

# Merck Serono Limited

An affiliate of Merck KGaA, Darmstadt, Germany

## Methodological note for HCP/ORDM/HCO disclosure 2025

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### Introduction

This Methodology note summarises the methodologies used in preparing Merck Serono Limited's (hereinafter "the Company") disclosure according to the EFPIA HCP/HCO Disclosure Code and the ABPI Code of Practice for the Pharmaceutical Industry to identify transfers of value, made directly or indirectly, to or for the benefit of a Recipient.

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# 1 Definitions

## 1.1 Recipients

Any HCO, HCP or ORDM, whose primary practice, principal professional address or place of incorporation is in Europe<sup>1</sup>.

### HCO

Any legal person

(i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations 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 or ORDMs 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 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:

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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.

(i) any official or employee of a government agency or other organisation (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 (a) all other employees of a Member Company and (b) a wholesaler or distributor of medicinal products.

### **Other Relevant Decision Maker (ORDM)**

Includes someone with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who is not a health professional.

If a transfer of value is made to a Recipient within the data year, the information about the transfer of value will be published as described in this methodological note, regardless of if the Recipient has subsequently retired, moved country of primary practice or otherwise moved out of scope, unless an objection is raised regarding legitimate interests as being the basis of lawful processing.

## **1.2 Kind of ToVs**

Direct and indirect transfers of value ("ToV"), 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.

### **- Aggregate ToVs**

For Transfers of Values, which cannot be disclosed on an individual basis for legal reasons, 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.

### **- R&D ToVs**

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 Medicines for Human Use (Clinical Trials) Regulations 2004);

(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;

- The types of ToVs disclosed are:
  - collaborative working, including joint working, in accordance with Clause 20 of the ABPI Code
  - donations and grants provided to healthcare organisations, institutions and other organisations in accordance with Clause 23 of the ABPI Code
  - fees and expenses paid for contracted services between companies and institutions, organisations or associations of health professionals, in accordance with Clause 24.6 of the ABPI Code
  - support of attendance by health professionals and other relevant decision makers at events/meetings whether paid directly, indirectly or via another party in accordance with Clause 10.11 of the ABPI Code
  - fees and expenses paid for contracted services to health professionals and other relevant decision makers, or to their employers on their behalf, in relation to Clause 24.6 of the ABPI Code
  - sponsorship, including contributions to costs related to events/meetings paid to healthcare organisations or to organisations managing events on their behalf, which may include support of health professionals not known to the company via the healthcare organisation by way of registration fees, accommodation and travel, in accordance with Clause 10.12 of the ABPI Code

## **2 Disclosure's Scope**

### **2.1 Products concerned**

Prescription Only Medicines.

### **2.2 Company concerned**

All affiliates of Merck KGaA, Darmstadt, Germany

### **2.3 Excluded ToVs**

- 1) solely related to over-the-counter medicines;
- 2) provision of materials and objects of informative or educational character;
- 3) meals;
- 4) samples;
- 5) fees charged by logistics agencies assisting in organising travel and meetings;
- 6) discounts, price reductions and other trading devices commonly used in the sale of medicinal products;
- 7) healthcare packages provided by private entities purchased by Signatories for their employees;
- 8) related to anonymous marketing research.

## **2.4 ToVs date**

Date of Transfer of Value is the date of the effective payment to the recipient. In case of sponsorship of HCP/HCO to attend medical/scientific meetings/events managed by third party, including 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.

## **2.5 Direct ToVs**

Transfers of value are represented as the cost amount for The Company and not the recipient's revenue.

## **2.6 Indirect ToVs**

- 1) Transfers of value provided to HCOs by a third-party company, e.g. through an organiser of medical events, are reported with the HCO as recipient.
- 2) Transfers of value to individual HCPs executed by a third-party company are reported with the individual HCPs as recipient.
- 3) 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, unless the names of the recipients are known.

## **2.7 Non-monetary ToVs**

Non-monetary/non-financial transfers of value are disclosed based on the financial valuation of the non-financial spend (goods / service time etc.).

## **2.8 ToVs in case of partial attendances or cancellation and refund**

In case of partial attendance or cancellation, or services not delivered, but value was transferred anyway e.g. according to contract clause, the transferred value is disclosed.

If no value was transferred, the information on the transfer of value is not part of disclosure.

Refunds will be included in the data year the refund is made.

## **2.9 Cross-border activities**

Cases of cross-border transfers of value to Recipients, falling in the scope of the ABPI Code, are disclosed in accordance with the Recipient's country of practice (HCP) or country of registration (HCO).

If one Recipient has several countries of practices / registration, the country in which context the assignment took place discloses the transfers of value.

## **2.10 R&D**

Research and Development ("R&D") Transfers of Value will be disclosed in aggregate. In scope are TOVs to Recipients related to the planning and conduct of:

- Non-clinical studies (as defined in the OECD Principles of GLP)
- Clinical trials (as defined in Medicines for Human Use (Clinical Trials) Regulations 2004)
- 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
- Non-interventional studies and activities not falling within the definition of R&D TOVs will be disclosed under the relevant HCO spend category.

The determination of R&D spend is based on The Company Healthcare's regular internal expense reporting and allocations derived from Clinical Operations Statistic.

## **2.11 Voluntary disclosure**

- Not applicable

# **3 Specific considerations**

## **3.1 Country unique identifier**

As guidance on the professional code in the EFPIA country, the unique identifiers include:

- the Full Name
- for a HCP: the City of Principle Practice
- for a HCO: the City where Registered
- the Country of Principal Practice
- the physical address of the Principal Practice; and

## **3.2 Self-incorporated HCP**

A self-incorporate HCP constitutes a HCO (see above section 'Definition of HCO')

## **3.3 Multi-year agreements**

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 the data year/ reporting period.

## **3.4 Country specificities**

Links to Collaborative Working executive summaries are included in the submission template, however for reference can also be found [here](#)

### **3.5 Quality Checks**

The Company employs a globally harmonized process and dedicated tools for the collection, processing, and reporting of transfer of value (ToV) data. Within this framework, multiple embedded quality assurance mechanisms ensure the accuracy, completeness, and consistency of the data. Periodic and systematic checks are conducted at various stages of the reporting cycle, including data validation, cross-functional reviews, and reconciliation procedures.

## **4 Data protection legal basis**

### **4.1 Consent collection**

- Not applicable

### **4.2 Legitimate interests**

Data subjects are informed in the contract of the lawful basis of processing for TOV being legitimate interests.

Objections can be raised to the LDPO, on a case by case basis, where consideration will be given, with a decision issued to the data subject with a right to bring the matter before the ICO. In considering each objection on its merits, the LDPO will assess (i) the nature of the personal data; (ii) the reasonable expectations of the data subject; and (iii) the likely impact of the processing.

Given the overriding objective of TOV disclosure is to provide confidence and transparency in the industry, the threshold to sustain an objection is high.

## **5 Form of disclosure**

### **5.1 Date of publication**

Disclosure will be made within six months after the end of the reporting period, on 30/06/2026

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.

### **5.2 Disclosure platform**

Disclosure reports will be published on central platform of the ABPI and the Company's own website by a link to the external ABPI platform where the disclosure report is published. The platform is publicly available at:

[www.disclosureuk.org.uk](http://www.disclosureuk.org.uk)

### **5.3 Disclosure language**

Reports will be disclosed in English language.

## **6 Disclosure financial data**

### **6.1 Currency**

Total value of the transfers of value is disclosed in GBP after conversion from foreign currencies. Our reporting tool utilises the monthly average exchange rate associated with the date of the payment/transfer of value to the recipient. The reference point of conversion is EUR.

### **6.2 VAT included or excluded**

Transfers of value are disclosed with VAT included where possible.

### **6.3 Calculation rules**

Transfers of value effected in the reporting period are summed up (for individuals or aggregated) according to the segmentation of the disclosure template requirements.

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).

Calculation is executed with amounts of harmonised (same) currency (see also note to Currency).

## **7 Additional Information**

Not applicable.