LEO Pharma Methodological Note

Disclosure under EFPIA and The Association of the Pharmaceutical Industry in Norway (LMI)

for LEO Pharma AS

Version 8.0, 2022 disclosure

Contents

1 Introduction

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 s LMI's Guidelines. 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 and s LMI's Guidelines.

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 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, HCOs, and Patient Organizations.

2 Purpose

This methodology note describes in detail how LEO Pharma, including LEO Pharma AS, 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.

3 Terminology and Definitions

Cross-border Engagement

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

Direct ToV

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

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.

II. Local Definition

As above

EFPIA

European Federation of Pharmaceutical Industries and Associations

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.

II. Local Definition

As above

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.

II. Local definition

As above

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.

Indirect ToV

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

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

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.

LEO Pharma Organizer

The person employed by LEO Pharma undertaking an activity that involves an HCP/HCO/Patient Organization on behalf of LEO Pharma.

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.

Paying Country

The entity within LEO Pharma that issues a payment/reimbursement or makes any other ToV to a specific HCP/HCO/Patient Organization, irrespective of whether the ToV is made via a Third Party.

Professional Conference Organizer (PCO)

A legal entity specialized in the organization and management of congresses, conferences, seminars and similar events.

Principal Practice Address

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

Recipient

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

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.

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, travel and the provision of hospitality.

4 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 alignment with LMI's Guidelines, 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.

4.1 Identification of HCP/HCO/Patient Organization

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

5 Scope and Content of HCP/HCO ToV Disclosure

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.

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.

5.1 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 5.4 or ii) when the HCP/HCO did not consent to disclosure, see section 5.12.

The disclosure on an individual level 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 5.5), and support for medical writing for independent publications, however see section 5.14.2.

5.2 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.

5.3 Aggregated Disclosure

Reportable ToVs are disclosed on an aggregated level in cases where i) the ToV is related to Research & Development Activities, see section 5.4 and, ii) the HCP has not provided his/her consent for disclosure, if required, as described in section 5.12.

5.4 Research and Development

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 experiments 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.

5.5 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.

5.6 ToVs in case of partial attendance or cancellation

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 section 5. 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.

5.7 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.

5.8 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 section 5 and within the applicable reporting period where the individual payments were made, see section 5.10.3.

5.9 Indirect ToVs

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 as described above in section 5.

5.9.1 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) nominated 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.

5.9.2 Clinical trials and studies

As described in section 5.9, 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 section 5.

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.

5.9.3 Sponsorships

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 and in accordance with section 5.

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.

5.9.4 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 in accordance with this section 5.

5.9.5 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.

5.10 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.

5.10.1 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).

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.

5.10.2 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.

5.10.3 Date of ToV

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.

5.11 Cross-border Engagement

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, see section 5.12.

5.12 Consent Management

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.

5.12.1 Consent collection

The consent, if required according to local requirements and local data protection laws, is obtained in a separate consent agreement that covers consent for disclosure of all ToVs provided to an HCP within the given reporting period.

5.12.2 Management of Recipient consent withdrawal

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.

5.12.3 Management of Recipient's request

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.

5.12.4 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.

5.13 Disclosure form

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.

5.13.1 Date of publication

ToV made by LEO Pharma to Norwegian HCPs and HCOs are published annually in June

5.13.2 Disclosure platform

ToV made by LEO Pharma to Norwegian HCPs and HCOs are published on LEO Pharma's website (leo-pharma.no)

5.13.3 Disclosure language

The ToV spreadsheet is in Norwegian and the Methodological Note is published in English.

5.14 Disclosure exclusions

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 LMI Guidelines, 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, see section 5.14.2. Such ToV will also be excluded from the ToVs for disclosure.

5.14.1 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.

5.14.2 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 (GPP3) 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.

6 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 and LMI Guidelines, 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 section 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.

7 Retention

LEO Pharma will maintain the relevant records of the ToV data for 6 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.

8 References

EFPIA Code of Practice, 2019.
PIF Guidellines