

## Introduction

MSD AFEE 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 (“EFPIA”) adopted in 2014 the Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations, which has been replaced by the EFPIA Code of Practice (“Code”), requiring its members, including MSD, to disclose pre-defined types of transfers of value to healthcare organizations and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. The same obligation is required by MSD AFEE also according to article 66 par. 7a of the Greek Law 4316/2014. 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 having its registered office or carrying out activities in Greece (i) that is a healthcare, medical or scientific association or healthcare 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 healthcare services.

Healthcare Professional (HCP) - any natural person that is being characterized as Healthcare Professional<sup>1</sup> under the applicable laws, is empowered to prescribe, purchase, supply, dispense, recommend, or administer a medicinal product as part of his/her practice and whose primary practice or principal professional address in Greece. This includes midwives. 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, 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, working in private or public sector, whose primary practice, main professional address or temporary residential address or place of incorporation is Greece.

Transfers of Value (ToVs) – 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 ToVs are ToVs 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 on clinical trials on medicinal products for human use]; and iii) non-interventional studies that are prospective in nature and that involve the collection of patient data by or on behalf of individual, or groups of, HCPs specifically for the study.

## Disclosure’s scope

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 up or cancel late their participation to events they have accepted to attend, the related disclosed ToV is equal to the amount of the costs MSD has not recovered.

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<sup>1</sup> Pursuant to Article 4 of Law 4238/2014 the following persons are characterized as Healthcare Professionals (HCPs): family physicians and physicians of other specialties, dentists and other healthcare professionals such as midwives, health visitors, nurses, social workers, physiotherapists, dietitians/nutritionists, psychologists, occupational therapists, medical laboratory technologists, medical and biological laboratory assistants, medical equipment operators.

Excluded ToVs. The following ToVs 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 medicinal products (for example, between MSD and a pharmacy); iii) medical samples, investigational compounds, and biological samples for study; and iv) informational or educational materials and items of medical utility of low price (no more than 15 euro), as well as meals.

ToV Recognition Date. ToVs are disclosed based on the date MSD made the ToV, not when the resulting income or benefit was received by the HCO/HCP.

All ToVs (direct and indirect) are disclosed after the original invoice receipt (expense type and expense amount).

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 ToVs to HCOs 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 HCPs to attend Events directly or indirectly through HCOs if this cannot be done in an adequate and accurate manner in compliance with the applicable laws and regulations, such as:
  - a. registration fees,
  - b. sponsorship agreements with HCOs 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 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 accommodation; 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 ("related expenses") and not as a fee for service or consultancy. Fees, on the one hand, and on the other hand ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

HCP ToVs. The following types of ToVs to HCP's are disclosed by MSD:

- i) contributions to costs related to Events such as:
  - registration fees, and
  - travel and accommodation (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, and investigator-initiated studies that do not meet the definition of Research & Development ToVs). To the extent incidental expenses incurred under a service or consultancy agreement are reimbursed (e.g., travel, registration and accommodation), such ToV is disclosed in the relevant category ("related expenses") and not as a fee for service or consultancy. Fees, on the one hand, and on the other hand ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts. In case of NHS HCPs that are paid via ELKEA, and University HCPs that are paid via ELKE, ToVs shall be disclosed on an individual level in the HCP's name.

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

Disclosing entities. This annual disclosure report covers all ToVs made to HCOs and HCP in Greece, whether by MSD AFEE or by its affiliates based in other countries.

### **Specific considerations**

Country unique identifier. To ensure disclosure of ToVs are allocated correctly, MSD has assigned a unique

identifier to each HCP and HCO. In Greece this is based on unique identification numbers provided by a) local CRM platform (Veeva) and b) MaaS (ex GCM platform)

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

Aggregate disclosure. ToVs that 1) may not be disclosed individually due to legal reasons, as well as 2) ToVs concerning Research and Development (R&D) activities and auxiliary activities to said activities (e.g. investigator meetings) are disclosed on an aggregated basis.

Non-interventional studies (NIS).

Aggregate disclosure of TOVs to HCPs and HCOs relating to NIS is limited to NIS that are prospective in nature. By contrast, TOV to HCPs and HCOs in the context of retrospective NIS must be reported on an individual name basis. If a distinction between prospective and retrospective non-interventional clinical trials is not possible TOV shall be disclosed on an individual basis.

Contributions provided to Events through PCOs. ToVs transferred through PCOs are reported in the name of the benefiting HCO. In the context of the agreement HCOs execute with contractors, they assign to the PCO the collection of sponsorships and the invoicing to the sponsors-companies. The contractor PCO, following the conclusion of the event, proceeds with a clearance, reviews, and delivers any surplus to the responsible scientific agencies. Following receipt of invoice, the budget/meeting owner submits the corresponding actual ToVs, in the MSD application, designed for automating the procedure of controlling & approving expenses for engagements with HCOs. This allows the appropriate reporting of ToVs.

### **Consent management**

Consent collection. In Greece, the consent of each HCP/HCO to disclose personal information is not deemed necessary since disclosure is obligatory for MSD AFEE to comply with applicable legislation and therefore is not relied upon as a legal basis. MSD AFEE provides HCPs and HCOs with information regarding the above disclosure obligations by incorporating relevant clauses in each contract with HCPs/HCOs.

### **Pre-Disclosure**

The usual PD process via the IQVIA portal was not supported by the Global Team this year, since there is no legal obligation for MSD Greece to proceed this way. As a back-up plan, and since the local team agreed to maintain a similar process to validate data before the official disclosure, the following steps were followed:

- Local GR Team notified HCPs and HCOs, through email or direct mail, that ToVs and sponsorships would be published on June 30<sup>th</sup>.
- They have been also notified that they have the possibility to contact MSD Greece (specific mailbox or central telephone line was proposed) to confirm accuracy of their data/amounts.

### **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, ToVs for 2023 will be reported no later than June 30<sup>th</sup>, 2024). 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.

Platform of Disclosure. A) Company website, freely and publicly available. B) EOF website, as per EOF's rules, time schedule and standards.

Disclosure language. MSD provides its annual disclosure in Greek language.

### **Disclosure financial data**

Currency and VAT. All disclosed ToVs are reported in local currency and exclusive of VAT except indirect ToVs for Travel and Accommodation which are disclosed inclusive of VAT. ToVs 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 ToVs 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.