

# **Lundbeck Methodological Note**

Implementing the EFPIA Code of Practice

June 2025 (edition 10)





#### Introduction

Lundbeck is an innovative, global pharmaceutical company that works with Healthcare Professionals (HCPs), Healthcare Organisations (HCOs) and Patient Organisations (POs) when developing and delivering new treatment options to people living with psychiatric and neurological diseases.

Our interactions with HCPs, HCOs and POs are well-regulated by legal requirements, codes of practices from industry associations we hold membership in, Lundbeck's internal procedures, as well as legal and ethical standards. The interactions include research activities, clinical development of new treatments, exchanges of scientific information, marketing, and sales activities.

Lundbeck is committed to promoting transparency by disclosing payments and other transfers of value to HCPs, HCOs and POs according to our global procedures that respect current laws and self-regulation from the industry associations we have joined e.g. the EFPIA Code of Practice.

Under this Code, we, as the EFPIA member company disclose the names of HCPs, HCOs and POs that have received payments or other transfers of value from us on an annual basis retrospectively for the previous year, according to the EFPIA disclosure category described in the EFPIA Code of Practice. The data is disclosed by HCP, HCO or PO and includes the total annual amount of value transferred by type of activity. Lundbeck discloses payments and other transfers for value to HCPs and HCOs in aggregate, if the HCP or HCO has used their legal right to refuse consent to individual disclosure, in accordance with the EFPIA Disclosure Code and local regulations.

#### **About this document**

The methodological note aims to explain to any interested party how the disclosed data has been put together and what it concerns. The document consists of two parts:

Part 1: General information

Part 2: Definitions

The document applies to data disclosed on <u>lundbeck.com</u> that covers transfers of value provided in the interaction between Lundbeck entities globally and HCPs, HCOs and/or POs.

#### Part 1: General information

#### **Disclosures on Lundbeck websites**

Lundbeck is disclosing the company's payments and other transfers of value in alignment with the EFPIA Disclosure Code and any defined local standard.

The Transfers of Value are available on either Lundbeck's global website (www.lundbeck.com), Lundbeck's local affiliates websites or specific national authorities or local association's platforms to which the direct links are provided on Lundbeck.com.

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## **Methodological Note**



On our website, one can find following categories of payments and other transfers of value:

- Individualised for HCPs/HCOs who have provided Lundbeck their consent to disclose the information according to data privacy legislation,
- Aggregated for HCPs/HCOs who have not provided their consent to disclose,
- Aggregated for interactions related to Research and Development as defined in the EFPIA Disclosure Code,
- All payments to POs, which are reported on an individual level.

#### **Part 2: Definitions**

#### Accommodation

Accommodation, and all expenses related to it (excluding meals and drinks), is relevant and provided to HCPs only in relation to Consultancy services. These expenses are included in the disclosure under "Travel and Accommodation" category.

## **Advisory Board**

Advisory Board is a group of external experts, assembles by Lundbeck to obtain professional guidance, advice, insights, or other information to further legitimate scientific business needs, on specific questions to which Lundbeck does not already know the answer or seeks insight/consulting to validate. Transfer of Value related to Advisory Board is disclosed under "fee for service and consultancy" category, unless it falls under the R&D definition, and in this case will be disclosed as ToV to R&D.

## **Aggregated disclosures**

Aggregate disclosures are limited to Research and Development and transfers of value that cannot be disclosed on an individual basis for legal reasons i.e. HCPs/HCOs who do not consent to make the transfers of value publicly available. These aggregated numbers for the HCPs and HCOs can be found on our website, and they are presented in EUR currency.

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#### Consent to disclose data

In countries where it is required by data privacy regulations, Lundbeck have taken all reasonable steps to obtain consents from the HCPs/HCOs to publicly disclose payments and other transfers of value. In accordance with EFPIA's guidance, partial consents are not acceptable. The data are reported in an aggregated sum, if this consent is not provided. In accordance with EU and national data privacy regulations, any HCP or HCO registered by Lundbeck can at any time request the information Lundbeck is holding about them. They can also withdraw the consent at any time. In such situation, Lundbeck will disclose the ToV on an aggregate level, and if data was already published, LU will re-publish the disclosure report.

## **Consent collection and withdrawals**

Lundbeck respects applicable data privacy legislation. If a stakeholder withdraws the provided consent for legal reasons, Lundbeck will adjust the publication accordingly within a reasonable time. Lundbeck has taken all reasonable steps to ensure the consent rates are as high as possible.

#### **Cross-border activities**

Cross-border interactions are defined as interactions with HCPs/HCOs and Patients who have their primary address outside of the country of the organising Lundbeck entity. Cross-border activities are disclosed in the country where the HCPs/HCOs/POs have their primary address.

## **Currency of disclosure**

All aggregate disclosures are made in EUR currency. Individualized disclosures for HCPs/HCOs who have provided Lundbeck their consent to disclose are made in local currency. If an HCP, HCO or PO is contracted through a Lundbeck entity in another country than the HCP/HCO or PO, they may receive payments in a currency other than their local currency. Currency conversion is managed within Lundbeck's systems to ensure appropriate and accurate conversions globally with local, EUR and DKK as standard company rates of reference.

## Data privacy

For the purpose of ensuring pre-approval, tracking, reporting and/or public disclosure of all transfers of value, Lundbeck collects and process personal data about HCPs and Patients, complying with applicable industry standards and relevant legislation, including the General Data Protection Regulation (EU) 2016/679 of 27 April 2016 ("GDPR") and any local legislation concerning data privacy supplementing the GDPR. Information may be shared with local health authorities, self-regulatory bodies, or local and/or international industry organizations, and data processors acting solely on Lundbeck's behalf and instructions, located within or outside the EU/EEA.

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## Direct and indirect transfers of value

Direct transfers of value are made directly from Lundbeck to an HCP or HCO. This includes payments transferred to the HCP's/HCO's bank account or for instance payment for transportation that Lundbeck has booked and provided as part of the interaction. Indirect transfers of value are made through a third party to HCPs/HCOs. This includes payments made by an agency that supports Lundbeck by booking transportation for stakeholders.

## **Disclosure language**

Disclosures are made in local language or as defined by local regulations. Disclosures made on Lundbeck's corporate website are made in English.

# Disclosure timing and revisions

The annual process for disclosures follows local laws and regulations. The data is revised if errors are identified or if a stakeholder withdraws their disclosure consent for legal purposes.

## **Donations and grants**

A donation is a voluntary contribution to eligible recipients e.g. HCOs provided by Lundbeck without receiving any benefit, compensation, favour or advantage in return. Grants are financial support to HCOs or Third Parties that is dedicated to supporting healthcare education, continuing medical education or the development of educational materials for scientific conferences and professional meetings, provided such education or materials are non-promotional in nature and do not provide Lundbeck with any benefit or value. Donations and grants to individual HCPs are not permitted.

## **Donations of medicinal products**

In specific situations, Lundbeck may consider requests for donations of its medicinal products for purposes in line with applicable laws, industry association codes of practice and current guidelines for donations of medicinal products from the World Health Organisation (WHO). This includes situations where a donation of Lundbeck medicinal products may be a temporary solution to a specific, well-defined problem e.g. assistance to hospitals or clinics that do not have other reasonable access to such medicine. Lundbeck discloses the financial value in line with the wholesaler purchasing price in the country.

#### **Dual-licensed HCPs**

In cases, where an HCP has got medical licence in more than one country, for the purpose of reporting it must be decided beforehand, which of his/her licence will be taken under consideration.

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#### **Excluded transfers of value**

Lundbeck is following the requirements set out in the EFPIA Disclosure Code and applicable local requirements. As per the EFPIA Disclosure Code, payments and other transfers of value for meals and drinks, informational and educational materials and statistical support for clinical studies should not be disclosed. Also, the intangible value of investigational compounds provided for research or studies as well as medical samples are not disclosed.

## Fees for service and consultancy

Lundbeck engages qualified HCPs and HCOs for genuine consultancy or other services including:

- Speaker engagements,
- Provision of consultancy services,
- Participation in advisory board meetings,
- Supporting medical research and education,
- Clinical development of new treatments (R&D is disclosed as aggregate),
- Providing scientific and educational information.

## **Healthcare Professional (HCP)**

A Healthcare Professional (HCP) is defined as any member of the medical, dental, pharmacy or nursing professions or any other person, who in the course of his or her professional activities may recommend, prescribe, purchase, supply or administer a medicinal product.

## **Healthcare Organisation (HCO)**

A Healthcare Organisation (HCO) is defined as any legal entity that is a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university, teaching institution or any entity through which one or more healthcare professionals provide services.

## **Investigator Meetings**

Investigator Meetings are non-promotional interactions related to clinical trials, where investigators and other side staff are engaged in actions related to trials. ToV related to the Investigator Meeting is categorized under R&D ToV.

## Multi-year engagements or activities

Some engagements last more than a year and payments are made as the activity progresses upon receipt of corresponding invoices. The transfers of value are recorded in the year they are provided and disclosed accordingly. For example, if an HCP is hired to speak at a scientific meeting in December, the possible payments for travel and accommodation will be recoded on the date of the meeting, while the payment for the services is paid 60 days later i.e. in the following year.

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## Partial attendance or cancellation of events

Lundbeck works to ensure that all interactions with HCPs and HCOs are planned and managed professionally according to applicable regulations. In a rare occasion e.g. due to illness or for other reasons a planned interaction and (some/all) related transfers of value will be cancelled. In these situations, Lundbeck will disclose only the actual transfers of values received and not those that are cancelled.

#### **Partners and Third Parties**

In some countries, Lundbeck has made agreements with Partners or Third Parties to promote and market Lundbeck's products. If these are pharmaceutical companies, they are mandated to disclose possible transfers of value according to the same rules as Lundbeck.

# **Patient Organisation (PO)**

A Patient Organisation (PO) is defined as a non-profit organisation including umbrella organisations to which they belong, mainly composed of patients or caregivers that represent or support the needs of patients or caregivers. Lundbeck is keen on working with Patients with knowledge or experience of condition, who are able to provide true picture of what it is like to live with a specific condition. We are encouraging open dialogue between patients and industry, which ensures the patient perspective becoming an integral part of how medicines are researched, developed and delivered to patients. Such interactions are treated in transparent way and are disclosed, based on EFPIA Code and other relevant regulations.

## **Registration fees**

Lundbeck acts in compliance with applicable rules and regulations when sponsoring or paying an HCP's registration fee to attend educational or scientific events.

## **Reporting Period**

Disclosures are made on an annual basis, covering full calendar years. Tracking of ToVs follow the payment date, not the date of actual event.

## Research & Development (R&D)

In an EFPIA disclosure context, Lundbeck adheres to EFPIAs Disclosure Code definition of R&D where the term covers any activity related directly to pre-clinical, clinical, and non-interventional studies. The payments and other transfers of value related to R&D are disclosed in aggregate per country.

#### Retention of data

The disclosed data is available to the public for a minimum of 3 years, while it's securely stored for retention purposes for up to five years or as defined locally.

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#### **Retired HCPs**

If an HCP retires during a reporting period, Lundbeck will retain the disclosed transfers of value available on Lundbeck's websites. Some HCPs will continue to provide advice to the healthcare community after they have retired. Lundbeck will generally include retired HCPs in the applicable regulation's definition of an HCP; however, this will depend on their role in society.

## **Self-incorporated HCPs**

Lundbeck considers legal entities with self-incorporated HCPs as an HCO.

# Sponsorship of events

Financial or in-kind support from Lundbeck (the sponsor) to fund or support an activity for example medical, scientific or promotional events or other activities that are organised by medical associations, patient organisations, local community organisations or the sponsor, where the sponsor receives a benefit or value in return.

#### **Transfers of value**

Any direct or indirect payment or other item of value e.g. sponsored meeting attendance, accommodation, meals, travel or informational materials, whether in cash or in kind.

## Transport and accommodation

Transport and accommodation can be provided to HCPs/HCOs, if it is necessary for performance of the interaction. In some countries, where it is customary and permitted by law, Lundbeck sponsors the participation of HCPs to attend promotional/non-promotional meetings. When meals are provided to HCPs during meetings or other events, Lundbeck adheres to industry codes of conduct and standards.

#### VAT included or excluded

In general, the disclosed payments and transfers of value are net amounts exclusive of VAT, while some travel and accommodation provided can include VAT.

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