

**Opella.**

# EFPIA Disclosure

## *Core Methodological Note*

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June 30, 2025

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## *Introduction*

The Disclosure Code requires all European Federation of Pharmaceutical Industries and Associations (EFPIA) member companies to disclose transfers of value.

Collaborative working between healthcare professionals and commercial life sciences organizations 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 patient outcomes and the management of diseases.

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 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.

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

## *What are the EFPIA Disclosure Code requirements?*

The EFPIA Disclosure Code requires that European affiliates of EFPIA-Member Companies collect and disclose transfers of value (TOV) made to European HealthCare Professionals and HealthCare Organisations wherever they might come from (inside or outside the country).

Transfers of value could be:

- in-cash (e.g. fees for service and consultancy to the final beneficiary HCP or HCO; sponsorships, grants, donations or other contributions to HCOs)
- in-kind (e.g. hospitality provided to HCPs during events or related to the conduct of the service and consultancy)
- direct: those made directly by a Member Company for the benefit of a recipient
- indirect: those made on behalf of a Member Company for the benefit of a recipient, or transfers of value made through an intermediate (i.e. Third Party) and where the Member Company knows or can identify the HCP/HCO that will benefit from the Transfer of Value
- cross-border engagement: when a transfer of value is made by a country which differs from the country of HCP practice or HCO place of incorporation

## *How was Disclosure Organized?*

The Transparency organization at Opella is implemented on a Global Level to collect and review data, collect consents where applicable and to publish Disclosure Reports on time with the help of a Global Reporting Tool.

## *Which Transfers of Value are disclosed?*

All transfers of value which occurred between January 1<sup>st</sup> and December 31<sup>st</sup>, (see section on “Actual Dates of transfer”) and corresponding to one of the categories described below, were captured and disclosed by *Opella srl*

### **Donations and grants to HCOs**

“Donations and Grants to HCOs” covered all financial contributions to HCOs to support:

- Medical or Scientific Research
- Medical or Scientific Education
- Healthcare Programs to achieve better health outcomes and patient care (e.g. disease screening).
- Scholarships and fellowships.
- Other types of activity as long as it promotes healthy behavior with a healthcare related objective.

Have not been reported in this category:

- Contributions to organizations to support an event which were disclosed in the “sponsorship agreements with HCOs or with Third Parties appointed by HCOs to manage an event” and “contribution to costs of events” (see below).
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### **Third Parties appointed by HCOs to manage an event**

A Third Party event meant a gathering of External Stakeholders (HCPs) organized independently from Opella.

Events included, but were not limited to, congresses, conferences, symposia, conventions, and educational meetings. The main objectives of these events were disease and product knowledge dissemination and scientific exchange to enhance HCP practice to the benefit of patients.

Examples of events include 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 between HCPs. These events keep the HCP’s knowledge current and state of the art, benefiting the care of their patients.

## **Sponsorship agreements with HCOs**

When an event was organized by a Third Party, a Professional Congress Organizer or a Medical & Scientific Society, Opella may have entered in a "sponsorship agreement" with the organizer for different type of activities:

- Company satellite symposium during which scientific lectures were delivered
- Booth rental where individualized scientific information could have been given at HCP's request
- Sponsorship of speakers or faculty (where Opella did not interfere in the selection of speakers, who were selected by the Event Organizing Committee)
- Sponsorship of Educational/Training courses (where Opella did not interfere in the selection of participants).
- Advertisement space (whatever the support i.e. paper, electronic, banner, or another format).

In the current EFPIA report, after careful analysis, it was decided to also publish the transfers of value of some non-HCO agencies, involved in logo visibility sponsorship expenditure, not linked to any provider

## **Contribution to costs of events**

An event was any gathering of External Stakeholders organized by, or on behalf of, Opella, which may have included the provision of hospitality (when regulations permitted). For disclosure, this category included 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.

- A National event was an event held in a country for which participating HCPs were uniquely from this country.
- An international event was an event for which participating HCPs were from different countries or for which participating HCPs were from a country different than where the event took place

In most cases, such events were managed by Third Parties (Congress Agencies, Travel Agencies, and Professional Congress Organizers) on our behalf.

The list of participants and related transfers of value for each participant were provided by these Third Parties (as stipulated in the Service Agreement).

Specific instructions were given to these Agencies.

Were excluded for transfers of value disclosure (unless differently specified according to country rules):

- No-shows and last-minute cancellations IF no characterized benefit was provided to the HCP
- Meeting room rental (by its own and when not linked to other expenses or meeting package)
- Mass group transportation (I.e. coach rental, by its own and when not linked to other expenses or package). In some cases, and when easily identifiable, these transfers of value were individually reported (the total amount was split by number of participants).
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### **Fees for service and consultancy**

On a regular basis, the Company entered into compensation-for-service arrangements with various External Experts to perform services or activities in medical or scientific-related domains for which Opella had legitimate needs and no internal capacity or knowledge. The services included involvement in Scientific meetings (e.g. as speaker or chairman), Boards and committees, Training and Medical Education, Consulting. The purpose of and the rationale for those needs, as well as the expected deliverables, were clearly documented in a written agreement (contract) before the performance of the service.

### **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.

### **Research & Development**

All R&D transfers of value to HCPs or HCOs related to the planning or conduct of :

- non-clinical studies (as defined in *OECD Principles on Good Laboratory Practice*);
- clinical trials (as defined in *EU Directive 2001/20/EC*);
- non-interventional studies that were prospective in nature and that involved the collection of patient data from specifically for the study

The data were disclosed in the aggregate section of the disclosure report.

Retrospective non-interventional studies were included in the R&D aggregated category of non-interventional studies as our Company manages these retrospective studies with the same processes and Ethical behavior as prospective studies.

*Investigator Sponsored Trials / Independent Investigator Trial (IST/IIT) were not included in the R&D aggregated disclosure as these studies do not belong to the above classification.*



## **Individual Disclosure**

*Other activities managed by R&D were ALWAYS included in the R&D aggregated disclosure as these studies belong to the above classification.*

## *How was the Disclosure of financial Data managed?*

### **Which actual dates were used for disclosure of Tov?**

Depending on the type (direct or indirect) and the nature (in cash or in kind) of transfers of value, two different conventional dates were used:

- For direct payments, the date of transfer of value used was the “clearing date” from our financial systems which corresponds to the date of wire transfer to the Recipient’s Bank account.
- For Transfers of value linked to an event with different types and dates of expenses (congress registration, flight tickets, hotel bills, etc.), by convention, all these transfers of value were reported with the same date, i.e. the 1st day of the event.
- For indirect payments, the date of transfer of value used is the “date” reported into the excel file prepared by the Agency which corresponds to the date of the wire transfer to the recipient’s bank account (payment term is usually 60-90 days after the invoice is booked by the Agency).
- Payments made in the current year for services or sponsoring that took place in previous year are included in the current year disclosure report.

### **How were the currencies and exchange rates managed?**

Local transfers of value were always paid and collected in the currency of the HCP/HCO.

### **How was the VAT managed?**

Disclosed transfers of value include VAT if applicable or Disclosed transfers of value do not include VAT if applicable.

## *Other Specific Considerations*

### **Which unique identifiers were used to accurately identify HCPs?**

Opella can utilize internal and external IDs to ensure an exact match of a transfer of value to an HCP or HCO.

### **Recipient versus Beneficiary**

Transfers of value are reported in the name of the covered recipient of the transferred value. In cases where the transfer of value was not provided directly to a reportable covered recipient, the final beneficiary of the transfer of value is selected as the disclosed covered recipient.

### **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 the reportable disclosure period.

## *How was the HCP informed consent managed?*

### **Collection of Informed Consent for service agreement**

The Company Legal Departments ensured that specific provisions about EFPIA Disclosure and National Code requirements and Personal Data Protection were included in our standard contracts. Any refusal to disclose a single contract in that specific fiscal year pushed all transfers of value into the aggregate reporting.

### **Personal Data Protection**

Opella is committed to protecting HCPs personal data and upholding applicable data protection laws and regulations. HCPs were informed that they may request at any time to be provided with information on their Personal Data stored by the Company and request that incorrect data be corrected or deleted.

They were informed of their Right of revocation, and that they voluntary granting of consent may be revoked at any time if they wish to exercise their right to “opt out” of disclosure on an identifiable basis.

### **Other Country information**

*The HCP consent (consultancy, congress) is gathered by a specific data collection form.*

## *How was the annual disclosure report managed?*

- Date of publication June 30<sup>th</sup>, 2025
- Disclosure platform [www.sanofi.it](http://www.sanofi.it)
- Disclosure language English and Italian

## *CONCLUSION*

This Methodological Note described the main Opella processes implemented for transparency purposes, and the rules and conventions made to prepare this annual Disclosure Report.

Our Company and healthcare professionals collaborated in a wide range of activities from clinical research to sharing best clinical practice and exchanging information on how our new medicines fit into the patient pathway. We believe that this Disclosure Report put these data in context, to ensure that patients and society understand and can have confidence in the relationship between our industry that makes the medicines they rely on and the professionals that prescribe them. Working together for patients is a partnership which benefits patients, clinicians, and healthcare systems.

*Who should be contacted in case of any question on these reports?*

E-mail address [informazioni.transparency@sanofi.com](mailto:informazioni.transparency@sanofi.com)