



# EFPIA Disclosure

*Sanofi Poland  
Methodological Note  
2025*



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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.

For Poland, this methodological note also explains how Sanofi interprets and implements the INFARMA Code of Good Practice, including Chapter VI on disclosure of Transfers of Value (ToVs) made by Signatories of the Code to HCPs, HCOs and, where applicable, POs. Disclosures concerning recipients whose professional address, primary practice, registered office, place of incorporation or primary place of operation is in Poland are prepared in accordance with the INFARMA Code of Good Practice.

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## 1. Definitions

### 1.1 Covered Recipients

Healthcare Professionals (HCPs): for Poland, any natural person who is a physician, dentist, pharmacist, physician assistant (senior physician assistant), nurse, midwife, medical laboratory scientist, paramedic or pharmaceutical technician; or any other person who, in the course of professional activities, is qualified to prescribe, purchase, supply, recommend or administer a prescription-only medicinal product for human use, and whose main place of practice is in Europe. For Polish disclosure purposes, ToVs are disclosed in Poland when the HCP has a professional address in Poland. HCPs also include relevant officials or employees of a government, agency or other organisation that may purchase, supply or administer medicinal products, where such persons participate in that process, and persons employed by Sanofi under employment contracts or civil law contracts, whose main occupation is practising one of the listed professions.

Healthcare Organizations (HCOs): for Poland, any legal person or entity that is a healthcare, medical or scientific association or organisation, irrespective of legal or organisational form, such as a hospital, clinic, foundation, university, other teaching institution or scientific society, except for POs, and/or any legal person or entity through which one or more HCPs provide services, whose business address, place of incorporation or primary place of operation is in Europe. HCOs do not include business enterprises dealing in medicinal products on a wholesale or retail basis. For Polish disclosure purposes, ToVs are disclosed in Poland when the HCO has its business address, registered office, place of incorporation or primary place of operation in Poland.

#### **Recipient:**

An HCP or HCO or PO that receives a direct or indirect ToV and whose relevant professional address, primary practice, registered office, place of incorporation or primary place of operation determines the country of disclosure under the INFARMA Code and the applicable EFPIA member association code.

#### **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. Where possible and appropriate, data will be disclosed in an aggregated manner.

### 1.2 Kind of ToVs

#### **Donations and grants**



For Poland, donations and grants are funds, benefits in kind or services provided to HCOs and/or POs for the clearly defined purpose of supporting healthcare, scientific research or education, without a reciprocal obligation of the recipient and without constituting an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. Donations and grants to individuals are not permitted under the INFARMA Code.

### **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).

For Poland, sponsorship means support provided by or on behalf of Sanofi, insofar as permitted by law, as a contribution towards the costs of a specific activity, including an event, performed, organized and/or prepared by an HCO, a PO or a Third Party.

### **Contribution to costs of events**

Events include professional, promotional, scientific and/or educational meetings, congresses, conferences, symposia and other similar events, organized or sponsored by or on behalf of Sanofi, where permitted.

Most events were 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 engaged external experts for services in medical or scientific domains for which Sanofi had legitimate needs and where internal expertise was lacking.

Services included:

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

All arrangements were 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**

The Poland HCP/HCO disclosure covers transfers of value made in direct or indirect connection with prescription-only medicinal products used in human medicine. Transfers of value solely related to over-the-counter medicines are excluded.

### **2.2 Company concerned**

Sanofi-Aventis Sp. z o.o.

### **2.3 Excluded ToVs**

The following transfers of value are excluded from the Poland HCP/HCO disclosure report:

- Transfers solely related to over-the-counter medicines.
- Transfers not specified in the INFARMA disclosure categories, including informational or educational materials and items of medical utility where permitted under the INFARMA Code.
- Meals and beverages, except where included as an inseparable part of a disclosed sponsorship/event support amount according to the applicable methodology.
- Medical samples.
- Transfers that are part of the ordinary course of purchases and sales of medicinal products by and between Sanofi and an HCP, such as a pharmacist, or an HCO, including rebates, discounts and other commercial facilitations.
- Transfers not made to or for the benefit of an identifiable covered recipient and not readily ascertainable as a ToV to an HCP/HCO/PO.

## 2.4 ToVs date

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

- **Direct ToVs:** the date used was 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 were reported using the same date, the first day of the event.

These date conventions are applied consistently to assign ToVs to the relevant calendar-year Reporting Period.

## 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

Where a transfer of value is cancelled or fully refunded and no benefit is provided to the HCP/HCO/PO, it is not reported. No-shows and last-minute cancellations are not reported where no characterized benefit was provided to the recipient. In case of partial attendance, only the benefits actually received by or for the benefit of the recipient are reported. Where cancellation fees are paid directly to a recipient under a service contract, those payments are reported in the applicable category.

## **2.9 Cross-border activities**

Cross-border transfers of value are disclosed in the country where the recipient has their professional address, primary practice, registered office, place of incorporation or primary place of operation, as applicable. For recipients with a professional address or registered office in Poland, disclosure is made according to the INFARMA Code, including ToVs made by foreign affiliates of Sanofi. For recipients outside Poland, disclosure is made according to the applicable local EFPIA member association code; where no relevant affiliate exists, Sanofi applies the INFARMA Code as applicable.

## **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 execution of:

- Non-clinical studies, as defined in OECD Principles on Good Laboratory Practice.
- Clinical trials, as defined in Regulation (EU) No. 536/2014 on clinical trials on medicinal products for human use.
- Prospective non-interventional studies involving the collection of patient data by HCPs.

Transfers of value related to retrospective non-interventional studies are disclosed on an individual named basis unless the activity otherwise meets the INFARMA definition of R&D Transfers of Value or individual disclosure is not possible under applicable law.

Externally sponsored research is included in the aggregated R&D disclosure only where the activity falls within the R&D definition above. Otherwise, the transfer of value is disclosed in the appropriate individual category.

### **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 educational donations that do not fall within the R&D aggregate category, disclosed under the appropriate INFARMA category depending on recipient and purpose.

### **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**

For Poland, a legal entity through which one or more HCPs provide services may qualify as an HCO. Where a transfer of value to such an entity relates to services provided by an identifiable individual HCP, Sanofi discloses the transfer of value on an individual HCP-named basis where possible, accurate, consistent and compliant with applicable laws and consent/privacy requirements. Where the final HCP recipient cannot be identified accurately or lawful individual disclosure is not possible, the transfer is disclosed under the relevant HCO or aggregate category, as applicable.

### **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.

For Poland, the relevant reporting period is the calendar year. ToVs are assigned to the reporting period using the date methodology described in section 2.4.

### **3.4 Country specificities**

#### **Cross-border transfer of value**

Cross-border transfer of value is reported in the country of the recipient's professional address, primary practice, registered office, place of incorporation or primary place of operation, as applicable.

#### **Aggregate vs. Individual Disclosure**

Except for R&D ToVs and other cases where individual disclosure is not possible under applicable law or consent/privacy requirements, ToVs are disclosed on an individual basis for each clearly identifiable recipient and by disclosure category. If

individual disclosure is not possible, aggregate disclosure includes the number of recipients concerned, the percentage of all recipients receiving ToVs in the relevant category, and the aggregate amount.

### **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 where applicable, and completing internal review and certification prior to publication.

## **4. Data protection legal basis**

### **4.1 Transparency consent collection**

Transparency consent relates to EFPIA/INFARMA transparency 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. Consent provisions are included in contracts signed by covered recipients, ensuring they are informed about disclosure obligations and their rights at the time of engagement.

If consent is refused for a specific contract, all related transfers of value for that fiscal year are reported in aggregate.

Consent withdrawal after publication is handled by removing or replacing the individual entry and republishing the relevant aggregate amount, where required and technically feasible.

Sanofi ensures:

- Covered recipients are informed of disclosure requirements at engagement and through contractual clauses or pre-disclosure communications.
- Only essential data is disclosed, such as recipient name, address or other required identifier, ToV amount and category/nature of ToV.
- Appropriate safeguards are in place, including secure systems, privacy notices and mechanisms for exercising rights under applicable data-protection laws.

## **5. Form of disclosure**

### **5.1 Date of publication**

The reporting period is the calendar year. Information about ToVs made to recipients in the previous year is published between 20 June and 30 June of each calendar year. The published information remains in the public domain for at least three years after first disclosure unless a shorter period is required by applicable law or the legal basis for data processing ceases to apply.

### **5.2 Disclosure platform**

The Poland disclosure is published on the Sanofi website with unrestricted public access and/or on a central internet platform operated by INFARMA or another relevant body where such a platform is available. The disclosure report is prepared using the INFARMA template structure where applicable. Records supporting the disclosure are retained for at least five years after the end of the relevant Reporting Period unless a different period is required by applicable law.

### **5.3 Disclosure language**

The Poland disclosure is made in Polish. Sanofi may also publish an English version for information purposes. In case of inconsistency between the Polish and English versions, the Polish version prevails for Poland transparency disclosure purposes.

## **6. Disclosure financial data**

### **6.1 Currency**

Local transfers of value were always paid and collected in the currency of the covered recipient. The Poland disclosure is made in Polish zlotys (PLN). ToVs paid in another currency are converted into PLN using the exchange-rate methodology described below.

### **6.2 VAT included or excluded**

ToVs are reported at gross value including VAT and other taxes. However, for indirect payments made by third parties or Sanofi affiliates outside Poland (cross-border), it is not always possible to know if payments include or exclude VAT and payment date assumptions are unknown.

### **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 Poland, 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 (standard rounding)
- **Event-related Costs:** for multi-component events, such as travel, accommodation and registration, the relevant costs are assigned to the first day of the event for reporting-date purposes and disclosed under the applicable category.

## 7. Additional Information

### Personal Data Protection

Sanofi is committed to protecting HCPs' personal data and complying with applicable data protection laws and regulations. HCPs were 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?

Contact: [Kodeks.Przejrzystosci@sanofi.com](mailto:Kodeks.Przejrzystosci@sanofi.com) for any post-disclosure disputes, questions concerning this methodological note or the disclosed report.