

# Methodological Note

Merck Serono Ltd. UK

An affiliate of Merck KGaA, Darmstadt, Germany

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## 1. Introduction

This Methodology note summarizes 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.

## 2. Definitions

### a. Recipients

The Public, including Patients and Journalists, whose primary residence is in Europe<sup>1</sup> and;

### b. Other Organisation

Any organisation

(i) that is a Third-Party Medical Education Provider, that is profit and/or non-profit Continuing Medical Education providers, medical societies, foundations, universities, clinics, and other scientific organizations dedicated to the professional medical learning (not otherwise defined as HCO in the ABPI Code)

### c. that is otherwise a Professional Congress Organiser(PCO)

(ii) through which services are provided to enhance or effect the

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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.

healthcare system in the United Kingdom, who are not HCOs as defined in the ABPI Code .

#### **d. Kinds of Transfer of Values**

Transfers of value ("ToV"), whether in cash, in kind or otherwise, made, in connection with the development and sale of prescription-only Medicinal Products exclusively for human use.

- **Aggregate ToVs**

Transfers of Values will be disclosed on an aggregate basis, combined under types of services. 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.

### **3. Scope of disclosure**

#### **a. Products concerned**

Prescription-only medicines.

Exception: 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.

#### **b. Excluded transfers of value**

- (1) solely related to over-the-counter medicines (except in some countries in which over-the-counter-medicines are required to be included in the disclosure);
- (2) provision of materials and objects of informative or educational character;
- (3) meals (except in some countries in which meals are required to be included in the disclosure);
- (4) samples ;
- (5) fees charged by logistics agencies assisting in organising travels 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

#### **c. Transfer of value date**

Date of Transfer of Value is the date of the effective payment to the recipient or the date the benefit is received.

#### **d. Direct transfer of value**

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

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

#### **e. Indirect transfer of value**

Transfers of value provided to a third party company, e.g. an organizer of medical events are reported with the HCO as recipient where possible in the ABPI Portal. If there is no HCO identified the transfer of value will be reported with the Other Organisation as the recipient.

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

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.

#### **g. Cross-border activities**

Cases of cross-border transfers of value to Recipients, falling in the scope of the Transparency Code, are disclosed in accordance with the Recipient's country of residence (Public, patient or journalist) or country of registration (Other Organisation).

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

### **4. Specific considerations**

#### **a. 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.

## **5. Disclosure Form**

### **a. Date of publication**

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

### **b. Disclosure platform**

Disclosure reports will be published by link on the central platform of the ABPI to the Company's own website where the disclosure report is published.

### **c. Disclosure language**

Reports will be disclosed in English language.

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

### **a. Currency**

Total value of the transfers of value is disclosed in GBP after conversion from foreign currencies. Our reporting tool utilizes 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.

### **b. VAT included or excluded**

Transfers of value are disclosed with VAT included where possible.

### **c. 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 harmonized (same) currency (see also note to Currency).