MSD Methodology Statement

Introduction

Merck Sharp & Dohme s.r.o. (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 an 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 HCPs provide services.

Healthcare Professional (HCP) - any natural person who as part of their professional activities may prescribe or dispense a medicinal product and whose primary practice or principal professional address is in the Czech Republic. For clarity, an HCP includes: i) any official or employee of a governmental agency or other organization (whether in the public or private sector) that may prescribe, or dispense 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.

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

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.

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.

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; and v) meals and drinks.

ToV Recognition Date. *ToV's are disclosed on the basis of the date the ToV is posted in accounting books, 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 an 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 attendances or cancellation. MSD only reports the ToV amount actually received by a Recipient in case of a partial attendance, not the full amount paid by MSD. In case of a cancellation, since nothing is directly or indirectly received by a Recipient, no ToV is reported by MSD, even if amounts have been paid by MSD to the Event organizer.

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 the Czech Republic are reported by MSD.

Disclosing entities. This annual disclosure report covers all ToV's made to HCOs and HCPs in the Czech Republic, whether by Merck Sharp & Dohme s.r.o. 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 the Czech Republic, this is based on the company identification number (IČ) for HCOs and a national medical registration number (from the Czech Medical Chamber or Czech Chamber of Pharmacists) for HCPs.]

Self-incorporated HCP. An HCP – physical entity – who can be identified based on the registration number of the Czech Medical Chamber will be registered under this number as an HCP. IČ (IN) does not turn a physical entity into a legal entity.

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.

Non-interventional studies. In those circumstances where MSD is unable, despite its best efforts, to determine whether ToV's made to an HCP by a CRO, on behalf of MSD, are prospective or retrospective in nature, such ToV's are treated as prospective and allocated in the aggregate to Research and Development.

Consent management

Consent collection. Unless disclosure is mandated by local legislation, data protection legislation in force in the Czech Republic, 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 the Czech Republic is by a stand-alone agreement covering all interactions with the HCP for an entire year.

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 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 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 2018 are reported no later than June 30, 2019). The information disclosed shall remain available for three (3) years thereafter, subject to individual disclosures being shifted to aggregate disclosure in the event of after-the-fact revocation of consent by the Recipient.

Disclosure platform. MSD provides its annual disclosure via a central platform on www.transparentnispoluprace.cz organized by Asociace Inovativního Farmaceutického Průmyslu (AIFP).

Disclosure language. MSD provides its annual disclosure in Czech and English.

Template. For consistency purposes, disclosures will be made using the structure set forth in the national Code on Disclosure, reflecting the requirements of the Code.

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 HCOs and HCPs reflect the amounts agreed in the contracts and on invoices submitted to MSD by HCOs or HCPs. 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.