Daiichi Sankyo UK Limited

Methodology notes for the Disclosure of Transfers of Value

Reporting Year: 2021

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I. GENERAL

1. Introduction

1.1. Daiichi Sankyo's mission is to contribute to the enrichment of quality of life around the world through the creation of innovative pharmaceuticals and through the provision of pharmaceuticals addressing diverse medical needs. To accomplish this, Daiichi Sankyo regularly work with healthcare professionals (HCPs), healthcare organisations (HCOs), and other relevant decision makers (ORDMs).

1.2. For example, Daiichi Sankyo may invite HCPs to speak at medical educational events or seek their advice and expertise on our services to patients and the healthcare community. Individuals and organisations may be compensated for providing these services to the industry and these payments are referred to as Transfers of Value (ToV).

1.3. ToV can also include, for example, sponsoring an individual to attend a medical congress by meeting their registration and reasonable travel and accommodation costs. Organisations may be provided with funding to help with education for healthcare professionals.

1.4. The requirement to disclose ToV is part of the requirements of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Association of the British Pharmaceutical Industry Code of Practice (ABPI).

1.5. The EFPIA Disclosure Code provides a common basis for reporting across Europe in relation to ToV. For more information on the EFPIA Disclosure Code please visit https://www.efpia.eu/relationships-code/disclosure-of-payments-to-hcps/

1.6. Daiichi Sankyo wholeheartedly supports the requirements of both EFPIA and the ABPI Code as we truly believe it will prove our interactions can stand up to any scrutiny. The Code will have a significant impact on improving transparency in relation to the financial details of interactions between Daiichi Sankyo UK and HCPs, ORDMs and HCOs, showing that these interactions are legitimate and with the purpose of improving patient outcomes. In taking this responsible step, we are ensuring the open co-operation between pharmaceutical companies and HCPs/ORDMs/HCOs continues for the benefit of patients.

1.7. For the UK, disclosures of ToV made to HCPs, ORDMs and HCOs during the calendar year 2021 will be available on www.disclosureuk.org.uk from 30th June 2022. The report will be made available for three years and will be amended if required.

This Methodological Note supports disclosures for HCPs and ORDMs made on a named and aggregate basis.

2. Purpose of the Methodological Note

The Methodological Note documents the disclosure methodologies and business decisions applied by Daiichi Sankyo UK in order to identify, collect and report Transfers of Value in the United Kingdom.

When there is uncertainty about whether a ToV disclosure is required, Daiichi Sankyo UK makes a full disclosure. Only if a ToV is clearly out of scope for ABPI disclosure will it be excluded from the published report.

3. Definitions

Term	Definition
Transfer of Value (ToV).	**'Transfer of Value'** (ToV) means a direct or indirect Transfer of Value, whether in cash, in kind or otherwise, in connection with the development or sale of medicines. A direct Transfer of Value is one made directly by a company to the recipient and for the benefit of a recipient. An indirect Transfer of Value is one made by a third party on behalf of a company for the benefit of a recipient or through an intermediate and where the company knows or can identify the recipient that will benefit from the Transfer of Value. Where activities of a non UK entity/affiliate results in ToV for a UK based HCP, ORDM or HCO, the TOV is required to be reported by Daiichi Sankyo UK.
Health Professional (HCP).	**'Health professional'** includes any member of the medical, dental, pharmacy or nursing profession and any other person who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine. In relation to the annual disclosure of ToV (Clause 28 of the ABPI Code of Practice), the term also includes any employee of a pharmaceutical company whose primary occupation is that of a practising health professional. UK HCPs are reportable recipients for ToV purposes.
Other Relevant Decision Makers (ORDMs).	**'Other relevant decision makers'** (ORDM) particularly includes someone with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who is not a health professional. UK ORDMs are reportable recipients for ToV purposes.

Healthcare Organisation (HCO).	**'Healthcare organisation'** (HCO) means either a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business
	address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more health professionals or other relevant decision makers provide services. If a healthcare organisation consists of only one health professional or other relevant decision maker, then it would be subject to the requirements in the Code regarding individual health professionals. If an organisation has characteristics of both a HCO and a patient organisation, reporting will be according to the nature of the ToV beneficiaries. UK HCOs are reportable recipients for ToV purposes.
Research and Development Transfers of Value	**'Research and Development Transfers of Value'** means, for the purposes of disclosure, ToV to health professionals or healthcare organisations related to the planning or conduct of: I. Non-clinical studies (as defined in the OECD Principles on Good Laboratory Practice) II. Clinical trials (as defined in Regulation 536/2014) III. Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, health professionals specifically for the study.
Third party	**'Third party'** means a legal person/entity or individual that represents a company or interacts with other parties on behalf of a company or relating to a company's medicine, such as distributors, wholesalers, consultants, contract research organisations, professional congress organisers, contracted sales forces, market research companies, advertising agencies, media buyers, providers of services related to events, public relations services, non-clinical services, non-interventional studies management services etc.
Clinical Research Organisation	'**Clinical Research Organisations'** (CRO) are service organisations that provide support to the pharmaceutical and biotechnology industries in the form of outsourced pharmaceutical research services (for both drugs and medical devices). CROs range from large, international full service organizations to small, niche specialty groups and can offer their clients the experience of moving a new drug or device from its conception to regulatory marketing approval without the drug sponsor having to maintain a staff for these services.

4. Cross Border Engagements and Payments

All UK based HCPs, ORDMs and HCOs that have received reportable ToV as a result of interactions with any Daiichi Sankyo operation will have the resulting ToV reported in the UK.

All disclosures are made in the country in which the HCP / ORDM primarily practices or in which the HCO has its legal domicile.

5. Currency

Where payments were made in a currency other than pound sterling (GBP), the exchange rate will vary according to the date on which the conversion calculation was made. For general purposes, the conversion rate should be regarded as the average monthly exchange rate when the event took place.

6. Value Added Tax (VAT)

Treatment of VAT depends on the TOV. Where DSUK hasn't claimed the VAT back, the gross figure i.e. including the VAT will be disclosed. Where DSUK has claimed the VAT back, we disclose the net value, i.e., excluding the VAT.

7. Co-marketing projects

Where Daiichi Sankyo jointly markets a product with another pharmaceutical company, Daiichi Sankyo will only declare those ToV made directly from Daiichi Sankyo bank accounts and listed in the company records as part of its normal business operations; or by third parties engaged by Daiichi Sankyo to act on its behalf. ToV made by its co-marketing partners will be disclosed separately by those organizations.

8. Reporting periods

8.1. Daiichi Sankyo will disclose the details of ToV in the year the ToV to a HCP, ORDM or HCO occurs. For honoraria this may mean,
for example, that some projects taking place at the end of the year will be disclosed as part of the next annual reporting year because the payment does not occur until January when the invoice has been received and settled. ToV for meetings are deemed to have occurred on the first date of the event.

8.2. Where contracts are valid for more than one year, and subject to milestone payments, the ToV is captured and disclosed in the year where payment against the achieved milestone(s) was made.

9. Partial/Non-attendance of HCPs and ORDMs and canceled events

9.1 ToV in the event of non-attendance at a Daiichi Sankyo organised meeting.

- Where Daiichi Sankyo has paid travel or accommodation on behalf of a HCP/ORDM to attend a Daiichi organised meeting, and the HCP/ORDM is not able to attend the meeting, ToV will not be reported.

9.2 ToV in the event of partial or non-attendance at third party events/congresses.

- Where Daiichi Sankyo has pre-paid registration fees on behalf of a HCP/ORDM to attend a third party meeting, and the HCP is not able to attend the meeting, ToV will not be reported.
- Cancellation fees are not reported.
- ToV in the event of an HCP/ORDM partially attending an event is disclosed. For example, where an HCP is scheduled to attend a three day congress but only attends the first and second days, the Transfer of Value will reflect his/her partial attendance.

9.3 ToV in the event of event cancellation.

- If a meeting or event is cancelled, ToV will not be reported for travel, accommodation, or registration fees paid on behalf of a sponsored HCP/ORDM to attend that meeting or event. Cancelation fees are likewise not reported.
- ToV will be reported on honoraria paid to HCPs/ORDMs and HCOs for partial delivery of services, as well as for any reimbursed expenses, for example travel cancelation fees.

10. Intermediaries

10.1 Intermediaries acting on behalf of Daiichi Sankyo

- All intermediaries (third parties) that represent or act on behalf of Daiichi Sankyo are subject to a written contract and are obliged to provide Daiichi Sankyo with any contribution made to HCPs, HCOs or ORDMs. If this information cannot be provided due to the nature of the contribution (e.g., market research), it is the intermediary's responsibility to disclose the costs of contributions.

10.2 Intermediaries acting on behalf of HCPs/ORDMs

- Where a Transfer of Value is made to a HCP or ORDM indirectly via a HCO the transfer is disclosed in the appropriate category in the name of the recipient HCP or ORDM.

10.3 Private companies

- The payment or benefit received by a private company – which may be a HCP or a legal entity owned by a HCP (which is then a HCO) – will be disclosed as a ToV made to the HCP where practicable to do so.

II. DATA PRIVACY

1. Informed consent

Data Privacy law requires that Daiichi Sankyo obtain permission from individual HCPs and ORDMs prior to disclosing personal data such as individual ToV. Daiichi Sankyo has made every effort to secure and retain a record of the necessary permissions. Consent is obtained on an annual basis.

Where permission has not been obtained or where the individual has refused permission, Daiichi Sankyo has declared the total spend as an aggregate figure within the relevant disclosure category.

2. Partial consent

There was no partial consent granted to disclose; the entire Transfer of Value is disclosed as aggregate if no permission is obtained from individual HCPs and ORDMs.

III. REPORTING CATEGORIES

The following table summarizes the key reporting categories:

Category	Sub-category	Activities
Donations and Grants (HCOs only).	n/a.	• Funds and benefits in kind or services given for the purpose of supporting healthcare, scientific research or education. • Charitable contributions to organisations involved in education and the setting of clinical standards. • Educational grants (e.g. fellowships, courses provided by a HCO where Daiichi Sankyo does not select the individual HCPs participating). • Service audits to improve service and patient pathways redesign. • Therapy reviews

Contribution to Cost of Events.	Sponsorship agreements.	• Placement of a brand logo in a conference program or invitation communication in exchange for supporting the program. • Providing funding for an event in return for a display booth or exhibition stand • Satellite symposia at a congress. • Exhibitor badges, subsistence, company editorial in conference programs, Abstract books, Flyers in delegate bags, and participant lists. • Sponsorship of third parties providing Continuing Medical Education content for HCPs and ORDMs.
	Registration fees.	• Fees paid for the HCPs and ORDMs to attend events or congresses not organised by Daiichi Sankyo.
	Travel & Accommodation.	• Travel (e.g., flight, train, taxi, car hires, tolls, mileage reimbursement, and parking). • Hotel accommodation.
Fee for services and consultancy.	Fees	• Speaker engagements. • Advisory Boards. • Study-related engagements. • Post-marketing surveillance studies. • Non-Interventional Studies that are retrospective in nature. • Medical writing. • Data analysis. • Marketing plans • Development of education materials. • General consulting / advising.
	Related expenses	• Travel (e.g. flight, train, taxi, car hires, tolls, mileage reimbursement, and parking). • Hotel accommodation.

Research and Development Transfers of Value.	n/a	• Clinical Trials. • Data Monitoring Committees related to studies. • Non-Interventional Studies that are prospective in nature. • Investigators Initiated Research (IIR). • Clinical and Research collaboration • Investigator fees for patient visits paid directly to clinical trial site staff or to CROs as an intermediary. Delayed or preliminary payments by CROs to clinical trial site staff are not considered. • Contribution to costs of Investigator Meetings and committees.
Collaborative Working including Joint working	n/a	• Collaborative working (including Joint working) which either enhances patient care or is for the benefit of patients or benefits the NHS and, as a minimum, maintains patient care. Collaborative working is between one or more pharmaceutical companies, HCOs and other organisations. • The Joint Working Executive Summaries can be found on the following web-link. https://www.daiichi-sankyo.co.uk/about-us/who-we-are/joint-working-summaries/ • The joint working values stated in the Executive Summaries represent Daiichi Sankyo's total financial commitment to the individual project(s). It does not necessarily represent total payments made in a calendar year as projects are subject to phased payments which may cross over into more than one calendar year.

IV. RESEARCH AND DEVELOPMENT

1. Outline

Research and Development Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Directive 2001/20/EC); or (iii) non-interventional studies (NIS) that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study. Non-interventional studies retrospective in nature follow the same disclosure process as HCP honoraria/service fees. The disclosure of such transfers of value on an individual HCP basis is subject to obtaining HCP´s informed consent as per country specific local requirements. In case the transfers of value for prospective and retrospective NIS cannot be

distinguished, the disclosure of transfers of value will be made on an individual HCP basis (HCP´s consent required) and therefore follows the same process as for retrospective NIS.

2. Composition of R&D Transfer of Value

The aggregate R&D Transfer of Value includes:

- Contribution to costs of Investigator Meetings and Committees
- Investigator fees for patient visits paid directly to clinical trial site staff or to CROs as an intermediary. Delayed or preliminary payments by CROs to clinical trial site staff are not considered

Other points to note:

- The aggregate R&D Transfer of Value does not include fees paid to Clinical Research Organisations (CROs).
- R&D fees are often in various currencies. Due to fluctuating exchange rates, a monthly average exchange rate the company uses for its own accounting each month is used to convert the currency into GBP.