



**Methodological Note to
2016 Disclosure Report
for
Aventis Pharma Limited
Genzyme Therapeutics Limited
and
Sanofi Pasteur**

INTRODUCTION

The European Federation of Pharmaceutical Industries and Associations (“**EFPIA**”) Disclosure Code requires all EFPIA member companies to disclose certain transfers of value (“**TOV**”) such as support to attend medical education events, speaker fees and consultancy to healthcare professionals (“**HCPs**”) and healthcare organisations (“**HCOs**”).

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

HCPs and organisations with whom they work provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and management 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 Sanofi 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 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 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 UK.

The 2016 Disclosure Report for Sanofi in the UK covers the support provided by Aventis Pharma Limited, Genzyme Therapeutics Limited and Sanofi Pasteur by means of monetary payments and/or other TOV made to HCPs and HCOs.

Clinical Studies are conducted by Sanofi in the UK on behalf of Aventis Pharma Limited, Genzyme Therapeutics Limited and Sanofi Pasteur R&D payments.

WHAT ARE THE ABPI CODE REQUIREMENTS?

The Association of the British Pharmaceutical Industry (“**ABPI**”) has translated the requirements of the EFPIA Disclosure Code in Clause 24.2 of the ABPI Code of Practice 2016 which states that the TOV which are declarable are:

- a) joint working;
- b) donations, grants and benefits in kind provided to institutions, organisations and associations;
- c) contracts between companies and institutions, organisations and associations;
- d) sponsorship of attendance by health professionals and other relevant decision makers at meetings;
- e) fees and expenses paid to health professionals and other relevant decision makers, or to their employers on their behalf; and

- f) 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

In accordance with Clause 1 of the ABPI Code of Practice 2016:

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

The term 'other relevant decision makers' abbreviated to ORDM particularly includes those with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who are not health professionals.

The term 'healthcare organisation' abbreviated to 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 Europe or an organisation through which one or more health professionals or other relevant decision makers provide services.

The term 'transfer of value' abbreviated to TOV 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. 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.

HOW WAS THE DISCLOSURE OF LOCAL TRANSFERS OF VALUE ORGANISED?

Data were collected, reconciled, and reported using a commercially available information system (the "**System**") which was customised to Sanofi's organisational requirements. This System is used by Sanofi to track payments to HCPs, ORDMs and HCOs within all EFPIA member countries.

TOVs were captured directly in the System for all direct payments to HCPs, ORDMs and HCOs. TOVs for indirect payments to HCPs, ORDMs and HCOs were recorded outside of the System and then uploaded separately at a later date.

All financial TOVs were reconciled against our internal financial systems where all transparency relevant vendors are flagged for the purposes of easily identifying coding to correct categories of spend.

HOW WAS THE DISCLOSURE OF CROSS-BORDER TRANSFERS OF VALUE ORGANISED?

When considering the Sanofi 2016 Disclosure Report, please note the following with respect to cross-border TOV:

Sanofi has disclosed TOVs that were paid to UK based HCOs, HCPs and ORDMs by international affiliates of Sanofi during the period 1 January 2016 and 31 December 2016.

Where a UK based HCP, ORDM or HCO was contracted prior to 2016 by an international affiliate of Sanofi, but actually received their TOV in 2016, these TOV have been included in the 2016 Disclosure Report.

Where a UK based HCP, ORDM or HCO was contracted by an international affiliate of Sanofi 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 have been included in the 2016 Disclosure Report. However, it should be noted there are instances where an international affiliate of Sanofi may not have paid a UK HCP, ORDM or HCO the service fee for an engagement that took place in 2016, until 2017. Therefore, it is possible that expenses only (that were paid in 2016) have been included in the 2016 Disclosure Report, in which case the service fee (paid in 2017) will be listed in the 2017 Disclosure Report.

SPECIFIC TRANSFERS OF VALUE

All TOV made by Sanofi to HCOs, HCPs and ORDMs in the UK between January 1st and December 31st, 2016 (see section on “Actual Dates of transfer”) and corresponding to one of the categories described below, were recorded in the System by Sanofi.

JOINT WORKING

In the UK, Sanofi worked in partnership with the NHS to develop and implement two (2) patient centred projects in 2016.

All TOV made in 2016 relating to Joint Working in the UK have been disclosed in the 2016 Disclosure Report.

The executive summaries of these Joint Working Agreements can be accessed via the links provided in the 2016 Disclosure Report. Executive summaries about the projects are also available on Sanofi UK’s website – www.sanofi.co.uk

DONATIONS, GRANTS AND BENEFITS IN KIND TO HCOS

Sanofi considered applications from HCOs for Medical and Educational Goods and Services (“**MEGS**”) throughout the course of 2016. Sanofi made donations, grants and benefits in kind to HCOs in 2016 where it served to enhance patient care, or benefit the NHS in maintaining patient care.

When considering the Disclosure Report 2016, please note the following with respect to MEGS:

- a) For financial grants Sanofi has recorded the date of TOV as the date the payment was processed by Sanofi.
- b) Where the TOV was provided as a service Sanofi has calculated the TOV based on the market rate for the service provided (e.g. the TOV for nurse services has been calculated based on the number of hours a nurse worked in an HCO and the market hourly rate for such a nurse).
- c) For services, Sanofi has recorded the date of TOV as the date the service was provided to the HCO.

SPONSORSHIP OF ATTENDANCE BY HCPS AND ORDMS AT MEETINGS

Sanofi received a number of applications from individual HCP/ORDMs requesting sponsorship to attend educational meetings during the course of 2016. This sponsorship was paid as a financial grant to the individual HCP.

In addition, Sanofi has organized group events (via a third party agency) whereby HCPs or ORDMs were sponsored to attend educational meetings during 2016. In these cases, the cost of sponsorship (e.g. event registration fee/travel) was paid directly by Sanofi to the event organizer/travel provider) and the TOV has been disclosed against the individual HCP.

When considering the 2016 Disclosure Report, please note the following with respect to individual event grants:

- a) Sanofi requested the HCP's consent to disclose the TOV on an individual named basis in the terms of the contract between Sanofi and the HCP – consent was requested on a per event basis; and
- b) Sanofi has recorded the date of TOV as the date payment was processed by Sanofi.

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

Sanofi contracted with a large number of HCPs/ORDMs during the course of 2016 to provide one or more of the following services:

1. Speaker;
2. Chairperson;
3. Training; and
4. Consultancy Services

When considering the 2016 Disclosure Report , please note the following with respect to HCP services:

- a) Sanofi requested the HCP's consent to disclose the TOV on an individual named basis in the terms of the contract between Sanofi and the HCP – consent was requested on a per event basis;
- b) Sanofi recorded the date of TOV as the date payment was processed by Sanofi.
- c) It should be noted that where services were provided by a HCP/ORDM in 2016 but Sanofi did not receive an invoice or completed fees and expenses claim form from the HCP/ORDM in 2016, or it was received in 2016 but was not actually paid in 2016, the TOV will not appear in the 2016 Disclosure Report. Where the invoice is paid in 2017, the TOV will be recorded in the 2017 Disclosure Report.

CONTRIBUTION TOWARDS THE COSTS OF MEETINGS PAID TO HCOS OR TO THIRD PARTIES MANAGING EVENTS ON THEIR BEHALF, WHICH MAY INCLUDE SPONSORSHIP OF HCPS OR ORDMS BY WAY OF REGISTRATION FEES/TRAVEL & ACCOMODATION

During 2016, Sanofi supported a number of meetings organised by UK based HCOs. Sanofi has contracted with the relevant HCO's declaring the specific contributions and the HCO has been informed of Sanofi's obligation to disclose such payments or other TOV.

When considering the 2016 Disclosure Report, please note the following with respect to HCO meeting sponsorship:

- a) Sanofi has recorded the date of TOV as either the date payment was made by the Sanofi field team personnel or the date payment was processed by Sanofi (as applicable for field team / head office meetings); and
- b) Where meetings took place in 2016 but Sanofi did not receive an invoice in 2016, or an invoice was received in 2016 but it was not paid in 2016, the TOV will not appear in the 2016 Disclosure Report. Where the invoice is paid in 2017, the TOV will be recorded in the 2017 Disclosure Report.

RESEARCH & DEVELOPMENT

R&D TOV are required to be reported on an aggregate basis and include:

- a) Direct and indirect payments (via a Clinical Research Organisation) related to clinical studies, including:
 - i. Sanofi sponsored studies (interventional and non-interventional studies); and
 - ii. Investigator sponsored studies ("ISS") (interventional and non-interventional studies)
- b) Drug supplied free of charge to a HCO for their use in an ISS. Please note that drugs supplied to HCOs are valued for disclosure purposes at the average market selling price of the drug during 2016.

WHICH ACTUAL DATES WERE USED FOR DISCLOSURE OF TOV?

The date of payment (clearing date) in the internal financial system, is the date Sanofi sent the funds to the recipient's bank. For transactions processed for payment directly from the System the clearing date is usually no more than fourteen (14) days after being entered into the financial system. For transactions processed by purchase order, the clearing date is usually thirty (30) days after the invoice has been received by the Sanofi accounting department.

The date of TOV for events is the date of the 1st day of the event (by convention); this convention was made as dates of congress registration, flight ticket booking, hotel booking etc. could vary.

HOW WERE THE CURRENCIES AND EXCHANGE RATES MANAGED?

- a) TOV were always collected in the currency of the HCP/HCO, for the UK this is British Pounds Sterling (GBP).
- b) Where an international affiliate of Sanofi paid a UK based HCP/ORDM (cross-border) expenses, the expenses were converted from the local currency into GBP, using the Sanofi Exchange Rate in force at that time.

- c) The amounts disclosed are those actually paid by Sanofi. They may differ slightly from the 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 amount paid by Sanofi, including VAT where applicable.

HOW WERE TOV RELATED TO CONSUMER HEALTH CARE – OTC PRODUCTS DISCLOSED?

To the best of our knowledge and ability Sanofi has disclosed all TOV so the data may contain some TOVs related purely to over-the-counter (“**OTC**”) products.

HOW WAS THE HCP INFORMED CONSENT MANAGED?

Sanofi is an ethical pharmaceutical company and we are required to comply with the relevant laws, regulations and applicable industry codes of practice governing our interactions with HCPs and HCOs, including but not limited to the Data Protection Act 1998. Aventis Pharma Limited (trading as Sanofi) and Genzyme Therapeutics Limited are registered with the Information Commissioner's Office (the UK data protection authority) as data controllers and has appointed an external data processor for the purposes of complying with its financial transparency obligations under the ABPI Code of Practice.

In order to legally disclose TOV data on an individual named basis, Sanofi has obtained consent from the HCPs on a per engagement basis by including a financial disclosure notice in each letter of agreement signed by the HCP and the website used for registration for events. The financial disclosure notice informs the HCP of how Sanofi will use their personal information and explains that with their consent this information (including the payments or other TOV made by Sanofi under the agreement) will be publically disclosed in accordance with the requirements of the ABPI Code of Practice. No sensitive personal information (as defined in the Data Protection Act) was collected or publically disclosed by Sanofi in the 2016 Disclosure Report.

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

CONTACTS

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EuDisclose

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For other enquiries related to the information in either this Methodological Note or the 2016 Disclosure Report please contact: gb-transparency@sanofi.com