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Methodological Note to HCP/HCO Disclosure Requirements in the LEO Group including specifications from Switzerland

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Contents

1 Introduction

Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs) provide the LEO Group with valuable, independent and expert knowledge from their experience within the field of dermatology and other areas that the LEO Group operates within. Their expertise will help the LEO Group to improve patients' quality of life.

The LEO Group is committed to uphold high ethical standards and to ensure compliance when interacting with HCPs and HCOs. EFPIA and IFPMA and similar local federations, including SGCI and vips, have implemented requirements on how the pharmaceutical industry engages with HCPs and HCOs whereby requirements to disclose Transfers of Value (ToV) made to HCPs or HCOs have emerged in many countries within recent years.

To ensure that the LEO Group's engagements with HCPs and HCOs are in compliance, appropriate, properly documented, transparent and do not compromise the HCP's/HCO´s independence, the LEO Group has developed an HCP Compliance Framework setting its origin in the LEO Code of Conduct, and consisting of a LEO Group policy, a LEO Group guideline and a LEO Group Standard Operating Procedure (SOP). The SOP specifically describes the process for engaging with HCPs and HCOs as well as the process for disclosure of ToV to HCPs/HCOs in the countries where applicable.

Having the HCP Compliance Framework supports the LEO Group in avoiding conflicts of interest, and creates transparency when engaging with HCPs and HCOs across borders.

2 Purpose

This methodology note describes in detail how the LEO Group, including LEO Pharmaceutical Products Sarath Ltd. Switzerland, ensures transparency with regards to the ToVs that the LEO Group makes to HCPs and HCOs. It outlines the general principles underlying the disclosure of HCP/HCO Spend Data by the LEO Group and describes the general principles by which the LEO Group has ensured that the HCP/HCO Spend Data is complete and accurate.

The methodology note is a requirement outlined in the EFPIA Disclosure Code section 3.05 and will be available to the public.

3 Terminology and Definitions

Activity

Any activity that requires a ToV between any entity within the LEO Group and an HCP/HCO

Cross-border Collaborations

Any interaction between any entity within the LEO Group and an HCP/HCO:

- where the Organiser is located in a country different from where the Activity is to take place, or
- where the Organiser is located in a country different from the HCP/HCO

Direct ToV

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

Donation/Grant

I. General definition

ToV provided by or on behalf of an entity within the LEO Group to an HCP/HCO (as per local requirements) for a philanthropic/humanitarian purpose and/or to support healthcare, medical education and/or research, without necessarily receiving or expecting consideration or compensation in return from the HCP/HCO. 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

Pecuniary benefits (general): in cash, as non-cash contributions, donations, grants or payments made either directly or indirectly in some other form for consultancy tasks or services, research and development, advertising, sales or other purposes, always in connection with medicinal products within the meaning of Section 131. Direct pecuniary benefits are those which a pharmaceutical company provides directly for a particular recipient. Indirect pecuniary benefits are those which a third party (e.g. supplier, agent, partner, subsidiary company or foundation) provides for a recipient in the name or on behalf of a pharmaceutical company, the identity of the pharmaceutical compa-ny being known or recognisable to the recipient.

Pecuniary benefits for research and development services: benefits within the meaning of Section 137 of the Pharma Cooperation Codex in connection with the planning or conduct of non-clinical studies (in compliance with GLP standards), clinical studies (compliant with GCP standards) and non-interventional studies (within the meaning of Section 4 of the Pharmaceutical Code).

EFPIA

European Federation of Pharmaceutical Industries and Associations

Fair Market Value (FMV)

The commercially reasonable price that a person customarily would pay for a particular service to be provided by an HCP/HCO, given the nature of the services, the qualifications and expertise of the HCP/HCO and the country in which the HCP/HCO is licensed. Volume or value of any purchases, prescriptions, referrals, or use of any LEO products by the HCP/HCO shall not be taken into consideration in the assessment of FMV.

Healthcare Professional (HCP)

I. General definition

The definition of an HCP varies from country to country and may include any member of the medical, healthcare, dental, pharmacy or nursing professions, or any other person, who in the course of his or her professional activities may prescribe, administer, recommend, purchase, pay for, reimburse, authorise, approve or supply healthcare services and/or medicinal products.

II. Local Definition

Healthcare professionals: physicians, dentists and pharmacists who are working in particular in a practice or hospital, together with pharmacists active in retail businesses, and persons who are authorised by Swiss law on therapeutic products, to prescribe, deliver or use prescription-only medicinal products for humans.

Healthcare Organisation (HCO)

I. General definition

An HCO is any legal person/entity:

- that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational 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 should apply.

II. Local definition´

Healthcare organisations: institutions, organisations, associations or other groups of healthcare professionals which provide healthcare services or consultancy tasks or other services in healthcare (e.g. hospitals, clinics, foundations, universities or other educational establishments, scientific societies or professional associations, community practices or networks, but not patient organisations).

HCP Compliance Person

Locally appointed person(s) responsible for supporting compliance of Activities involving HCPs/HCOs, both organised locally and as part of a Cross-Border Collaboration

HCP/HCO Spend Data

All reportable ToV made to an HCP/HCO

Indirect ToV

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

LEO Group

LEO Pharma A/S (HQ) and any affiliate, production site, regional office, representative office, local sales office, company, cooperation, firm, partner-ship, subsidiary, or other entity controlled by or in common control with LEO Pharma A/S

Local Finance

The finance function in the country where the Organiser is employed

National Engagement

An HCP/HCO engagement made between an entity within the LEO Group and an HCP/HCO from the same country as the concerned entity

Organiser

The appointed person who has the overall responsibility for the interaction with an HCP/HCO, no matter where the business unit, department or function of such person is located (e.g. HR, R&D, sales & marketing, etc.)

Paying Country

The entity within the LEO Group that issues a payment/reimbursement or makes any other ToV to a specific HCP/HCO

Principal Practice Address

The address where an:

- HCP performs the majority of his/her healthcare related services.
- HCO has its place of incorporation.

Recipient

The HCP/HCO receiving a ToV from an entity within the LEO Group

Third Party

Any company or individual who is not a member of LEO Group or a LEO employee, and who:

- is hired to provide products or services to the LEO Group or to act on behalf of the LEO Group (i.e. vendor or service provider), or
- enters a business partnership or collaboration with the LEO Group (i.e. business partner).

The definition includes e.g. contract manufacturing organisations, academic and commercial contract research organisations, consultants, distributors, market research companies, and advertising agencies, organisations, associations, institutions and other parties or persons not affiliated with the LEO Group.

Transfer of Value (ToV)

Any direct or indirect Transfer of Value, 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 HCP Compliance Process

The global process for engaging with HCPs and HCOs in the LEO Group as well as the process for disclosure of ToV (the Global HCP Compliance Process) consists of six steps.

Figure 1. Global HCP Compliance Process

The Global HCP Compliance Process is aligned with the requirements set out by the EFPIA. The implementation of the process in each country must follow the national requirements in which case additional local procedures

may be in place in order to meet local compliance requirements for HCP/HCO engagements and the disclosure of HCP/HCO spend.

All engagements with HCPs/HCOs must have a clearly identified Organiser. The Organiser cannot make any commitments to an HCP/HCO prior to the contractual arrangement. No contract can be signed with an HCP/HCO before the legitimate need for the Activity has been assessed (business need) and the proposed HCP/HCO has been evaluated based on objective criteria considering the required qualifications identified and documented in connection with evaluating the business need (HCP nomination).

When issuing the payment for the performance of the Activity, the Organiser must check that all reportable ToVs to HCPs/HCOs made in connection with an Activity for which he/she is responsible have been marked with a LEO unique identifier for the HCP/HCO, and are paid in accordance with the financial procedure in his/her country to ensure that all HCP/HCO Spend Data can be captured in the financial systems.

The HCP/HCO Spend Data is extracted from the financial systems or manually captured by the Organiser. For ToVs made to HCP/HCOs through a Third Party, the Third Party is responsible for tracking and providing the Organiser with the HCP/HCO Spend Data.

The HCP Compliance Person compiles the HCP/HCO Spend Data from Local Finance, Organiser and Third Party and ensures the consolidation of the HCP/HCO Spend Data. When the HCP/HCO Spend Data has been consolidated, the HCP Compliance Person prepares the disclosure report of all HCP/HCO Spend Data for HCPs/HCOs with Principal Practice Address in the country of the HCP Compliance Person.

4.1 Identification of HCP/HCO

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

In connection with ToVs made by a Third Party, LEO assigns the LEO unique identifier to the HCP/HCO after having received the HCP/HCO Spend Data from the Third Party.

5 Scope and Content of EFPIA Disclosure

The LEO Group is responsible for disclosing both Direct and Indirect ToVs made on behalf of the LEO Group to HCPs and HCOs in connection with activities relating to LEO 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.

The LEO Group has assigned an HCP Compliance Person for each country who is overall responsible for ensuring the accurate and complete disclosure of the HCP/HCO Spend Data in accordance with local requirements. The HCP Compliance Person in the country where the HCP/HCO has his/her/its Principal Practice Address (country of HCP) must warrant that there is a process in place for ensuring disclosure of all reportable ToVs in the country of the HCP/HCO, including both National Engagements and Cross-Border Collaborations, regardless of whether they consist of Direct or Indirect ToV and regardless of whether the ToV has been initiated by LEO or upon request by the HCP/HCO.

5.1 Individual Disclosure

The reportable ToV is disclosed under the name of the specific HCP to whom the ToV was made (individual level) based on the LEO unique identifier in all cases except i) when the Activity performed by an HCP/HCO concerns specific Research & Development services as defined in section 5.3 or ii) when the HCP did not consent to disclosure, see section 8.

The disclosure on 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 expenses related to such activities.

The disclosure on 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.

5.2 Aggregated Disclosure

The reportable ToV is disclosed on an aggregated level in cases where i) the ToV is related to Research & Development Activities, see section 5.3 and, ii) the HCP/HCO has not provided his/her consent for disclosure, if required, as described in section 8.

5.3 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 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 hourly fees paid to an HCP/HCO in his capacity as international/national coordinating investigator, investigator fees and fees in connection with memberships in a data review/monitoring committee, advisory board or medical consulting in relation to a specific clinical trial. Advisory boards, medical consulting and/or data review that cover more than one trial are disclosed on an individual basis.

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

5.4 Local Disclosure Requirements for Aggregated Disclosure

In an aggregated form (listing of all the healthcare professionals concerned or of all the healthcare organisations affected), the pharmaceutical companies shall disclose direct or indirect pecuniary benefits to healthcare professionals or healthcare organisations as follows:

- for each reporting period, the amounts of the pecuniary benefits falling within one of the above categories but which for legal reasons cannot be disclosed individually for each healthcare professional or healthcare organisation;
- the number of healthcare professionals covered by the disclosure in aggregated form, the total amount of the pecuniary benefit granted and its percentage distribution between the healthcare professionals concerned.

5.5 Investigator Initiated Studies (IIS)

Financial assistance for the purpose of supporting an Investigator Initiated Study (IIS) that is designed as a retrospective non-interventional study is disclosed on an individual level while financial assistance for the purpose of supporting an Investigator Initiated Study (IIS) that is designed as a prospective non-interventional study is disclosed on an aggregated level.

Any retrospective Investigator Initiated Study is disclosed as fee for service as directed by the EFPIA (EFPIA Disclosure Code, FAQ, Question 3.01 - 20), although the LEO Group considers such ToV as a donation/grant as the

activity is not performed on behalf of LEO and LEO is not involved in the pl anning 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 LEO required to be performed in connection with the Activity. The HCP will be paid in accordance with the terms defined in the agreement with the HCP, e.g. hourly fee based on hours spent on the preparation, and the ToV will be disclosed according to section 5.1-5.5.

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. The LEO 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 5.1-5.5.

5.8 Internal events

In connection with professional educational meetings held by the LEO Group for HCPs/HCOs at the LEO Group´s premises, e.g. in connection with EADO, any potential ToVs, such as meals and travel, will be reported under the individual HCP. Meals will only be reported in the countries with requirements to report such ToVs. The local thresholds and any applicable requirements are always adhered to. Rental of bus to transport several HCPs from the same location to the event is not included in the disclosure.

5.9 Indirect ToVs

The LEO Group may engage with HCPs/HCOs through a Third Party. In such case, the LEO Group is responsible for disclosure of any Indirect ToV made to the concerned HCPs/HCOs. The Indirect ToVs is disclosed on the same level as any Direct ToV on either the individual or the aggregated level according to this section 5. Indirect ToVs is for instance made in connection with clinical trials sponsored by the LEO Group where the management of the clinical trial, including payment to HCPs/HCOs, is handled through a Contract Research Organisation.

It is not considered an Indirect ToV if a) the LEO Group requests services to be performed by a Third Party and the services partly require the involvement of an HCP/HCO in order for the Third Party to deliver, and b) the LEO Group does not require a specific HCP/HCO to perform such services and c) the payment to the HCP/HCO is not

specified in the contract between the concerned LEO entity and the Third Party. The HCP/HCO would in these cases not be performing services on behalf of the LEO Group but on behalf of the Third Party.

5.9.1 Indirect ToV – through an HCO

The LEO Group may engage with an HCP indirectly through an HCO. In such cases, the LEO 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 is clearly identified in the contract between the LEO entity and the HCO that the ToV is being transferred to the HCP personally, such Indirect ToV is tracked and disclosed under the individual HCP and not under the HCO.

If the HCP employed by the HCO is performing the services as part of his/her regular employment with the HCO and is paid his/her normal salary, such payment is not considered an Indirect ToV and such payments are not disclosed as a ToV under the individual HCP but instead under the HCO.

5.9.2 Indirect ToV - Distributors

In cases where a distributor engages directly with HCPs/HCOs and promotes LEO products on behalf of the LEO Group, any such ToV made to HCPs/HCOs are considered an Indirect ToV and are to be disclosed by the LEO Group.

In cases where a distributor is selling LEO products to HCPs/HCOs (as applicable in the concerned country) as part of ordinary purchases and not on behalf of the LEO Group, or not representing the LEO Group, any such ToV made to HCPs/HCOs are not considered an Indirect ToV, and such ToVs made to HCPs/HCOs are not to be disclosed by the LEO Group.

5.9.3 Indirect ToV – Market Research Studies

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

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

6 Financial data

To ensure that the HCP/HCO Spend Data disclosed by the LEO Group is consistent, certain decisions have been made on which data points to be used in the capture and tracking of the HCP/HCO Spend Data.

6.1 Currency

The currency used in the disclosure reports is the currency in which the invoice has been issued or, for travel and expenses, the local currency in the country in which the expense was paid.

6.2 VAT

VAT is not included in ToVs in connection with direct spend, such as fee for service while VAT is included in ToVs related to indirect spend, such as meals, drinks, hotels and travel.

6.3 Date of ToV

For ToVs related to a payment of an invoice, including both fees and reimbursements, the payment date is used for disclosure as the HCP/HCO did not receive the benefit of the ToV until that date.

Likewise, for ToVs related to a specific event, travel and accommodation which were paid by the LEO Group directly, the payment date (receipt date) is used.

However, if the Activity/event took place by the end of a reporting year and the payment did not occur until the beginning of the new reporting year, the actual Activity/event date is used.

7 Cross-Border Collaborations

Any ToV made in connection with a Cross-Border Collaboration is tracked via the financial systems in the Paying Country and the LEO unique identifier. The HCP/HCO Spend Data from the Paying Country is provided to the HCP Compliance Person in the country of the HCP/HCO. The HCP Compliance Person in the country of the HCP/HCO is responsible for checking if the ToV to the HCP/HCO needs to be reported on an individual or aggregated level, according to local requirements. In addition, if reporting is required on an HCP-level, the HCP Compliance Person in the country of the HCP must check if consent has been granted by the specific HCP, see section 8.

8 Consent Management

In certain countries, the LEO Group is obliged to obtain consent from the individual HCP/HCO for the disclosure of the HCP's personal data/HCO data and the ToVs made to the HCP/HCO. If such disclosure and pertaining con-

sent is required as per local law, the Organiser ensures that consent from the HCP/HCO is obtained, in accordance with local requirements and local data protection laws. The HCP Compliance Person in the country of HCP/HCO must verify that consent has been obtained before disclosure of personal data and ToVs.

8.1 Consent collection

For Activities under a contractual arrangement, the consent, if required according to local requirements and local data protection laws, is obtained via the contract, or in a separate consent agreement that is signed prior to the performance of the Activity in connection with the contract negotiations (consent per HCP/HCO). Without any further notice the agreement is valid for 5 years after signature and will have to be renewed before the next Activity can take place.

For ToVs outside of a contract, e.g. meals during business or sales meetings, the consent, if required according to local requirements and local data protection laws, must be obtained in a separate written letter of consent in cases where such ToVs are reportable.

For Indirect ToVs, the Third Party is responsible for collecting the consent. The Third Party will add to the tracking report if the HCP/HCO has provided his/her consent.

The Organiser provides the HCP Compliance Person in the country of the HCP/HCO with a copy of the signed contract or signed consent agreement if requested by the HCP Compliance Person in case the consent of the HCP/HCO may need to be documented in connection with the disclosure.

8.2 Management of recipient consent withdrawal

Every HCP/HCO has the right to withdraw their consent for the public disclosure. In these cases the payments published under the name of the HCO/HCP has to be removed from the public domain and the amount is added to the aggregate total of payments made to HCP/HCOs

8.3 Management of recipient’s request

If a HCP/HCO does not agree with the published payment information the data is reviewed and if a mistake has been made or inaccurate data was published, the published payment information will be revised once the correct figure has been agreed.

8.4 Partial consent

The HCP Compliance Person in the country of the HCP/HCO will verify that consent has been provided before disclosure of the HCP/HCO Spend Data. If consent has been declined by the HCP/HCO for some ToVs but not for all, all ToVs made for that specific HCP/HCO will be disclosed on an aggregated level.

9 Disclosure form

For the disclosure, the country-specific applicable disclosure templates will be used. The HCP/HCO Spend Data will be disclosed in accordance with the country-specific requirements.

9.1 Date of publication

30 June 2016

9.2 Disclosure platform

www.leo-pharma.ch

9.3 Disclosure language

English and German

10 Disclosure exclusions

The LEO Group has excluded certain ToVs made to HCPs/HCOs from the HCP/HCO Spend Data in accordance with the excluded disclosures stated in the EFPIA Disclosure Code, section 1.02 and in the Swiss Pharma Cooperation Code section 233.

In addition, in some cases the LEO Group provides certain non-financial support to HCPs/HCOs that cannot be assigned a monetary value, and the LEO Group has evaluated that these transfers of non-financial support are not to be considered a transfer of value, see section 10.1. Such transfer will also be excluded from the HCP/HCO Spend Data.

10.1 Non-financial support

Literature publications that relates to LEO originated data and analyses may be developed collaboratively between an HCP (external author) and the LEO Group (internal author). In accordance with Good Publication Practice for Communicating Company-Sponsored Medical Research (GPP3) and as stated in the LEO Group guideline on Scientific, Medical and/or Technical Publications, the LEO Group does not pay honoraria to authors, hence this is

not a ‘fee for service’ set-up, instead authors contribute to these publications freely by using their time and intellectual resources.

To facilitate the development of publications so that the LEO 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 Group or from an external medical writing agency.

Support where the LEO Group provides a medical writer to an HCP in order to assist the HCP in a publication is not considered a ToV to the HCP as 1) no fee-for-service activity occurs whereby the HCP obtains no financial benefit 2) the value of the support provided by the LEO Group to authors is to society at large, the scientific community, patients, and the LEO 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 to be transferred to the HCP; and 3) the support cannot be linked to a specific payment and thereby cannot be tracked.

11 Medical Devices, Over-the-counter Medicines and Emollients

The LEO Group both operates within the field of Medical Devices, Over-the-counter Medicines and Prescription Only Medicines (POM).

For Cross-Border Collaborations, if not directed otherwise by the HCP Compliance Person in the country of the HCP/HCO, any ToV made to an HCP/HCO is captured and tracked, regardless of whether the Activity performed relates to prescription-only medicines, medical devices, over-the-counter medicines or emollients.

12 References

- EFPIA Disclosure Code: EFPIA HCP/HCO Disclosure Code, EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations, Consolidated Version 2014, 06 June 2014 – final editing 11 July 2014.
- Code of conduct of the pharmaceutical industry in Switzerland on cooperation with healthcare professional circles and patient organizations (Pharma Cooperation Code) - of 6 September 2013 (as per: 1 July 2015).