 2017.

Where a CZ HCP was contracted prior to 2017 by an International Affiliate, but actually received their TOV in 2017, the 2017 Disclosure report includes these TOV.

Where a CZ HCP was contracted by an International Affiliate to provide a service in 2017, he/she would have received the benefit of the related expenses, i.e. costs of flights, accommodation, and ground transportation in 2017. These TOV are disclosed in the Disclosure Report 2017. However, it should be noted there are instances where an International Affiliate may not have paid the fee for service to a CZ HCP for an engagement in 2017 until 2018. Therefore, it is possible that for an individual HCP, there will only be related expenses listed that were paid to them in 2017 in the Disclosure Report 2017, and the fee for service paid in 2018 will be listed in the Disclosure Report 2018.

## SPECIFICATION OF TRANSFERS OF VALUE

All transfers of value made by Sanofi to HCOs and HCPs in the CZ between January 1st and December 31st, 2017 (see section on "Actual Dates of transfer") and corresponding to one of the categories described below, were captured in the system for Sanofi.

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## DONATIONS AND GRANTS TO HCOS

Sanofi considered applications from HCOs for donations and grants throughout the course of 2017. Sanofi made donations and grants to HCOs in 2017 where it served to enhance patient care or academic research to enhance medical knowledge.

Sanofi has recorded the date of TOV as the date the payment was processed by Sanofi.

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## SPONSORSHIP OF ATTENDANCE OF HCPS AT MEETINGS

Sanofi CZ supported individual HCPs to attend meetings during the course of 2017 in order to let them increase their professional knowledge. Expenses related to registration fees, traveling and accommodation were matched with an individual HCP and realized either by direct payments or through third parties, e.g. agencies. The following should be noted when considering the Disclosure Report 2017 with respect to these:

- Sanofi requested the individual HCPs consent to disclose the TOV. Consents were collected on a per event basis.
- Sanofi has recorded the date of TOV as the date of the starting day of the Event.

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## FEES AND EXPENSES PAID TO HCPS, OR TO THEIR EMPLOYER ON THEIR BEHALF

Sanofi has contracted a large number of HCPs during the course of 2017 to provide one or more of the following services:

1. Speaker
2. Chairperson
3. Training
4. Consultancy

The following should be noted when considering the Disclosure Report 2017 with respect to these:

- Sanofi requested the individual HCPs consent to disclose the TOV. Consents were collected on a per event basis.
- Sanofi has recorded date of TOV as the date the payment was processed and released by Sanofi for payment to the HCP.
- It should be noted that where services were provided in 2017 but Sanofi did not receive an invoice or completed fee and expense form in 2017, or it was received in 2017 but which was not actually paid in 2017, the TOV will not appear in the 2017 Disclosure Report. Where the invoice was paid in 2018, the TOV will be recorded in Sanofi's 2018 Disclosure Report. By the same token, if the contract was signed and/or service was realized before 2017 but the payment was realized during 2017, such a case appears in 2017 report. All above concerns also long-term contracts with an individual HCP.

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## CONTRIBUTION TOWARDS THE COSTS OF MEETINGS PAID TO HCOS OR TO THIRD PARTIES MANAGING EVENTS ON THEIR BEHALF

During the course of 2017, Sanofi has supported a number of meetings organized by HCOs. Sanofi has contracted with the HCO's declaring the specific contributions. The HCO has been clearly informed of Sanofi's obligation to disclose such payments.

The following should be noted when considering the Disclosure Report 2017 with respect to these:

- Sanofi has recorded the date of TOV as the date of payment
- It should be noted that where meetings took place in 2017 but Sanofi did not receive an invoice in 2017, or an invoice was received in 2017 but it was paid later on, the TOV will not appear in the 2017 Disclosure Report. By the same token, if the Event was held before 2017 but the payment was realized during 2017, such a case appears in 2017 report.

## RESEARCH & DEVELOPMENT

R&D transfers of value are required to be reported on an aggregate basis.

### WHICH ACTUAL DATES WERE USED FOR DISCLOSURE OF TOV?

The disclosure of TOV for 2017 includes all payments done during 2017 and TOV related to events held in 2017. Event costs have been allocated to the starting date of the event, even though the actual transaction date would have been different.

### HOW WERE THE CURRENCIES AND EXCHANGE RATES MANAGED?

- Transfers of value are disclosed in Czech Crowns (CZK).
- When an international Affiliate of Sanofi paid a CZ based HCP (cross-border) expenses, the expenses were converted from the local currency into CZK using the Sanofi Exchange Rate in force at that time.
- Amounts disclosed are those actually paid by Sanofi. They could be slightly different from amounts received by the HCP/HCO as they do not take into consideration any exchange fees or other fees applied by the recipient's bank.

### HOW WAS THE VAT MANAGED?

The TOV reported is the total, including VAT and reduced by a withholding tax where applied.

### HOW WAS THE HCP INFORMED CONSENT MANAGED?

Sanofi is an ethical pharmaceutical company and is required to comply with the relevant laws, regulations and applicable industry codes of practice governing interactions with healthcare professionals ("HCPs") and healthcare organizations ("HCOs"), including but not limited to the Personal Data Protection Act. sanofi-aventis, s.r.o. as a representative of the Sanofi in the Czech Republic is a holder of the specific registration with the Office for Personal Data Protection (the CZ data protection authority) for the purposes of complying with its financial transparency obligations under the AIFP Disclosure Code.

Sanofi has asked for a written consent from all HCPs related to an individual disclosure of any kind of TOV. Consents were requested together with any kind of disclosable interaction with an HCP on per engagement basis. HCP's information are disclosed in aggregated form if the consent has not been

obtained or has been withdrawn later on. In May 2018, all HCPs were informed about the exact sums that are going to be disclosed by registration letters.

Consents were not requested from HCOs since there is not such a requirement in the Czech law for legal entities. Hence, all TOV related to HCOs are disclosed individually. Despite of this, HCOs were informed about the exact sum that is going to be disclosed by registration letters to let them check it's correctness and to obtain an acknowledgement or confirmation that the transfer of value is not HCO's trade secret.

HCPs are legally entitled to withdraw their consent at any time in writing and requesting that their personal information is not publically disclosed. In such cases, all TOV were removed from the individual disclosure and are disclosed in aggregate. It is Sanofi's policy that partial consent (i.e. the disclosure of some but not all engagements) is not permitted. If a HCP can be identified, Sanofi believes that it is most transparent if the TOV data published reflects all engagements with the individual concerned rather than only selected TOV. Therefore, when a HCP has withdrawn consent for any single engagement with Sanofi, their entire TOV data has been disclosed in aggregate.

## CONTACTS

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