



**Methodological Note to
2018 Disclosure Report
for
Aventis Pharma Limited
Genzyme Therapeutics Limited**

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 and consultancy fees to healthcare professionals (“**HCPs**”) and grants to 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 recorded and verified for disclosure by Sanofi in the UK.

Sanofi is made up of different legal entities and in the UK, Sanofi conducts its business through Aventis Pharma Limited, and Genzyme Therapeutics Limited.

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 2019 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 2019:

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 technology 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.

All direct TOVs to HCPs, ORDMs and HCOs were recorded directly in the System. Indirect TOVs to HCPs, ORDMs and HCOs were recorded outside of the System and then uploaded separately after the event.

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 2018 Disclosure Report, please note the following with respect to cross-border TOV:

Sanofi has disclosed TOVs received by UK based HCOs, HCPs and ORDMs from international affiliates of Sanofi during the period 1 January 2018 and 31 December 2018.

Where a UK based HCP, ORDM or HCO was contracted prior to 2018 by an international affiliate of Sanofi, but actually received their TOV in 2018, these TOVs have been included in the 2018 Disclosure Report.

Where a UK based HCP, ORDM or HCO was contracted by an international affiliate of Sanofi to provide a service in 2018 he/she would have received the related in-kind benefit (i.e. costs of flights, accommodation, and ground transportation) in 2018. These TOVs have been included in the 2018 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 2018, until 2019. Therefore, it is possible that in-kind benefits only (that were provided in 2018) have been included in the 2018 Disclosure Report, in which case the service fee along with reimbursed expenses (paid in 2019) will be listed in the 2019 Disclosure Report.

SPECIFIC TRANSFERS OF VALUE

All TOVs made by Sanofi to HCOs, HCPs and ORDMs in the UK between January 1st and December 31st, 2018 (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 patient centred projects in 2018.

All TOVs made by Sanofi in 2018 relating to Joint Working in the UK have been disclosed in the 2018 Disclosure Report.

The executive summaries of these Joint Working Agreements can be accessed via the links provided in the 2018 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 2018. Sanofi made donations, grants and benefits in kind to HCOs in 2018 where it served to enhance patient care, or benefit the NHS in maintaining patient care.

When considering the 2018 Disclosure Report, 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.
- c) For services, Sanofi has recorded the date of TOV as the date the service was first provided to the HCO.

SPONSORSHIP OF ATTENDANCE BY HCPS AND ORDMS AT MEETINGS

Sanofi has organised group events (via a third party agency) whereby HCPs or ORDMs were sponsored to attend educational meetings during 2018. In these cases, the cost of sponsorship (e.g. event registration fee/travel) was paid directly by Sanofi to the event organiser/travel provider) and the TOV has been disclosed against the individual HCP.

When considering the 2018 Disclosure Report, please note the following with respect to HCP/ORDM sponsorship to attend educational meetings:

- a) HCPs/ORDMs consent to disclose the TOV on an individual named basis was obtained by the third party agency during registration to an event on the website – consent was requested on a per event basis; and
- b) Sanofi has recorded the date of TOV as the date the meeting.

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 2018 to provide one or more of the following services:

- 1. Speaker;
- 2. Chairperson;
- 3. Training;
- 4. Advisory Board; and
- 5. Consultancy Services

When considering the 2018 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 (for further information, please see ‘*How was HCP informed consent managed?*’ below.
- 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 2018 but Sanofi did not receive an invoice or completed fees and expenses claim form from the HCP/ORDM in 2018, or it was received in 2018 but was not actually processed for payment in 2018, the TOV will not appear in the 2018 Disclosure Report. Where the invoice is processed for payment in 2019, the TOV will be recorded in the 2019 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 2018, Sanofi supported a number of meetings organised by UK based HCOs. Sanofi has contracted with the relevant HCO’s detailing the specific contributions and the HCO has been informed of Sanofi’s obligation to disclose such payments or other TOV.

When considering the 2018 Disclosure Report, please note the following with respect to HCO meeting sponsorship:

- a) Sanofi recorded the date of TOV as the date payment was processed by Sanofi.
- b) Where meetings took place in 2018 but Sanofi did not receive an invoice in 2018, or an invoice was received in 2018 but it was not paid in 2018, the TOV will not appear in the 2018 Disclosure Report. Where the invoice is paid in 2019, the TOV will be recorded in the 2019 Disclosure Report.

RESEARCH & DEVELOPMENT

R&D TOVs 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 2018.

WHICH ACTUAL DATES WERE USED FOR DISCLOSURE OF TOV?

The 2018 Disclosure Report includes all Transfers of Value processed by Sanofi to HCPs and HCOs between the 1st January 2018 and the 31st December 2018.

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 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 healthcare professionals, including but not limited to the Data Protection Act 2018 (the “**DPA**”) and the General Data Protection Regulation (the “**GDPR**”). Aventis Pharma Limited and Genzyme Therapeutics Limited are registered with the Information Commissioner’s Office (the UK data protection authority) as data controllers and have appointed a third party data processor for the purposes of complying with its financial transparency obligations under the ABPI Code of Practice.

Following implementation of the GDPR in May 2018, Sanofi reviewed its data processing activities relating to the public disclosure of TOV data on an individual named basis [and conducted a re-consent exercise]. Sanofi relies on written consent from the HCP as the legal basis for processing personal information for this purpose. All HCPs engaged by Sanofi during 2018 were informed about how Sanofi uses their personal information (including public disclosure of payments or other TOV in accordance with the requirements of the ABPI Code of Practice) and given the opportunity to ‘opt in’ or ‘opt out’ of public disclosure on an individual named basis.

In the event that a HCP did not consent (or later withdrew their consent) to public disclosure on an individual named basis, their TOV data was aggregated to allow Sanofi to publically disclose summary statistics that did not include any personal information. It is Sanofi’s policy that partial consent (the disclosure of some but not all TOVs) 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, their entire TOV data has been disclosed in aggregate.

CONTACTS

For data protection enquiries please contact Sanofi’s Data Protection Officer at GB-DataProtection@sanofi.com.

For media enquiries please contact: 0845 372 6263

For other enquiries related to the information in either this Methodological Note or the 2018 Disclosure Report please contact: gb-transparency@sanofi.com