

Date of publication/revision: July 2020

Lundbeck UK Ltd Methodological Note

Supporting the implementation of the ABPI Code of Practice Disclosure of Transfers of Value to Healthcare Professionals, Other relevant Decision Makers and Healthcare Organisations

Preamble

As an innovative and responsible pharmaceutical company, specialising in supporting the lives of patients living with psychiatric and neurological disorders, Lundbeck works with healthcare professionals and other relevant decision makers, such as researchers (HCPs, ORDMs) and healthcare organisations (HCOs), such as hospitals, clinical practices and universities, to develop and commercialize new leading treatment options.

We are committed to keep our collaborative working professional, free of undue influence and always transparent. Therefore, we contribute to, and follow, applicable European and country industry codes that promote increased transparency.

Lundbeck works with HCPs and HCOs throughout the pharmaceutical value chain, from early discovery, research activities and clinical studies of medicines under development, through to sales and marketing activities once a medicine has a Marketing Authorisation and is available for patients.

About this document

This Methodological Note will provide you with relevant details about how we support an open and transparent relationship between ourselves, HCPs, ORDMs and HCOs. For further information on our commitments please see information at the following link:

<https://www.lundbeck.com/uk/the-community/healthcare-professional-disclosures>

The disclosure of transfers of value (ToVs) in the UK is in full accordance with the ABPI Code of Practice.

Statement for the disclosure of 2019 data during the COVID-19 pandemic in 2020

As part of the pharmaceutical industry's annual disclose of transfers of value to HCPs, ORDMs and HCOs via the Disclosure UK platform and in order to ensure accuracy of the published data, the ABPI writes to all of the HCPs, ORDMs and HCOs named in companies disclosure data ahead of its publication on Disclosure UK at the end of June (over 20,000 in June 2019).

Given the unprecedented pressure on the NHS and healthcare professionals in responding to the COVID-19 pandemic, in April 2020 the ABPI and PMCPA agreed that it would not be appropriate for industry to write to HCPs, ORDMs or HCOs to request that disclosure data be reviewed. Doing so would add additional work for NHS professionals at this time. To avoid this, and in-line with guidance provided by the ABPI, Lundbeck's 2019 transfer of value data was initially published on Disclosure UK in aggregate form.

Commitment to Transparency

The pharmaceutical industry is committed to preserving the integrity of Disclosure UK and transparency in our interactions with HCPs, ORDMs and HCOs. The ABPI continues to explore how the full disaggregated 2019 data can be submitted to Disclosure UK in line with data from previous years.

Consent to Disclose

HCPs and ORDMs are asked to give their consent so that Lundbeck can disclose the information about our ToVs. The HCPs are protected by European and UK data protection regulations and if consent is not given Lundbeck will report their ToVs in an aggregated sum.

Lundbeck makes all reasonable efforts at global and national level to obtain the highest level of consent to disclose ToVs from HCPs/ORDMs to achieve the objectives of transparency under the ABPI Code of Practice.

For 2019 activities Lundbeck had interactions with a total of 91 HCPs/ORDMs, of which 74 provided consent for individual disclosure, representing an overall non-disclosure rate of 18.7%.

Research and Development disclosures

Lundbeck adheres to the definition of Research and Development ToVs as defined by the ABPI Code of Practice. All ToVs related to the planning and conduct of clinical studies in the UK are excluded from the individual disclosures and are provided as a total aggregate value for the year.

Calculation rules

Lundbeck adheres to the general principle of “following the money”. This means that the actual date when a ToV is made is used for disclosures.

Examples:

- Payments for services are usually tracked up to 60 days after the services have taken place
- Travel and accommodation are tracked on the day the flight departed/arrived or the meeting took place - meaning the day the recipient became a beneficiary
- Travel/accommodation or meeting registration fees supported by Lundbeck are disclosed regardless of whether the HCP/ORDM attended the meeting.

Consent collection and withdrawals

Consent to disclose ToVs for individual HCPs/ORDMs is managed annually.

Lundbeck adheres to all applicable data protection regulations and if an HCP/ORDM withdraws their consent, Lundbeck will adjust its disclosures accordingly within a reasonable time. Withdrawal of consent is considered to apply retrospectively to ToVs made prior to withdrawal of consent within the calendar year, and prospectively to future ToVs. Lundbeck always works to ensure that consent rates are as high as possible.

Country unique identifier

Lundbeck uses OneKey numbers to identify individual HCPs, ORDMs and HCOs, if available. Otherwise, HCPs/ORDMs and HCOs are identifiable by their names and addresses.

Cross-border activities

Globally, Lundbeck has implemented processes and procedures to ensure that all activities are managed professionally and in compliance with any global and local regulations. Cross-border activities where other Lundbeck entities have engaged a UK HCP/ORDM or HCO are included in the UK disclosures.

Currency

Disclosures of ToVs for HCPs, ORDMs and HCOs based in the UK are made in Sterling. If a stakeholder is contracted through another Lundbeck entity, they might receive payments in another currency. Currency conversion is managed within Lundbeck’s systems to ensure appropriate and accurate conversions globally, with Euros and Danish Kroner as standard company rates of reference.

Data Protection and Privacy

Lundbeck Ltd is firmly committed to protecting the privacy of any personal information collected. Details of how we will use and protect that information are available in our privacy policy which is on our website at: www.lundbeck.com/uk

Direct and indirect Transfers of Value

Direct ToVs are those made directly from Lundbeck to a HCP, ORDM or HCO.

Examples are, a payment transferred to an HCP's, ORDM's or HCO's bank account, or transportation that Lundbeck has booked and provided as part of collaborations.

Indirect ToVs are those made through a third party to a HCP, ORDM or HCO.

Examples include an agency working on Lundbeck's behalf booking transportation for HCPs, or an HCP/ORDM working through a limited company.

Both direct and indirect ToVs are disclosed according to the ABPI Code of Practice. For HCPs or ORDMs working for a limited company, the ToV is disclosed against the individual. Should an HCP/ORDM working through a limited company withdraw consent to disclose, then the ToVs are declared as aggregate.

Identifiability of HCPs, ORDMs and HCOs

Lundbeck track and disclose all activities where the HCP/ORDM or HCO can be identified by Lundbeck. For most of Lundbeck's activities this is the case.

For Market Research projects the identity of HCPs, ORDMs or HCOs may not be known to Lundbeck and no tracking or disclosures are made.

Management of requests from HCPs, ORDMs and other stakeholders

Any HCP, ORDM or HCO that has worked with Lundbeck or participated in a Lundbeck organised or sponsored event, can at any time reach out to Lundbeck to request the information that is held on them, and receive this information in accordance with European and UK data protection regulations.

Multi-year engagements or activities

Some engagements last more than a year, and payments are made as the activity progresses. The ToVs are recorded in the year they are provided and disclosed accordingly.

Partial attendance or cancellation of events

Lundbeck works with HCPs, ORDMs and HCOs to always make sure that any interaction is planned professionally and managed according to global and UK regulations. On rare occasions, a planned ToV will not be provided. On these occasions, Lundbeck will disclose only the actual tangible ToV and

not those that are cancelled. Lundbeck will disclose ToVs in situations where an HCP cancels planned activities without notice, and TOV has already occurred either directly or indirectly, for example non-attendance at a meeting where registration/travel has already been paid.

Patient Organisations

In accordance with the ABPI code of Practice, disclosure of any payments to Patient Organisations are published separately on the Lundbeck UK website, at the following link.

<https://www.lundbeck.com/uk/the-community/patient-organisation-disclosures> .

Partial consent

In accordance with the ABPI Code of Practice, if consent to disclose is partially withdrawn, all ToVs to that individual will be disclosed on an aggregate basis.

Partners and Third Parties

Lundbeck has commercial agreements with other pharmaceutical companies. All ToVs made in association with these commercial agreements are disclosed by Lundbeck if the HCP, ORDM or HCO has a contractual relationship with Lundbeck and receives the ToV directly from Lundbeck.

Retired HCPs

In cases where disclosure are made against any retired HCPs, the institution field in the disclosure is denoted as N/A, but full address details are provided.

Retention of Data

Published data is retained for 5 years. Lundbeck will store the data securely for this period of time, after which it will be appropriately deleted or anonymized.

Value Added Tax (VAT)

ToVs include VAT if applicable.

Further Information

For further information, please contact Lundbeck UK at united_kingdom@lundbeck.com