

MSD Methodology Statement

Introduction

“Merck Sharp & Dohme” UAB (MSD) believe that interactions between pharmaceutical companies and healthcare professionals have a profound and positive influence on the quality of patient treatment and the value of future research. Recently, there is a growing expectation that such interactions are transparent. As such, the European Federation of Pharmaceutical Industries and Associations adopted in 2014 the Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations (Code), requiring its members, including MSD, to disclose pre-defined types of transfers of value to healthcare organizations and healthcare professionals on an annual basis. This Methodology Statement defines the relevant types of transfers to be disclosed, which transfers are excluded, and other relevant information to assist the reader understand how MSD collected, organized and reported the disclosed data.

Definitions

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

Event – all promotional, scientific 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), organized or sponsored by or on behalf of MSD.

Healthcare Organization (HCO) – any legal person (i) that is a healthcare, medical or scientific organization such as a hospital, clinic, foundation, university or other teaching institution or learned society (but not a patient organization) or ii) through which one or more HCP’s provide services.

Healthcare Professional (HCP) - any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who as part of their professional activities may prescribe, purchase supply or administer a medicinal product and whose primary practice or principal professional address in Lithuania. This includes midwives. For clarity, a HCP includes: i) any official or employee of a governmental agency or other organization (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and ii) any employee of MSD whose primary occupation is that of a practicing HCP, but excludes: x) all other employees of MSD and y) a wholesaler or distributor of medicinal products.

Patient organizations (PO) - non-for-profit legal person/entity (including the umbrella organisation to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in Lithuania.

Recipients – any HCO or HCP whose primary practice, main professional address or place of incorporation is Lithuania.

Transfers of Value (ToV's) – direct and indirect transfers of value, whether in cash, in kind or otherwise, made in connection with the development and sale of medicinal products for human use.

A Direct ToV is one made by directly MSD for the benefit of a Recipient. Social tax paid by company on top of agreement is not disclosed.

An Indirect ToV is one made by a third party (such as a contractor, travel agent, partner or affiliate) on behalf of MSD for the benefit of a Recipient where the Recipient knows it is from, or can identify, MSD.

Research and Development ToV's are ToV's 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 Regulation (EU) 536/2014); and iii) non-interventional studies that are prospective in nature and that involve the collection of patient data.

Support provided for PO is the monetary value of the financial support and costs incurred or the non-monetary benefit that the PO receives when a reasonable monetary value cannot be attributed to the non-financial support, and the value transferred to PO for the contractual services provided for MSD.

Disclosure's scope

Excluded ToVs. The following ToV's are expressly excluded under the Code from disclosure: i) those solely related to over-the-counter medicines; ii) are part of ordinary course 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) meals and drinks that remain below the limits set by the Innovative Pharmaceutical Industry Association (IFPA) of Lithuania.

ToV Recognition Date. Both, Direct and Indirect ToV's 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 ToV's concerning travel and accommodation are disclosed on the start date of the Event; ToV's are disclosed on the basis of the date the ToV is posted in COMET, not when the resulting income or benefit was received by the HCO/HCP.

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

- i) donations and grants that support healthcare (including charitable product donations and logistic assistance to people in emergency need);
- ii) contributions to costs related to Events, including sponsorship of HCP's directly or indirectly through HCO'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, acquiring advertising space (in paper, electronic or other format), arranging a satellite symposia at a congress, sponsoring of speakers or faculty, the costs of drinks or meals provided by the HCO if part of an inclusive

- package, and courses provided by a HCO where MSD does not select the individual HCPs that participate), and
- c. travel and accommodations; and
 - iii) fees for service and consultancy (examples include retrospective non-interventional clinical studies and epidemiological studies). To the extent incidental expenses incurred under a service or consultancy agreement are reimbursed (e.g., travel and accommodation), such ToV is disclosed in the relevant category and not as a fee for service or consultancy.

HCP ToV's. The following types of ToV's 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 speakers' 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 ToV's). To the extent incidental expenses incurred under a service or consultancy agreement are reimbursed (e.g., travel and accommodation), such ToV is disclosed in the relevant category and not as a fee for service or consultancy.

ToVs in case of partial attendance. MSD only reports the ToV amount actually received by a Recipient in case of a partial attendance, not the full amount paid by MSD.

ToVs in case of cancelled events and participations. In case third-party events are cancelled independent of the will of MSD and 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.

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

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

Specific considerations

Country unique identifier. In order to ensure disclosure of ToV's are allocated correctly, MSD has assigned a unique identifier to each HCP and HCO. In Lithuania, this is based on the company number/a randomly created "running" number for HCOs and a national personal identification number (which is the stamp number of HCP)/a randomly created "running" number for HCPs and self-incorporated HCPs.

Self-incorporated HCP. Disclosure is made on the Recipient's name. So, a Fee for Service paid to a legal entity owned by a HCP is disclosed under the name of the legal entity (an HCO) and not the HCP's individual name as the HCO is the Recipient of the ToV.

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

Consent management

Disclosure provisions of HCP ToVs for the years 2015-2019

Consent collection. Unless disclosure is mandated by local legislation, data protection legislation in force in Lithuania, as reflected by the more stringent requirements contained in the General Data Protection Regulation (EU) 679/2016, requires MSD to obtain the consent of each HCP to disclose their personal information. MSD has made its best effort 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 Lithuania is by a stand-alone agreement (Consent) covering all interactions with the HCP for 5 (five) years.

Management of Recipient consent withdrawal. A Recipient has the right to withdraw their consent at any time. If this occurs prior to MSD's publication of the ToV, then the Recipient's ToV's shall be reported on an aggregate basis only with no disclosure of the Recipient's name. If consent is withdrawn by a Recipient after the publication of the relevant year's ToV's, then the Recipient's name and ToV's shall be removed and the corresponding amount of ToV's will be added to the aggregate reporting for the remainder of the three (3) year period for which the publication remains available.

Partial consent. In the event an HCP consents to disclosure of only a portion of the ToV's they have received (which is not in the interest of MSD or EFPIA), MSD will disclose the entire amount of the HCP's ToV's in the aggregate without naming the HCP. 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 provisions of HCP ToVs since 2020

Since 1 January 2020 pursuant to Order No V-1537 of the Minister of Health of the Republic of Lithuania of 23 June 2020 "On the approval of information on the values transferred to the recipients of the transferred values, the provision of data of legal entities and personal data of health care and/or pharmacy specialists to the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania and information on the transferred values and the procedure for publishing personal data of health care and/or pharmacy specialists", MSD is obliged by law and does not request consent of HCP to disclose personal data and all ToVs, excluding undisclosed ToVs and R&D related ToVs, which are disclosed in aggregate.

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, ToV's for 2020 are reported no later than June 30, 2021). The information disclosed shall remain available for three (3) years thereafter.

Disclosure platform:

- i) MSD provides its annual disclosure of R&D ToV's and support provided for POs via its own web site <https://www.msd.lt> and a central platform called <https://www.vaistukodeksas.lt> organized by

IFPA and VGA – associations of companies engaged in pharmaceutical marketing in Lithuania.

- ii) Pursuant to article 51 of the Law on Pharmacy No X-709 2, MSD provides its annual disclosure of ToVs transferred to HCPs and HCOs, except for support provided under the Law on Charity and Sponsorship, and personal data of HCPs and HCOs to the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania and publishes active links to these reports on its website <https://www.msd.lt>.

Disclosure language. Pursuant to the legislation of the Republic of Lithuania, HCP and HCO ToVs are disclosed in Lithuanian, reports on R&D-related ToVs and Support provided for POs are disclosed in Lithuanian and English.

Disclosure financial data

Currency and VAT. All disclosed ToV's are reported in local currency and exclusive of VAT except indirect ToV's for Travel and Accommodation which are disclosed inclusive of VAT. ToV's paid in other currencies are converted to local currency at the exchange rate applicable on the date the cost is incurred.

How is VAT Managed?

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 by guidance to all data providers based on "net amounts". If VAT cannot accurately be excluded, the full ToV amount is disclosed exceptionally.