

Methodology document for CSL Seqirus Germany

30 June 2024

Introduction

This core methodology note provides guidance on the Seqirus-specific decisions that relate to how we collect, aggregate, and report disclosure data relating to:

- Individual healthcare professionals (HPCs)
- Healthcare organizations (HCOs)
- Patient Organizations (POs)

This note outlines the global position from Seqirus in relation to the EFPIA Disclosure Code. Practice in each country affiliate will depend on local laws and requirements of the local industry code.

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Section 1: Data collection and reporting	<ul style="list-style-type: none"> • Company-specific decisions on how we gather, analyze, and report data
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Item	Seqirus decision
Tax and VAT	We will publish the total Transfer of Value paid by Seqirus, or its 3 rd Party Contractor, including VAT where applicable
Transfer of Value dates	<p>We will disclose payments and TOV based on the data on the reporting period within which the TOV was made.</p> <p>For example, this is:</p> <ul style="list-style-type: none"> • The date payment was made to the recipient by check or wire transfer, such as fees paid, grants, donations, and sponsorship <p>Or, where a payment is not directly made, such as:</p> <ul style="list-style-type: none"> • The date the TOV took place, e.g. for an event an HCP participated in, their travel and accommodation <p>We will disclose payments and TOV made by a 3rd Party Contractor in the reporting period within which the event occurred, provided the 3rd Party Contractor has made payment to the HCP.</p>
Transfer of Value when a contract extends over several years	Where a contract with an HCP or HCO runs for a number of years, we would publish the actual payment made during the relevant reporting period.
Transfer of Value if the HCP does not attend or an event is cancelled	<p>We will only attribute any TOVs that are incurred and can be reasonably associated to the HCP.</p> <p>In the circumstances when a flight or accommodation is booked but the event is cancelled, or the HCP does not attend, no TOV will be attributed to that HCP.</p>
Cross-border Transfers of Value	<p>We collate all cross-border TOVs to HCPs and HCOs.</p> <p>We report the transactions in the disclosure report for the country where the recipient has its principal practice in Europe.</p>
Currency	<p>All payments and TOV will be disclosed in the local currency of the Seqirus reporting entity.</p> <p>If the original payment is made in another currency, it will be converted using the Seqirus-approved exchange rate applicable at the time the payment or TOV was made.</p> <p>e.g. If Seqirus USA makes a payment in USD to an HCP located in Spain, the payment amount will be converted to Euros for Spanish reporting.</p>

Section 2: Managing Consent	<ul style="list-style-type: none"> • How we manage the disclosure consent process for Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs)
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Consent action	Seqirus decision
Consent status	<p>We will only collect data that is:</p> <ul style="list-style-type: none"> • Allowed to be collected according to data privacy law • Explicitly provided by HCP or HCO for disclosure purposes <p>Before disclosure, all HCPs will be informed of our data privacy policy and asked to provide consent to us for publishing any details of any TOV they receive from us unless disclosure is not subject to consent under local laws. This will be transparently worded in a privacy notice and a consent statement.</p> <p>If this consent is denied, we will only publish the total value of the TOV without specifying the name of the recipient.</p>
Managing partial of unknown consent	<p>Consent requirements vary between countries.</p> <p>In general, we will only disclose the TOV value under the individual section of the disclosure report if the HCP gives his/her consent for reporting on all TOVs.</p> <p>In all other cases, we will aggregate the total amount of the TOV where:</p> <ul style="list-style-type: none"> • An HCP only gives partial consent to publication • We do not receive written notification of consent for all TOV
Revocation of consent	<p>Consent requirements vary between countries.</p> <p><u>Before the disclosure report is published</u></p> <p>If an HCP revoked his/her consent before the report is published, we will update the data and include the TOV in the aggregated section of the disclosure report.</p> <p><u>After the report is published</u></p> <p>If the HCP revoked his/her consent after the report is published, we will update the information at the first reasonable time.</p>
Number of individuals who have agreed to TOVs being disclosed and number in aggregate	<p>For 2023 data, 20 HCPs have agreed to TOVs being disclosed individually, and 23 are disclosed in aggregate, so 54% of HCPs are in aggregate. No HCPs have disclosed some TOVs individually and some in aggregate, as we will only disclose the TOV under the individual section of the disclosure report if the HCP gives his/her consent for reporting on all TOVs.</p>

Section 3: Managing report submission	<ul style="list-style-type: none"> • How and where we report disclosure
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Reporting action	Seqirus decision
Disclosure method	We will publish the disclosure report for Seqirus companies located in Germany, Italy, Spain and Switzerland on the following Seqirus corporate website: https://www.csl.com/we-are-csl/our-businesses-and-products/disclosures
Disclosure period	Each reporting period will cover a full calendar year, unless the local association sets a different period.
Retention period – public	The disclosure report will remain in the public domain for at least three (3) years.
Retention period – record-keeping	We will ensure that all the TOV required to be disclosed are documented and retained for a minimum of five (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.

Section 4: Categories for disclosure	<ul style="list-style-type: none"> • Which types of payment of Transfer of Value are included in our disclosure report
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Donations, grants, R&D, fees for service and consultancy

Description	Types of Transfer of Value involved
Donations and grants to HCOs	Donations and Grants to HCOs that support healthcare, including donations, grants, and benefits in kind, to institutions, organizations, or associations that: <ul style="list-style-type: none"> • are comprised of HCPs And/or <ul style="list-style-type: none"> • provide healthcare service, professional guidelines, consensus statements, scientific meetings and patient support
Fees for service and consultancy - Fees	TOV resulting from or related to contracts between member companies and institutions, organizations, associations, or HCPs under which such institutions, organizations, associations or HCPs provide any type of services to Seqirus, or any other type of funding not covered in the previous categories. For example: <ul style="list-style-type: none"> • Speaker fees • Speaker training • Data analysis • Development of educational materials • General consulting/advising
Fees for service and consultancy <ul style="list-style-type: none"> • Related expenses agreed in the fee for service of consultancy contract 	Related expense agreed in the fee for service or consultancy contract. For example: <ul style="list-style-type: none"> • Fees for airfare, train, boat, or ferry (including booking fees) • Car rental, care service, taxi transfers • Parking fees • Petrol • Tolls
Research and development (Disclosed at an aggregate level)	Research and development TOV to HCPs/HCOs associated with: <ul style="list-style-type: none"> • Non-clinical (good laboratory practice [GLP]) • Clinical trials in Phase I to Phase IV • Investigator-sponsored studies • Non-interventional studies

Donations, grants, R&D, fees for service and consultancy

Description	Types of Transfer of Value involved
<p>Contribution to costs of events (as per HCP code):</p> <p>1. Sponsorship agreements</p>	<p>Events include:</p> <ul style="list-style-type: none"> • All scientific professional meetings, congresses, conferences, symposia and other similar events • Sponsorships with HCOs/third party appointed by and HCO to manage and event <p>For example:</p> <ul style="list-style-type: none"> • Rental of booths at an event • Advertisement space (in paper, electronic, or other format) • Satellite symposia at a congress • Sponsoring of speakers/faculty • Drinks or meals provided by the organizers (where included in the Sponsorship Agreement) • Courses provided by an HCO (where Seqirus does not select the individual HCPs participating)
<p>Contribution to cost of events:</p> <p>1. Registration fees</p>	<p>Registration fees related to attending a congress or symposia</p>
<p>Contribution to cost of events:</p> <p>2. Travel and accommodation</p>	<p>Travel in relation to attending a congress or symposia</p> <p>Accommodation in relation to attending a congress or symposia</p> <p>For Example:</p> <ul style="list-style-type: none"> • Fees for airfare, train, boat, or ferry (including book fees) • Car rental, car service, taxi transfers • Parking fees • Petrol • Tolls

Section 5:
Definitions

- List of key terms

Term	Definition
Healthcare Professional (HCP)	<p>Any natural person that:</p> <ul style="list-style-type: none"> • Is a member of the medical, dental, pharmacy, or nursing professions • While carrying out his or her professional activities, may prescribe, purchase, supply, recommend, or administer a medicinal product • Works with their primary practice, principal professional address, or place of incorporation in Europe
Healthcare Organization (HCO)	<p>Any legal person/entity that:</p> <ul style="list-style-type: none"> (i) Is a healthcare, medical, or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university, or other teaching institution or learned society (except for patient organizations within the scope of Article 21) (ii) With a business address, place of incorporation, or primary place of operation in Europe <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> (iii) Through which one of more HCPs provide service
Patient Organization (PO)	<p>A non-for-profit legal person/entity (including the umbrella organization to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers</p>
Transfer of Value (TOV)	<p>Direct and indirect transfer of value, whether in cash, in kind, or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of generic or branded prescription-only medicinal products exclusively for human use.</p> <p>Direct TOV are those made directly by Seqirus for the benefit of a recipient</p> <p>Indirect TOV are those made by a third party on behalf of Seqirus for the benefit of a recipient, for example travel or accommodation to an event organized by and external agency.</p>

Full definitions can be found in the EFPIA Disclosure Code, Definitions.

Section 6: Sources of further information	<ul style="list-style-type: none"> • Resources from EFPIA member organizations • Your local Seqirus contact
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Resources from EFPIA Member Organizations

- **Germany:** <https://www.fsa-pharma.de/de/kodizes/ueberblick/kodizes-auf-einen-blick>

How we can help at Seqirus

For specific questions relating to this year’s report and process	<ul style="list-style-type: none"> • Contact your country’s transparency department Andrea Jenner (andrea.jenner@seqirus.com) or transparency.reporting@seqirus.com
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