Methodological Note

EFPIA Transparency reporting

Sanofi s.r.o.

Introduction

The European Federation of Pharmaceutical Industries and Associations (EFPIA) introduced disclosure requirements in 2014 to promote transparency in the pharmaceutical industry. Sanofi fully supports this initiative and values collaboration with healthcare professionals (HCPs) and organizations (HCOs).

This methodological note explains how Sanofi interprets and implements EFPIA Disclosure Code requirements, providing context for disclosed data and outlining our relationships with HCPs and HCOs.

Sanofi complies with all applicable laws and aligns reporting with the most stringent standards where local requirements differ from EFPIA.

EFPIA Disclosure operates as a unified transparency framework that consolidates two previously separate initiatives. The system tracks and publishes transfers of value from AIFP member companies to healthcare professionals (HCPs), healthcare organizations (HCOs), and professional congress organisers (PCOs). PCOs are not classified as HCOs under the AIFP Code and the transfer of value is disclosed as continuing medical education support (CME). As of 2025, these disclosure projects merge into a single platform, enabling uniform publication of all transfers of value across HCPs, HCOs, and PCOs.

1. Definitions

1.1 Covered Recipients

Healthcare professionals (HCPs): Any person entitled to either prescribe or dispense a medicine. This definition follows the legal definition of HCP in the Czech Advertising Regulation Act. With regards to this legal definition, transfers of values to other healthcare professionals, e.g. nurses, do not fall within the scope of the disclosure obligation.

Healthcare Organizations (HCOs): Any legal person (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations within the scope of the AIFP Code of relationships between Pharmaceutical industry and Patient Organizations) whose

business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.
The healthcare organization is also the company or other legal entity established by another healthcare professional who might also be its employee.

Professional Congress Organisers ("PCOs"): EFPIA Code defines PCO as "a company/individual specialised in the organisation and management of congresses, conferences, seminars and similar events (all "Events")". While excluding from this definition commercial companies involved in the organisation of travel (travel agencies) or accommodation (hotels, banquets in hotels, etc.). This definition is further clarified by the AIFP Code to include an entity that organises professional events in the Czech Republic using contributions from member companies to cover the costs of continuing medical education events, while at the same time being entities that are not considered to be health care organisations (HCOs) under the AIFP Code rules.

Treatment of retired and deceased HCPs:
Transfers of Value (ToV) are disclosed for all health professionals who received a ToV during the reporting period, including those who have since retired or deceased. Disclosure reflects the status at the time of the interaction.
Where Sanofi is contacted by next of kin or an employer regarding a deceased health professional, we will handle this on a case-by-case basis.

1.2 Kind of ToVs

Donations and grants

Financial contributions to support:

- Medical or scientific research
- Medical or scientific education
- Healthcare Programs aimed at better health outcomes (e.g. disease screening)
- Scholarships and fellowships.

Sponsorship agreements

For events organized by third parties (e.g. Professional Congress Organizers, Medical & Scientific Societies), Sanofi may enter sponsorship agreements covering:

- Company satellite symposia with scientific lectures
- Booth rental for providing scientific information upon HCP request
- Sponsorship of speakers or faculty (selected by the event organizer, without Sanofi influence)

- Sponsorship of educational/training courses (participant selection independent of Sanofi)
- Advertisement space (paper, electronic, banner, or other formats).

Contribution to costs of events

Events include any scientific or educational gatherings (e.g., congresses, conferences, symposia, advisory boards, training meetings) organized by or on behalf of Sanofi, sometimes with hospitality where permitted.

Most events are managed by third parties (e.g., Congress Agencies, Travel Agencies) under service agreements, which included participant lists and related ToVs.

Fees for service and consultancy

Sanofi regularly engages external experts for services in medical or scientific domains for which Sanofi has legitimate needs and where internal expertise is lacking.
Services included:

- Speaking or chairing scientific meetings
- Participation in boards and committees
- Training and medical education
- Consulting

All arrangements are documented in written contracts detailing purpose, rationale, and deliverables before service performance.

Related expenses agreed in the fee for service or consultancy contract

Related expenses agreed in the fees for service or consultancy contract covered reasonable expenses linked to accommodation, flight, and ground transportation incurred by the Expert in carrying out the service.

Payments and other benefits provided by the PCO are not divided into special categories for disclosure purposes. Sanofi discloses sponsorships and contributions to event-related costs that have been negotiated in sponsorship agreements with PCOs.

2. Disclosure's Scope

2.1 Products concerned

Sanofi shall document and disclose Transfers of Value that are related to prescription medicines and are made, directly or indirectly, to or for the benefit of a Recipient.

2.2 Company concerned

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2.3 Excluded ToVs

Without limitation, Transfers of Value that (i) are solely related to over-the-counter medicines; (ii) are listed in Articles 17 and 19 of the AIFP Code, such as items of medical utility, samples; or (iii) are part of ordinary course purchases and sales of medicinal products by and between a Sanofi company and an HCP (such as a pharmacist) or an HCO do not fall within the scope of the disclosure obligation.

2.4 ToVs date

Depending on the type (direct or indirect) and nature (in cash or in-kind) of the transfers of value, two conventions are applied:

- **Direct ToVs**: the date used is the "clearing date" from our financial system, corresponding to the wire transfer date to the recipient's bank account.
- **Event-related ToVs**: for ToVs linked to an event (e.g. congress registration, flights, hotel), all transfers are reported using the same date, the first day of the event.

2.5 Direct ToVs

Transfers of value made directly by Sanofi for the benefit of a recipient.

2.6 Indirect ToVs

Transfers of value made on behalf of Sanofi for the benefit of a recipient, or transfers of value made through an intermediate (i.e. Third Party) and where Sanofi knows or can identify the covered recipient that will benefit from the transfer of value.

2.7 Non-monetary ToVs

A non-monetary Transfer of Value refers to any benefit provided to a covered recipient without a direct monetary payment. Examples include travel and accommodation for congress attendance, registration fees for educational events, and other in-kind benefits.

If the benefit is provided via a third party (e.g., event organizer), the value is attributed to the recipient and disclosed under their name.

2.8 ToVs in case of partial attendances or cancellation and refund

No-shows and last-minute cancellations are not reported, as no characterized benefit is provided to the HCP.

2.9 Cross-border activities

Cross-border transfers of value to covered recipients are disclosed in accordance with applicable transparency regulations, with reporting responsibilities assigned to the affiliate in the recipient's country of practice.

2.10 R&D

Sanofi discloses all R&D-related transfers of value in the aggregated R&D section when linked to the planning or conduct of:

- Non-clinical studies (*OECD Principles on Good Laboratory Practice*)
- Clinical trials (*EU Directive 2001/20/EC*)
- Prospective non-interventional studies involving patient data collection.

Individual Disclosure

Activities managed by R&D but not directly related to study planning or conduct are disclosed individually, including:

- Expert committees (e.g., advisory boards for drug submission, regulatory strategy, pharmacovigilance analysis)
- Medical lectures or presentations on pathology, disease, or product mechanism of action
- Reports on scouting, partnering, innovation, or comparative analysis
- Research grants and other educational donations.

2.11 Voluntary disclosure

Transfer of Values to PCO: The transfers of value to the PCO are benefits provided by Sanofi in connection with continuing medical education relating to the support of congresses and other scientific and educational events and meetings organised by third parties in the Czech Republic, provided in the form of a contribution to the costs incurred in connection with such events.

3. Specific considerations

3.1 Country unique identifier

Sanofi uses internal and external identifiers to ensure accurate matching of each transfer of value to the correct covered recipient.

3.2 Self-incorporated HCP

HCP - physical entity - who can be identified based on the registration number of the Czech Medical Chamber or Czech Chamber of Pharmacists will be registered under this number as an HCP. IČ (IN) does not turn a physical entity into a legal entity.

3.3 Multi-year agreements

Multi-year agreements cover a series of services or sponsored activities/events spanning multiple years. Transfers of value associated with these agreements are disclosed according to the relevant reporting period.

3.4 Country specificities

Disclosure consent
Transparency disclosure consent consideration is required for HCPs only.
Transfer of Values to PCO
Sanofi supports continuing medical education relating to the congresses and other scientific and educational events and meetings organised by PCOs.

3.5 Quality Checks

Sanofi applies rigorous quality controls to ensure accuracy and compliance, to the best of our knowledge, before disclosure. These include validating covered recipient details, verifying financial data, reviewing reporting categories, removing duplicates, confirming consent, and completing internal review and certification prior to publication.

4. Data protection legal basis

4.1 Transparency consent collection

Transparency consent relates solely to EFPIA disclosure requirements. It determines whether transfers of value are disclosed individually by name or in aggregate.

Informed Consent Collection

Sanofi collects informed consent from covered recipients where required by law or local codes. Sanofi Czech Republic ensures that specific provisions concerning EFPIA Code of Ethics, the AIFP Code of Ethics and personal data protection rules are included in Sanofi's standard contracts and invitational letters.

If consent status is positive, all related transfers of value are disclosed on individual basis for the respective fiscal year.

If consent status is negative, all related transfers of value for that fiscal year are reported in aggregate.

When consent withdrawal is received, the situation is individually evaluated by data controller (Sanofi) and data processor (AIFP) based on the level of withdrawal and the respective transfers of value are re-submitted from individual to aggregate form.

5. Form of disclosure

5.1 Date of publication

Publication date: within 6 months after the end of the relevant Reporting Period (30th June)

5.2 Disclosure platform

Publication platform provided by AIFP: www.transparentnispoluprace.cz

5.3 Disclosure language

Language of publication: Czech and English

6. Disclosure financial data

6.1 Currency

Local transfers of value are always paid and collected in the currency of the covered recipient.

6.2 VAT included or excluded

The payments are disclosed including VAT.

6.3 Calculation rules

Sanofi applies the following calculation principles for transfers of value:

- **Indirect payments**: for payments made via third parties or Sanofi affiliates outside Czech Republic, it is not always possible to know if payments include or exclude VAT and payment date assumptions are unknown
- **Currency conversion**: when payments occur in different currencies, conversion is based on the exchange rate at the time of payment or a standard monthly corporate rate
- **Rounding**: amounts are rounded to the nearest whole number (standard rounding)
- **Event-related Costs**: for multi-component events (e.g. travel, accommodation, registration), all costs are aggregated on the first day of the event (as per EFPIA convention).

7. Additional Information

Personal Data Protection

Sanofi is committed to protecting HCPs personal data and complying with applicable data protection laws and regulations. HCPs are informed that they may request, at any time, information on their personal data stored by Sanofi and request correction or deletion of inaccurate data.

Who should be contacted in case of any question on this report?

For further information on this report, please contact:

cz-transparency@sanofi.com

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