LEO Pharma Global Methodological Note

Disclosure under EFPIA

Version 9.0, 2026 disclosure

Contents

1 Introduction **4**
2 Definitions **4**
2.1 Recipients 4
2.2 Kind of Transfer of Values (ToV) 5
3 Disclosure´s scope **8**
3.1 Products concerned 8
3.2 Company concerned 8
3.3 Excluded ToVs 8
3.4 ToVs date 9
3.5 Direct ToVs 9
3.6 Indirect ToVs 9
3.7 Non-monetary ToVs 10
3.8 ToVs in case of partial attendances or cancellation and refund 10
3.9 Cross-border activities 10
3.10 R&D 10
3.11 Voluntary disclosure (anything discloses beyond the national code) 10
4 Specific considerations **10**
4.1 Country unique identifier 10
4.2 Self-incorporated HCPs 11
4.3 Multi-year agreements 11
4.4 Country specifities 11
4.5 Quality checks 11
5 Data protection legal basis **11**
5.1 Consent collection 11
5.2 Legitimate interest 12
6 Form of disclosure **13**
6.1 Date of publication 14
6.2 Disclosure platform 14
6.3 Disclosure language 14
7 Disclosure financial data **14**
7.1 Currency 14
7.2 VAT 14
7.3 Calculation rules 14
8 Additional information **15**
8.1 Aggregated Disclosure 15
8.2 Clinical trials and studies 15
8.3 Disclosure of ToVs provided to Patient Organizations 15
8.4 Distributors 16
8.5 EFPIA 16
8.6 HCO services and R&D collaborations 16
8.7 Healthcare Compliance Representatives 16
8.8 Individual Disclosure 16
8.9 Market Research Studies 17
8.10 Master agreements 17
8.11 National Engagement 17
8.12 Principal Practice Address 17
8.13 Recipient 17
8.14 Retention 17
8.15 Third Party 18
8.16 Virtual events 18

1 Introduction

This methodology note describes in detail how LEO Pharma, ensures transparency with regards to the ToVs that LEO Pharma provides to HCPs, HCOs and Patient Organizations. It outlines the general principles underlying the disclosure of ToVs by LEO Pharma and describes the methodology applied to collect and disclose the ToV data.

The methodology note is a requirement outlined in the EFPIA Code of Practice, Chapter 5, and will be available to the public.

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. please add if there any other codes that need to be met
In the same manner, LEO Pharma is committed to ensuring transparency of its engagements with Patient Organizations in accordance with the EFPIA Code of Practice. please add if there any other codes that need to be met

To ensure that LEO Pharma's engagements with HCPs, HCOs and Patient Organizations are in compliance, appropriate, properly documented, transparent and do not compromise the independence of the HCP, HCO or Patient Organization, LEO Pharma has developed a Global Healthcare Compliance process.

The global process for engaging with HCPs, HCOs and Patient Organizations 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 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 Organization and the ToV provided is processed in accordance with the LEO Pharma HCP/HCO/Patient Organization 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 Organizations 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 Organization details needed for the disclosure.

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

2 Definitions

2.1 Recipients

Healthcare Professional (HCP)

I. 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. If the local definition differs from the general one, please write it here.

The following section addresses the treatment of retired and deceased HCPs.

The disclosure of a ToV granted to a retired HCP depends on the continued fulfilment of the above definition of an HCP after retirement. If that is the case, we adhere to the general disclosure rules that apply to HCPs.

If the HCP no longer meets the above definition after retirement, we do not report ToVs granted after retirement, but we do report ToVs granted before retirement during the relevant reporting period.

In the event of the death of a healthcare professional, the following options are available.

ToVs provided to the HCP;

1. The information will be available on the website in accordance with the stipulated retention period, until the deadline expires.

2. Are transferred to the aggregated report.

3. ToVs have been eliminated from the report.

Modify the section highlighted in green in accordance with local regulations. Select the only option you intend to follow and remove the others.

Healthcare Organization (HCO)

I. General definition

Any legal person/entity:

- that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as hospital clinic, foundation, university or other teaching institution or learned society (except for Patient Organizations) or
- through which one or more HCPs provide services.

This definition may vary locally; in which case, the local definition in the country where the HCO has its business address or place of incorporation prevails.

If the local definition differs from the general one, please write it here.

Patient Organization

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

If there are any recipients other than those listed above for whom ToV payments made by LEO must be reported, please list them here and provide their definition as well.

2.2 Kind of Transfer of Values (ToV)

Transfer of Value (ToV)

Any Direct or Indirect ToV provided to an HCP/HCO/Patient Organization by LEO Pharma, whether monetary, in kind or otherwise, made, whether for promotional purposes or not, in connection with the development and/or sale of products. This includes, but is not limited to, payments of fees for services, registration fees, sponsorships, donations, grants, accommodation, travel and the provision of hospitality.

Contribution to cost 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) organized or sponsored by or on behalf of LEO Pharma.

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 organized or created by LEO Pharma and/or independent organization. When providing sponsorship of events/meetings to organizations, associations, etc. such contributions may include costs for subsistence (food and drink).

Donation/Grant

I. General definition

Financial or Non-Financial Support provided by LEO Pharma to an eligible Recipient for an altruistic, professional or scientific, or humanitarian purpose, or to support a specific educational or research project. Donations and Grants are provided without receiving or expecting any benefits in return from the Recipient, but Grants may be conditional upon certain requirements and obligations agreed between the involved parties. Donations/Grants may take many forms, including financial support, chemical compounds or equipment for research or healthcare purposes and/or medical products.

This definition may vary locally; in which case, the local definition prevails.

Fee for services and Consultancy

The EFPIA Disclosure Code also requires the reporting of payments made to HCPs and HCOs for services rendered, as consultancy, advisory boards, speaking engagements, and research collaborations. LEO Pharma discloses these fees to maintain transparency about the financial relationships between LEO Pharma and the HCPs/HCOsPOs. Such engagements are often necessary for advancing medical innovation and development through expert advice and collaboration.

Research and Development (R&D)

Research and Development activities are by EFPIA divided into 3 main activity types:

(i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice);

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

(iii) NIS that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study.

Non-clinical study:

This category includes any ToVs made to an HCP/HCO in connection with an experiment or a set of ex-periments 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.

Investigator Initiated Studies (IIS)

Financial support to an Investigator Initiated Study (IIS) that is retrospective in nature is disclosed on an individual level while financial support to an IIS that is prospective in nature is disclosed on an aggregated level under Research and Development.

Financial support provided to a retrospective IIS is disclosed as fee-for-service, although the activity is not performed on behalf of LEO Pharma and LEO Pharma is not involved in the planning and conduct of the study. The HCP/HCO is conducting such study at his/her/its own initiative and is assuming all responsibility for the conduct of the study.

Sponsorships

Definition of a PCO:

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

LEO Pharma may provide support/sponsorship to PCOs/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 (or Patient Organization) and hence not a Recipient under the EFPIA 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.

3 Disclosure´s scope

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, donations, grants, financial support, travel, hospitality, and other expenses related to an activity involving an HCP and/or HCO.

As described, LEO Pharma has assigned a Healthcare Compliance Representative for each country who is overall responsible for ensuring disclosure of ToVs in accordance with local requirements. The Healthcare Compliance Representative in the country where the HCP/HCO has his/her/its Principal Practice Address/place of incorporation must ensure disclosure of all reportable ToVs in the country of the HCP/HCO, including both National Engagements and Cross-border Engagements, regardless of whether they consist of Direct or Indirect ToVs and regardless of whether the ToV has been initiated by LEO Pharma or upon request by the HCP/HCO.

3.1 Products concerned

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.

3.2 Company concerned

LEO Pharma …….. and LEO Pharma A/S and its subsidiaries and any other entity controlled by or in common control with LEO Pharma A/S.

Please add the name of the local LEO affiliate

3.3 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, 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.

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 no 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.

LEO Pharma employees' attendance at conferences

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

3.4 ToVs date

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 date of activity 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, the date of activity will be used as date of ToV, whenever possible, for the following types of expenses: congress registration, travel and accommodation.

3.5 Direct ToVs

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

3.6 Indirect ToVs

Transfers of Value made to an HCP/HCO/Patient Organization on behalf of an entity within LEO Pharma through an intermediary (Third Party). LEO Pharma must know about and/or be able to identify the HCP/HCO/Patient Organization that will benefit from the ToV in order for the ToV to be considered an Indirect ToV.

LEO Pharma may engage with Third Parties who are engaging HCPs/HCOs as part of services delivered to LEO Pharma. It is evaluated for each specific engagement whether ToVs made to HCPs/HCOs by a Third Party on behalf of LEO Pharma are considered Indirect ToVs.

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.

Indirect ToVs are for instance ToVs made in connection with clinical trials sponsored by LEO Pharma where the conduct of the clinical trial, including payments to HCPs/HCOs, is handled through a Contract Research Organization (CRO).

LEO Pharma is disclosing any Indirect ToV on the same level as Direct ToVs, i.e., either on an individual or aggregated level.

3.7 Non-monetary ToVs

LEO Pharma considers reportable ToVs to include transfers that are monetary, in kind or otherwise. Where non-financial support cannot reasonable be quantified and has been assessed not to constitute a ToV, it is excluded from disclosure.

3.8 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 in accordance with the standard disclosure process 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.

3.9 Cross-border activities

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

the country of the activity, and/or

the country of the LEO Pharma contracting entity

Any ToVs made in connection with a Cross-border Engagement are tracked by the Paying Country, as described previously. The ToVs from the Paying Country are made available to the Healthcare Compliance Representative in the country of the HCP/HCO for disclosure. This process ensures that LEO Pharma discloses not only ToVs from National Engagements, but also all ToVs from Cross-border Engagements. If disclosure is not related to Research and Development, the Healthcare Compliance Representative in the country of the HCP must ensure that consent has been collected for the specific HCP.

3.10 R&D

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

The definitions of these three types can be found in section 2.2. under Research and Development (R&D).

ToVs generated during R&D activities are included in the aggregated EFPIA report. 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.

If local regulations stipulate otherwise, please modify the text accordingly.

3.11 Voluntary disclosure (anything discloses beyond the national code)

LEO …….. does not disclose any other ToVs beyond the requirements set out in the EFPIA Code of practice.

Please modify if local regulations require otherwise.

4 Specific considerations

4.1 Country unique identifier

Country unique identifiers are only used when it is essential to meet local disclosure requirements. However, even such cases LEO Pharma primarily us the LEO internal identifier to ensure that every activity and ToV associated with each HCP/HCO can be identified and tracked within our systems, and the reports are disclosed with the highest quality.

Please modify the text if you use local country unique identifier.

4.2 Self-incorporated HCPs

A self-incorporated HCP is a one-person company owned by an HCP, in which case the self-incorporated HCP is a legal entity and hence considered an HCO. Payments to self-incorporated HCPs are disclosed in the name of the HCO, the HCP's one-person company, being the Recipient of the payment.

However, 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.

If local regulations stipulate otherwise, please modify the text accordingly.

4.3 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.

4.4 Country specifities

If there are country-specific rules that are not covered in any of the previous sections, they should be detailed here.

4.5 Quality checks

The global process for engaging with HCPs, HCOs and POs 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 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 Organization/Member of the Public and the ToV provided is processed in accordance with the LEO Pharma HCP/HCO/Patient Organization/ 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 Organizations/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 Organization/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 Organizations/Members of the Public by his/her LEO Pharma entity, whereas the Healthcare Compliance Representative in the country of HCP/HCO/Patient Organization/Member of the Public is responsible for preparing the local disclosure report(s) containing all ToVs provided by LEO Pharma to HCPs/HCOs/Patient Organizations/Members of the Public with Principal Practice Address in the country of the Healthcare Compliance Representative.

5 Data protection legal basis

5.1 Consent collection

In a number of countries, LEO Pharma is obliged to obtain consent from the individual HCP for the disclosure of the HCP's personal data and the ToVs made to the HCP. If such disclosure and pertaining consent is required as per local law and requirements, the Healthcare Compliance Representative in the country of HCP ensures that consent from the HCP is obtained, both in connection with Direct and Indirect ToVs, in accordance with local requirements and local data protection laws. In case consent for disclosure is also required for HCOs in a given country according to local data protection laws, it is the responsibility of the Healthcare Compliance Representative in the country of the HCO to obtain such consent.

Please describe the local process.

The HCP can withdraw his/her consent at any time. In such case, LEO Pharma will disclose the related ToVs on an aggregated level and will re-publish the disclosure report(s), if the data was already published.

Withdrawal of consent is managed by the Healthcare Compliance Representative in the country of the HCP and local laws should be taken into consideration on a case-by-case basis.

A request from an HCP for withdrawal of his/her consent can be received by any employee in LEO Pharma, who then needs to inform the Healthcare Compliance Representative in the country of the HCP for further handling.

Partial consent

The Healthcare Compliance Representative in the country of the HCP will verify that consent has been collected before disclosure of the ToVs. Since consent is collected in a separate consent agreement on an HCP level, covering all ToVs within a given disclosure period, all ToVs made for that specific HCP will either be disclosed on an individual or an aggregated level (except ToVs in connection with Research and Development) within a given disclosure period.

This means that if an individual HCP receives a number of ToVs from LEO Pharma throughout the reporting period and he/she decides to withdraw his/her consent for one or more of those ToVs, LEO Pharma will disclose all of the ToVs provided to the HCP on an aggregated level.

5.2 Legitimate interest

Please indicated if you are using a legitimate interest based disclosure approach instead of requesting consent.

If this is followed the description must be detailed and must include among the others the balancing test and the righ to object.

Here is an example I received from Gill from the UK. Thank you Gill. This is the specific UK version, but you can use this as a guide when describing your approach.

“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:

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.

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.
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."

6 Form of disclosure

For the disclosure, the country-specific applicable disclosure template(s) will be used. The ToVs will be disclosed in accordance with the country-specific requirements.

6.1 Date of publication

The ToVs will be published within the timelines defined by the requirements in the country of disclosure and in accordance with the EFPIA Code of Practice. In **name of the country** not later than 30th of June……

6.2 Disclosure platform

The ToVs will be available on either the specific LEO Pharma entity's company website or on the specific national authority's or local association's platform in accordance with the local requirements. For LEO Pharma entities without a local company website, the ToVs will be published on the company website of LEO Pharma A/S (HQ).

Please add the link to the local disclosure site/page

6.3 Disclosure language

The ToVs will be disclosed in the language defined by the requirements in the country of disclosure and in accordance with the EFPIA Code of Practice.

Please write in which language you disclose the report.

7 Disclosure financial data

To ensure that the ToVs disclosed by LEO Pharma is consistent, certain decisions have been made on which data points to be used in the capture and tracking of the ToVs.

7.1 Currency

The currency used in the disclosure report is the local currency (add the local currency) in the country where the disclosure is made (the country of the HCP/HCO) in this case name of the country…….

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.

7.2 VAT

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.

7.3 Calculation rules

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).

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.

8 Additional information

In this section we have collated further information to assist HCPs/HCOs/Pos in comprehending the methodology we follow.

8.1 Aggregated Disclosure

Reportable ToVs are disclosed on an aggregated level in cases where i) the ToV is related to Research & Development Activities, see section 3.10 and, ii) the HCP has not provided his/her consent for disclosure, if required, as described in section 5.1.

8.2 Clinical trials and studies

LEO Pharma may engage with CROs to conduct clinical trials on behalf of LEO Pharma. Indirect ToVs provided to HCPs/HCOs through CROs are disclosed in accordance with Global Healthcare Compliance process.

However, in cases where an HCP is employed by a CRO, as a member of the CRO staff, and the HCP, as part of his/her regular employment with the CRO, is performing services to which LEO Pharma has contracted the CRO, payment to the CRO for such services is not considered an Indirect ToV to the HCP as long as the HCP will only be paid his/her normal salary as a member of the CRO staff. Furthermore, payment to the CRO will not be disclosed, as CROs are not considered HCOs.

8.3 Disclosure of ToVs provided to Patient Organizations

LEO Pharma is committed to ensuring transparency in its relationship with Patient Organizations and will, in accordance with the EFPIA Code of Practice, make publicly available any ToVs and non-financial support provided by LEO Pharma to Patient Organizations in countries with disclosure requirements.

In accordance with the Global Healthcare Compliance Process as described in this document 4 of this document, the Healthcare Compliance Representative in the country of the Patient Organization is responsible for preparing the disclosure report with the Direct and Indirect ToVs provided to Patient Organizations from his/her country and disclosing such ToVs in accordance with local disclosure requirements.

Where applicable according to local disclosure requirements, a global LEO Pharma Patient Organization disclosure template will be used by the LEO Pharma entity containing, as a minimum, the following information:

- Country of Patient Organization
- Name of Patient Organization
- Address of Patient Organization
- Type of engagement (type of support/contracted services)
- Type of ToV (financial/non-financial)
- Description of the engagement (description of the nature of the support/contracted services)
- Amount/non-financial support (where no meaningful monetary value can be assigned)
- Currency
- LEO Pharma Paying Country

The LEO Pharma Patient Organization disclosure report per LEO Pharma entity will be disclosed on the local LEO Pharma company website in the country of the Patient Organization, unless local disclosure requirements state otherwise.

The LEO Pharma Patient Organization disclosure reports cover ToVs made within a full calendar year for a given disclosure period and are disclosed on an annual basis by the date specified in the local disclosure requirements. The disclosed amounts are exclusive of VAT where possible.

The disclosure of ToVs and non-financial support provided to Patient Organizations by LEO Pharma also includes ToVs made by LEO Pharma to individual patients (e.g., for speaker services) who are acting on behalf of a Patient Organization as representatives of the Patient Organization.

As far as the transparency obligations related to the ToVs, data retention obligations associated therewith are governed by statutory, audit and compliance requirements. Local law prevails where applicable. Local LEO Pharma affiliates are responsible for conducting adequate assessments of the applicable law.

8.4 Distributors

LEO Pharma may engage with distributors who promote and distribute LEO Pharma products. In some cases, distributors are working independently from LEO Pharma and act on their own behalf and do not represent or act on behalf of LEO Pharma in the distribution or promotion of products. In such cases, any ToVs provided to HCPs/HCOs by the distributor are not considered Indirect ToVs and will not be disclosed by LEO Pharma.

In cases where a distributor is acting on behalf of or under the instructions of LEO Pharma and is providing a ToV to an HCP/HCO on behalf of LEO Pharma, such ToVs are considered Indirect ToVs and will be disclosed by LEO Pharma as following the Third party disclosure process.

8.5 EFPIA

European Federation of Pharmaceutical Industries and Associations

8.6 HCO services and R&D collaborations

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) nom-inated by LEO Pharma, will such indirect ToV be disclosed against the individual HCP.

If LEO Pharma cannot confirm that the HCP employed by the HCO, and nominated by LEO Pharma for performance of services, is the beneficiary of the ToV paid to the HCO, such payment is not considered an Indirect ToV and such payment is not disclosed as a ToV against the individual HCP, but against the HCO as the Recipient of the payment.

8.7 Healthcare Compliance Representatives

Locally appointed LEO Pharma employee(s) responsible for supporting compliance of activities involving HCPs/HCOs/Patient Organizations, both organized locally and across borders. The Healthcare Compliance Representative is also responsible for the local disclosure of ToVs provided – by any LEO Pharma entity – to HCPs/HCOs/Patient Organizations with Principle Practice Address in the country within the responsibility of the Healthcare Compliance Representative

8.8 Individual Disclosure

The reportable ToV is disclosed against the name of the specific HCP/HCO to whom the ToV was made (individual level), except i) when the activity performed by an HCP/HCO concerns specific Research & Development services as defined in section 3.6 or ii) when the HCP/HCO did not consent to disclosure, see section 5.1.

The disclosure on an includes, but is not limited to, fee-for-service activities, consultancy advice, advisory board activities, general advice, non-blinded market research, conference registration fees, and all disclosable expenses related to such activities. R&D advisory boards, medical consulting and/or data review not related to a specific clinical trial are also disclosed on an individual basis.

Expenses related to travel and accommodation, such as costs of flights, trains, car hire, tolls, parking fees, taxis and hotel accommodation are disclosed under each individual HCP who has benefitted from the travel and accommodation.

The disclosure on an individual level also includes services in connection with non-interventional retrospective studies (such as consultancy advice in relation to a database study and medical chart review study), investigator initiated studies that are retrospective in nature (see section 2.2), and support for medical writing for independent publications, however see section 3.3.

Whether individual disclosure is needed must be performed by local LEO Pharma affiliates respectively for their own jurisdictions.

8.9 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.

8.10 Master agreements

In connection with master agreements, the HCP/HCO will be paid in accordance with the fee and terms for travel and expense reimbursement described in the master agreement or in the separate work order prepared for each separate activity requested to be performed by the HCP/HCO. The LEO Pharma unique identifier is assigned at the beginning of the collaboration and will remain assigned to the HCP/HCO, and any ToV will be disclosed according to Global Healthcare compliance process and within the applicable reporting period where the individual payments were made.

8.11 National Engagement

An Engagement made between a LEO Pharma entity and an HCP/HCO/Patient Organization from the same country. The activity must also occur in the same country.

8.12 Principal Practice Address

The address where an HCP performs the majority of his/her healthcare related services.

8.13 Recipient

The HCP/HCO/Patient Organization receiving a ToV either directly or indirectly from an entity within LEO Pharma.

8.14 Retention

LEO Pharma will maintain the relevant records of the ToV data for time period in accordance with applicable law, industry guidelines and local regulations after the end of the relevant reporting period, unless a different period is required under applicable national data privacy or other laws or regulations. Where time period for retention is not specified by applicable

law, the relevant records shall be maintained for 6 years after publishing the data or the end of the relevant reporting period whatever is the longest.

Data relating to the Inactive HCPs shall be retained in accordance with applicable law, ideally pseudonymized if possible in accordance with applicable law, in particular:

- Statutory financial retention requirements,
- Anti-bribery and audit requirements,
- EFPIA publication duration requirements.

Local LEO Pharma affiliates are responsible for conducting adequate assessments on the applicable law. In particular, affiliates must confirm whether national law extends data protection rights beyond death and restricts publication of deceased individuals' data.

8.15 Third Party

An individual or legal entity with whom LEO Pharma is collaborating, in whichever way, and/or who is acting on behalf of LEO Pharma, including, without limitation contract manufacturing organizations, academic and commercial contract research organizations, consultants, distributors, market research companies, and advertising agencies, organizations, associations, institutions and other parties or persons not affiliated with LEO Pharma.

8.16 Virtual events

The conduct of HCP engagements in a virtual setting (virtual engagements) has increased in recent years, and the LEO Pharma healthcare compliance framework and inherent processes apply to virtual engagements in the same manner as non-virtual engagements. Hence, ToVs from virtual engagements will be tracked and disclosed in accordance with the methodology described in this document. This includes registration fees for virtual, or recorded, events which are considered ToVs in the same manner as registration fees paid for live events.