Daiichi Sankyo UK Limited

Methodology notes for the Disclosure of Transfers of Value

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I. GENERAL

1. Introduction

Daiichi Sankyo regularly work with healthcare professionals (HCPs), healthcare organisations (HCOs), and other relevant decision makers (ORDMs), for example inviting them to speak at medical educational events or seeking their advice and expertise on our services to patients and the healthcare community. Individuals may sometimes be compensated for providing these services to the industry and these payments are referred to as Transfers of Value (Tov).

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.

The requirement to disclose Transfers of value 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).

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 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/HCOs continues for the benefit of patients.

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

For the UK, disclosures of ToV payments made to HCPs and HCOs during 2016 are available on www.disclosureuk.org.uk portal.

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 to HCPs, ORDMs and HCOs resident in the United Kingdom.

3. Transfers of value definitions

Term	Definition
Transfer of Value (ToV).	The term 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 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 where the identity of the company

	is known to, or can be identified by, the recipient. Transfers of value can take place as a result of legal agreement/contract between any DS entity/affiliate and the UK based reportable recipient. Where a non UK entity/affiliate contracts with a UK based HCP or HCO, the TOV is required to be reported by DSUK.
Health Care Professional (HCP).	Healthcare professionals (HCPs) are defined as 'members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine. UK HCPs are reportable recipients for Transfers of value purposes.
Other Relevant Decision Makers (ORDMs).	The term 'other relevant decision makers' (ORDM) particularly includes those 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 are not health professionals. UK ORDMs are reportable recipients for Transfers of value purposes.
Health Care Organisation (HCO).	A healthcare organisation (HCO) is either a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other 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. UK HCOs are reportable recipients for Transfers of value purposes.

4. Cross Border Engagements and Payments

All UK based HCPs and HCOs that have received Transfers of value as a result of engagements with any Daiichi Sankyo operation, will have the resulting Transfers of value reported in the UK. All disclosures are made in the country in which the HCP practices or in which the HCO is located.

5. Currency

Where payments were made in a currency other than £s, the exchange rate will vary according to the date on which the conversion calculation was made. For general purposes, the conversion date 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 payments made directly from Daiichi Sankyo bank accounts or by Daiichi Sankyo employees and listed in the company records as part of its normal business operations. Transfers of value 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 the payment in the year the transfer of value to HCP, ORDM or HCO is actually made. However, there may be exceptions to this, for example some projects taking place at the end of the year will be disclosed as part of the next annual reporting year because the payment may not occur until January when the invoice has been received and settled.

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 the milestone has been achieved.

9. Partial/Non-attendance of HCPs and ORDMs

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 to attend a Daiichi organised meeting, and the HCP/ORDM is not able to attend the meeting, the 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, the 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.

10. Intermediaries

10.1 Intermediaries acting on behalf of Daiichi Sankyo

- All intermediary (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 intermediaries 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 received by the contracting entity – which may be a HCP, a legal entity owned by the HCP (which is then a HCO) – will be disclosed as a Transfer of value made to the HCP.

II. DATA PRIVACY

1. Informed consent

Data Privacy law requires that Daiichi Sankyo obtain permission from individual HCPs prior to disclosing personal data such as individual transfers of value. Daiichi Sankyo has made every effort to secure and retain a record of the necessary permissions.

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

2. Partial consent

Where only partial permissions has been granted to disclose transfer of value by an HCP, the entire transfer of value to this particular HCP is disclosed as aggregate.

III. REPORTING CATEGORIES

The following table summarizes the key reporting categories:

Category	Sub-category	Activities
Donations and Grants (HCOs only).	n/a.	• 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).
Medical Education Goods and Services		• Service audits to facilitate service and patient pathways redesign.

Contribution to Cost of Events.	Sponsorship agreements (HCOs only).	• Placement of a brand logo in a conference program or invitation communication in exchange for supporting the program. • Funding an event in return for a display booth • Satellite symposia at a congress. • Exhibitor badges, subsistence, company editorial in conference programs, Abstract books, Flyers in delegate bags, and participant lists.
	Registration fees.	• Fees paid for the HCPs and ORDMs to attend events 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. • 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 & Research Collaboration.
Joint working	n/a	• Collaborations where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient-centred projects and share a commitment to successful delivery.

IV. RESEARCH AND DEVELOPMENT

1. Definition

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 Organizations (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.