



Disclosure 2016

Methodological Note

Lithuania

INTRODUCTION

The EFPIA Disclosure Code requires all EFPIA member companies to disclose transfers of value such as support to attend medical education events, speaker fees and consultancy to healthcare professionals and healthcare organizations.

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 transfers of value were collected and verified for disclosure by Sanofi in Lithuania.

The disclosure report covers the monetary payments to health care professionals as well as medical congresses' travelling, hotel and registration costs. Financial support to healthcare organizations has also been disclosed. The clinical studies of Sanofi and Genzyme are included to the disclosure report.

Collaborative working between HCPs and pharma industry has long been a positive driver for advancements in patient care and progression of innovative medicine. HCPs and organizations with whom they work provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical experience.

The pharmaceutical industry can provide a 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 hereby improve patient care overall.

HCPs and HCOs should be fairly compensated for the expertise and services.

The EFPIA Disclosure Code will protect the integrity of the industry-healthcare professional relationship, and represents a step towards fostering better transparency and building greater trust between the pharmaceutical industry, the medical community and society across Europe.

WHAT ARE THE REQUIREMENTS OF THE LITHUANIAN HCP/HCO DISCLOSURE CODE?

The EFPIA Disclosure Code in Clause 24.2 and the Lithuanian HCP/HCO Disclosure Code state that the transfers of value that are to be disclosed are:

- Donations and grants provided to healthcare organisations and associations
- Contracts between companies, organisations and associations
- Sponsorship of attendance at meetings for healthcare professionals
- Fees and expenses paid to healthcare professionals or to their employers on their behalf

Contributions towards the costs of meetings paid to healthcare organisations or to third parties managing events on their behalf, which may include sponsorship of health professionals by way of registration fees and accommodation and travel.

DEFINITIONS

The term 'health professional' (HCP) includes members of the medical, dental, pharmacy and nursing professions who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine.

The term 'healthcare organisation' (HCO) means either a healthcare, medical or scientific association 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 Lithuania or an organisation through which one or more health professionals provide services.

The term 'transfer of value' means a direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines. 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.

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 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 THE DISCLOSURE OF CROSS-BORDER TRANSFERS OF VALUE ORGANIZED?

Sanofi has disclosed TOVs that were paid to Lithuanian HCOs and HCPs by International Affiliates during the period 1 January 2016 and 31 December 2016.

Where a Lithuanian HCP was contracted prior to 2016 by an International Affiliate, but actually received their TOV in 2016, the 2016 Disclosure report includes these TOV's. Where a Lithuanian HCP was contracted by an International Affiliate to provide a service in 2016 he/she would have received the benefit of the related expenses i.e. costs of flights, accommodation, and ground transportation in 2016. These TOVs will be disclosed in the Disclosure Report 2016. However, it should be noted there are instances where an International Affiliate may not have paid the fee for service to a Lithuanian HCP for an engagement in 2016 until 2017. Therefore, it is possible that for an individual HCP there will only be related expenses listed that were paid to them in 2016 in the Disclosure Report 2016, and the fee for service paid in 2017 will be listed in the Disclosure Report 2017.

SPECIFIC TRANSFERS OF VALUE

All transfers of value made by Sanofi to HCPs or HCOs in Lithuania between January 1st and December 31st, 2016 and corresponding to one of the categories described below.

DONATIONS AND GRANTS TO HCOs

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

SPONSORSHIP OF ATTENDANCE BY HCPs AT MEETINGS

This sponsorship was paid to the individual HCP. In the case of Third Party Agency organized group events, the costs of sponsorship were paid directly by Sanofi with the TOV being disclosed against the individual HCP.

The following should be noted when considering the Disclosure Report 2016 with respect to these:

- Sanofi requested the individual HCPs consent to disclose the TOV in the 2016 data collection phase
- Sanofi has recorded the date of TOV as the date the payment was processed by Sanofi in the case of financial grants or the date of the meeting in the case of group events.

FEES AND EXPENSES PAID TO HCPs OR TO THEIR EMPLOYER ON THEIR BEHALF

Sanofi has contracted with a large number of HCP during the course of 2016 to provide one or more of the following services:

- Speaker / Chairperson
- Training
- Consultancy

The following should be noted when considering the Disclosure Report 2016 with respect to these:

- Sanofi requested the individual HCPs consent to disclose the TOV in the 2016 data collection phase
- Sanofi has recorded date of TOV as the date the payment was processed and released by Sanofi for payment to the HCP.
- If an event has been held during 2016, but the costs have been paid in 2017, the TOV will be recorded in Sanofi's 2017 Disclosure Report.

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

During the course of 2016 Sanofi has supported a number of meetings organized by HCOs. Support has included:

- Contribution to cost of events
- Exhibition stand payments
- Payments of advertisement
- Attendance fees

The following should be noted when considering the Disclosure Report 2016 with respect to these:

- Sanofi has recorded the date of TOV as the date the payment
- If an event has been held during 2016, but the costs have been paid in 2017, the TOV will be recorded in Sanofi's 2017 Disclosure Report

RESEARCH & DEVELOPMENT

R&D transfers of value are required to be reported on an aggregate basis and include:

- Direct and Indirect payments to:
 - Interventional studies
 - Non-interventional and observational studies
- Investigator sponsored trials (ISS)

WHICH ACTUAL DATES WERE USED FOR DISCLOSURE OF TOV?

The disclosure of transfer of value for 2016 includes all payments done during 2016 and transfers of value related to events held in 2016. 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 euro (EUR)
- When a Lithuanian HCP has received payments in other currency, the expenses were converted into EUR using the exchange rate in force at that time.

HOW WERE TAXES MANAGED?

- Fees for service and consultancy are disclosed as gross sums before taxes
- Event costs and travel and accommodation expenses all include VAT
- Support given directly to a registered associations does not include VAT

HOW WERE THE HCP CONSENTS MANAGED?

Sanofi has requested a written consent from all the HCPs related to disclosure of transfers of value. Consents have been requested during the year of 2016 and HCPs have been informed in 2017 the exact sums that will be disclosed. HCPs information will be disclosed in the aggregated disclosure if the consent has not been given or withdrawn. It is Sanofi's policy that partial consent (the disclosure of some but not all engagements) is not permitted.

The clause on the disclosure has been incorporated in the written contracts with HCOs.

HCP can withdraw their consent at any time with a separate notice. If the consent is withdrawn, all transfer of value data will be removed from the individual disclosure and will be disclosed in aggregate.

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