

Leadiant Biosciences Limited: Methodological note for HCP/ORDM/HCO disclosure 2025

Data year: 2025

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This note describes the methodology used by Leadiant Biosciences Limited (“Leadiant”) to identify, collate and report transfers of value disclosures, in compliance with the Association of British Pharmaceutical Industry (ABPI) code.

The ABPI code requires disclosures of all transfers of value to healthcare organisations (HCOs), healthcare professionals (HPs) and other relevant decision makers (ORDMs) in the year before the year of disclosure.

This note will report on transfers of value made in the period January 1st and December 31st, 2025.

Information about disclosable payments made by Leadiant to members of the public or to Patient Organisations is disclosed on Leadiant’s company website, as required and if paid.

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1 Definitions

1.1 Recipients

Healthcare Organisation (HCO)

Refers to either a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more health professionals or other relevant decision makers provide services. If a healthcare organisation consists of only one health professional or other relevant decision maker, then it would be subject to the requirements in the Code regarding individual health professionals.

Healthcare Professional (HCP):

Includes any member of the medical, dental, pharmacy or nursing profession and any other person who during their professional activities may administer, prescribe, purchase, recommend or supply a medicine. The term also includes any employee of a pharmaceutical company whose primary occupation is that of a practising health professional.

Other relevant decision makers (ORDM):

Includes someone with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who is not a health professional.

1.2 Kind of ToVs

Means a direct or indirect transfer of value, whether in cash, in-kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines. A direct transfer of value is one made directly by a company for the benefit of a recipient. An indirect transfer of value is one made on behalf of a company for the benefit of a recipient or through an intermediate and where the company knows or can identify the recipient that will benefit from the transfer of value.

2 Disclosure's Scope

2.1 Products concerned

Chenodeoxycholic acid Leadiant 250mg x 100 hard capsules

2.2 Company concerned

This disclosure report and methodological note pertain to the Transfers of Value (ToV) made by **Leadiant Biosciences Limited** (hereinafter "**Leadiant**").

For the purposes of this disclosure, the "Company Concerned" includes: Leadiant Biosciences Limited and Leadiant GmbH.

2.3 Excluded ToVs

Leadiant Biosciences Limited excludes the following categories from this disclosure report, as they fall outside the scope of the ABPI Code or are specifically exempted under the transparency requirements:

- Commercial Transactions: Ordinary course of business transactions involving the purchase and sale of medicinal products (e.g., standard trade discounts or commercial price rebates to wholesalers or hospitals).
- Incidental Hospitality: Modest subsistence provided during a business meeting (e.g., a working lunch) that does not exceed the local UK hospitality threshold of £75 per person (excluding VAT).
- Informational/Educational Materials: Inexpensive items directly relevant to the practice of medicine or pharmacy (e.g., anatomical models, medical textbooks, or patient-facing leaflets) provided they do not exceed a value of £30 per item.
- Package Deal Services: Services that are integral and essential to the administration of a medicine (e.g., a bundled diagnostic test or a homecare nursing service specified in the SmPC) are generally excluded where they are considered part of the "Product Purchase."
- Employee Fundraising: Charitable donations made to an HCO that were raised via independent employee fundraising activities (e.g., a bake sale or marathon sponsorship) where the company did not provide corporate funds.
- Samples: Medicinal samples provided to HCPs in accordance with Clause 21 of the ABPI Code.

2.4 ToVs date

Leadiant Biosciences Limited applies a consistent methodology for determining the "Reporting Date" for all Transfers of Value (ToVs) to ensure they are captured in the correct calendar year (1st January to 31st December).

2.5 Direct ToVs

Monetary Transfers of Value (Direct Payments): we follow the Payment Date logic.

The ToV is disclosed in the year the payment transaction was completed (i.e., when the funds left our bank account), regardless of when the contract was signed or when the service was performed.

2.6 Indirect ToVs

Where a transfer of value is made to a health professional indirectly via a healthcare organisation, where possible Leadiant aims to disclose the transfers of value made to the health professional that the payment benefits, as per the ABPI code.

2.7 Non-monetary ToVs

For ToVs where no direct payment is made to the recipient (e.g., flight bookings, hotel accommodation, or registration fees paid to a third-party agency), we use the Event Date.

The value is disclosed in the year the activity took place.

2.8 ToVs in case of partial attendances or cancellation and refund

Leadiant Biosciences Limited applies the following methodology to ensure that disclosed amounts accurately reflect the value received by the recipient or the costs irrevocably incurred by the company:

- Partial Attendance: Where a recipient attends only a portion of an event (e.g., one day of a three-day congress), Leadiant Biosciences Limited discloses the full cost of the registration and travel if these were non-refundable and pre-paid. However, for "Fee for Service" (e.g., speaking fees), we only disclose the payment corresponding to the sessions delivered or the time worked.
- Cancellation by the Recipient: if an HCP cancels their attendance, any non-refundable costs (e.g., flight tickets or hotel deposits already paid) are included in the disclosure.
- If a cancellation fee was paid to the HCP as per a contract, this fee is disclosed under "Fee for Service."
- Cancellation by the Company: If Leadiant Biosciences Limited cancels an event, any cancellation payments made to contracted HCPs (to compensate for their cleared diary) are disclosed as a Transfer of Value.
- Refunds: If a Transfer of Value is refunded by the recipient to the company, or if a third-party vendor (e.g., a travel agency) issues a refund for a previously disclosed ToV, the amount is deducted from the recipient's total in the reporting period in which the refund was received. This may result in a "negative" value if the refund relates to a ToV from a previous year.

2.9 Cross-border activities

Leadiant Biosciences Limited operates as a global organisation, and interactions with UK-based Healthcare Professionals (HCPs), Other Relevant Decision Makers (ORDMs), and Healthcare Organisations (HCOs) may be initiated and funded by overseas affiliates.

In accordance with the ABPI and EFPIA Codes, Transfers of Value (ToV) are disclosed in the country where the recipient has their primary physical practice or place of incorporation. Therefore, any ToV made by a non-UK affiliate of Leadiant Biosciences Limited to a UK-based recipient is captured and included in this UK Disclosure Report.

To ensure completeness, we utilise a centralized global transparency system that flags any recipient with a UK country code.

On an annual basis, our corporate financial team export all UK-related transactions.

These are then:

- reviewed by the UK Compliance team for categorisation under the ABPI Code.
- converted into GBP (£) using the exchange rate logic defined in Section 3.3.
- consolidated with local UK payments to ensure a single, comprehensive figure per recipient.

Conversely, if the UK affiliate of Leadiant Biosciences Limited provides a ToV to an HCP based outside of the UK (e.g., an Italian doctor speaking at a London-based event), that value is excluded from this report and is instead provided to the relevant local affiliate for disclosure in that HCP's home country.

2.10 R&D

All Transfers of Value (ToV) related to the planning or conduct of non-clinical studies, clinical trials, and non-interventional studies are disclosed in the Aggregate R&D section of the report, as permitted by the ABPI Code.

Leadiant Biosciences Limited includes ToVs related to the following activities in this category:

- Clinical Trials: Phases I through IV, including investigator-initiated trials (IITs) where the company provides financial support for a specific research protocol.
- Non-Clinical Studies: Laboratory-based research as defined in the OECD Principles on Good Laboratory Practice.
- Non-Interventional Studies (NIS): Prospective studies of authorised medicines where the medicinal product is prescribed in the usual manner (e.g., observational registries or post-authorisation safety studies).

The aggregate total includes investigator fees, the cost of trial-related equipment provided to HCOs, and reimbursement for travel and accommodation for investigators attending trial-specific meetings (e.g., Investigator Meetings).

ToVs that do not have a documented research objective - such as general advisory boards on therapeutic areas or medical education grants - are not included in this aggregate total and are instead disclosed on an individual basis under the relevant categories.

2.11 Voluntary disclosure

Not Applicable. Leadiant Biosciences Limited has not made any voluntary disclosures beyond the mandatory requirements of the ABPI Code for this reporting period.

3 Specific considerations

3.1 Country unique identifier

To ensure the accuracy of data and to prevent the duplication of records for individuals or organisations, Leadiant Biosciences Limited utilises unique identifiers for all recipients.

In the United Kingdom, there is no single cross-industry transparency identifier; therefore, we apply the following logic:

- For Healthcare Professionals (**HCPs**): We primarily use the professional registration number provided by their respective statutory regulatory body. This includes GMC (General Medical Council) numbers for doctors, NMC (Nursing and Midwifery Council) numbers for nurses, and GPhC (General Pharmaceutical Council) numbers for pharmacists.
- For Other Relevant Decision Makers (**ORDMs**): As ORDMs may not hold a clinical registration number, we use a proprietary internal ID linked to their full name and primary NHS business address to ensure unique record-keeping.
- For Healthcare Organisations (**HCOs**): We use a combination of the NHS Trust/Board code, the CQC (Care Quality Commission) ID, or the Companies House registration number for private entities.

These identifiers are used during the data collection and "cleansing" phase to consolidate all Transfers of Value (ToVs) made to a single individual or entity throughout the year, regardless of the department or location where the service was provided.

3.2 Self-incorporated HCP

In accordance with the ABPI Code of Practice, Leadiant Biosciences Limited identifies and categorises Transfers of Value (ToV) based on the ultimate individual beneficiary rather than the legal entity receiving the payment. To ensure accurate classification, we perform the following "reasonable effort" checks during the engagement and "Know Your Customer" process.

Transfers of Value to self-incorporated HCPs are processed under the legal basis of Legitimate Interests, consistent with our treatment of all individual HCPs.

Should a self-incorporated HCP exercise their Right to Object to individual disclosure and the objection is upheld, the ToV will be moved to the Aggregate section of the report to protect the individual's privacy while maintaining total financial transparency.

3.3 Multi-year agreements

Where a contract for any Transfer of Value runs for more than one year and thus disclosure cycles, Leadiant Biosciences Limited will disclose Transfers of Value relating to that contract in the year the Transfer of Value was made (which may be different to the year in which the contract was agreed or signed).

3.4 Country specificities

In addition to the standardised methodologies described throughout this document, Leadiant Biosciences Limited applies the following UK-specific rules in accordance with the ABPI Code of Practice:

- Other Relevant Decision Makers (ORDMs): Unlike many other jurisdictions, the UK disclosure includes ORDMs. We identify these as NHS staff who are not clinically registered but have the power to influence the purchase or supply of medicines. Their ToVs are disclosed under the "Individual" section of the report.

- Sole Traders / Single-HCP Corporations: Where an interaction is with an HCP who operates as a limited company but is the sole practitioner (Self-incorporated HCP), we disclose the value against the individual's name, rather than as a payment to an HCO, to ensure the highest level of UK transparency.
- Hospitality Thresholds: While the cost of modest hospitality is excluded from this financial report (per Section 2.3), all hospitality provided in the UK is strictly capped at £75 per person (excluding VAT) to align with ABPI standards.
- Legitimate Interests: We confirm that for all UK-based recipients, the legal basis for individual disclosure is Legitimate Interests under UK GDPR.

3.5 Quality Checks

To identify all transfers of value, all payments for Grants, Sponsorship, Donations and Consultancy fees made in 2025 by Leadiant Biosciences Limited were screened, and those fitting the requirements of transfers of value were included.

These were cross-checked against the compliance approval system in the company for the period between 1st of January 2025 and 31st December 2025

4 Data protection legal basis

4.1 Consent collection

In accordance with the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018, Leadiant Biosciences Limited has determined that the processing of personal data for the purpose of transparency disclosure is based on Legitimate Interests (Article 6(1)(f)).

4.2 Legitimate interests

Leadiant Biosciences Limited discloses the data based on legitimate interests.

We have conducted a formal Legitimate Interests Assessment which concluded that the public interest in transparency - aimed at maintaining the integrity of the relationship between the pharmaceutical industry and healthcare professionals - outweighs the individual's expectation of privacy in a professional capacity.

This approach ensures a more complete and accurate disclosure report for the UK public.

This legal basis applies to the disclosure of the name, primary business address, and specific Transfers of Value (ToV) for all Healthcare Professionals (HCPs) and Other Relevant Decision Makers (ORDMs) engaged by [Company Name] in the UK.

While we do not require "Consent" to publish this data, we respect the individual's Right to Object under Article 21 of the UK GDPR. If an HCP/ORDM provides a valid reason related to their specific situation (e.g., a verifiable security or safety risk), their data will be moved from the "Individual" section to the "Aggregate" section of the report.

5 Form of disclosure

5.1 Date of publication

27-March-2026

5.2 Disclosure platform

All transfers of value are disclosed on the Disclosure UK portal, irrespective of where the recipient of the transfer of value resides.

Transfers of Value Disclosure is made even if the payments, etc. are made by Leadiant's overseas affiliates.

5.3 Disclosure language

English.

6 Disclosure financial data

6.1 Currency

GBP – British Pound Sterling

6.2 VAT included or excluded

Leadiant Biosciences Limited discloses the exact amount paid to the HP, HCO or ORDM. This may include VAT, if VAT was included on the invoice. For transfers of value where a product is provided free of cost for research, the amount disclosed is calculated using the unit list price in the country concerned.

6.3 Calculation rules

All transfers of value specified in our disclosure are denominated in pounds sterling. If the original payment was made in Euro (EUR), we have converted the amount into GBP using the foreign exchange rate on closing of the day of payment. The amounts disclosed in GBP may therefore vary from the exact amount paid in the local currency.

7 Additional Information

[Not applicable]