Methodological Note

Merck Group Switzerland

Merck (Schweiz) AG
Allergopharma AG
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1. Introduction

This Methodology note summarizes the methodologies used in preparing Merck's disclosure according to

EFPIA HCP/HCO Disclosure Code

and

Pharma Cooperation Code (Code of Conduct of the Pharmaceutical Industry in Switzerland on cooperation with Healthcare Professional Circles and Patient Organizations of September 6, 2013)

and identifying transfers of value, made directly or indirectly to or for the benefit of a Recipient.

2. Definitions

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

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 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.

[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.

Kind of ToVs
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 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)
- (iv) investigator sponsored trials (IST)

3. Disclosure's scope

Products concerned
Prescription-only medicine.

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.

Excluded transfers of value

a. 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);
b. provision of materials and objects of informative or educational character;
c. meals (except in some countries in which meals are required to be included in the disclosure);
d. samples ;
e. fees charged by logistics agencies assisting in organising travels and meetings;
f. discounts, price reductions and other trading devices commonly used in the sale of medicinal products;
g. related to anonymous 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 Merck 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 attendance or cancellation, or services not delivered, but value was transferred anyway e.g. according to contract clause, the transferred value is disclosed.
b. If no value was transferred, the information on the transfer of value is 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:

- 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.
- 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.

b. Disclosure of aggregated data:

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

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 publically disclosed depends on local applicable personal data protection laws and regulations.

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

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.

Contribution to costs of events
According to the Swiss Therapeutic Products Act (Art 33) and its interpretation by Swissmedic and the professional associations, Merck is obliged to invoice HCPs with 1/3 (doctors in training "assistant physicians" 1/5) of the expenses. The disclosed amounts are the effective contributions paid to the HCPs or HCOs.

Methodology for Research and Development ToV's
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).
d. Investigator sponsored trials (IST) (as defined in the EFPIA Disclosure FAQ document)

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

Consent collection

a. Disclosure consent declaration is obtained for 5 years, starting 1st of January of the calendar year of signing the declaration.
b. Disclosure consent declaration is obtained with each assignment according as to the local law or codices in the country of practice / registration of the recipient.

Management of recipient consent withdrawal

a. If the consent to disclose individual data and transfer of value is withdrawn, the individual data will be removed from the disclosed form and website(s) at the latest within 14 days after receipt of withdrawal.
b. 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.

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.

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

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.

Disclosure platform

Disclosure reports will be published on www.merckgroup.com/en/responsibility/regulations_and_guidelines/transparency/transparency.html. Legal stipulations in some countries require disclosure on an external central platform run by the government or a regulatory authority. In this case, Merck will provide a link to the external source where the disclosure report is published.

Disclosure language

Reports will be disclosed in English.

7. Disclosure of financial data and calculation rules

Currency

a. Total value of the transfers of value is disclosed in local currency 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 (CHF 1,0896) of 31 Dec 2016.

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).