

Lundbeck Methodological Note

Implementing the EFPIA Code of Practice

June 2022 (edition 7)



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, the EFPIA member companies will disclose the names of HCPs, HCOs and POs that have received payments or other transfers of value from them. The data is disclosed by HCP, HCO or PO and includes the total annual amount of value transferred by type of activity e.g. a grant to an HCO, an HCP consultancy fee, payment for travel or registration fees for an HCP attending a medical education congress.

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:

- Pages 2-4 introduce the topic and how we present the data
- Pages 5-10 provide an alphabetical description of specific topics

The document applies to data disclosed on lundbeck.com that covers payments and other transfers of value provided in the interaction between Lundbeck entities globally and HCP/HCO recipients from the following countries: BULGARIA, CROATIA, HUNGARY and UKRAINE.

On lundbeck.com we also provide a country overview of the remaining websites where Lundbeck is disclosing payments and other transfers of value to HCPs, HCOs and POs according to local regulations in line with the EFPIA Disclosure Code.

The following disclosures have been made:

- First disclosure was made on 30 June 2016 for payments made in 2015;
- Second disclosure was made on 30 June 2017 for payments made in 2016;
- Third disclosure was made on 29 June 2018 for payments made in 2017;
- Fourth disclosure was made on 30 June 2019 for payments made in 2018;
- Fifth disclosure was made on 30 June 2020 for payments made in 2019;
- Sixth disclosure was made on 30 June 2021 for payments made in 2020;
- Seventh disclosure was made on 29 June 2021 for payments made in 2021.

Changes to the document since last edition

The Methodological Note was changed since edition 6 to update the disclosures on Lundbeck website, to reflect simpler process of searching for individualised HCP/HCO/PO data, due to updated configuration of new Lundbeck.com website.

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.

On our website, you will find three 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 are reported on an individual level

On the webpage section with the individualised HCP/HCO/PO data from years 2015 - 2020 (FIND INDIVIDUAL DISCLOSURE LINKS) you can search for HCP/HCO/PO, filter by year or country and expand to see the actual numbers by clicking "details".

FIND INDIVIDUAL DISCLOSURE LINKS

YEAR ▼ COUNTRY ▼

2019 ✕ BULGARIA ✕

The individual disclosures for year 2021 are uploaded in PDF files and can be downloaded as separate documents.

Specific topics

Aggregated disclosures	5
Consent to disclose data	5
Consent collection and withdrawals	5
Cross-border activities	5
Currency	5
Date of value transfer	5
Direct and indirect transfers of value	6
Disclosure language	6
Disclosure timing and revisions	6
Donations and grants	6
Donations of medicinal products	6
Excluded transfers of value	6
Fees for service and consultancy	7
Healthcare Professional (HCP)	7
Healthcare Organisation (HCO)	7
Identifiability of HCPs and HCOs	7
Multi-year engagements or activities	7
Partial attendance or cancellation of events	7
Partners and Third Parties	8
Patient Organisation (PO)	8
Registration fees	8
Research & Development (R&D)	8
Retention of data	8
Retired HCPs	8
Self-incorporated HCPs	8
Sponsorship of events	8
Transfers of value	9
Transport and accommodation	9
VAT included or excluded	9

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 making the transfers of value publicly available. These aggregated numbers for the HCPs and HCOs can be found on our website, and they are converted and presented in EUR currency.

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 EFPIAs guidance, partial consents are not acceptable. The data will be 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.

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 who have their primary practice outside of the country of the organising Lundbeck entity. Cross-border activities are disclosed in the country where the HCPs/HCOs have their primary practice address.

Currency

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.

Date of value transfer

The date of the transfer of value to the HCP/HCO determines the year of disclosure. Payments for services are made and recorded approx. 30 - 60 days after the - the invoice has been received. Travel and accommodation is recorded on the day the flight departed/arrived or the meeting took place i.e. the date an HCP became a beneficiary.

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.

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:

- Supporting medical research and education
- Clinical development of new treatments (R&D is disclosed as aggregate)
- Informing other HCPs about the benefits and risks of our products
- Obtaining feedback and advice about our products
- 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.

Identifiability of HCPs and HCOs

Lundbeck tracks and discloses all activities where HCPs or HCOs can be identified by us. For most of Lundbeck's activities this is the case. For market research activities and some educational activities where support is provided upon request as a donation or grant, the identity of HCPs or HCOs is not known to Lundbeck and no disclosure is made.

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 recorded on the date of the meeting, while the payment for the services is paid 60 days later i.e. in the following year.

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.

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.

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 for up to five years or as defined locally. Lundbeck will store the data securely for this period after which it will be appropriately deleted.

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 a 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.