LEO Pharma Methodological Note

Disclosure under EFPIA and the Association of the Pharmaceutical Industry in Norway (LMI) for LEO Pharma AS

Version 6.0, 2020 disclosure

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1 Introduction

Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs) provide the LEO Pharma Group with valuable, independent and expert knowledge from their experience within the field of dermatology and other areas that the LEO Pharma Group operates within. The expertise of HCPs and HCOs helps the LEO Pharma Group improve patients' quality of life.
The LEO Pharma Group believes it is fair and reasonable that HCPs and HCOs are compensated for the legitimate services and expertise that they provide. In addition, the LEO Pharma Group supports the education of HCPs and activities within healthcare and research. At the same time, the LEO Pharma Group acknowledges the need for and is committed to ensuring transparency of such Transfers of Value (ToV) provided to HCPs and HCOs, as required by the EFPIA Code of Practice, as well as by the Association of the Pharmaceutical Industry in Norway (LMI)

The LEO Pharma Group also interacts with Patient Organizations to improve research and support education. In the same manner as for HCPs and HCOs, the LEO Pharma Group is committed to ensuring transparency of its engagements with Patient Organizations in accordance with the EFPIA Code of Practice and the industry rules of the Association of the Pharmaceutical Industry in Norway (LMI).

To ensure that the LEO Pharma Group'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, the LEO Pharma Group has developed a healthcare compliance framework. The healthcare compliance framework supports the LEO Pharma Group in avoiding conflicts of interest, and creates transparency when engaging with HCPs, HCOs and Patient Organizations locally, and across borders. This framework also covers the processes that LEO Pharma have put in place to ensure tracking and disclosure of ToVs provided to HCPs, HCOs and Patient Organizations.

1.1 The impact of COVID-19 on the 2020 disclosure data

As a result of the COVID-19 pandemic, the nature of LEO Pharma engagements with HCPs, HCOs and Patient Organizations in many cases changed to virtual during 2020. The LEO Pharma healthcare compliance framework and inherent processes apply to virtual engagements in the same manner as non-virtual engagements and 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 and will be disclosed in accordance with section 5 and 6 of this document.

For planned events that were cancelled due to COVID-19 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. See also section 5.6. Where events were converted from face-to-face to virtual, the ToVs provided e.g. in the form of a virtual registration, will be disclosed as per above description.

2 Purpose

This methodology note describes in detail how the LEO Pharma Group, including LEO Pharma AS, ensures transparency with regards to the ToVs that the LEO Pharma Group provides to HCPs, HCOs and Patient Organizations. It outlines the general principles underlying the disclosure of ToVs by the LEO Pharma Group and describes the general principles by which the LEO Pharma Group has ensured that the ToV data is complete and accurate.

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, or
- the country of the LEO Pharma contracting entity

Direct ToV

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

Donation/Grant

I. **General definition**

Financial or Non-Financial Support provided by the LEO Pharma Group 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 Organisations) 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 Person

Locally appointed LEO Pharma employee(s) responsible for supporting compliance of activities involving HCPs/HCOs/Patient Organizations, both organized locally and as part of a Cross-border Engagement, and who 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 Person.

Indirect ToV

Transfers of Value made to an HCP/HCO/Patient Organization on behalf of an entity within the LEO Pharma Group through an intermediary (Third Party). The LEO Pharma Group 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 Group

LEO Pharma A/S (HQ) and any affiliate, production site, regional office, representative office, local sales office, company, cooperation, firm, partnership, subsidiary, or 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 fall in the definition of a Patient Organization.

Paying Country

The entity within the LEO Pharma Group 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 the LEO Pharma Group.

Third Party

An individual or legal entity with whom the LEO Pharma Group is collaborating, in whichever way, and/or who is acting on behalf of the LEO Pharma Group, 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 the LEO Pharma Group.

Transfer of Value (ToV)

Any direct or indirect Transfer of Value provided to an HCP/HCO/Patient Organization by the LEO Pharma Group, 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 the LEO Pharma Group 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 industry rules of the Association of the Pharmaceutical Industry in Norway (LMI), in which case additional local procedures may be in place, in order to meet local compliance requirements for HCP/HCO/Patient Organization engagements and the disclosure of ToVs provided to HCPs/HCOs/Patient Organizations by the LEO Pharma Group.

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 Person 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 person in the country of HCP/HCO/Patient Organization is responsible for preparing the local disclosure report(s) containing all ToVs provided by the LEO Pharma Group to HCPs/HCOs/Patient Organizations with Principal Practice Address in the country of the Healthcare Compliance Person.

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 the LEO Pharma Group 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

The LEO Pharma Group is responsible for disclosing both Direct and Indirect ToVs made on behalf of the LEO Pharma Group 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 earlier in this document, the LEO Pharma Group has assigned a Healthcare Compliance Person for each country who is overall responsible for ensuring the accurate and complete disclosure of the ToVs in accordance with local requirements. The Healthcare Compliance Person 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 the LEO Pharma Group or upon request by the HCP/HCO.

5.1 Individual Disclosure

The reportable ToV is disclosed under the name of the specific HCP/HCO to whom the ToV was made (individual level) based on the LEO Pharma unique identifier in all cases 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 5.11.

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 05)), and support for medical writing for independent publications, however see section 5.13.2..

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.

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.

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 04 and, ii) the HCP has not provided his/her consent for disclosure, if required, as described in section 5.11.

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 the LEO Pharma Group 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.

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 the LEO Pharma Group and the LEO Pharma Group 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

If an activity is cancelled, no ToV will be made to the HCP/HCO, unless the HCP/HCO has already performed certain preparatory work that the LEO Pharma Group 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 0. In case the LEO Pharma Group has paid any expenses prior to an activity and the activity is cancelled, no ToV will be disclosed on the HCP/HCO given that the HCP/HCO did not receive any benefits from the pre-payment made by the LEO Pharma Group. 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 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 5.9.3.

5.8 Indirect ToVs

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

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

The LEO Pharma Group 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 0.

5.8.1 Indirect ToV – through an HCO

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

If it can be clearly identified by the LEO Pharma Group that a ToV in such cases is being transferred to the HCP personally via the HCO, such indirect ToV is tracked and disclosed under the individual HCP and not under the HCO.

If the LEO Pharma Group cannot confirm that any HCP employed by the HCO receives a personal benefit from the ToV paid to the HCO, such payment is not considered an Indirect ToV and such payments are not disclosed as a ToV under an individual HCP but instead under the HCO as the Recipient of the payment.

5.8.2 Indirect ToV – through a CRO

As described in section 5.8, the LEO Pharma Group 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 full-time employee, and the HCP is performing services to which LEO Pharma has contracted the CRO as part of his/her regular employment with 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.

5.8.3 Indirect ToV – through a PCO

The LEO Pharma Group may provide support / sponsorship to PCOs 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 an HCP/HCO, as e.g. a scientific committee, speaker, chair or attendee, will receive a ToV by means of the support/sponsorship provided by the LEO Pharma Group, and the LEO Pharma Group knows or can identify the HCP/HCO that will benefit from the ToV, such ToV will be considered an Indirect ToV. Such Indirect ToVs to HCPs/HCOs provided through PCOs will be disclosed under the name of the benefiting HCP/HCO with no mentioning of the name of the PCO and in accordance with section 5.

In case the LEO Pharma Group is providing support / sponsorship to a PCO, but the LEO Pharma group is not able to identify the benefiting HCP/HCO, 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, in order to ensure transparency of the sponsorships provided by the LEO Pharma Group to educational/scientific events, the LEO Pharma Group requires the PCO to publish the sponsorship on the website of the specific conference.

In case an educational/scientific event is organized by an HCO, and not a PCO, any ToV will be disclosed in the name of the HCO, or in the name of any indirectly benefitting identifiable HCP.

5.8.4 Indirect ToV - Distributors

The LEO Pharma Group may engage with distributors who promote and distribute LEO Pharma products. In some cases distributors have an arms-length responsibility towards the LEO Pharma Group and act on their own behalf and do not represent or act on behalf of the LEO Pharma Group 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 the LEO Pharma Group.

In cases where a distributor is acting on behalf of or under the instructions of the LEO Pharma Group and is providing a ToV to an HCP/HCO on behalf of the LEO Pharma Group, such ToVs are considered Indirect ToVs and will disclosed by the LEO Pharma Group and in accordance with this section 5.

5.8.5 Indirect ToV – Market Research Studies

The LEO Pharma Group may engage with a Third Party in order to conduct market research studies or similar activities where the LEO Pharma Group does not know the identity of the HCP/HCO engaged on behalf of the LEO Pharma Group by the Third Party, and the HCP/HCO does not know the identity of the LEO Pharma Group (double-blinded market research). In such cases, the LEO Pharma Group is not able to track and disclose any ToV made to the HCP/HCO by the Third Party on behalf of the LEO Pharma Group and therefore such ToV will not be disclosed.

If an HCP requires to know the identity of the company performing the market research, this will be revealed in accordance with the guidelines in the EphMRA Code of Conduct. However, to protect the anonymity of the respondents/HCPs, the name of the respondents/HCPs will still not be revealed to the LEO Pharma Group and the LEO Pharma Group will therefore not disclose any ToV made in connection with the market research.

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

5.9 Financial data

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

5.9.1 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 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.

5.9.2 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.

5.9.3 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.

5.10 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 Person in the country of the HCP/HCO for disclosure. This process ensures that the LEO Pharma Group 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 Person in the country of the HCP must ensure that consent has been collected for the specific HCP, see section 5.11.

5.11 Consent Management

In a number of countries, the LEO Pharma Group 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 Person 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 Person in the country of the HCO to obtain such consent.

5.11.1 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.

5.11.2 Management of Recipient consent withdrawal

The HCP can withdraw his/her consent at any time. In such case, the LEO Pharma Group 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 Person in the country of the HCP and local laws should be taken into consideration on a case by case basis.

5.11.3 Management of Recipient's request

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

5.11.4 Partial consent

The Healthcare Compliance Person 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 the LEO Pharma Group throughout the reporting period and for some reason decides to withdraw his/her consent for one or more of those ToVs, the LEO Pharma Group will disclose all of the ToVs provided to the HCP on an aggregated level.

5.12 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.

5.12.1 Date of publication

ToV from LEO Pharma AS to HCPs/HCOs will be published annually latest 30^{h} June, together with this Methodological Note

5.12.2 Disclosure platform

ToV from LEO Pharma AS to HCPs/HCOs will be published on LEO Pharma's website (leo-pharma.no). The link to the ToV information will be made available in LMI's web site (lmi.no).

5.12.3 Disclosure language

The ToV spreadsheet and the Methodological Note will be in English.

5.13 Disclosure exclusions

The LEO Pharma Group 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 industry rules of the Association of the Pharmaceutical Industry in Norway (LMI), such as meals and drinks.

In addition, in some cases the LEO Pharma Group provides certain non-financial support to HCPs/HCOs that cannot be assigned a monetary value, and the LEO Pharma Group has evaluated that these transfers of non-financial support are not to be considered a transfer of value, see section 5.13.2. Such ToV will also be excluded from the ToVs for disclosure.

5.13.1 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, the LEO Pharma Group does not consider such ToV disclosable and it would be part of ordinary course purchases.

5.13.2 Support for publications

Literature publications that relate to **LEO Pharma originated data and analyses** may be developed collaboratively between an HCP (external author) and the LEO Pharma Group (internal author). In accordance with Good Publication Practice for Communicating Company-Sponsored Medical Research (GPP3) and as stated in the LEO Pharma Group guideline on Scientific, Medical and/or Technical Publications, the LEO Pharma Group 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 the LEO Pharma Group 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 the LEO Pharma Group or from an external medical writing agency.

Support where the LEO Pharma Group 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 the LEO Pharma Group to authors is to society at large, the scientific community, patients, and the LEO Pharma Group, 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, the LEO Pharma Group will disclose editorial service fees provided to a medical writer to support an HCP in a publication that is made independent of the LEO Pharma Group 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 the LEO Pharma Group, the LEO Pharma Group requires transparency and the (co)authorship and contributorship, including any financial contributions from the LEO Pharma Group will be mentioned.

6 Disclosure of ToVs provided to Patient Organizations

The LEO Pharma Group is committed to ensuring transparency in its relationship with Patient Organizations and will, in accordance with the EFPIA Code of Practice and the industry rules of the Association of the Pharmaceutical Industry in Norway (LMI), make publicly available any ToVs and non-financial support provided by the LEO Pharma Group 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 Person 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. In case no local LEO Pharma website is available in the country of the Patient Organization, the LEO Pharma Patient Organization disclosure report for that specific country will be published on the global LEO Pharma company website.

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.

In countries where consent from the Patient Organization is required in order to disclose the ToVs provided to the Patient Organization on an individual named basis, such consent must be obtained by the Healthcare Compliance Person in the country of the Patient Organization.

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

7 Retention

The LEO Pharma Group 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

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8 References

EFPIA Code of Practice, 2019.

The industry rules of the Association of the Pharmaceutical Industry in Norway (LMI).