

CSL BEHRING DISCLOSURE METHODOLOGY DOCUMENT

COVER PAGE

Methodology document for CSL Behring UK

7th March 2019

Introduction

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

- individual healthcare professionals (HCPs)
- healthcare organisations (HCOs)

This note outlines the global position from CSL Behring 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, analyse and report data
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Item	CSL Behring decision
Tax and VAT	We will publish the total Transfer Of Value paid by CSL Behring including VAT where applicable
Transfer of Value dates	<p>We will disclose payments and TOV based on the date on the reporting period within which the TOV was actually made.</p> <p>For example, this is:</p> <ul style="list-style-type: none"> the date payment was wired to the recipient, 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 a TOV took place, e.g. for an event an HCP participated in, their travel and accommodation
Transfer Of Value when a contract extends over a number of years	Where a contract runs for a number of years with an HCP or HCO, 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 HCP does not attend, no TOV will be attributed to that HCP.</p>
Cross-border Transfers Of Value	<p>We collate all cross-border TOV 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 local currency.</p> <p>If the original payment is made in another currency, it will be converted using the CSL Behring-approved exchange rate applicable at the time the TOV or payment was made.</p>

**Section 2:
Managing consent**

- How we manage the disclosure consent process for Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs)

Consent action	CSL Behring 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 an HCP or HCO for disclosure purposes <p>Before disclosure, all HCPs (and HCOs where applicable) will be informed of our Disclosure Code policy and asked to provide consent.</p> <p>For example, this will be transparently worded in a consent statement or contract.</p> <p>We require all HCPs to provide their consent to us for publishing any details of any TOV they receive from us.</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 or unknown consent	<p>Consent requirements vary between countries.</p> <p>In general, only if the HCP gives his/her consent for reporting on all TOV will we then disclose that value under the individual section of the disclosure report.</p> <p>In all other cases, we will normally aggregate the total amount of the TOV, for example 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> 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> 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 2018 data 158 HCPs have agreed to ToVs being disclosed individually and 37 are disclosed in aggregate, so 23% 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

- How and where we report disclosure

Reporting action	CSL Behring decision
Disclosure method	We will publish disclosure reports for CSL Behring UK on the ABPI Disclosure portal - https://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 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 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 or Transfer Of Value are included in our disclosure report

Donations, grants, R&D, fees for services 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, organisations or associations that: <ul style="list-style-type: none"> • are comprised of HCPs and/or • provide healthcare
Fees for service and consultancy <ul style="list-style-type: none"> - Fees 	TOV resulting from or related to contracts between member companies and institutions, organisations, associations or HCPs under which such institutions, organisation, association or HCPs provide any type of services to CSL Behring, 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 education materials • General consulting/advising
Fees for service and consultancy <ul style="list-style-type: none"> - Related expenses agreed in the fee for service or consultancy contract 	Related expenses agreed in the fee for service or consultancy contract For example: <ul style="list-style-type: none"> • Fees for airfare, train, boat or ferry (incl. booking fees) • Car rental, car services, 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

Event-related payments

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 an HCO to manage an 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 organisers (where included in the Sponsorship Agreement) • Courses provided by an HCO (where CSL Behring 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 (incl. booking fees) • Car rental, car services, taxi transfers • Parking fees • Petrol • Tolls

**Section 5:
Definitions**

- List of key terms

Term	Definition
Healthcare Professional (HCP)	<p>Any 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 Organisation (HCO)	<p>(i) A healthcare, medical or scientific association or organisation (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 the PO Code)</p> <p>(ii) With a business address, place of incorporation or primary place of operation in Europe OR</p> <p>(iii) Through which one or more HCPs provide services</p>
Transfer Of Value	<p>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.</p> <p>Direct TOV are those made directly by CSL Behring for the benefit of a recipient.</p> <p>Indirect TOV are those made by a third party on behalf of CSL Behring for the benefit of a recipient, for example travel or accommodation to an event organised by an external agency.</p>

Full definitions can be found in the EFPIA Disclosure Code, Section 6.

**Section 6:
Sources of further
information**

- Resources from EFPIA [Insert your local code if required]
- Your local CSL Behring contact

Resources from ABPI

Support relating to the Disclosure Code is regularly updated on the website of The Association of the British Pharmaceutical Industry (ABPI):

- www.abpi.org.uk

How we can help at CSL Behring

For specific questions relating to this year's report and process

- Contact your country's transparency department at Linda Keeble (linda.keeble@cslbehring.com) or email complianceuk@cslbehring.com