

EFPIA Disclosure 2016 Methodology Note

Sanofi Pasteur MSD Commitment

The success of Sanofi Pasteur MSD (subsequently, "SPMSD" or "we") is based on the success of our vaccines and the value that they provide to our key stakeholders and customers, including patients, healthcare professionals ("HCPs") and healthcare organizations ("HCOs"). The value of any SPMSD vaccine is recognized as long as we maintain trust in the way we conduct business. SPMSD policies and procedures ensure we maintain the trust of our stakeholders in all interactions with healthcare professionals, government officials and other stakeholders.

All SPMSD interactions are therefore consistently carried out with respect for the special responsibilities we have towards patients and the healthcare systems in which we carry out our professional duties and in a manner consistent with the SPMSD Code of Ethics and all applicable laws and regulations. Specifically, SPMSD commits to the following principles:

- SPMSD does not provide or offer any benefit, service or anything of value to any HCP or HCO, for the purpose of improperly or corruptly influencing that person's or organization's decisions or recommendations with respect to any aspect of SPMSD's products or business.
- In order to help avoid even the appearance of improper influence, SPMSD actively evaluates and manages potential conflicts of interest prior to engaging any HCP in an interaction or offering anything of value, or prior to engaging any third party to interact with HCPs or HCOs on SPMSD's behalf.
- All our interactions with HCPs and HCOs have a legitimate, well-articulated business purpose consistent with SPMSD's mission of bringing vaccines to patients who need them.
- The criteria for selecting HCPs and HCOs as service providers or as recipients of medical education or any other kind of benefit from SPMSD are always made based on objectively justifiable criteria tied to the legitimate business purpose for the activity.
- HCPs and HCOs who participate in SPMSD activities or provide services to SPMSD are not engaged in greater numbers or more frequently than is reasonably required to achieve the business purpose.
- HCPs who perform services for SPMSD receive a fair market value compensation for their work, based on local market standards in the country of their practice. When, in connection with a promotional, scientific or professional meeting, SPMSD offers hospitality to HCPs, we make sure that the hospitality is in all cases modest and reasonable under the circumstances, conducive to the main purpose of such a meeting, and never exceeding the applicable limits established by applicable laws and codes.
- SPMSD conducts its interactions with HCPs and HCOs in a transparent manner. All disclosures to or approvals that may be required from an HCP's employer, or from an organization with which an HCP is associated (whether under its own rules or under applicable law or industry codes), in connection with the engagement by SPMSD of a HCP as a service provider or selection of a HCP to receive sponsorship or other benefits from SPMSD are made or obtained prior to committing to an interaction.
- In order to demonstrate that the business of SPMSD is at all times conducted according to the SPMSD Code of Ethics, policies and procedures, we accurately record all engagements, payments and other transfers of value to HCPs and HCOs, and where required by applicable laws and codes, we track and disclose such information in the manner required.

Table of contents

Definition of Interactions and Related Transfer of Value (ToV) Disclosed	2
Cross-border Interactions.....	3
Tax Treatment.....	4
Disclosure on an Individual HCP named Basis vs Disclosure on a HCO basis.....	4
Disclosure on an Individual HCP Named Basis vs Disclosure on an Aggregate Basis.....	4
Currency.....	4

Introduction

The aim of this Methodology Note is to provide a clear and simple explanation of how Sanofi Pasteur MSD discloses interactions with Healthcare Professionals (subsequently "HCPs") and Organizations (subsequently, "HCOs") for the reporting year 2015, in accordance with EFPIA Disclosure Code. In particular, we would like to provide a basic framework as to how SPMSD has interpreted and intended to apply the said Code.

In the event of any doubt over whether the details of any specific Transfer of Value (subsequently "ToV") need to be published, SPMSD has assumed in the interests of transparency that such details should be published. SPMSD only refrains from publishing the details of those ToV where this is clearly not required under the EFPIA Disclosure Code.

Definition of Interactions and Related Transfer of Value (ToV) Disclosed

The following Transfers of Value are disclosed:

- **Fees for Service and Consultancy.** SPMSD discloses all fees related to any type of service engagements. The ToV is deemed effective on the **date of payment**. Therefore all fees paid to HCPs/HCOs between January 1st and December 31st 2015 are disclosed for the year 2015, although, in some cases, services were performed in 2014.
 - **Fees related expenses.** In this category, SPMSD discloses all expenses (other than fees) related to service engagements, including travel, accommodation, meals and any other reasonable expenses that SPMSD agreed to disburse for or reimburse to the HCP/HCO. The ToV is deemed effective on the **date of payment**. Therefore all expenses paid between January 1st and December 31st 2015 are disclosed for the year 2015, although, in some cases, the expense consideration occurred in 2014. For service engagements comprising events, such as advisory boards, SPMSD made all reasonable efforts to split and allocate expenses either to the event (for event related travel and accommodation costs, see below) or to the service (for the service engagement related expenses).
- **Contribution to costs of events.**



- SPMSD discloses every **sponsorship of HCPs** (registration fees, travel and accommodation) to attend events. The ToV is deemed effective on the **date of the event**. Therefore any sponsorship of HCPs to attend an event between January 1st and December 31st 2015 is disclosed in 2016, although, in some cases, payment to third party service providers occurred earlier, in 2014, or later in 2016.
 - All costs such as flight, train, car hire, toll, parking fees, taxis, bus shuttle and hotel accommodation are disclosed under “travel and accommodation” expenses. When costs have been engaged for a group of HCPs then the expense is equally allocated to each benefiting HCP (e.g. bus shuttle, or joint taxi fares).
- SPMSD discloses every **sponsorship of HCO-owned** scientific and medical education events in exchange for which SPMSD receives promotional opportunities or services. To be noted that:
 - In case the HCO appointed a **third-party** to manage its event, and SPMSD signed the sponsorship agreement with and paid the latter only, SPMSD discloses the whole sponsorship amount as a transfer of value made to the former. If the event is owned by **several HCOs**, SPMSD divides the whole sponsorship amount in equal shares and discloses for each HCO accordingly. *Since there is no direct financial interaction between SPMSD and the HCO(s), this method of disclosure does not presume that the HCO(s) has/have actually perceived the amounts disclosed in the report from the third-party event organizer.*
 - In case SPMSD financially supported a HCO to manage/organize an event, but did not get any promotional opportunity or service in return, the transfer of value is disclosed as a donation and grant made to the relevant HCO (see below).
- **Donations and grants** to HCOs: SPMSD discloses all transfers of value made to HCO with no promotional or financially-valuable consideration for SPMSD. We also include here funding of basic research or funding of investigator-initiated studies not related to current or upcoming SPMSD products or their target medical conditions.
- **Research and Development:** SPMSD discloses all transfers of value made directly or indirectly (e.g. pass-through costs managed by our CROs - contract research organizations) to HCPs and HCOs both for services related to SPMSD-sponsored studies, and for funding of investigator initiated studies. By "study" we designate any study, regardless of phase of development, including clinical trials, epidemiological, or pharmaco-epidemiological studies or other non-interventional research aimed at assessing current care (products or techniques), as well as observational surveys, or medico-economic studies.

Cross-border Interactions

SPMSD Sweden discloses all transfers of value made to HCPs / HCOs whose professional address is in Sweden pursuant to Ethical Rules for the Pharmaceutical Industry in Sweden (LER) whether the transfer of value was made by SPMSD Sweden or by SPMSD Headquarters located in France or any other SPMSD affiliate operating in the following European countries: Andorra, Austria, Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Norway, Portugal, San Marino, Spain, Sweden, Switzerland, the Netherlands, the United Kingdom and Vatican.

Conversely, any ToV made by SPMSD Sweden to HCPs or HCOs based in another European country is published by SPMSD affiliate in that country pursuant to the national code of that country.

Tax Treatment

SPMSD discloses ToV as follows:

- **VAT is not included** in the following transfers of values:
 - Fees for service and consultancy;
 - Sponsorship agreements with HCOs;
 - Donations and grants;
 - Research and Development (safe for the below).
- **VAT is included** in the following transfers of values:
 - Fees related expenses;
 - Registration fees, travel and accommodation costs.
- The **withholding income tax** is included in the fees for service and consultancy.

Indirect payments of ToV to HCPs and HCOs

In the event ToV to HCPs or HCOs are made by third-parties on behalf of SPMSD (e.g. event agencies or contract research organizations), we disclose the details of those ToV under the name of the relevant HCP or HCO. Our contractual arrangements with third parties include obligations in terms of ToV reporting as well as data consent collection for the disclosure of details related to indirect ToV.

Disclosure on an Individual HCP named Basis vs Disclosure on a HCO basis

SPMSD ensures that disclosure on an individual HCP named basis is made each time SPMSD knows or can identify the HCP that benefited from the transfer of value. This is the case of private practices/clinics and consultancy firms whose sole owner is a HCP. On the contrary, this is generally not the case of HCPs employed by HCOs where the agreement is signed with and payments are made to the HCO.

Disclosure on an Individual HCP Named Basis vs Disclosure on an Aggregate Basis

Given the **data protection legal requirements**, SPMSD requires all HCPs to provide their consent to the disclosure of any ToV they received from SPMSD. If despite our efforts they refuse or withdraw their consent, SPMSD discloses the ToV on an aggregate basis, i.e. without specifying the name of the recipient. If only partial consent to disclosure is given (e.g. yes to travel and accommodation costs, but no to consultancy fees), the amount of all the ToV in relation the HCP concerned is disclosed on an aggregate basis.

Currency

Each ToV disclosed in our report is denominated in the local currency, SEK.