Methodological Note

Merck Serono Ltd. UK

Contents

1. Introduction

This Methodology note summarizes the methodologies used in preparing Merck Serono Limited's (hereinafter "Merck") 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

Any HCP or HCO, whose primary practice, principal professional address or place of incorporation is in Europe[1].

b. 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.

[1] 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.

c. 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:

(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 (a) all other employees of a Member Company and (b) a wholesaler or distributor of medicinal products.

d. Kinds of Transfer of Values

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 Merck for the benefit of a Recipient.
- **Indirect ToVs**
  Transfers of value made on behalf of Merck for the benefit of a Recipient, or transfers of value made through an intermediate and where the Merck 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.
- **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 HCP Code);

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. 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.

d. Direct transfer of value

Transfers of value are represented as the cost amount for Merck 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

(1) 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.

(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.

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 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).

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

h. Disclosure Type

Disclosure of individual data:

(1) If the signed consent declaration, with disclosure explicitly consented in a given validity period, is obtained the individual data and transfer of value in the reporting period are disclosed as required by the EFPIA disclosure template.

(2) If in the closed contract, the disclosure consent has been explicitly granted by signature, and consent has not been denied (non-consented) or withdrawn in at least one assignment by signature the individual data and transfer of value in the reporting period are disclosed as required by the EFPIA disclosure template. This is applied for countries with individual consent declaration required by local law or codices.

Disclosure of aggregated data:

(1) Signed consent declarations with disclosure explicitly non-consented in the given validity period lead to disclosure of aggregated data of transfer of value in the reporting period as required by the EFPIA disclosure template.

(2) Transfers of value to recipients from which consent declaration could not be obtained are disclosed on an aggregated basis.

(3) If in any (at least one) contract closed, with transfer of value in the reporting period, the disclosure consent has explicitly not been granted by signature all transfers of value in the reporting period to the recipient are disclosed on an aggregated basis as required by the EFPIA disclosure template. This is applied for countries with individual consent declaration required by local law or codices.

4. Specific considerations

a. 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
- where applicable: the Unique Country Local Identifier (e.g. a professional code)

Whether such full details can be publicly disclosed depends on local applicable personal data protection laws and regulations

b. Self-incorporated HCP

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

c. 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 payed to the recipient in a given calendar year/ reporting period.

d. Methodology for Research & Development spend documentation

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

- Non-clinical studies (as defined in the OECD Principles of GLP)
- Clinical trials (as defined in Directive 2001/20/EC)
- 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)
- 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 Merck Healthcare's regular internal expense reporting and allocations derived from Clinical Operations Statistic.

5. Consent management

a. Consent collection

Disclosure consent declaration is obtained for 5 years, starting 1st of January of the relevant calendar year.

b. Management of recipient consent withdrawal

If the consent to disclose individual data and transfer of value is withdrawn the individual data are removed from the disclosed form within a period of 14 days after submitting written withdrawal.

Consent may not be partially withdrawn or granted for selected assignments. Withdrawal of a disclosure consent for selected assignments leads to revocation of disclosing any individual data in the reporting period.

c. Management of recipient's request

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

d. Partial consent

No partial consent is granted. The Recipient only may give full consent to any aspect of disclosure or may decline consent in full.

6. Disclosure Form

a. 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.

b. 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.

c. Disclosure language

Reports will be disclosed in English language.

7. 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 daily exchange rate associated with the date of the payment/transfer of value to the HCP.

(1) Reference point of conversion is EUR.
(2) The source for the daily rates feeding our reporting tool is http://www.xe.com/en/

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).