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Disclosure 2021

*Methodological
Note for Sanofi
Greece and Opella*

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June 30, 2022

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1. Introduction

This Methodological Note describes the main Sanofi and Opella (member of Sanofi group) processes and methods used to prepare this annual disclosure report on transfer of value to HCP/HCO for 2021.

The EFPIA Disclosure Code requires all European Federation of Pharmaceutical Industries and Associations (EFPIA) member companies to disclose transfers of value (TOV) such as support to attend medical education events, speaker fees and consultancy to healthcare professionals (HCPs) and healthcare organizations (HCOs), wherever they might come from (inside or outside the country).

2. What are the Greek Disclosure Requirements?

Law 4316 (FEK270A/24.12.2014) defines the **legislative obligation** of each pharmaceutical company to disclose by name at its website and at the dedicated website of the National Organization for Medicines (EOF), at the latest within six months after the end of each calendar year, every transfer of value granted to third parties - Healthcare Professionals and Health Care Organizations. The transfer of values related to Research and Development activities, as well as non-interventional studies (with or without study drug), are to be disclosed in an aggregate manner by the pharmaceutical company.

Furthermore, as a member of EFPIA since 1982, the Hellenic Association of Pharmaceutical Companies (Syndesmos Farmakeytikon Epixiriseon Ellados – SFEE) has adopted its own relevant Disclosure Code which can be found at it's webpage. Sanofi as a member of SFEE is committed to comply with the said code.

How is the disclosure of local transfers of value organized?

Data were captured from various sources such as our financial system (invoices, payments), and other data (attendee sheets, expense details) provided from internal and external sources.

All information documented in the Disclosure report reflect Company's efforts in good faith to comply with Disclosure obligation and ensure accuracy of data in the best of our knowledge.

How is the disclosure of cross-border transfers of value organized?

Sanofi and Opella disclose ToVs paid to Greek HCPs/HCOs by other affiliates of the Group during the period between 1 January 2021 and 31 December 2021. Where a Greek HCP/HCO was contracted prior to 2021 by an International affiliate but actually received the ToV in 2021, the 2021 Disclosure report includes these ToVs.

3. Which transfers of value are disclosed?

All transfers of value to a Greek HCP or HCO made by the group company Sanofi and any company of the group worldwide for the year 2021, based on the methodology described in this document. Respectively for Opella.

Donations and Grants to HCO

Sanofi and Opella considered applications from HCOs and made donations where it served to enhance patient care or academic research, enhance medical knowledge, or support healthy behavior with a healthcare related objective.

Sponsorship agreements with HCOs or with third-parties appointed by HCO to manage an event or activity.

Sanofi and Opella entered in "sponsorship agreements" with HCOs and organizers –congress organizers appointed by the hosting HCO – for different type of activities:

- Company satellite symposium during which scientific lectures are delivered
- Booth rental where individualized scientific information is provided to HCP at their request
- Advertising space (e.g. paper, electronic, banner or any other format)
- Sponsorship of Educational/Training courses (where Sanofi or Opella did not have any say in the selection of participants)

Contribution to costs of events

A Third Party or Company event may have included the provision of hospitality to HCPs (regulations allowing). For purpose of disclosure, this category includes any kind of scientific or educational events (product or non-product-related events, congresses, conferences, symposia, advisory board meetings, consulting meetings, training meetings, round table discussion, etc.) regardless of the number of participants.

Most events supported by Sanofi and Opella are managed by third-parties (congress agencies, travel agencies, and congress organizers). The list of participants and related transfers of value for each participant are provided by these third-parties (as stipulated in their Service Agreement).

The cancellation fees are excluded from disclosure

Fees for Service and consultancy

Sanofi and Opella have contracted with a number of HCPs to provide one or more of the following services:

- Speaker

- Chairperson
- Training
- Consultancy

Note: The ToVs are disclosed by HCP (recipient) regardless of beneficiary (which might be an HCO). In the case where the HCP is employed by an HCO, ToVs are disclosed under the name of the HCP, when HCP has been selected by Sanofi or Opella & is named within the respective compensation-for-service agreement.

Related expenses agreed in the fee for service or consultancy contract.

Related expenses included in the fees for service or consultancy cover reasonable expenses linked to accommodation, travel costs (flight and ground transportation), and are disclosed in this category when linked to relevant fee.

Research & Development

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

- Direct and Indirect payments for Clinical Studies, including:
 - Interventional studies
 - Non-interventional and observational studies

Investigator sponsored trials

4. How is the disclosure of financial data managed?

Which actual dates are used for disclosure of TOV?

The disclosure of Transfers of values for 2021 is handled as below:

- Direct ToVs are reported based on payment date
- Indirect ToVs related to events, and conducted through third party/ congress organizers, are reported based on event date (1st day of event)
- Donations are disclosed based on the date of payment.

How are currencies and exchange rates managed?

Local transfers of value are always made in the currency of the HCP/HCO's country.

International (cross-border) transfers of value are sometimes made in a currency different from the HCP/HCO's country currency. In those cases, the official Company monthly exchange rates are used.

How is the VAT and other withholdings managed?

Transfers of value to an HCO (the recipient) for services rendered by an HCP are reported as transfers of value to the HCP in question (the beneficiary),

Transfers of value to third party –usually a professional congress organizer– (the recipient) that represents, or acts on behalf of an HCO, are reported as transfers of value to the HCO in question (the beneficiary)

Multi-year agreements

Multi-year agreements cover a series of services or sponsored activities/events across multiple years. The associated transfers of value will be disclosed per calendar year as required by the EFPIA and local disclosure code.

5. Contacts

For enquiries related to the methodological note and the disclosure report please contact: SanofiDisclosure.Greece@sanofi.com

6. Personal data protection

Sanofi and Opella are highly committed to protecting HCP's personal data and upholding applicable data protection laws and regulations. Maintenance of HCPs personal data for disclosure purposes has been properly declared to the Greek Data Protection Authority. Disclosure obligation is a legislative requirement in Greece (L.4316/2014), therefore, only the prior information - and not the individual consent for disclosure - is required.

Sanofi's legal department ensures that specific provisions concerning the EFPIA Disclosure Code, the national disclosure code, local law requirement and personal data protection are included in Sanofi's standard contracts and invitation. The HCPs are informed about their rights, as provided in the GDPR (REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC), namely the rights to have access, to obtain a rectification, to obtain the deletion of their data in case this is allowed by the legislation and to request a limitation of the data processing in the situations set forth by applicable law.