

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 Croatia or another legal entity through which one or more health professionals or other relevant decision makers provide services, owned by them or their family members.

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.

Patient Organisation (PO) - association or other form of organization of patients and caregivers (the term "caregiver" means persons directly involved in the care of patients on non-professional grounds, such as family members, guardians etc.) established in line with the laws of the Republic of Croatia, which on non-profit basis protects and promotes the interests of its members. Patient Organizations are also international associations, organizations, alliances, unions, networks, coordination and other forms of association of patients and their caregivers and Patient Organizations which are established and operate pursuant with the laws of the EU member- countries in which they have registered seat.

Recipients – any HCO, HCP or PO whose primary practice, main professional address or place of incorporation/registration is in Croatia.

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 prescription-only medicines.

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 Ordinance on Good Laboratory Practice and OECD Principles on Good Laboratory Practice); ii) clinical trials (as defined in Regulation (EU) 536/214); and iii) non-interventional studies that are prospective in nature and involve the collection of subject data by Health professionals specifically for the study (as defined in Medicinal Products Act and Ordinance on Clinical Trials and Good Clinical Practice).

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) those that 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 and v) 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. travel and accommodations
 - c. 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); and
- iii) 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.

Contributions provided to Events through PCOs.

ToV's through PCOs are reported

- i) in the name of benefitting HCO (through include the name of Recipient PCO), if not included in direct ToVs to the HCO. The tripartite agreement is signed, including both the HCO and PCO as parties. Pursuant to the agreement the HCO is to be named as the recipient of

the ToV, whether it is received directly or via PCO.

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.
- iii) The aggregate records are used for reporting group expenses (e.g. group transportation, the cost of accreditation for HCPs by Croatian Medical Chamber) when the number of recipients and recipient information are not and cannot be collected.

ToVs in case of partial attendances. 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.

ToVs in case of cancelled participations or no-shows. In case of a HCP's timely cancellation, no ToV will be disclosed. In case invited HCPs do not show or cancel late their participation to events they have accepted to attend, the related ToV is disclosed equal to the amount of the costs MSD has not recovered.

ToVs in case of cancelled events and participations. In case third-party events are cancelled independent of the will of MSD, the related ToV is disclosed equal to the amount of the costs MSD has not recovered.

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 Croatia are reported by MSD.

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

Specific considerations

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.

Non-interventional studies

EFPIA Guidance criteria is used to determine whether a non-interventional study is prospective or retrospective. If it is a retrospective non-interventional study, the ToVs will be disclosed under "consultancy/fee-for-services".

Consent management

Consent collection. Data Protection legislation in Croatia 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 Croatia is through the completion of a due diligence certification prior to the provision in Croatia of any ToV. Effective 30 June 2016 MSD Croatia specified that ToVs will not be provided to HCPs who do not agree to consent. Excluded from this are circumstances where only travel within Croatia has been provided.

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

Partial consent. MSD Croatia 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 its own web site.

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.

TAX. Disclosed ToV's to HCO's and HCP's reflect the amounts agreed in the contracts and on invoices submitted to MSD by HCO's or HCP's. The data collection and reporting is based on "net amounts" exclusive of VAT, and in cases where MSD pays taxes and social security contributions on behalf and for the account of HCPs, also net of such taxes and contributions. If VAT cannot accurately be excluded, as in the case of travel and accommodation costs, the full ToV amount is disclosed exceptionally.

Working with other Pharmaceutical Companies

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