



Methodological Note

EFPIA Transparency
reporting

SANOFI-AVENTIS Zrt.

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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.

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1. Definitions

1.1 Covered Recipients

Healthcare professionals (HCPs): natural persons having medical qualifications, participating in the recommendation, prescription, procurement, selling, distribution or administering of medicinal products and in the provision of health services, including, in particular, physicians, pharmacists, healthcare professionals, members of healthcare service provider staff or any other specialist working in health care. In the application of this Code, the definition of healthcare professionals includes the following: (i) any official or employee of a government, agency or other organisation (whether in the public or private sector) that may prescribe, purchase, recommend or administer Medicinal Products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) wholesalers or distributors of Medicinal Products, and their employees.

Healthcare Organizations (HCOs): any legal person, entity, individual entrepreneur (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 Article 21) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more Healthcare Professionals provide services.

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.

2. Disclosure's Scope

2.1 Products concerned

Prescription medicine available only by medical prescription issued by a healthcare professional authorized to prescribe.

2.2 Company concerned

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2.3 Excluded ToVs

Excluded from disclosure without limitation: Benefits that (i) are solely related to over-the-counter medicines; (ii) Items of Medical Utility, Meals, Medical Samples; or (iii) are part of ordinary course purchases and sales of Medicinal Products.

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

Not applicable

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

In Hungary, when fees are paid to a self-incorporated entity through which a single healthcare professional provides services (egyéni vállalkozó), the disclosure must be made in the name of the 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 and HCOs.

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. In Hungary, the transparency disclosure consent collection is required for HCPs and HCOs.

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 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

Sanofi must complete the disclosure within 6 months after the end of the relevant Reporting Period.

5.2 Disclosure platform

Reports are published on local Sanofi Hungary website.

5.3 Disclosure language

Hungarian and English available on the platform.

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

VAT is included in most cases.

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 Hungary, 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 two decimal places
- **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:

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