Daiichi Sankyo Nordics ApS

Methodology for Disclosure of Transfer of Value

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I. GENERAL

1. Introduction

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) and healthcare organizations (HCOs).

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 organizations may be compensated for providing these services to the industry and these payments are referred to as Transfers of Value (ToV).

The requirement to disclose ToV is part of the requirements of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the local Codes in the Nordics. 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/.

Daiichi Sankyo supports the requirements of both EFPIA and the local Codes 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 ApS 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.

2. 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-Nordic entity/affiliate results in ToV for a Nordic based HCP or HCO, the TOV is required to be reported by Daiichi Sankyo ApS.
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, according to the local Codes in the Nordic countries.
Healthcare Organization (HCO).	'Healthcare organization' (HCO) means either a healthcare, medical or scientific association or organization such as a hospital, clinic, foundation, university or other teaching institution or society whose business address, place of incorporation or primary place of operation is in Europe or an organization through which one or more health professionals or other relevant decision makers provide services. If a healthcare organization 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. 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.
Clinical Research Organization	'Clinical Research Organizations' (CRO) are service organizations 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.

3. Cross Border Payments

All disclosures are made in the country in which the HCP practices or in which the HCO is located.

Daiichi Sankyo Nordics ApS is the affiliate of the European Headquarter of Daiichi Sankyo in Europe. As such we publish only transfer of value to HCOs and HCPs based in the Nordics (Sweden, Norway, Finland, Denmark).

4. Currency

Where payments were made in a currency other than official currencies in the Nordics countries (Sweden, Norway, Denmark, Finland), 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.

5. Added value tax

All values provided in our report are net values, i.e. do not include value added tax.

6. 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.

7. Reporting date

Daiichi Sankyo will disclose the details of the payment on the date the transfer of value to HCPs/HCOs is actually made. This may mean that some projects taking place at the end of the calendar year will be disclosed as part of the next annual reporting period because the payment may not occur until January when the invoice has been received and settled.

8. Intermediaries

8.1 Intermediaries acting on behalf of Daiichi Sankyo

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

8.2 Intermediaries acting on behalf of HCO/HCP

Where the intermediary is a professional conference organizer (PCO), Daiichi Sankyo declares the Transfers of Value in the appropriate category in the name of the sponsored HCO/HCP.

8.3 Private companies and associated charities

The payment received by the contracting entity – which may be an HCP, a legal entity owned by an HCP (which is then an HCO) or an HCO – will be disclosed as a Transfer of Value made to that entity.

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 permission 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

According to EFPIA Guidance and country local disclosure code Travel and accommodation expenses related to advisory boards and other consulting meetings are published under “Fee for service and consultancy” where applicable in accordance with the local regulation.

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 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.

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

The aggregate R&D transfer of value does not include fees paid to Clinical Research Organizations (CROs)