

# Methodology document for CSL Seqirus Ireland

27th March 2025

#### **Introduction**

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

- Individual healthcare professionals (HCPs)
- Healthcare organisations (HCOs)
- Other relevant decision makers (ORDMs)

This note outlines the global position from CSL 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.

Transfers of Value made to Patient Organisations and the e Public, Including Patients and Journalists will continue to be disclosed separately on the CSL Seqirus website (<u>https://www.csl.com/we-are-csl/our-businesses-and-products/disclosures#Seqirus</u>)

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Section 1:	Company-specific decisions on how we gather, analyse, and report data
Data collection and reporting	

ltem	CSL Seqirus decision
Tax and VAT	We will publish the total Transfer of Value paid by CSL Seqirus, or its 3 <sup>rd</sup> Party Contractor, including VAT where applicable
Transfer of Value dates	We will disclose payments and TOV based on the data on the reporting period within which the TOV was made.
	For example, this is:
	• The date payment was made to the recipient by check or wire transfer, such as fees paid, grants, donations, and sponsorship
	Or, where a payment is not directly made, such as:
	• The date the TOV took place, e.g. for an event an HCP participated in, their travel and accommodation
	We will disclose payments and TOV made by a 3 <sup>rd</sup> Party Contractor in the reporting period within which the event occurred, provided the 3 <sup>rd</sup> party has made payment to the HCP.
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	We will only attribute any TOVs that are incurred and can be reasonably associated to the HCP.
if the HCP does not attend or an event is cancelled	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.
Cross-border	We collate all cross-border TOV to HCPs and HCOs.
Transfers of Value	We report the transactions in the disclosure report for the country where the recipient has its principal practice in Europe.
Currency	All payments and TOV will be disclosed in GBP.
	If the original payment is made in another currency, it will be converted using the CSL Seqirus- approved exchange rate applicable at the time the payment or TOV was made.
	e.g. If CSL Seqirus USA makes a payment in USD to an HCP located in the UK, the payment amount will be converted to GBP for UK reporting.

Section 2: Managing Consent	<ul> <li>How we manage the disclosure consent process for Healthcare Professionals (HCPs), and Other Relevant Decision Makers (ORDM)</li> </ul>
Consent action	Seqirus decision
Consent status	We will only collect data that is:
	<ul> <li>Allowed to be collected according to data privacy law</li> <li>Explicitly provided by HCP or HCO for disclosure purposes</li> </ul>
	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.
	If this consent is denied, we will only publish the total value of the TOV without specifying the name of the recipient.
Managing partial	Consent requirements vary between countries.
of unknown consent	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 <b>all</b> TOVs.
	In all other cases, we will aggregate the total amount of the TOV where:
	<ul> <li>An HCP only gives <b>partial</b> consent to publication</li> <li>We do not receive written notification of consent for all TOV</li> </ul>
Revocation of	Consent requirements vary between countries.
consent	Before the disclosure report is published
	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.
	After the report is published
	If the HCP revoked his/her consent after the report is published, we will update the information at the first reasonable time.
Number of individuals who have agreed to TOVs being disclosed and number in aggregate	For 2024 data, 6 HCPs have agreed to TOVs being disclosed individually, and 2 are disclosed in aggregate, so 25% 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.

Section 3:	How and where we report disclosure
Managing report submission	

Reporting action	CSL Seqirus decision
Disclosure method	CSL Seqirus will publish the disclosure report for any HCP, ORDM, or HCO located in the UK on the ABPI Disclosure portal – hppts://portal.disclosureuk.org.uk
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 must be 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

• Which types of payment of Transfer of Value are included in our disclosure report

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:
	are comprised of HCPs
	And/or
	• 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 CSL Seqirus, or any other type of funding not covered in the previous categories.
	For example:
	<ul> <li>Speaker fees</li> <li>Speaker training</li> <li>Data analysis</li> <li>Development of educational materials</li> <li>General consulting/advising</li> </ul>
Fees for service	Related expense agreed in the fee for service or consultancy contract.
and consultancy	For example:
<ul> <li>Related expenses agreed in the fee for service of consultancy contract</li> </ul>	<ul> <li>Fees for airfare, train, boat, or ferry (including booking fees)</li> <li>Car rental, care service, taxi transfers</li> <li>Parking fees</li> <li>Petrol</li> <li>Tolls</li> </ul>
Research and development	Research and development TOV to HCPs/HCOs associated with:
	Non-clinical (good laboratory practice [GLP])
(Disclosed at an	Clinical trials in Phase I to Phase IV
aggregate level)	<ul> <li>Investigator-sponsored studies</li> <li>Non-interventional studies</li> </ul>

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

Description	Types of Transfer of Value involved
Contribution to costs of events (as per HCP code): 1. Sponsorship agreements	<ul> <li>Events include:</li> <li>All scientific professional meetings, congresses, conferences, symposia and other similar events</li> <li>Sponsorships with HCOs/third party appointed by and HCO to manage and event</li> <li>For example:</li> <li>Rental of booths at an event</li> <li>Advertisement space (in paper, electronic, or other format)</li> <li>Satellite symposia at a congress</li> <li>Sponsoring of speakers/faculty</li> <li>Drinks of meals provided by the organizers (where included in the Sponsorship Agreement)</li> <li>Courses provided by and HCO (Where CSL Seqirus does not select the individual HCPs participating)</li> </ul>
Contribution to cost of events: 1. Registration fees	Registration fees related to attending a congress or symposia
Contribution to cost of events: 2. Travel and accommodation	<ul> <li>Travel in relation to attending a congress or symposia</li> <li>Accommodation in relation to attending a congress or symposia</li> <li>For Example: <ul> <li>Fees for airfare, train, boat, or ferry (including book fees)</li> <li>Car rental, car service, taxi transfers</li> <li>Parking fees</li> <li>Petrol</li> <li>Tolls</li> </ul> </li> </ul>

## Section 5: • List of key terms Definitions • List of key terms

**CSL Seqirus** 

Term	Definition
Healthcare Professional (HCP)	A person of any of the following classes:(i)Registered medical practitioners(ii)Registered dentists(iii)Registered pharmacists(iv)Registered nurses
Healthcare Organization (HCO)	Any healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for a Patient Organisation within the scope of Annex III of this Code) whose business 6 IPHA CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY, V8.6 address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more HCPs or other relevant decision makers provide services.
Transfer of Value	Direct and indirect TOV, 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.
	Direct TOV are those made directly by CSL Seqirus for the benefit of a recipient Indirect TOV are those made by a third party on behalf of CSL Seqirus for the benefit of a recipient, for example travel or accommodation to an event organized by and external agency.

Full definitions can be found in the IPHA Code of Practice for the Pharmaceutical Industry Edition 8.6, Section 1.

Section 6:	Resources from EFPIA [Insert your local code if required]	
Sources of further information	Your local CSL Seqirus contact	

### **Resources from IPHA**

Support relating to the Disclosure Code is regularly updated on the website of the Irish Pharmaceutical healthcare Association (IPHA):

• https://www.ipha.ie/codes-of-practice/

#### How we can help at CSL Seqirus

For specific	Contact your country's transparency department
questions relating to this	Andrea Jenner (andrea.jenner@.seqirus.com) or transparency.reporting@seqirus.com
year's report and	
process	