

# Methodological Note

## - Merck Oy Finland -

an affiliate of Merck KGaA, Darmstadt, Germany

### 1. Introduction

This Methodological note summarizes the methodologies used in preparing the company's disclosure according to the EFPIA HCP/HCO Disclosure Code and local Pharma Industry Finland (PIF) Code of Ethics, and identifying transfers of value made directly or indirectly to or for the benefit of a Recipient.

All the company's HCP/HCO Transfer of Values are covered with written agreement.

### 2. Definitions

#### **Recipients**

Any Healthcare Professional or Healthcare Organization, whose primary practice, principal professional address or place of incorporation is in Europe<sup>1</sup>.

#### **Healthcare Organization (HCO)**

Any legal person

- (i) that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organizations within the scope of the EFPIA PO Code) whose business address, place of incorporation or primary place of operation is in Europe or
- (ii) through which one or more HCPs provide services.

#### **HCP**

Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or

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<sup>1</sup> As defined in the EFPIA HCP/HCO Disclosure Code: Those countries currently include the following 33 countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and the United Kingdom.

administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCP includes:

- (i) any official or employee of a government 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 a Member Company whose primary occupation is that of a practicing HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.

### **Kind of Transfers of Value (ToV)**

Direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only Medicinal Products exclusively for human use.

- **Direct ToVs**

Transfers of value made directly by the company for the benefit of a Recipient.

- **Indirect ToVs**

Transfers of value made on behalf of the company for the benefit of a Recipient, or transfers of value made through an intermediate and where the company knows or can identify the HCP/HCO that will benefit from the Transfer of Value. ("Follow the Money").

- **Aggregate ToVs**

For Transfers of Values, which cannot be disclosed on an individual basis for legal reasons (e.g. HCP used right to object to the processing of her/his personal data), the amounts attributable to such ToVs will be disclosed on an aggregate basis. The aggregate disclosure identifies (i) the number of Recipients covered by such disclosure, and (ii) the aggregate amount attributable to Transfers of Value to such Recipients.

- **Research and Development Transfers of Value**

Transfers of Value to HCPs or HCOs 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 Directive 2001/20/EC)

(iii) 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, HCPs specifically for the study (Section 15.01 of the Efpia HCP Code)

### **Reporting Period**

Full calendar year, starting with the calendar year 2015.

### **3. Disclosure's scope**

#### **Products concerned**

Prescription-only medicine.

In addition to disclosing ToV's concerning prescription-only medicine, some countries are bound by legislation or local Pharma Association provisions to disclose their OTC interactions as well. The company has not had any OTC interactions during the reporting period.

#### **Included Transfer of Value**

Disclosed ToVs for Individual HCP include:

- a. HCP's name and clinic name, address, city and country of principal practice
- a. Contributions to the costs of events (registration fees and travelling and accommodation costs).
- b. Fee for service and consultancy with related travel and accommodation costs when relevant to the contract. E.g. Speaker fee, general consulting or advising, compensation for medical writing or data analysis, medical development of informational and/or educational material.

Disclosed information and ToVs for HCO include:

- a. HCO's name and address, city and country where registered
- b. Donations and grants allocated to institutions, organizations or associations or societies.
- c. Contributions to the costs of events, e.g. venue costs, speaker fees, study materials, moderate working meals, HCP participation costs (registration fee, travelling and accommodation costs).
- d. Sponsorships provided for the organization of events, e.g. rentals of exhibition stand or booth, purchase of advertising space or timeslot for satellite symposium.
- e. Fee for service and consultancy with related travel and accommodation costs when relevant to the contract.

#### **Excluded transfers of value**

- a. Provision of materials and objects of informative or educational character;

- b. Meals in connection to HCP/HCO meetings if not part of sponsorship for organizing an event;
- c. Medical samples ;
- d. Fees charged by logistics agencies assisting in organising travels and meetings;
- e. Discounts, price reductions and other trading devices commonly used in the sale of medicinal products;
- f. Healthcare packages provided by private entities purchased by Signatories for their employees;
- g. Related to anonymous ("double-blinded") marketing research

### **Transfer of value date**

- a. Date of Transfer of Value is the date of the effective payment to the recipient.
- b. If the payment is executed at several different dates (e.g. for one and the same assignment fees are payed at another date than travel costs) the date of the largest amount of payment effected is taken as payment date.
- c. In case of sponsorship of HCP/HCO to attend medical/scientific meetings/events managed by third party incl. payment by third party the event date is taken as transfer of value date if the effective payment date of registration fees to event organizer, accommodation costs to hotels etc. significantly differ from the transfer of value date (= receipt of the congress batch, date of accommodation etc.) of the recipient.

### **Direct transfer of value**

- a. Transfers of value are represented as the cost amount for the company and not the recipient's revenue.
- b. Non-financial transfers of value are disclosed based on the financial valuation of the non-financial spend (goods / service time spend etc.).

### **Indirect transfer of value**

- a. Transfers of value provided to HCOs by a third party company, e.g. through an organizer of medical events are reported with the HCO as recipient.
- b. Transfers of value to individual HCPs executed by a third party company are reported with the individual HCPs as recipient.
- c. Transfers of value to individual HCPs (e.g. invitations, covering travel or accommodation costs) executed by a HCO are reported as transfer of value to the HCO.

### **Transfer of value in case of partial attendances or cancellation**

- a. In case of partial engagement or cancellation of engagement, already transferred value is disclosed unless HCP hasn't object to the processing of her/his personal data.
- b. If in case of partial engagement or cancellation of engagement no value was transferred to HCP/HCO, the potential costs for the company are not part of disclosure.

### **Cross-border activities**

- a. Cases of cross-border transfers of value to HCPs/HCOs, falling in the scope of the Transparency Code, are disclosed in accordance with the recipient's country of practice (HCP) or country of registration (HCO).
- b. If one HCP/HCO has several countries of practices / registration the country in which context the assignment took place discloses the transfers of value.

### **Disclosure Type**

#### **a. Disclosure of individual data:**

- Transfers of values are disclosed individually by each identifiable recipient. Merck Oy moves to disclosing transfers of values of healthcare professionals based on legitimate interest as of 2023. The individual data and transfer of value in the reporting period are disclosed as required by the Efpia disclosure template.

#### **b. Disclosure of aggregated data:**

- If a healthcare professional objects to the processing of her/his personal data Merck Oy will disclose via aggregated transfer of value data in the reporting period as required by the Efpia disclosure template.

## **4. Specific considerations**

### **HCP/HCO identification details**

As guidance on the professional code in the EFPIA country and based on the local personal data protection laws and regulations, the identification details include

- for a HCP: HCP Name and the Name, Address, City and Country of Principle Practice

- for a HCO: HCO Name, Address, City and Country where Registered Note. The Unique Country Local Identifier (e.g. a professional code) is not collected in Finland based on local personal data protection laws and regulation.

### **Self-incorporated HCP**

A self-incorporate HCP constitutes a HCO (see above section 'Definition of HCO') and disclosure of ToV will be handled accordingly.

### **Multiannual agreements and transfers of value in different calendar years**

In the case of multiannual agreements or other agreements based on which the transfers of value were provided in different calendar years, the information is included in the report about those which were effectively paid to the recipient in a given calendar year / reporting period.

### **Methodology for R&D spend documentation**

Research and Development Transfers of Value will be disclosed in aggregate.

In scope are ToV to HCPs/HCOs related to the planning and conduct of:

- a. Non-clinical studies (as defined in the OECD Principles of GLP)
- b. Clinical trials (as defined in Directive 2001/20/EC)
- c. 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, HCPs specifically for the study (cfr Section 15.02 of the EFPIA HCP Code)

Also Investigator Sponsored Studies (ISS) will be disclosed in aggregate category.

Non-interventional studies that are retrospective in nature will be disclosed under the individual HCO spend category.

The determination of R&D spend according to EFPIA regulations is based on the company Healthcare's regular internal expense reporting and allocations derived from Clinical Operations Statistic.

## 5. Legitimate interest

As a member company of Pharma Industry Finland, Merck Oy moves to disclosing transfers of value of healthcare professionals based on legitimate interest as of concerning disclosure of data from 2023. To the extent that legitimate interest is the basis for processing, the healthcare professional will no longer be specifically requested for consent to the disclosure of their data. However, healthcare professionals have the right to object to the processing of her/his personal data. If so desired, the healthcare professional must actively notify Merck by submitting a request via [Data Privacy Portal](#).

For healthcare professionals who have objected the disclosure by their name the data is disclosed in a summary form so that the individual is not identifiable. The data subject has the right to object to the processing of their data also afterwards, in which case the data will be deleted from public registers without delay.

### **Management of recipient's request**

Requests and/or complaints by Recipients may be lodged with the local company Legal Entity and the company contact person named in the HCP/HCO contract.

## 6. Disclosure Form

### **Date of publication**

Disclosure will be made within six month after the end of the reporting period. The exact date of publication varies between the EFPIA Countries and depends on legal stipulations.

In Finland the disclosure will take place each year in June.

All belated payments with a date falling in a closed-out reporting period will be consolidated over the year and published each year in Q4.

## **Disclosure platform**

Disclosure reports will be published on [the company website](#).

Legal Stipulations in some countries require disclosure on an external central platform run by the government or a regulatory authority or Industry association. In Finland there will be a direct link from local Pharma Industry Finland (PIF) website to the company website for disclosure and vice versa.

<http://www.laaketeollisuus.fi/laakkeet/markkinointi/laakeyrytysten-jaterveydenhuollon-ammattilaisten-yhteisty>

## **Disclosure language**

Reports will be disclosed in local language and English, using a bilingual disclosure template.

# **7. Disclosure of financial data and calculation rules**

## **Currency**

- a. Total value of the transfers of value is disclosed in local currency (EUR) after conversion from foreign currencies per the exchange rates adopted on the day of documenting the effective payments in the electronic system.
- b. Reference point of conversion is EUR.
- c. Basis of the calculation of transfer rates is the company-internal exchange rate table which is updated monthly.
- d. Basis of the calculation of transfer rate for R&D costs is the official local exchange rate (EUR) of the last day of each year.

## **VAT included or excluded**

Transfers of value are disclosed with VAT included.

## **Calculation rules**

- a. Transfers of value effected in the reporting period are summed up (for individuals or aggregated) according to the segmentation of the Efpia disclosure template requirements.
- b. Only amounts of payments effected within the given calendar year (= reporting period) are considered with the calculation (see also note re ToV date and ToV in different calendar years).
- c. Calculation is executed with amounts of harmonized (same) currency (see also note to Currency).