

MSD Sweden Methodology Statement

Introduction

Merck Sharp & Dohme (Sweden) AB (MSD) believes 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

Event – all promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including advisory board meetings, expert input forums, 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.

Health Care 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 is in Sweden. 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.

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.

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

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 directly by 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 article 2(a) of Directive 2001/20/EC); 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 that are part of ordinary course purchases and sales of medicines (for example, between MSD and a pharmacy); ii) medical samples, investigational compounds and biological samples for study; iii) informational or educational materials and items of medical utility and; iv) meals and drinks that remain below the limits set by *Läkemedelsindustriföreningen (LIF)*, the pharmaceutical industry association of Sweden.

ToV Recognition Date. 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. Direct ToV's are disclosed on the basis of the date MSD made the ToV, not when 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 Value. TOV disclosures reflect the actual value or cost provided by MSD to the Recipient 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, and investigator initiated studies that do not meet the definition of Research & Development ToV's);
- ii) contributions to costs related to Events, such as:
 - 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). The income obtained by healthcare organizations or associations via such sponsorships may only cover actual, documented, reasonable and direct costs that are necessary in order to carry out the professional parts of a meeting; and
- iii) fees for service and consultancy (examples include retrospective non-interventional studies and epidemiological studies, speaker fees or advisory board participation fees). Also other types of fees for service may occur for instance medical services within development or

conduct of a patient support program. 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 category “related expenses” 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) 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 retrospective non-interventional 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 category “related expenses” and not as a fee for service or consultancy.

Research and Development ToV’s will be disclosed on an aggregate country level. This includes ToVs made by CROs on behalf of MSD to HCOs for the conduct of clinical trials.

ToVs in case of partial attendances or cancellation. Since ToV’s 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, and no ToV has occurred, no ToV will be disclosed.

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 Sweden are reported in Sweden by MSD Sweden.

Disclosing entities. This annual disclosure report covers all ToV’s made to HCO’s and HCP in Sweden, whether by MSD Sweden or by its affiliates based in other countries. For Events arranged by international organizations (e.g., international congresses), the disclosure will be made by the local MSD-entity in the country where the international organization has its primary address, not where the Event took place.

Specific considerations

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.

Non-interventional studies. In those circumstances where MSD is unable, despite its best efforts, to determine whether ToV’s made to a 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. The European Data Protection Regulation requires MSD to obtain the consent of each HCP and for all HCOs defined as “*enskild firma*” 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 Sweden is by a stand-alone agreement covering all interactions with the HCP for an entire year. For HCPs or *enskild firma* (HCO) where no consent was obtained, their ToVs will be reported as aggregate disclosure together with the total number and percentage of non-consenting Recipients. For non-*enskild firma* HCOs, no consent is needed and all ToVs will be disclosed on individual HCO level.

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 will 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 will 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.

General Data Protection Regulation, GDPR, that comes into effect in May 2018 is extending the requirements for consent management and information to the data subject when companies are required to publish a transfer of value. A consent from the individual (e.g. a consultant) is required before any pharmaceutical company can publish any transfer of value. The requirements also apply to so called “*Enskild firma*” (special Swedish company type). Consent shall be given by written agreement. It is of utmost importance that individual / *enskild firma* consent to the publication in order to achieve transparency.

For health care organizations (hospitals, clinics, organizations, limited companies or trading companies) no consent is required before publication.

In line with the recommendation of the LIF Board, MSD publishes all individual data from publication made in 2016-2017 in aggregated form (for value transfers 2015-2016).

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 2019 are reported no later than May, 2020). 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 called “*LIFs samarbetsdatabas – Öppen rapportering av värdeöverföringar*” on www.lif.se/etik/samarbetsdatabaser organized by Swedish Pharmaceutical Industry Association (LIF).

Disclosure language. MSD provides its annual disclosure in Swedish.

Disclosure financial data

Currency and VAT. All disclosed ToV's are reported in local currency (SEK) and exclusive of VAT with the exception of ToV for travel and/or lodging that is invoiced for reimbursement by the HCP, which is 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.

Indirect ToV's for Travel and accommodation that are received from MSD entities abroad and reported manually to the disclosure database, are converted to local currency at the reporting day's exchange rate (not at the rate going back to the Travel date).