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Methodological Note to HCP/HCO Disclosure Requirements in the LEO Group including specifications from LEO Pharma nv/sa Belgium for Luxembourg

LEO®

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, IFPMA and similar local federations, including including APL and Mdeon, have implemented requirements on how the pharmaceutical industry engages with HCPs and HCOs and requirements to disclose Transfers of Value (ToVs) 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 principle procedure 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 including LEO Pharma nv/sa Belgium, 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

Means made available to institutions, organisations or associations that are made up of healthcare professionals and/or that provide healthcare or conduct research, are only allowed if they are made available for the purpose of supporting healthcare or research and if they do not constitute an inducement to recommend, prescribe, purchase, sell, supply or administer medicinal products.

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

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 or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. This definition of healthcare professional incudes i) any official or employee of a government agency or other organisation (whether in the public or private sector) who may prescribe, purchase, supply, recommend or administer medicinal products and ii) any employee of a pharmaceutical company whose primary occupation is that of a practising healthcare professional. All other em-

ployees of a pharmaceutical company and wholesalers or distributors of medicinal products are excluded from this definition.

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

Any association or organisation, active in the field of healthcare at medical or at scientific level, irrespective of the legal or organisational form, such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations) within the scope of chapter 6 of the Code, with business address, place of incorporation or primary place of operation is in Europe or through which one or more healthcare professionals provide services.

HCP Compliance Person

Locally appointed person 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 ToVs made to an HCP/HCO, including master data associated to the HCP/HCO which is needed for the disclosure

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. The Activity must also occur in the same country.

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).

A LEO unique identifier for the HCP/HCO is assigned to the recipient of the ToV, and the ToV is processed in accordance with the global HCP/HCO financial procedure 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 including master data associated to the HCP/HCO which is needed for the disclosure.

The HCP Compliance Person compiles the HCP/HCO Spend Data from the financial systems, Organiser and Third Party and ensures the consolidation of the HCP/HCO Spend Data in the global LEO HCP/HCO spend tracking and reporting tool. 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 the LEO Group 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.

4.2 Additional Local HCP Compliance Process (if applicable)

The same process in general as described above.
But here it concerns activities, organised in Belgium or abroad (cross-border), and with the participation of HCP/HCO of Luxembourg (meaning, principal professional address or place of incorporation in Luxembourg).

This guide is about Transparency and Disclosure of Transfer of Value, meaning any direct or indirect payments, whether in cash, in kind or otherwise made, whether for promotional purposes or otherwise and in connection with the development and sale of prescription-only medicinal products for human use.
LEO Pharma nv/sa Belgium is strongly encouraged to include, in her contracts with HCPs (or HCO, where applicable), provisions relating to the recipient's consent, prior to disclose any Transfer of Value at the individual level and Activity level.
The HCP/HCO engagements need to be reported and published on the website of LEO Pharma nv/sa Belgium (as non APL member).

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 ensure 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 the LEO Group or upon request by the HCP/HCO.

5.1 Local Disclosure Requirements

- Transfers of value must be disclosed on an annual basis, covering a full calendar year.
- Disclosures shall be made within 6 months after the end of the relevant reporting period.

General Assumptions:

- Language of disclosure is French
- Limited to ToV in connection with the development and sale of prescription-only medicinal products for hu-man use
- Only applicable ToV between the dates selected (date of the payment in the reporting year) will be included in the report
- All amounts will be in the country specific currency, €
- All amounts do not include VAT
- Publication on line during 3 years
- Minimum retention term for underlying records is minimum 5 years after the end of the relevant reporting period

- Consent is obtained per Activity and per HCP/HCO, as this is part of the Agreement
- Data will be disclosed on individual or aggregated basis (based on consent given or not)
- Data will be uploaded according to the principle “one line per HCP” as listed in the EFPIA template, with all ToVs aggregated and according to the LEO spend categories

• HCP: Following transfers of value are reportable:

- Contribution to costs of scientific events: Registration Fees and Travel & Accommodation, cfr. Article 31 of the Code
- Fee for service and consultancy: Fees and agreed related expenses

• HCO: Following transfers of value are reportable:

- Grants and Donations, cfr. Article 38, paragraph 3 of the Code
- Contribution to costs of scientific events: Sponsorship agreements, Registration Fees and Travel & Ac-commodation, cfr. Article 31 of the Code
- Fee for service and consultancy: Fees and agreed related expenses

• R & D: Reportable as aggregate amount for all research payments to HCP or HCO.

The Methodology Guide is not applicable to any ToV in connection Medical devices, Over-The-Counter Medicines or emollients.

5.2 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 unique identifier in all cases except i) when the Activity performed by an HCP/HCO concerns specific Research & Development services as defined in section 5.5 or ii) when the HCP/HCO 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 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.

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, and investigator initiated studies that are retrospective in nature, see section 5.7.

5.3 Local Disclosure Requirements for Individual Disclosure

Individual disclosure for HCPs and HCOs (one line per HCP/HCO), meaning all transfers of value during a year for an individual HCP/HCO will be summed up.

But for each HCP, his/her consent must be obtained before the processing of his/her data. If no consent has been obtained, the disclosure for this HCP will be on an aggregated basis (see section 5.6).
In the case of payment to a hospital (department), it must first be verified whether the money is transferred on the account of the university, the hospital, the department, or a doctor's association active in (or acting as) the de-partment. If the money is transferred on the account of a hospital (i.e. a HCO), disclosure in name of the hospital would suffice according to the "follow the money" rule. However, a further split by department can be considered in order to enhance transparency of such payments.
Before publishing, the bank accounts of hospitals (department) must be checked, whether the bank account be-longs to that specific hospital (department).

5.4 Aggregated Disclosure

The reportable ToV is disclosed on an aggregated level in cases where i) the ToV is related to Research & Devel-opment Activities, see section 5.5 and, ii) the HCP/HCO has not provided his/her/its consent for disclosure, if re-quired, as described in section 8.

5.5 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 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 fees in connection with memberships in a data review/monitoring committee, advisory board or medical con-sulting 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 individ-ual basis.

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

5.6 Local Disclosure Requirements for Aggregated Disclosure

LEO Pharma nv/sa Belgium is strongly encouraged to include provisions relating to the recipient's consent to disclose ToV in his contracts with HCPs (or HCOs, where applicable). When no consent was obtained, the ToVs must be disclosed on aggregate basis.

- R & D: aggregated and yearly amount
- HCP: aggregated, meaning anonymous, if no consent was obtained, prior the processing of his/her data.

When a HCP withdraws his/her consent for the information to be publicly disclosed, then LEO Pharma nv/sa Belgium is obligated to remove payments made to that individual from the public domain. Instead the payments will be added to the aggregate total of payments made to HCPs that have not given consent to disclose and this aggregate figure will be published along with the number of HCPs that did not give consent.
This means that per category of ToV a total amount for all the HCPs combined ("grouped disclosure") will be disclosed, together with the number of the recipients in this category as well as the percentage of aggregate disclosure compared to the total number of recipients disclosed. However, the data must be uploaded (via the template) as one amount per HCP, but of course without further identification of the HCP ("one line per anonymous HCP").

5.7 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 Investigator Initiated Study (IIS) that is prospective in nature is disclosed on an aggregated level under Research and Development.

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 the LEO Group and the LEO 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.

5.8 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 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 according to section 5.2-5.7.

5.9 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 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 5.2-5.7.

5.10 Indirect ToVs

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

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

The LEO 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 this section 5.

5.10.1 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 a LEO entity and an 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 ordinary 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.

5.10.2 Indirect ToV - Distributors

In cases where a distributor engages directly with HCPs/HCOs and the distributor exclusively 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.

5.10.3 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 HCP/HCO engaged on behalf of the LEO Group by the Third Party, and the HCP/HCO does not know the identity of the LEO Group. 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.

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 Group and the LEO 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 Group, the LEO Group requires the Third Party to track the ToV made to the HCP/HCO 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 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.

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.
All amounts to be disclosed as ToV, do not include VAT.

6.3 Date of ToV

For ToVs related to a payment of an invoice, including both fees and reimbursements, the payment date (clearing date) is used for disclosure.

Likewise, for ToVs related to a specific event, e.g. travel and accommodation, which were paid directly by the LEO Group, the payment date (receipt date or credit card transaction date) is used. For flights and hotels booked in advance, the actual flight/hotel date is used whenever possible.

7 Cross-Border Collaborations

Any ToVs made in connection with a Cross-Border Collaboration are tracked via the financial systems in the Paying Country and the LEO unique identifier. The HCP/HCO Spend Data from the Paying Country is uploaded to the global LEO HCP/HCO spend tracking and reporting tool and will be available to the HCP Compliance Person in the country of the HCP/HCO for disclosure. If disclosure is not related to Research and Development, the HCP Compliance Person in the country of the HCP must ensure consent has been collected for the specific HCP/HCO, 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 consent is required as per local law and requirements, the HCP Compliance Person in the country of HCP/HCO ensures that consent from the HCP/HCO is obtained, both in connection with Direct and Indirect ToVs, in accordance with local requirements and local data protection laws.

8.1 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 in accordance with the EFPIA Disclosure Code of all HCP/HCO Spend Data within the given reporting period and for as long as legally possible.

8.2 Management of recipient consent withdrawal

For each HCP, his/her consent must be obtained before the processing of his/her data. The written consent 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 Activity).
But when a HCP withdraws his/her consent for the information to be publicly disclosed, than LEO Pharma nv/sa Belgium is obligated to remove payments made to that individual from the public domain. Instead the payments will be added to the aggregate total of payments made to HCPs that have not given consent to disclose and this aggregate figure will be published along with the number of HCPs that did not give consent.

8.3 Management of recipient's request

HCPs should contact LEO Pharma nv/sa Belgium, in case he/she does not agree with the payment information LEO Pharma nv/sa Belgium holds. Where mistakes have been made or inaccurate data posted, LEO Pharma nv/sa Belgium will revise the payment information once the correct figure has been agreed.
When no legitimate consent is provided, the data cannot be published on an individual basis. If a HCP signed a contract, wherein the consent declaration was not in accordance with the privacy legislation, and his/her individual data were subsequently placed on the website of LEO Pharma nv/sa Belgium (as non APL member), it must be considered that this was done without his/her consent. Hence, the data must be retroactively removed.

8.4 Partial consent

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

9 Disclosure form

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

9.1 Date of publication

HCP/HCO engagements to be reported annually, before June 1st, and made public within 6 months after the end of the relevant reporting year.

9.2 Disclosure platform

For annual disclosure, publication on the website of LEO Pharma nv/sa Belgium (as no APL member).

9.3 Disclosure language

Language of disclosure is French.

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.

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 also operates within the field of Medical Devices, Over-the-counter Medicines and emollients.

The HCP Compliance Person in the country of the HCP/HCO, does capture and track only ToV of local Activities/Events or Cross-Border Collaborations, made to an HCP/HCO or Third Party, if ToV is in connection with the development and sale of Prescription Only Medicinal Products for human use.

12 Retention

The LEO Group will maintain the relevant records of the HCP/HCO Spend Data for a minimum of 5 years after the end of the relevant reporting period, unless a shorter period is required under applicable national data privacy or other laws or regulations.

13 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.