

## EFPIA HCP/HCO Disclosure Code

# Methodology Note

## MSD Norway

### 1. Introduction

MSD Norway (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. 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 exempt from disclosure as well as other relevant information to aid the reader in understanding how MSD collects, organizes and reports disclosable data.

### 2. 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 Norway (e.g. medical doctor, dentist, veterinarian, fish-health biologist, registered nurse, pharmacist, optometrist, dental hygienist as well as students of the corresponding disciplines).

**Patient organizations (PO)** - non-for-profit legal person/entity (including the umbrella organization 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 Norway.

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

**Transfers of Value (ToVs)** – direct and indirect transfers of value through a banking institution 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 agency, partner or affiliate) on behalf of MSD and for the benefit of a Recipient, where the Recipient knows it is from, or can find out that it is from, MSD.

**Research and Development ToVs** 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. Support provided for PO is disclosed in a separate report.

### 3. Disclosure's Scope

**Excluded ToVs.** The following ToVs are excluded from disclosure:

- i) those solely related to over-the-counter drugs;
- ii) those that are part of standard drug purchasing and sale procedure (for example between MSD and a pharmacy);
- iii) drug samples, investigational compounds and biological samples for study;
- iv) informational or educational materials and items of medical utility;
- v) meals and refreshments below the threshold set by LMI, the pharmaceutical industry association of Norway.

**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 ToVs.** The following types of HCO ToVs are disclosed by MSD:

- i) donations and grants in support of healthcare (including charitable product donations and logistical assistance provided as emergency aid to people in need);
- ii) contributions toward expenses incurred from attending events, including sponsorship of HCPs directly or indirectly through HCOs for event attendance, such as:
  - a. registration fees
  - b. sponsorship agreements with HCOs or with third parties appointed by an HCO to cover: managing an event (includes hiring a stand or an exhibition space, acquiring advertising space (in print, electronic or other format); arranging a satellite symposium at a congress; sponsorship of speakers/faculty; expenses on refreshments or meals provided by an HCO if part of a package; and courses provided by an HCO, where MSD does not select the individual HCP attendees;
  - c. travel and accommodations;
- iii) service and consultancy fees (includes, for example, retrospective, non-interventional studies, clinical trials and epidemiological studies). Insofar as incidental expenses incurred under a service or consultancy agreement are reimbursed (e.g., travel and accommodations), such ToVs are disclosed in the relevant category and not as a service or consultancy fee.

**HCP ToVs.** The following types of HCP ToVs are disclosed by MSD:

- i) contributions toward event-related expenses, such as:
  - a. registration-fees, when permissible (N.B.! Norway prohibits the pharmaceutical industry from funding registration fees for congresses/meetings hosted by a third party); and
  - b. travel and accommodations (such as expenses on air fares, rail fares, car rentals, toll fees, parking fees, taxis and hotel accommodation);
- ii) service and consultancy fees (includes, for example, speaker fees, speaker training, medical writing, data analysis, development of educational materials, general consultancy and advisory services by serving on advisory boards/expert input forums, 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 and Development ToVs). Insofar as incidental expenses incurred under a service or consultancy agreement are reimbursed (e.g., travel and accommodations), such ToVs are disclosed in the relevant category and not as a service or consultancy fee.

**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 HCOs or HCPs whose primary practice, main professional address or place of incorporation is in Norway are reported by MSD.

**Disclosing entities.** The annual disclosure report covers all ToVs made to HCPs and HCOs in Norway whether by MSD Norway or by its affiliates based in other countries.

#### 4. Specific Considerations

**Country unique identifier.** In order to ensure the correct allocation of ToV disclosures, MSD has assigned a unique identifier to all HCPs and HCOs. In Norway, this is based on a randomly generated serial number for HCOs and self-incorporated HCPs, and a randomly generated serial number for HCPs.

**Self-incorporated HCP.** The Recipient's name is stated in the disclosure. Fees-for-service paid to a legal entity owned by an HCP will thus be disclosed under the legal entity's name (an HCO) and not under the HCP's personal name, since the HCO is the ToV Recipient.

**Multi-year contracts.** Disclosure is made on the basis of the year in which the actual ToV was made, and not on the basis of a pro rata fraction of the intended total ToV under the agreement.

**Group expenses.** The Disclosure Code does not necessitate allocation of the ToV to the individual members of a group of HCPs, meaning that the expenses reimbursed for such groups, on bus travel, for example, will be disclosed in aggregate without identification of the individual members of the group.

**Non-interventional studies.** In cases where MSD is unable, despite its best efforts, to determine whether a ToV to an HCP made by a CRO on behalf of MSD is prospective or retrospective, such a ToV will be reported as prospective under Research and Development.

#### 5. Consent Management

Since 2021, Norwegian Association of Pharmaceutical Manufacturers (LMI) has decided that no consent collection for individual HCP is required in Norway. Thus MSD is obliged to disclose ToVs 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.

#### 6. Disclosure Form

**Date of disclosure.** MSD publishes ToVs for the preceding calendar year no later than 6 months after the end of the relevant reporting period (for example, ToVs for 2021 are reported by no later than June 30, 2022). The information disclosed must then remain available for three (3) years after publication.

**Disclosure platform.** MSD publishes its annual disclosure on its own website (www.msd.no).

**Disclosure language.** MSD publishes its annual disclosure in Norwegian.

## **7. 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.