

# MSD Methodology Statement

## Introduction

MSD Pharmaceuticals (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

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 entity (i) that is a healthcare, medical, pharmaceutical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution, patient organizations, whose business address, place of incorporation or primary place of operation is in Russia or (ii) which provides services through one or more healthcare professionals.

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 Russia. 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.

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

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) pre-clinical studies; (ii) clinical trials; or (iii) post-registration observation (non-interventional) studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, healthcare professionals specifically for the study.

## 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; vi) group transfers

ToV Recognition Date. 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 are disclosed on the start date of the Event;

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);
- 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 if a part of an inclusive package,
  - 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 if a part of an inclusive package.

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
  - b. travel and accommodations (such as costs of flights, trains, parking fees, taxis and hotel accommodation);
- 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.

Aggregate Disclosure. For Transfers of Value where certain information, which can be otherwise reasonably allocated to one of the categories set forth above, cannot be disclosed on an individual basis for legal reasons, MSD shall disclose the amounts attributable to such Transfers of Value on an aggregate basis. Such aggregate disclosure shall identify, for each category, (i) the number of Recipients covered by such disclosure, on an absolute basis and as a percentage of all Recipients, and (ii) the aggregate amount attributable to Transfers of Value to such Recipients.

Research and Development Transfers of Value. Research and Development Transfers of Value in each Reporting period shall be disclosed by MSD on an aggregate basis.

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 cancellation, since nothing is directly or indirectly received by a Recipient, no ToV is reported by MSD.

Cross-border activities. Regardless of which MSD entity contracts with and pays a Recipient, all HCOs or HCPs, whose primary practice, main professional address or place of incorporation is in Russia, are reported by MSD Pharmaceuticals LLC.

Disclosing entities. This annual disclosure report covers all ToV's made to HCOs and HCPs in Russia, whether by MSD Pharmaceuticals LLC or by its affiliates based in other countries.

### **Specific considerations**

Country unique identifier. In order to ensure disclosure of ToV's is allocated correctly, MSD has assigned a unique identifier to each HCP and HCO. In Russia, this is based on VAT registration number for HCO's and Name and MSDC ID for HCP's.

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. Data Protection legislation in Russia requires MSD to obtain the consent of each HCP and HCO 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 HCPs. The means by which MSD has obtained consent in Russia is by a separate consent in each contract covering all interactions with the HCP for an entire year / and separate consent letter for each HCO for unlimited period.

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 to ToV's will be added to the aggregate reporting for the remainder of the 3 year period for which the publication remains available. In case of incidents, such as death of the Recipient, MSD reserves the right to report all ToV's for that Recipient on the aggregated basis only.

#### **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 2017 are reported no later than June 30, 2018). 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 web site msd.ru.

Disclosure language. MSD provides its annual disclosure in Russian and English languages.

#### **Disclosure financial data**

Currency and VAT. All disclosed ToV's are reported in local currency and exclusive of VAT, depending on local system settings. DTOV of HCP's includes 13% Personal Income Tax.