



**Methodological Note to
2021 Disclosure Report
for
Aventis Pharma Limited
and
Opella Healthcare UK Limited**



1) 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**”).

Cooperative 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 Opella Healthcare UK Limited. It should be noted Opella Healthcare UK Limited is a Consumer Healthcare business and primarily covers over-the-counter products.

2) 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 28.2 of the ABPI Code of Practice 2021 which states that the TOV which are declarable are:

- a) collaborative working, including joint working in accordance with Clause 20;
- b) donations and grants provided to healthcare organisations, institutions and other organisations in accordance with Clause 23;
- c) fees and expenses paid for contracted services between companies and institutions, organisations or associations of health professionals in accordance with Clause 24.6;
- d) support of attendance by health professionals and other relevant decision makers at events/meetings whether paid directly, indirectly or via another party in accordance with Clause 10.10;
- e) fees and expenses paid for contracted services to health professionals and other relevant decision makers, or to their employers on their behalf, in relation to Clause 24.6; and



- f) sponsorship, including contributions to costs related to events/meetings paid to healthcare organisations or to organisations managing events on their behalf, which may include support of health professionals not known to the company via the healthcare organisation by way of registration fees, accommodation and travel, in accordance with Clause 10.11.

3) DEFINITIONS

In accordance with Clause 1 of the ABPI Code of Practice 2021:

The term 'health professional' abbreviated to HCP includes any member of the medical, dental, pharmacy or nursing profession and any other person who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine. In relation to the annual disclosure of transfers of value (Clause 28), the term also includes any employee of a pharmaceutical company whose primary occupation is that of a practicing health professional.

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

The term 'healthcare organisation' abbreviated to HCO means either a healthcare, medical or scientific association or organisation 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.

4) HOW WAS THE DISCLOSURE OF LOCAL TRANSFERS OF VALUE ORGANISED?

Data was 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.



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

When considering the Sanofi 2021 Disclosure Report, please note the following with respect to cross-border TOV:

Sanofi has disclosed TOVs received by UK based HCPs, ORDMs and HCOs from international affiliates of Sanofi during the period 1 January 2021 and 31 December 2021.

Where a UK based HCP, ORDM or HCO was contracted prior to 2021 by an international affiliate of Sanofi, but actually received their TOV in 2021, these TOVs have been included in the 2021 Disclosure Report.

Where a UK based HCP, ORDM or HCO was contracted by an international affiliate of Sanofi to provide a service in 2021 he/she would have received the related in-kind benefit (i.e. costs of flights, accommodation, and ground transportation) in 2021. These TOVs have been included in the 2021 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 2021, until 2022. Therefore, it is possible that in-kind benefits only (that were provided in 2021) have been included in the 2021 Disclosure Report, in which case the service fee along with reimbursed expenses (paid in 2022) will be listed in the 2022 Disclosure Report.

6) SPECIFIC TRANSFERS OF VALUE

All TOVs made by Sanofi to HCPs, ORDMs and HCOs in the UK between January 1st and December 31st, 2021 (see section on “Actual Dates of transfer”) and corresponding to one of the categories described below, were recorded in the System by Sanofi.

A) COLLABORATIVE WORKING, INCLUDING JOINT WORKING

In the UK, Sanofi worked in partnership with HCOs (NHS and where applicable other organisations) to develop and implement patient centred or NHS centred projects in 2021.

All TOVs made by Sanofi in 2021 relating to Collaborative Working (including Joint Working) in the UK have been disclosed in the 2021 Disclosure Report.

The executive summaries of these Collaborative Working Agreements can be accessed via the links provided in the 2021 Disclosure Report. Executive summaries about the projects are also available on Sanofi UK’s website – www.sanofi.co.uk

B) DONATIONS AND GRANTS

Sanofi considered applications from Organisations for Medical and Educational Goods and Services (Donations and Grants since 1st July 2021) and other benefits of kind as part of package deals throughout the course of 2021. Sanofi made Donations, Grants and provisions of benefits in kind to Organisations in 2021 in areas of healthcare, education and research.

When considering the 2021 Disclosure Report, please note the following with respect to Donations and Grants:



- a) For 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 Organisation.

C) FEES AND EXPENSES PAID TO HCOS, INSTITUTIONS, ORGANISATIONS AND ASSOCIATIONS

Sanofi has contracted with HCOs, Institutions, Organisations or Associations in 2021 to provide fee for services.

When considering the 2021 Disclosure Report, please note the following with respect to contracted services:

- a) The total sum of the transfer of value to the HCO or Organisation (e.g. the service fee/expenses) will be disclosed
- 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 HCO/Organisation in 2021 but Sanofi did not receive an invoice from the HCO/Organisation in 2021, or it was received in 2021 but was not actually processed for payment in 2021, the TOV will not appear in the 2021 Disclosure Report. Where the invoice is processed for payment in 2022, the TOV will be recorded in the 2022 Disclosure Report.

D) SUPPORT OF ATTENDANCE BY HCPS AND ORDMS AT EVENTS/MEETINGS

Sanofi has organised group events (via a third party agency) whereby HCPs/ORDMs were supported to attend educational meetings during 2021. In these cases, the cost of event registration fee and travel was paid directly by Sanofi to the event organiser/travel provider and the TOV has been disclosed against the individual HCP/ORDM.

When considering the 2021 Disclosure Report, please note the following with respect to HCP/ORDM support to attend educational events/meetings:

- a) Provided a HCP/ORDM has not objected to Sanofi processing and disclosing his/her personal data in this way, the total sum of the transfer of value to the HCP/ORDM (e.g. the event registration fee/travel costs) will be disclosed on an individual named basis; and
- b) Sanofi has recorded the date of TOV as the date of the meeting.

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

Sanofi contracted with HCPs/ORDMs during the course of 2021 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 2021 Disclosure Report, please note the following with respect to HCP/ORDM services:

- d) Provided a HCP/ORDM has not objected to Sanofi processing and disclosing his/her personal data in this way, the total sum of the transfer of value to the HCP/ORDM (e.g. the service fee/expenses) will be disclosed on an individual named basis.
- e) Sanofi recorded the date of TOV as the date payment was processed by Sanofi.
- f) It should be noted that where services were provided by a HCP/ORDM in 2021 but Sanofi did not receive an invoice or completed fees and expenses claim form from the HCP/ORDM in 2021, or it was received in 2021 but was not actually processed for payment in 2021, the TOV will not appear in the 2021 Disclosure Report. Where the invoice is processed for payment in 2022, the TOV will be recorded in the 2022 Disclosure Report.

F) 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 2021, Sanofi sponsored 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 2021 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 2021 but Sanofi did not receive an invoice in 2021, or an invoice was received in 2021 but it was not paid in 2021, the TOV will not appear in the 2021 Disclosure Report. Where the invoice is Processed for payment in 2022, the TOV will be recorded in the 2022 Disclosure Report.

G) 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) Drugs 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 2021.



7) WHICH ACTUAL DATES WERE USED FOR DISCLOSURE OF TOV?

The 2021 Disclosure Report includes all Transfers of Value processed by Sanofi to HCP/ORDMs and HCOs between the 1st January 2021 and the 31st December 2021.

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.

8) HOW WERE THE CURRENCIES AND EXCHANGE RATES MANAGED?

- a) TOV were always collected in the currency of the HCP/ORDM or 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/ORDM or HCO as they do not take into consideration any exchange fees or other fees applied by the recipient's bank.

9) HOW WAS THE VAT MANAGED?

The TOV reported is the total amount paid by Sanofi, including VAT where applicable.

10) HOW WERE TOV RELATED TO CONSUMER HEALTHCARE – OTC PRODUCTS DISCLOSED?

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

11) LEGAL BASIS FOR PROCESSING & DISCLOSING TOV DATA

Effective from 1 January 2020, Sanofi switched from relying on written consent from HCPs/ORDMs to legitimate interests as the legal basis of processing and disclosing transfers of value data under the applicable data protection legislation (the EU General Data Protection Regulation, as supplemented in the UK by the UK Data Protection Act 2018).

Sanofi believes that the publication of transfer of value data, particularly on a named basis, serves important legitimate interests because it serves to:

- protect and instil public confidence in the integrity of the relationship between the pharmaceutical industry and HCPs/ORDMs;
- represent a step towards fostering greater transparency and building greater trust between the pharmaceutical industry, the medical community and society;
- safeguard public health by promoting HCP/ORDM's accountability to patients for decisions about their treatment;



- demonstrate commitment to continual education and development of HCP/ORDMs to provide better care to patients; and
- enable Sanofi to most fully comply with its disclosure obligations, for instance under the Association of the British Pharmaceutical Industry (ABPI) Code of Practice.

To balance the legitimate interests described above against the interests, rights and freedoms of the relevant individual HCP/ORDMs, Sanofi provides HCP/ORDMs with information about how and why their personal data will be processed and disclosed, with specific instructions to contact GB-Transparency@sanofi.com if they wish to exercise their right to “opt out” of disclosure on an identifiable basis.

Provided a HCP/ORDM did not object to Sanofi processing and disclosing his/her personal data in this way, the total sum of all transfers of value made by Sanofi to the HCP/ORDM was disclosed on an individual named basis. In the event that a HCP/ORDM opted out of public disclosure on an individual named basis, their TOV data was aggregated to allow Sanofi to publicly disclose summary statistics that did not include any personal information. It is Sanofi’s policy that partial disclosure (the disclosure of some but not all TOVs) is not permitted. If a HCP/ORDM 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/ORDM has opted out, the entire TOV data relating to that HCP/ORDM has been disclosed in aggregate.

12) CONTACTS

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

For media enquiries please contact: +44 (0) 118 354 3554

For other enquiries related to the information in either this Methodological Note or the 2021 Disclosure Report please contact: gb-transparency@sanofi.com

CERTIFICATE FOR NON-PROMOTIONAL ITEMS (PMCPA)

Version: 1 . 0

Document Number: MAT-XU-2303108

Document Name: Updated UK Methodological Note for HCP/HCO ABPI Disclosure Submission 2021

Country: Great Britain Northern Ireland

Product: General Corporate

Material Type: Publication Summary

Material Intent: Non-Promotional

Certification Type: Certification

Audience: General Public

Additional Audience:

Intended Use: External Use

Method of Dissemination: Pro-active

Material Owner: Val Sandhu

I have examined the final form of the material and in my belief it is in accordance with the requirements of the relevant regulations relating to advertising and this Code, and is a fair and truthful representation of the facts.

Role	Signature
Tiziano Poletti - Medical	Date: 23-Jun-2023 07:50:33 GMT+0000