LEO Pharma Healthcare Compliance Protocol for Third Parties

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1 Purpose of the Healthcare Compliance Protocol

The purpose of this Healthcare Compliance Protocol is to outline the specific requirements that you, as a Third Party, must adhere to when interacting with HCPs, HCOs, Patient Organizations and/or Patients ("Healthcare Partners") in connection with services performed for or on behalf of LEO Pharma.

For interactions with Healthcare Partners, additional requirements or internal approval procedures of LEO Pharma apply. The internal approval process may take up to 35 business days. Furthermore, the interaction with a Healthcare Partner may require additional local approval by e.g. the authorities.

You are not allowed to interact with Healthcare Partners from countries where the compliance requirements have not been specified in the agreement or otherwise have been agreed in writing.

2 Engagements with Healthcare Partners

Any engagements that Third Parties have with Healthcare Partners in connection with services performed for or on behalf of LEO Pharma must comply with the ethical codes of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) & the European Federation of Pharmaceutical Industries and Associations (EFPIA) to which LEO Pharma is committed, as well as any other applicable national laws, requirements and/or codes. This means that you must ensure that:

- Healthcare Partners are only engaged if there is a documented legitimate need for the services to be performed by the Healthcare Partner(s)
- the Healthcare Partner(s) chosen to perform the services are selected based on appropriate qualifications and credential the Healthcare Partner, e.g. check company registration, authorization registries, applicable debarment lists, inspection reports etc, see example of US credentialing of HCPs in section 2.1
- the number of Healthcare Partners retained is not greater than the number reasonably necessary to achieve the identified need
- fees and expenses are reasonable and constitute fair market value
- travel and hospitality provided to Healthcare Partners or representatives of HCOs/Patient Organizations comply with this Healthcare Compliance Protocol
- Healthcare Partners are only engaged for services/activities (or otherwise provided funding) for the purpose of supporting healthcare or research
- engagements of Healthcare Partners never constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products
- a contract with the Healthcare Partner is signed prior to initiating the service/activity
- in countries with disclosure requirements, the right to process and transfer to LEO Pharma data relating to the Healthcare Partner is obtained. Data relating to Healthcare Partners includes, but is not limited to name, address, license number, profession, type of services provided, payment information and data on transfers of value ("Data")

- in countries with consent requirements, the Healthcare Partner is informed that LEO Pharma may collect consent for the disclosure of Data in accordance with local requirements directly from the Healthcare Partner at any given point in time prior to disclosure
- Any transfers of value made to the Healthcare Partner is captured and tracked and that consent for disclosure is collected from the Healthcare Partner, if requested by LEO Pharma.
- Provide the Healthcare Partner with the LEO Pharma Privacy Policy (available here: https://leo-pharma.com/privacy-policy) if personal data concerning the Healthcare Partner is provided to LEO Pharma.

2.1 Credentialing HCPs

The HCPs must be credentialed in accordance with any local processes for fee for service arrangements with HCPs, e.g. checks against authorization registries, applicable debarment lists, inspection reports etc.

As an example, the following checks must be made for HCPs from the USA:

1. Primary Source License status (State licensure data base)
2. Google search
3. OIG Exclusions Database: The Department of Health and Human Services, Office of Inspector General List of Excluded Individuals/Entities US DHHS Office of the Inspector General: https://exclusions.oig.hhs.gov/
4. General Services Administration's List of Parties Excluded from Federal Programs US General Services Administration: GSA System for Award Management (SAM): https://www.sam.gov/SAM/
5. Food and Drug Administration's FDA Debarment List (Drug Product Applications): https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/fda-debarment-list-drug-product-applications
6. FDA Inspection Classification Database Search: https://www.accessdata.fda.gov/scripts/inspsearch/
    - Definitions for Codes: https://www.accessdata.fda.gov/scripts/inspsearch/
7. FDA Clinical Investigators - Disqualification Proceedings: https://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&previewMode=true&displayAll=true
8. FDA Clinical Investigator Inspection List: https://www.fda.gov/vaccines-blood-biologics/compliance-actions-biologics/clinical-investigator-inspection-list-l-p
9. Office of Foreign Assets Control: https://sanctionssearch.ofac.treas.gov/
10. Board Certification (where applicable) www.certificationmatters.org
11. Sex offender federal database checks. https://www.nsopw.gov/

3 Travel and Hospitality

All forms of travel and hospitality offered to Healthcare Partners and representatives of HCOs/Patient Organizations must be solely related to the main purpose of the service/activity to be performed.

Hospitality must:

- be appropriate and within a reasonable level
- be strictly limited to travel, meals and accommodation

- only be provided to persons who qualify as meeting participants/consultants in their own right
- not include any sponsoring or organizing of entertainment events (e.g. sporting or leisure)

Accommodation and venue must:

- maximum be 4 stars
- not be renowned for their entertainment facilities
- not be extravagant or luxurious, e.g. resorts

Flights:

- For professional events to which Healthcare Partners or representatives of HCOs/Patient Organizations have been invited as delegates, economy class must be used. For overseas destinations, economy plus (i.e. "economy flex" or "premium economy") may be used if approved by LEO Pharma.
- For consultants providing professional services, economy class or economy plus should be used. Business class may be used for overseas destinations of more than 6 hours duration if approved by LEO Pharma.

Reimbursement of expenses must only be made for expenses actually incurred and only against receipts.

4 Tracking the Transfers of Value (HCPs, HCOs and Patient Organizations)

In order for LEO Pharma to be able to live up to its obligations relating to transparency of transfers of value made to HCPs, HCOs and Patient Organizations by Third Parties, you must:

- insert HCP/HCO/Patient Organization relevant Data into respectively the **LEO Pharma Third Party Transparency Sheet (HCP/HCO)** and/or the **LEO Pharma Patient Organization Transparency Sheet**, provided by LEO Pharma
- verify the accurateness and completeness of the Data inserted in the transparency sheet(s)
- as agreed in the contract with LEO Pharma, send the duly completed transparency sheet(s) with the HCP/HCO/Patient Organization transfers of value no later than 30 days after a transfer of value has been made to a HCP, HCO and/or Patient Organization, including documentation as requested by LEO Pharma, to the designated LEO Pharma contact person
- inform LEO Pharma in case of disputes from HCPs/HCOs/Patient Organizations on the disclosed data

5 Additional Requirements for Patient Interactions

In some countries, interactions directly between a pharmaceutical company and individual patients are prohibited or restricted by law, and therefore it is **not even allowed to contact a Patient until guidance from LEO Pharma has been provided**. Generally, a Patient should be contacted through a Patient Organization, an HCP or an HCO.

Contracts for Patients may contain sensitive or special categories of personal data which requires a higher level of data protection. Before exchanging a contract with a Patient by e-mail, you must carefully check that the recipient e-mail is correct, and the e-mail must be encrypted.

6 Double-blinded activities

A double-blinded activity is an activity where the identity of LEO Pharma is not known to the Healthcare Partner and the identity of the Healthcare Partners is not known (and will not be made known) to LEO Pharma.

For double-blinded activities, same standards as described in sections 2 and 3 apply, except for the fact that:

- flights and accommodation cannot be provided in connection with double-blinded activities
- disclosure on an individual basis is not required due to the anonymity of the Healthcare Partner and LEO Pharma, hence section 4 of this Healthcare Compliance Protocol does not apply

As a Third Party, you are responsible for credentialing the Healthcare Partner who remains anonymous to LEO Pharma.

In some countries, additional requirements may apply for double-blinded activities, e.g. for US HCPs, you must:

- ensure that no HCPs licensed by the states of Vermont or Minnesota participate in a market research activity
- determine if the HCPs are employed by federal or state governments that prohibit the HCP's participation in market research
- credential the HCP based on the following:
    - OIG Exclusions Database: The Department of Health and Human Services, Office of Inspector General List of Excluded Individuals/Entities US DHHS Office of the Inspector General: https://exclusions.oig.hhs.gov/
    - General Services Administration's List of Parties Excluded from Federal Programs US General Services Administration: GSA System for Award Management (SAM): https://www.sam.gov/SAM/
    - Food and Drug Administration's FDA Debarment List (Drug Product Applications): https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/fda-debarment-list-drug-product-applications
    - Office of Foreign Assets Control: https://sanctionssearch.ofac.treas.gov/

7 Definitions

The definitions given in the Agreement to which this Healthcare Compliance Protocol is enclosed, shall have the same meaning when used in this Healthcare Compliance Protocol, unless the definition in question is explicitly defined in this Healthcare Compliance Protocol.