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Methodological Note North Macedonia

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INTRODUCTION

The EFPIA (*European Federation of Pharmaceutical Industries and Associations*) Disclosure Code requires all 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).

This methodological note provides an overview of the main processes implemented at Sanofi in Croatia to collect, reconcile and disclose those transfers of value.

Collaboration between healthcare professionals and Pharmaceutical Companies has long been a positive driver for advancements in patient care and progression of innovative medicine. Healthcare professionals and organizations with whom they work provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and management experience. As the primary point of contact with patients, the medical profession can offer invaluable and expert knowledge on the management of diseases and patient outcomes.

To complement this, the pharmaceutical industry can provide a legitimate forum for the education of healthcare professionals and the exchange of knowledge among healthcare professionals and industry. This expert knowledge helps to adapt our products to better suit patients and thereby improve patient care overall.

We believe that healthcare professionals and organizations should be fairly compensated for the legitimate expertise and services they provide to us. At the same time, we acknowledge legitimate 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.

What are the EFPIA/ IF! disclosure code requirements?

The EFPIA Disclosure Code requires that European affiliates of EFPIA-Member Companies collect and disclose transfers of value made to European HCPs and HCOs wherever they might come from (inside or outside the country). The local Code of conduct of Innovative pharmaceutical companies' of Farmabrend Nova implements all requirements of the EFPIA code regarding disclosure of HCPs and HCOs transfers of values.

Annex 1 of Farmabrend Nova Code, explains definitions for **HCP** who is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a Medicinal Product and whose primary practice, principal professional address is in North Macedonia. To avoid suspicion, the HCP definition includes: (i) all employees or employees of a government body or other organization (whether in the public or private sector)

who may prescribe, procure, deliver or take medical products and (ii) any employee of the Member Company whose primary occupation is healthcare worker, but with the exception of (x) all other employees of the Member Company and (y) wholesalers or distributors of medical products.

HCO are all legal entities (i) that are associations or organizations for healthcare, care, or science (whether in legal or organizational form) such as hospitals, clinics, foundations, a university, or other educational institution or scientific society (except patient organizations, in the sense of the separate Code) whose headquarters, place of establishment or primary place of management is located in North Macedonia or (ii) through which one or more HCPs provide services.

The term "transfers of value" could relate to: fees for service and consultancy to HCP or HCO; sponsorships, grants, donations or other contributions to HCOs; hospitality provided during events or related to the conduct of the service and consultancy. Transfers of value can be: direct - those made directly by Sanofi a Farmabrend Nova Member Company for the benefit of a recipient or indirect - transfers of value made through an intermediate (i.e. Third-party; e.g. Congress Management Agencies) and where Sanofi, a Farmabrend Nova Member Company knows or can identify the HCP/HCO that will benefit from the Transfer of Value.

How is the disclosure of local transfers of value organized?

Data about locally incurred and processed transfers of value were captured from various sources. Direct payments were automatically uploaded into the commercially available electronic database customized to Sanofi organizational requirements. Indirect payments were manually entered in the database.

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

A "Cross-border transfer of value" was defined as a transfer of value made by any Sanofi entity based in a country which is differed from the country (North Macedonia) where the HCP is practicing or where the HCO is incorporated. A specific HCP/HCO validation and engagement process was implemented to allow collection of cross-border transfers of value and to ensure compliance with the local requirements (rationale of the request, the fair market value of the fees proposed and respect of the country hospitality rules). All these kind of transfers of value were collected in the same platform as local direct and indirect ToVs.

Which transfers of value are disclosed?

All transfers of value which occurred between January 1st and December 31st, 2021 and corresponding to one of the categories described below, will be disclosed. This report includes the transfers of value for Sanofi, Genzyme and Sanofi Pasteur.

Donations and grants to HCOs

“Donations and Grants to HCOs” cover all financial contributions to HCOs to support: medical or scientific education; healthcare programs to achieve better health outcomes and patient care (e.g. disease screening); other types of activity as long as it promotes healthy behavior with a healthcare related objective. Donations of medicines and vaccines for humanitarian purposes made in response to a request by a non-profit or charitable organization are **not reported** in this category, as well as grants, donations or other contributions to patient organizations and patient groups.

Sponsorship transfers of value to HCOs or TO third-parties appointed by HCO to manage an event

A Company event is defined as a gathering of HCPs organized by Sanofi. A Third-Party event is defined as a gathering of HCPs organized independently from Sanofi.

Examples of events are: congresses, conferences, symposia, conventions and educational meetings. The main objectives of these events are the dissemination of disease and product knowledge and to stimulate scientific exchange of knowledge between HCPs. These events keep the HCP’s knowledge current and state of the art, benefiting the care of their patients.

For a Third-party event (irrespective if interactions are contractual or non-contractual), ToVs will be disclosed on the name of the HCO, no matter made directly to the HCO itself or indirectly to a congress organizer appointed by the hosting HCO - for different type of activities:

- Sanofi satellite symposium during which scientific lectures are delivered
- Booth rental where individualized scientific information is provided to HCP at their request
- Advertisement space (e.g. paper, electronic, banner, or any other format; or advertisement during coffee breaks).

Contribution to costs of events

A Third Party or Sanofi event may have included the provision of hospitality to HCPs (transport, accommodation and registration fee). For the 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. The following transfers of value were excluded from disclosure: no-shows and last-minute cancellations as no characterized benefit was provided to the HCP, meeting room rental for Sanofi organized events. Mass group transportation (e.g. coach rental) were disclosed as an amount split on equal parts for all concerned participants.

Fees for service and consultancy

On a regular basis, Sanofi enters into compensation-for-service arrangements with various HCPs and HCOs to perform services or activities in medical or scientific-related domains for which Sanofi had legitimate needs and no internal capacity or knowledge. The services include involvement in scientific meetings (e.g. as speaker or chairman), boards and committees, training and medical education, and consulting. The purpose of and the rationale for those services rendered by HCPs and HCOs, as well as the expected deliverables, are clearly documented in a written agreement (contract) before the performance of the service.

The selection of HCPs and HCOs is based exclusively on objective criteria such as education, university degree, expertise and experience (e.g. scientific program level, participation in clinical studies) in a particular therapeutic area. The HCPs are compensated for the service based on their country of practice fair market value (FMV) determination, i.e. North Macedonia.

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

Related expenses included in the fees for service or consultancy contract cover reasonable expenses linked to accommodation, travel costs (flight and ground transportation) incurred by the HCP in carrying out the service. No other expenses are allowed for reimbursement. In strict compliance with Sanofi's and EFPIA's hospitality rules, expenses are reimbursed only after verification of the documentation (e.g. original receipts or other supporting documents).

Research & Development - Aggregated disclosure

Sanofi discloses in the Aggregated R&D section, all R&D-related transfers of value to HCOs related to the planning or conduct of the following:

- non-clinical studies
- clinical trials
- non-interventional studies that are prospective in nature and that require the collection of patient data specifically for the purpose of the non-interventional study

Ethics Committee fees as mandatory fees were not disclosed.

Which actual dates are used for disclosure of Tov?

Two different transfer dates were used: for direct payments, the **date of transfer of value** is used from our financial systems. For transfers of value linked to an event with different types and dates of expenses (congress registration, flight tickets, hotel bills, etc.), all these transfers of value are reported on the **1st day of the event**.

How are currencies and exchange rates managed?

Local transfers of value are always paid and collected in the currency of the HCP/HCO's country, i.e. MKD. International (cross-border) transfers of value are always paid in a currency eur, and the amount of the transfer of value is converted using the official exchange rate of the National Bank of NORTH Macedonia on the date of the transaction.

How are disclosed amounts calculated?

All the amounts disclosed as transfers of value for **direct payments** are inclusive of all taxes additions (e.g. VAT) and deductions (e.g. withholding taxes, social charges and personal tax). For **HCOs** all amounts, disclosed as transfers of value for direct payments include VAT. Those kind of costs contain no deductions (e.g. withholding taxes, social charges and personal tax). For **HCPs** all the amounts disclosed as transfers of value for direct payments are disclosed reduced for deductions (e.g. withholding taxes, social charges and personal tax). Since VAT is not applicable for these kind of costs and recipients, the amount disclosed can be considered as net. For legal entities owned by HCPs who are treated as HCO and for HCPs who are private health care institutions, the amounts disclosed correspondents to the method described for HCOs. For HCPs who are physical persons in VAT system, the amounts are disclosed as transfers of value with included VAT. These kind of costs are reduced for deductions (e.g. withholding taxes, social charges and personal tax). All **indirect payments** are disclosed including VAT.

Which Transfers of value are excluded from disclosure?

Transfers of value that were solely related to over-the-counter medicines or medical devices; Informational and educational materials and items of medical utility of minimal nominal value; Meals and drinks; Medical samples.

Recipient versus Beneficiary

The term Recipient means any natural person (HCP) or legal entity (HCO) which receives a transfer of value. In case of **direct transfer of value**, the **recipient** is the entity which is mentioned in the service agreement or purchase order and to which the payment is due after the service has been delivered (holder of the bank account on which the money is transferred). The term Beneficiary means the natural person (HCP) or legal entity (HCO) who ultimately benefits from the transfer of value. The **beneficiary** of a transfer of value, if different from the recipient, is always known to Sanofi. **Direct transfers of value** are those made directly by Sanofi for the benefit of a Recipient. **Indirect transfers of value** are those made through an intermediate and where Sanofi knows or can identify the HCP/HCO that will benefit from the Transfer of Value (Beneficiary). All direct transfers of value in the disclosure report are linked to the Recipient of the transferred value; indirect transfers of value are linked to the ultimate

Beneficiary of the transferred value ('follow the money' principle was applied). E.g.: indirect payments of the expenses for a legal entities owned by HCPs who are treated as HCO are reported as transfers of value to the HCP (the beneficiary), payment of sponsorships to a third party (the recipient) that represents, or acts on behalf of an HCO, are reported as transfers of value to the HCO in question (the beneficiary).

How is the HCP informed consent managed?

HCPs have an option to choose between individual and aggregate (sum of transfers of value per category without mentioning HCP's privacy data) disclosure. A consent form was included for the HCP to either (i) agree to the individual disclosure of all transfers of value, or to (ii) refuse the individual disclosure, in which case the amounts were reported on an aggregate basis. Sanofi did not allow HCPs to give partial consent, that is "to pick & chose" which transfers he/she wishes to disclose individually. Any refusal by a given HCP of individual disclosure in a single contract in 2021 pushed all of his/her reportable transfers of value into the aggregate reporting category for 2021. Sanofi respects the right of every HCP to agree or not with the individual disclosure as it is not a formal legal requirement in North Macedonia. Consents were not requested from HCOs since it is not the requirement in the data protection law in North Macedonia. Data for legal entities owned by HCP who are treated as HCOs and who have selected "not agree" option in the consent attached, even those the consent was not applicable for them, are disclosed aggregately.

Personal Data Protection

Sanofi is highly committed to protecting HCP's personal data and upholding applicable data protection laws and regulations and therefore discharged its aforementioned obligations only with HCP's prior consent and knowledge. The informed consent explained which types of personal data will be collected, stored and published. By signing this informed consent, the HCP consents to the processing of his/her personal data in accordance with the procedures set out in the informed consent and for the only purpose of transfers of value disclosure. The HCPs is informed that he/she may request at any time to be provided with information on their personal data stored by Sanofi, and demand that incorrect data be corrected or deleted. HCPs are also informed of their right to revoke in written their voluntary consent at any time without any detrimental effect on their relationship with Sanofi.

What is the process in case of post-disclosure request for modification?

HCPs can withdraw their consent at any time also in the post disclosure period, in writing, requesting that their personal information is not individually disclosed. In such cases, after authentication of the HCP, the Sanofi Transparency Manager ensures that all transfers of value made by Sanofi to that particular HCP are

disclosed in aggregate. Required modification should be taken into account within 28 days.

CONTACT

In case of any question concerning this Methodological Note or the disclosure report, please contact us using following contact details: Sanofi-aventis Makedonija dooel Skopje, Luj Paster 11/1/4, 1000 Skopje.