

MSD Methodology Statement

Introduction

This Methodology Statement defines the relevant types of transfers to be disclosed, which transfers are excluded, and other relevant information to assist the reader to understand how MSD collected, organised and reported the disclosed data.

Definitions

Clinical Research Organisation (CRO) – an organisation that provides services to the pharmaceutical, biotechnology, and medical device industries in the form of research support outsourced on a contract basis. A CRO is not a HCO.

Event – scientific meetings, promotional meetings, or professional meetings, congresses, conferences, symposia, and other similar events (including advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies), organised or sponsored by or on behalf of MSD.

Healthcare Organisation (HCO) – 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.

Health Professional (HCP) - includes 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. It also includes 'other relevant decision makers', particularly 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. It also includes any employee of MSD whose primary occupation is that of a practicing health professional.

Recipients – any HCO or HCP whose primary practice, main professional address or place of incorporation is in the United Kingdom.

Transfers of Value (ToVs) – means a direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes 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.

A Direct ToV is one made directly by MSD for the benefit of a Recipient.

An Indirect ToV is one made on behalf of MSD 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.

Research and Development ToVs are ToVs to an HCO or HCP 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); and iii) non-interventional studies that are prospective in nature and involve the collection of data from, or on behalf of, individual or groups of health professionals specifically for the study.

Disclosure's scope

Excluded ToVs. The following ToVs are expressly excluded under the Code from disclosure: i) those solely related to over-the-counter medicines; ii) are part of the ordinary course of business purchases and sales of medicines (for example, between MSD and a pharmacy); iii) medical samples, investigational compounds and biological samples for study; iv) informational or educational materials and items of medical utility, v) patient organisations and; vi) meals and drinks

ToV Recognition Date. ToVs are disclosed on the basis of the date MSD made the ToV, not when the resulting income or benefit was received by the HCO/HCP. *Indirect ToVs concerning travel and accommodation are disclosed on the basis of the date that the event took place; Direct ToVs are disclosed on the basis of the date the ToV is posted to our finance systems.*

ToV Value. TOV disclosures reflect the actual value or cost provided by MSD and not the resulting income or benefit to the HCO/HCP.

HCO ToVs. The following types of ToVs to HCO's are disclosed by MSD:

- i) Donations, grants and benefits in kind provided to institutions, organisations and associations that support healthcare;
- ii) contributions towards the costs related to Events, paid to HCOs or to third parties managing events on their behalf, which may include sponsorship of HCP's to attend Events, such as:
 - a. registration fees,
 - b. sponsorship agreements with HCO's or with third parties appointed by an HCO to manage an Event (examples include hiring a booth or stand space, arranging a satellite symposia at a congress, sponsoring of speakers or faculty,); and
 - c. travel and accommodations
- iii) Fees for service and related expenses paid to a HCP or to their employer on their behalf
- iv) Joint Working
- v) Contracts between companies and institutions, organisations or associations of HCPs under which such institutions, organisations or associations provide any type of services on behalf of MSD; provided for the purpose of supporting research or medical and educational goods or services.

HCP ToVs. The following types of ToVs to HCP's are disclosed by MSD:

- i) contributions to costs related to Events such as:
 - a. registration fees, and
 - b. travel and accommodations (such as costs of flights, trains, car hire, tolls, parking fees, taxis and hotel accommodation); and
- ii) fees for service and consultancy (examples include speaker fees, speaker training, medical writing, data analysis, development of educational materials, general consulting and advising via advisory boards/expert input fora, fees for participating in market research when the identity of the HCP is known to MSD, and investigator-initiated studies that do not meet the definition of Research & Development ToVs). To the extent incidental expenses incurred under

a service or consultancy agreement are reimbursed (e.g., travel and accommodation); such ToV is disclosed as related expenses and not as a fee for service or consultancy.

ToVs in case of partial attendances or cancellation. Since ToVs are reported on the basis of what MSD paid, and not what the Recipient received, the full amount paid by MSD shall be reported in case of a partial attendance. In case of a HCP cancellation, no ToV will be disclosed.

Cross-border activities. Regardless of which MSD entity contracts with or pays a Recipient, all HCO's or HCP's whose primary practice, main professional address or place of incorporation is in the United Kingdom are reported by MSD.

Disclosing entities. This annual disclosure report covers all ToVs made to HCO's and HCP in the United Kingdom, whether by Merck Sharp & Dohme Limited or by its affiliates based in other countries.

Specific considerations

Cubist. On January 21, 2015, the MSD group acquired Cubist Pharmaceuticals, a pharmaceutical company specialising in antibiotics. Cubist was an affiliate member of EFPIA and was aware of the disclosure obligations under the Code. To the extent Cubist made a ToV to a HCO or HCP in the United Kingdom, relating to a Cubist product, clinical study or public policy, is reported as a MSD ToV.

Multi-year agreements. Disclosure is made on the basis of the year the actual ToV was provided and not on the basis of a pro rata amount of the intended total ToV under the agreement.

Consent management

Consent collection. Data Protection legislation in the United Kingdom requires MSD to obtain the consent of each HCP to disclose their personal information. MSD has made reasonable efforts to obtain such consent so as to be as transparent as possible about the nature and scale of its interactions with HCP's. The means by which MSD has obtained consent in the United Kingdom is through the completion of a due diligence certification prior to the provision of any ToV. Effective 30 June 2016 MSD UK specified that ToVs will not be provided to HCPs who do not agree to consent. Exceptions include, i) agreements in place prior to 30 June 2016; and ii) when only travel within the UK has been provided.

Management of Recipient consent withdrawal. A Recipient has the right to withdraw their consent at any time, however, MSD UK will not engage or provide benefits to any HCP who does not consent to the disclosure of transfers of value.

Partial consent. MSD UK will not report partial disclosure as partial disclosure under the individual disclosure category would be misleading with respect to the nature and scale of the interaction between MSD and the HCP.

Disclosure Form

Date of publication. MSD publishes the ToV for the preceding calendar year no later than 6 months after the end of the relevant reporting period (for example, ToVs for 2015 are reported no later than June 30, 2016). The information disclosed shall remain available for three (3) years thereafter.



Disclosure platform. MSD provides its annual disclosure via a central platform called the AGS 360 Portal organised by the ABPI.

Disclosure financial data

Currency. All disclosed ToVs are reported in local currency. ToVs paid in other currencies are converted to local currency at the exchange rate applicable on the date the cost is incurred.

VAT. VAT is included when relevant.

Working with other Pharmaceutical Companies

Transfers of Value are divided between each of the pharmaceutical companies participating in the project.