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LEO Pharma UK Methodological note for HCP/ORDM/HCO disclosure 2025

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LEO Pharma is committed to ensuring transparency of Transfers of Value (ToV) provided to HCPs and HCOs, as required by the EFPIA Code of Practice, as well as the ABPI Code of Practice for the Pharmaceutical Industry. In the same manner, LEO Pharma is committed to ensuring transparency of its engagements with Patient Organisations in accordance with the EFPIA Code of Practice and the ABPI Code.

To ensure that LEO Pharma's engagements with HCPs, ORDMs and HCOs are in compliance, appropriate, properly documented, transparent and do not compromise the independence of the HCP, ORDM or HCO, LEO Pharma has developed a healthcare compliance framework. This framework also covers the processes that LEO Pharma has put in place to ensure tracking and disclosure of ToVs provided to HCPs, ORDMs or HCOs.

Contents

1 Definitions

1.1 Recipients

Healthcare Professionals (HCPS)

General definition

The definition of an HCP varies from country to country and may include any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his/her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product.

The local definition in the country where the HCP has his/her Principal Practice Address prevails.

Local Definition

The term ‘health professional’ includes members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine. In relation to the annual disclosure of transfers of value (Clause 28 of the ABPI Code of Practice), the term

also includes any employee of a pharmaceutical company whose primary occupation is that of a practicing health professional.

Other Relevant Decision Makers (ORDMs)

This particularly 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.

Retired HCPs/ORDMs are those who worked as above but have ceased working in these roles.

Healthcare Organisation (HCO)

'Healthcare organisation' means 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.

Patient Organisation

Not-for-profit organisation (including the umbrella organisation to which they belong), mainly composed of patients, that rep-resents and/or supports the needs and interests of patients. A Patient who is representing a Patient Organisation is considered a representative of the concerned Patient Organisation and hence falls within the definition of a Patient Organisation.

1.2 Kind of ToVs

LEO Pharma is responsible for disclosing both Direct and Indirect ToVs made on behalf of LEO Pharma to HCPs and HCOs in connection with activities relating to LEO Pharma prescription-only medicines in countries with disclosure requirements. This includes, but is not limited to, payments for the performance of services, registration fees, sponsorships, financial support, travel, hospitality, and other expenses related to an activity involving an HCP and/or HCO.

Donations and grants

Donations and grants are funds, benefits-in-kind or services freely given for the purpose of supporting healthcare, scientific research, or education, with no consequent obligation on the

recipient organisation, institution, and the like to provide goods or services to the benefit of the pharmaceutical company in return. Donations and grants to individuals are prohibited. In general, donations are physical items, services or benefits in-kind which may be offered or requested. Grants are the provision of funds.

Collaborative Working

This refers to pharmaceutical companies working with other organisations to deliver initiatives which either enhance patient care or are for the benefit of patients or alternatively benefit the National Health Service (NHS) and, as a minimum, maintain patient care. Collaborative working is generally between one or more pharmaceutical companies, healthcare organisations and other organisations. Joint working is a limited form of collaborative working as set out in Clause 20.4 of the ABPI Code of Practice.

Contracted service fees and expenses

HCPs and ORDMs may be used as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing meetings, involvement

in medical/scientific studies, clinical trials or training services, writing articles and/or publications, participation at advisory board meetings, and participation in market research where such participation may involve remuneration and/or hospitality. There may be expenses in relation to provision of such services such as travel expenses to and from a venue. Both of these would be reported as transfers of value.

Contribution to costs of events

Events include all professional, promotional, scientific and educational meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) organised or sponsored by or on behalf of a company.

Contribution to costs of such events in relation to the disclosure of transfers of value means providing or covering the costs of travel, accommodation and/or registration fees to support the attendance of an individual to an event organised or created by a company and/or independent organisation. When providing sponsorship of events/meetings to organisations, associations, etc. such contributions may include costs for subsistence (food and drink).

Research and Development (R&D)

This means, for the purposes of disclosure, transfers of value to health professionals or healthcare organisations related to the planning or conduct of:

i. non-clinical studies (as defined in the OECD Principles of Good Laboratory Practice)

ii. clinical trials (as defined in Regulation 536/2014)

iii. non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual or groups of health professionals specifically for the study.

Sponsorships

This means a contribution, financial or otherwise, in whole or in part provided by or on behalf of a company, towards an activity (including an event/meeting or material) performed, organised, created, etc. by an HCO or other independent organisation.

A Professional Conference Organizer (PCO) is a legal entity specialized in the organisation and management of congresses, conferences, seminars and similar events.

LEO Pharma may provide support/sponsorship to HCOs in connection with educational/scientific activities. The financial assistance can be used for preparation and/or conduct of the educational/scientific event, sponsoring of speakers, registration fees, travel, accommodation, meals and drinks. If the PCO is organizing the educational/scientific activity on behalf of an HCO, the disclosure of the full sponsorship amount will be made on the HCO. If an HCP, as e.g., a scientific committee member, speaker, chair or attendee, will receive a ToV by means of the support/sponsorship provided by LEO Pharma, and LEO Pharma has been involved in the selection of the HCP that will benefit from the ToV, such ToV will be considered an Indirect ToV. Indirect ToVs to HCPs/HCOs provided through PCOs/HCOs will be disclosed against the name of the benefiting HCP/HCO with no mentioning of the name of the PCO.

In case LEO Pharma is providing support/sponsorship to a PCO, but LEO Pharma is not able to identify the benefiting HCO, and/or has not been involved in the selection of the HCPs, this ToV will not be disclosed as the PCO is not an HCP/HCO and hence not a Recipient under the ABPI Code of Practice. However, to ensure transparency of the sponsorships provided by LEO Pharma to educational/scientific events, LEO Pharma requires the PCO to publish the sponsorship on the website of the specific conference and related materials and communications.

2 Disclosure's Scope

2.1 Products concerned

Prescription Only Medicines [POMs] only.

2.2 Company concerned

LEO Pharma UK (LEO Laboratories Limited) and LEO Pharma A/S and its subsidiaries and any other entity controlled by or in common control with LEO Pharma A/S.

2.3 Excluded ToVs

LEO Pharma has excluded certain ToVs made to HCPs/HCOs from the disclosure in accordance with the excluded disclosures stated in the EFPIA Code of Practice, Section 23.03, and the ABPI Code of Practice, such as meals and drinks.

In addition, in some cases LEO Pharma provides certain non-financial support to HCPs/HCOs that cannot be assigned a monetary value, and LEO Pharma has evaluated that these transfers of non-financial support are not to be considered a transfer of value. Such ToV will also be excluded from the ToVs for disclosure. These are Support for Publications.

Literature publications that relate to LEO Pharma originated data and analyses may be developed collaboratively between an HCP (external author) and LEO Pharma (internal author). In accordance with Good Publication Practice for Communicating Company-Sponsored Medical Research (GPP2022) and as stated in LEO Pharma guideline on Scientific, Medical and/or Technical Publications, LEO Pharma does not pay honoraria to authors. Instead, authors contribute to these publications freely by using their time and intellectual resources.

To facilitate the development of publications so that LEO Pharma can meet the obligation to publish results from clinical trials and other research activities in a timely manner, often professional medical writers are used. They can be employees of LEO Pharma or from an external medical writing agency.

Support where LEO Pharma provides a medical writer to an HCP in order to assist the HCP in a publication related to LEO Pharma originated data and analysis is not considered a ToV to the HCP as 1) no fee-for-service activity occurs whereby the HCP obtains financial benefit, and 2) the value of the support provided by LEO Pharma to authors is to society at large, the scientific community, patients, and LEO Pharma, as it speeds up the process in which we share data, analysis, and interpretation to increase the overall knowledge about our products/patient solutions in development and in clinical use, i.e. there is no value transferred to the HCP.

However, LEO Pharma will disclose editorial service fees provided to a medical writer to support an HCP in a publication that is made independent of LEO Pharma in the name of the HCP/HCO in the fee-for-service category in accordance with the terms defined in the agreement with the HCP/HCO.

For all publications supported by LEO Pharma, LEO Pharma requires transparency and the (co)authorship and contributorship, including any financial contributions from LEO Pharma will be mentioned..

2.4 ToVs date

The scope of this ToV disclosure is January 2025 to December 2025.

LEO Pharma will make disclosures annually in respect of each calendar year, and within the first six months after the end of the calendar year in which the ToVs/payments were made.

The information will remain in the public domain for a minimum of three years from the time of first disclosure.

LEO Pharma will maintain the relevant records of the ToV data for 5 years after the end of the relevant reporting period, unless a different period is required under applicable national data privacy or other laws or regulations.

For payments/reimbursements to HCPs/HCOs, the date of the ToV is the date the payment/reimbursement was made, i.e., the date the payment was cleared in the finance system (clearing date), and not the date the services were provided by the HCP/HCO. For reimbursements in relation with investigator meetings, the date that the ToV was submitted for payment by the LEO Pharma Organizer is used as date of ToV.

The payment clearing date will be used as date of ToV for air travel and accommodation booked by LEO Pharma.

Furthermore, for ToVs related to events such as congresses, payment clearing date will be used as date of ToV, whenever possible, for the following types of expenses: congress registration, travel and accommodation.

2.5 Direct ToVs

Transfers of Value made directly by an entity within LEO Pharma to an HCP/HCO/ORDM.

These include fees for service, grants, financial sponsorships.

2.6 Indirect ToVs

This include Transfers of Value made to an HCP/HCO/ORDM on behalf of an entity within LEO Pharma through an intermediary (Third Party).

An Indirect ToV generally includes situations where the identity of the HCP/HCO is specified in the contract with the Third Party or the identity of the HCP/HCO benefitting from the ToV is otherwise known by LEO Pharma and it is clear to LEO Pharma that the HCP is the ultimate beneficiary of the ToV.

It also includes Transfers of Value made to an HCP/HCO/ORDM on behalf of an entity within LEO Pharma e.g. travel, paying for venue hire as part of event sponsorship.

LEO Pharma must know about and/or be able to identify the HCP/HCO/ORDM that will benefit from the ToV in order for the ToV to be considered an Indirect ToV.

LEO Pharma may engage with an HCP indirectly through an HCO. In such cases, LEO Pharma may request performance of services from a specific HCP employed by the HCO, i.e., the HCP is nominated by LEO Pharma, or the HCO may itself decide that a specific HCP employed by the HCO performs the services.

Only if the contract with the HCO specifies that payments made to the HCO will be used, in full or in part, to pay HCP(s) nominated by LEO Pharma, will such indirect ToV be disclosed against the individual HCP.

2.7 Non-monetary ToVs

There are no non-monetary ToVs included for 2025.

2.8 ToVs in case of partial attendances or cancellation and refund

In case of planned activities that were cancelled and where no ToV was provided to the HCP/HCO, such planned ToVs will not be disclosed. This includes cases where flight and hotel were booked for HCPs for their participation in planned events or meetings and where the HCP did not make use of the booked flight and/or hotel and hence did not receive any benefits. If the HCP/HCO has already performed certain preparatory work that LEO Pharma required to be performed in connection with the activity, the HCP/HCO will be paid in accordance with the terms defined in the agreement with the HCP/HCO, e.g., hourly fee based on hours spent on the preparation, and the ToV will be disclosed. Similarly, in cases where an HCP, whose attendance at a congress is sponsored by LEO Pharma, does not attend the congress, the related ToV(s) is not disclosed on the condition that the non-attendance can be justified and is documented.

2.9 Cross-border activities

Any Engagement between LEO Pharma and an HCP/HCO/ORDM where the HCP/HCO/ /ORDM is located in a country different from:

• the country of the activity, and/or

• the country of the LEO Pharma contracting entity

2.10 R&D

Research and Development activities are by EFPIA divided into 3 main activity types: non-clinical study, clinical trial and non-interventional study.

Non-clinical study: This category includes any ToVs made to an HCP/HCO in connection with an experiment or a set of experi-ments in which a test item is examined under laboratory conditions, in greenhouses or in the field to obtain data on its properties and/or its safety. This typically relates to research activities where LEO Pharma requires services performed by an HCP/HCO in order to complete the activity.

Clinical trial: This category includes any ToVs made to an HCP/HCO in connection with a clinical trial, such as fees paid to an HCP/HCO in his capacity as international/national coordinating investigator and investigator fees and honorarium in connection with memberships in a data review/monitoring committee, advisory board or medical consulting in relation to a specific clinical trial.

Non-interventional study: Includes any ToVs made to an HCP/HCO in connection with a non-interventional prospective study, such as fees paid to an HCP/HCO in his capacity as international/national coordinating investigator or principal Investigator.

The disclosure on an R&D aggregate level includes fee-for-service, honorarium and all disclosable expenses related to R&D activities as per this section.

2.11 Voluntary disclosure

None.

3 Specific considerations

3.1 Country unique identifier

A LEO Pharma unique identifier assigned to each individual HCP/HCO/ORDM to ensure 1) unique identification of any HCP, HCO, ORDM to whom LEO Pharma is providing a transfer a value (the Recipient A of the ToV), and 2) that the ToV made to a specific HCP/HCO/ORDM will not be reported more than once due to e.g. errors in the contact details of the HCP/HCO/ORDM. The LEO Pharma unique identifier contains the details of the HCP/HCO/ORDM needed for disclosure, including the Principal Practice Address**.**

Unique identifiers provided by commercial providers are also used**.**

3.2 Self-incorporated HCP

A self-incorporated HCP is a one-person company owned by an HCP. In line with the ABPI Code of Practice requirements, where such a legal entity (HCO) is owned by one HCP, the reportable ToV is disclosed against the HCP, being the recipient of the payment.

Benefits in kind such as air travel and accommodation booked by LEO Pharma will be disclosed in the name of the HCP since for such ToVs the HCP him/herself is the actual beneficiary.

3.3 Multi-year agreements

For multi-year agreements the date of the ToV is the date the payment/reimbursement for a service was made, i.e., the date the payment was cleared in the finance system (clearing date), and not the date the services were provided by the HCP/HCO. For reimbursements in relation with investigator meetings, the date that the ToV was submitted for payment by the LEO Pharma Organizer is used as date of ToV.

3.4 Country specificities

Details of support for Collaborative Working can be found https://www.leo-pharma.co.uk/our-responsibility/supporting-healthcare-professionals-and-the-nhs

3.5 Quality Checks

The global process for engaging with HCPs, HCOs and ORDMs in LEO Pharma as well as the process for disclosure of ToVs (the Global Healthcare Compliance Process) is aligned with the requirements set out by EFPIA. The implementation of the process in each country must follow the national requirements in alignment with the ABPI Code of Practice, in which case additional local procedures may be in place.

As part of the Global Healthcare Compliance Process, a LEO Pharma unique identifier is assigned to each HCP/HCO/Patient Organisation/Member of the Public and the ToV provided is processed in accordance with the LEO Pharma HCP/HCO/Patient Organisation/ Member of the Public finance procedures to ensure that all ToVs made in the LEO Pharma finance systems can be captured.

The ToVs are extracted from the finance systems or manually captured by the LEO Pharma Organizer. For ToVs made to HCP/HCOs/Patient Organisations/Members of the Public through a Third Party, the Third Party is responsible for tracking and providing the LEO Pharma Organizer with the ToVs provided on LEO Pharma's behalf, including the HCP/HCO/Patient Organisation/Member of the Public details needed for the disclosure.

The Healthcare Compliance Representative in Paying Country is responsible for tracking all ToVs provided to HCPs/HCOs/Patient Organisations/Members of the Public by his/her LEO Pharma entity, whereas the Healthcare Compliance Representative in the country of HCP/HCO/Patient Organisation/Member of the Public is responsible for preparing the local disclosure report(s) containing all ToVs provided by LEO Pharma to HCPs/HCOs/Patient Organisations/Members of the Public with Principal Practice Address in the country of the Healthcare Compliance Representative.

4 Data protection legal basis

4.1 Consent collection

Legitimate Interests is the lawful basis used to publish individual HCP/ORDM information.

4.2 Legitimate interests

Objective

The overriding objective of the ABPI Code is to ensure high quality patient care which in turn ensures patient safety. This relies on many things including appropriate relationships between health professionals and others and the pharmaceutical industry. There must be no undue influence. Transparency in interactions is one of many requirements in the ABPI Code which aims to ensure appropriate relationships and thus confidence in treatment decisions. Increased transparency in this area on Disclosure UK supports patients and the public to have confidence that the relationship between pharmaceutical companies and individuals is open and ethical. Therefore LEO Pharma has chosen to use the method of Legitimate Interest as the method to publish individual HCP/ORDM information with regard to transfers of value provided by the company.

Method

LEO Pharma has carried out a Legitimate Interests Assessment to assess whether it is a viable lawful basis to use for the disclosure of transfers of value.

The Legitimate Interests Assessment consists of a 3-part test:

1. The purpose test: are you able to identify the legitimate interest?

The following was assessed;

The legitimate interest LEO Pharma has as a pharmaceutical company to meet its obligations under the ABPI Code and to boost the confidence of the public and other interested stakeholders in the company's relationships with individuals, in accordance with the Objective;

The legitimate interest of the ABPI in receiving the data for publication, to help meet the overall Objective;

The legitimate interests of patients and wider society in better understanding how the pharmaceutical industry and individuals interact and the relationship between specific individuals and identified pharmaceutical companies, as underscored by the Objective.

2. The necessity test: is the processing necessary for the purpose for which the data is processed, or is there a less intrusive method of reaching that aim?

Publishing transfers of value figures in aggregate does not meet the overall Objective because it does not allow patients or the public to understand which individuals are receiving payments and 'benefits in kind' from specific companies. Transparency on an individual healthcare professional level is necessary to achieve the Objective since it is the ethical behaviour of individuals that requires scrutiny, which aggregated information does not achieve.

3. The balancing test: are the legitimate interests identified by the data controller overridden by the interests and fundamental rights and freedoms of the data subject?

i) The personal data does not contain "special category data" or data relating to criminal convictions, both of which are defined terms under the GDPR and carry a higher level of

sensitivity under the GDPR. The data also does not relate to a vulnerable category of data subjects such as children, the elderly or the incarcerated.

ii) The data does contain financial information, which individuals do generally consider to be more “private” than some other categories of data. However, it is made clear to individuals when they agree to work with pharmaceutical companies that there are obligations in relation to transparency and avoiding conflicts of interest regarding the work they carry out, and therefore they are put on notice from the beginning of the relationship that their financial information will not have the same level of confidentiality that they might expect for other types of financial data.

iii) The data also relates to individuals in their professional rather than personal capacity and therefore generally carries less expectation of confidentiality and sensitivity.

The processing of the data would be reasonably expected due to the following factors:

The industry practice of disclosing transfer of value data, at least in aggregate, has been in place since 2012 and from 2016 on Disclosure UK, so this is not an entirely new concept for individuals;

Individuals will already be aware through their professional bodies and place of work that transparency in the pharmaceutical sector is an industry priority and that the ABPI and other stakeholder bodies such as NHS England have been encouraging greater transparency for many years now;

The overall purpose and method of disclosure is generally understood by individuals and can be given even more clarity in the updated privacy notice of the disclosing company;

The personal data is collected directly from the individual who has a direct relationship with LEO Pharma (contractual or otherwise), so the individual is fully aware of what personal data is being collected.

In principle, the processing of the data is not of a type inherently likely to result in a high risk to an individual’s rights and freedoms and therefore it is not necessary to carry out a Data Protection Impact Assessment.

It is difficult to see why any harm, and certainly not unjustified harm, would be caused in the vast majority of transfer of value disclosures, given the business nature of the relationship.

LEO Pharma has concluded that Legitimate Interest is a viable lawful basis to use for the disclosure of transfers of value.

In the case of objections being raised by individuals, this will be managed by LEO Pharma Legal and Compliance in the UK. The Balance Test will be repeated as part of the Legitimate Interests Assessment (LIA), taking into account the specific circumstances of the individual who has objected.

This further balancing test will be recorded in writing and the outcome (whether or not the request is being granted) will be communicated with the individual without undue delay and at the latest within one month from the date of the request.

5 Form of disclosure

5.1 Date of publication

30/03/26

5.2 Disclosure platform

Disclosure UK – www.disclosureuk.org.uk

5.3 Disclosure language

English

6 Disclosure financial data

6.1 Currency

The currency used in the disclosure report is the local currency in the country where the disclosure is made (the country of the HCP/HCO). i.e. GBP.

ToVs that are not paid in the currency used in the country of the HCP/HCO will be converted into the currency used in the country of the HCP/HCO via a conversion to EURO. The conversion calculations are based on a fixed yearly currency rate.

6.2 VAT included or excluded

The published ToV amounts are exclusive of VAT, except in some cases where the VAT amount cannot be accurately excluded, in which case the disclosed amounts are inclusive of VAT. For payments subject to withholding tax, the published ToV amounts are inclusive of the withholding tax amount.

6.3 Calculation rules

ToVs that are not paid in the currency used in the country of the HCP/HCO will be converted into the currency used in the country of the HCP/HCO via a conversion to EURO. The conversion calculations are based on a fixed yearly currency rate.

7 Additional Information

Market Research Studies

LEO Pharma may engage with a Third Party in order to conduct market research studies or similar activities where LEO Pharma does not know the identity of the HCP/HCO engaged on behalf of LEO Pharma by the Third Party, and the HCP/HCO does not know the identity of LEO Pharma (double-blinded market research). In such case, no disclosure will be made. Likewise, for market research where the identify of LEO Pharma is known to the HCP, but the identity of the HCP is unknown to LEO Pharma, no disclosure of any ToV made in connection with the market research will be made.

For market research studies where the identity of the HCP/HCO is known by LEO Pharma, LEO Pharma requires the Third Party to track the ToV made to the HCP/HCO in order for LEO Pharma to disclose such ToVs.

LEO Pharma employees' attendance at conferences

In cases where LEO Pharma employees sign up for a conference for regular conference attendance through the standard regis-tration webpage, LEO Pharma does not consider such ToV disclosable, and it would be part of ordinary course purchases.]