

## HCP/HCO Disclosure

### Methodological note

2026 Disclosure Report of Transfers of Value made in 2025

#### Introduction

In 2014, by introducing the disclosure requirements, EFPIA and its Member Association FarmaForum have demonstrated their commitment to self-regulation but also the legitimacy of the interactions with HCPs, and HCOs.

Member Companies and companies that are members of Member Associations are required to disclose transfers of value<sup>1</sup> made to HCPs and HCOs. This disclosure includes, by HCP or HCO, the total amounts of value transferred, by type of activity.

The disclosure is aligned with the laws and regulations of Slovenia. The methodological note is required for disclosure based on the EFPIA Code requirements as transposed in national code provisions.

This methodological note defines the relevant types of transfers of value disclosed, which transfers of value are eventually excluded, and other relevant information to assist the reader to understand how MERCK SHARP & DOHME, inovativna zdravila d.o.o. (hereinafter also referred to as MSD) collected, organized and reported the disclosed data.

#### Definitions

- **Recipients** typically refer to any individual or entity that receives a payment or benefit from MSD as part of their collaboration or interaction. The type of recipients include:
  - **Healthcare Professionals (HCPs):** This category encompasses physicians, pharmacists, nurses, and other medical practitioners who provide healthcare services, as well as any official or employee

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<sup>1</sup> Transfers of Value are direct and indirect payment, whether in cash, in kind or otherwise or reimbursement provided to HCPs and HCOs.

- of the government, agency, or other organization (whether in the public or private sector) that may prescribe, purchase, supply, recommend or administer medicinal products.
- **Healthcare Organizations (HCOs):** These can include self-entrepreneurs, hospitals, clinics, universities, professional associations, or any other institutions that provide healthcare services or conduct medical research or through which one or more HCPs provide services. These do not include Contract Research Organizations (CROs) nor Patient Organizations.
  - **Patient Organization (PO):** This category includes non-for-profit legal persons/entities (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.
- **Transfers of Value (ToV)** refer to both direct and indirect ToV, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of medicinal products for human use. **Direct ToVs** are those made directly by MSD for the benefit of a Recipient. **Indirect ToVs** are those made by a third party (such as a contractor, travel agent, business partner, or affiliate) on behalf of MSD for the benefit of a Recipient where MSD knows or can identify the Recipient that will benefit from the ToV.
- Below are the category types of ToV, along with their definitions:
- **Donations and Grants** mean providing funds, goods, or services freely to support healthcare, scientific research or education, charitable causes or specific projects that do not yield a direct benefit to MSD, including investigator-initiated studies that do not meet the definition of Research & Development ToVs).
  - **Sponsorships** are defined as funding in support of an event, meeting, program, or other type of project that is related to medical education, scientific information sharing, or other related information sharing when MSD receives booth or stand space, opportunity to display company banners, opportunity to conduct an ancillary meeting, or other opportunities to have its name, scientific information or medical products associated with the activity.

- **Contributions to Costs of Events** are ToV made to cover expenses associated with promotional, scientific, or professional meetings, congresses, conferences, symposia, and other similar events (including advisory board meetings, expert input forums, group input 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. These costs may cover the costs of meals, travel, accommodation, and/or registration fees to support the attendance of an individual HCP.
- **Fees for Services and Consultancy** are ToV made for professional services, such as speaker fees, consulting or advisory board fees, or participation in studies not in the scope of R&D ToV as defined below. This category pertains to direct compensation for specific services rendered by HCPs and HCOs.
- **Research and Development (R&D) ToV** are 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 536/2014); or (iii) prospective non-interventional studies that involve the collection of patient data from or on behalf of HCPs specifically for the study.

### Disclosure's scope

- **Products concerned:** the report includes all reportable ToV related to MSD prescription-only-medicines.
- **Companies concerned:** the report includes all reportable ToV made to Recipients in Slovenia by MSD as well as Merck & Co., Inc., Rahway, NJ, USA and its affiliates.
- **Excluded ToVs** under the EFPIA disclosure framework typically refer to the following:
  - **Meals.** MSD does not provide or offer any meal (food and beverage) to HCPs, HCO members and PO Representatives, unless the value of such meal does not exceed the monetary threshold set by the relevant industry association. For meals in connection with events

taking place in Slovenia the monetary threshold is €80. Any ToV below this amount is not disclosed in this report.

- **Informational or educational materials and items of medical utility** provided by MSD do not require disclosure, provided they meet specific criteria detailed in the EFPIA Code of practice: they are (i) inexpensive; (ii) directly relevant to the practice of medicine or pharmacy, (iii) directly beneficial to the care of patients; and (iv) do not offset routine business practices of those who receive them. The nominal value threshold for such materials and items in Slovenia is €42.
- **Medical Samples** are excluded from the disclosure report. In accordance with national and/or EU laws and regulations, MSD may supply a limited number of medicinal products on an exceptional basis and for a limited period under the following conditions:
  - the medicinal product is not intended for peroral use;
  - the medicinal product does not require any special storage conditions, such as a cold chain;
  - no more than two years have elapsed from obtaining of the marketing authorisation or approval of a change of marketing authorisation that requires a new application;
  - the recipient must keep a record of received samples and must not resell them;
  - samples must be in the smallest packaging on the market;
  - samples must not contain narcotic and psychotropic substances.
- ToVs that are part of **ordinary course purchases and sales** of medicinal products by and between MSD and a HCP (for example a pharmacist) or a HCO.
- ToVs Related to **Patients** and **non-HCPs**.
  
- **ToVs date:** Direct ToVs are disclosed based on the date MSD made the ToV, not when the resulting income or benefit was received by the HCO/HCP. Indirect ToVs concerning travel and accommodation are disclosed based on the start date of the event.
  
- **Direct ToVs.** The natural or legal person that holds the bank account on which the money is transferred is considered the recipient of the ToV and

will be disclosed. Direct ToVs are captured in the ERP System and flow into MSD transparency reporting system. They are then mapped to the appropriate EFPIA disclosure ToV category for reporting.

- **Indirect ToVs.**

- **Indirect ToVs through Professional Conference Organizers (PCOs).** When an event (e.g., congress, conference, symposium) is organized by a third party and the ToV is paid to that third party, and we know or can identify the HCO that will benefit from the ToV, we will disclose that ToV under the name of the relevant HCO. As a general principle, we report the full sponsorship amount. We will report a smaller amount only if we are specifically informed about the actual ToV that was transferred to the HCO. For example, this may occur when the HCO has licensed the name of an established event and receives only a set percentage of sponsorship funds as license fees.

- **Indirect ToVs to HCPs through HCOs.**

If we learn that part of ToVs we provided to a HCO have been forwarded to HCPs, we will disclose each such ToV under the name of the relevant HCP and the remaining part under the name of the HCO.

- **Indirect ToVs through third parties for R&D activities.** We will not disclose details of any ToV provided to CROs engaged by us except in the following situations:

- If the CRO is made up of healthcare professionals or is affiliated with a medical institution (such as a university hospital or a publicly funded organization). In this case, the CRO is treated as an HCO, and any ToV provided to it will be published in line with the general rules.
- If the CRO is used as an intermediary to provide ToVs to HCPs and HCOs (“pass-through costs”). In this case, we will publish those ToVs in accordance with the general rules.

- **Indirect ToVs through other third parties**

- Distributors and other commercial partners: In principle, ToVs made to HCPs/HCOs by distributors and other commercial partners working with MSD are disclosed by these distributors and commercial partners according to the disclosure requirements which apply to them. However, if the distributor makes a ToV on behalf of MSD (e.g. influencing the promotional activities and selection of recipient), that ToV is disclosed by MSD.
  - Travel agencies and other companies engaged by MSD to arrange travel and accommodation for HCPs: Travel agencies are contractually obliged to provide MSD with accurate information with respect to travel and accommodation costs which have actually been provided to individual participants. MSD discloses the related ToV except for the administrative costs of that travel agency will not be reported.
- **Non-monetary ToVs.** Non-monetary transfers of value are disclosed based on the financial valuation of the benefits (goods / service time spend etc.) as available on the market. For example, lending a meeting room in our office for the benefit of an HCO or a PO would be determined by the cost of renting a similar meeting room in a hotel.
  - **ToVs in case of partial attendances or cancellation and refund.** ToVs are reported based on what MSD paid, and not on what the Recipient received. Therefore, in case of partial attendance, the full amount paid by MSD is reported. In case of cancelled events, any costs incurred by MSD are reported provided that (i) events are cancelled for reasons that are independent of MSD (e.g. war, pandemic, late HCP cancellations), (ii) MSD could not get totally refunded and (iii) the benefitting HCPs are clearly identified (e.g. HCPs who formally agreed to attend).
  - **Cross-border activities.** MSD discloses all reportable TOVs made to any HCP, HCO or PO whose primary practices, principal professional addresses or places of incorporation are in Slovenia regardless of whether the TOV is made by MERCK SHARP & DOHME, inovativna zdravila d.o.o., Merck & Co., Inc., Rahway, NJ, USA or any of its group affiliates. Any TOV made by MERCK SHARP & DOHME, inovativna zdravila d.o.o. to HCPs,

HCOs or POs whose primary practices, principal professional addresses or places of incorporation are in another country will be disclosed according to the national requirements of that country.

- **R&D.** Under the EFPIA guidance on disclosure of Non-Interventional Studies (NIS), TOVs relating to NIS that are **prospective** in nature are reported on **aggregate** level in the R&D category, whereas TOVs relating to **retrospective** NIS are reported on an **individual** HCP/HCO named basis in the 'Fee for service and consultancy' category. In case ToVs cannot be distinguished whether they report to prospective or retrospective NIS, they are reported on an individual HCP/HCO named basis.

### Specific considerations

- **Country unique identifier**

As guidance under the professional code in EFPIA countries, unique identifiers include:

- Full name
- For HCPs: city of principal practice
- For HCOs: city of registration
- Country of principal practice
- Physical address of the principal practice
- In Slovenia also a randomly created "running" number for HCOs and for HCPs.

These details may only be publicly disclosed in accordance with applicable local personal data protection laws and regulations. The unique country-specific local identifier field will be completed only when the relevant data is available.

- **Self-incorporated HCP.** Disclosure is made based on the Recipient's identity. A TOV made to a legal entity owned by an HCP is disclosed under the name of the legal entity (an HCO) and not under the HCP's name.
- **Multi-year agreements.** Disclosure is made based on the year the actual ToV was provided and not based on a pro rata amount of the intended total ToV under the agreement.

- **Quality Checks.** Data will be pre-validated before it is consolidated and prepared for disclosure. Data validations are performed regularly throughout the year and cover all sources of data. There are control steps and error reports within the process to immediately identify missing data and mismatches. The quality check is linked to a KPI and subject of a regular and frequent review. Data checks are following a methodology performed in and above countries.

### **Data protection legal basis**

- **Consent collection.** Before any engagement with MSD, each individual HCP is asked whether they agree to the disclosure of TOV received from MSD during the calendar year. They always have the right to legally object to the processing of their data. In this case the TOV will be published in the aggregate form so they could not be identified. The number of Recipients included in the aggregate disclosure is included in the total number of Recipients disclosed.
  - Individual HCPs also have the right to legally **withdraw** their consent after it has been originally granted. In this case, their individual TOV related data will be deleted from the individual disclosure section and added to the aggregated disclosure section of the report.
  - If an HCP grants partial consent to any aspect of disclosure e.g. the recipient does not allow disclosure of all categories or of all ToV, all ToV made to that individual HCP are disclosed in the aggregate section of the report.
- **Consent collection.** The data protection rights or other fundamental rights of HCPs do not outweigh the legitimate interest of the pharmaceutical companies and the general public in the disclosure of TOV in accordance with the EFPIA Code and the national Personal Information Protection Act (ZVOP-2). Based on this assessment, MSD in Slovenia processes and discloses TOV made to HCPs based on individual consent by each HCP allowing the disclosure of 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 Slovenia is by stand-alone agreement covering all interactions with the HCP.

- **Management of Recipient consent withdrawal.** A Recipient has the right to withdraw his/her consent at any time. If this occurs prior to MSD's publication of the ToV, then the Recipient's ToVs 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 ToVs, then the Recipient's name and ToVs shall be removed and the corresponding amount of ToVs 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 ToVs they have received (which is not in the interest of MSD or EFPIA), MSD shall disclose the entire amount of the HCP's ToVs 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.

### Form of Disclosure

- **Date of publication.** The present report was published in June 2026 and covers all TOVs made between Jan. 1<sup>st</sup> and Dec. 31<sup>st</sup> 2025.
- **Disclosure platform.** The present report is published on <https://www.msd.si/odgovornost/eticno-in-pregledno-poslovanje-druzbe/porocanje-po-kodeksu-ravnanja/>.
- **Disclosure language.** The present report is published both in Slovenian and English.

### Disclosure financial data

- **Currency.** All disclosed ToVs are reported in EUR. As a matter of principle, ToVs paid in other currencies were converted to EUR at the exchange rate applicable on the date the cost was incurred. As an exception, Indirect ToV's for Travel and accommodation that were received from MSD entities abroad, were converted to EUR at the exchange rate applicable on the date the cost is incurred.
- **Taxes.** TOV reflects the actual value or cost paid by MSD to the Recipient after taxes have been deducted (net amount). They are exclusive of VAT except for ToV for travel and/or lodging that is invoiced for reimbursement by the HCP, which is disclosed inclusive of VAT.

