Methodological Note

- Merck Oy Finland -

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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[1].

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

[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.

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 compnay 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. no consent provided), 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

When consented by HCP diclosed 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 according to applicable consent status.

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:

- If the voluntary, separate, specified, signed consent declaration, with disclosure explicitly consented for a given validity period (one calendar year retrospectively), is obtained 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:

- Signed consent declarations with disclosure explicitly non-consented in the given validity period (one calendar year retrospectively) 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 during first contact and after two reminding contacts are disclosed on an aggregated basis in applicable category.

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 payed 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. Consent management

Consent collection

The issue of data protection and confidentiality is a topic we take very seriously and we follow applicable national and European data protection regulations. Consent shall be totally voluntary, separate and specified. In the company separate disclosure consent declaration signed by HCP is collected retrospectively for each calendar year. Consent includes specified list of all ToVs received during the reporting period. HCP voluntarily decides to consent or non-consent all the specified received ToVs as required by the Efpia disclosure Code ("All or nothing").

Management of recipient consent withdrawal

a. If the consent to disclose individual data and all transfer of values are withdrawn the individual data are removed from the disclosed form and such ToVs will be disclosed in aggregated HCP category in due course, though within a period of 14 days at the latest, after submitting written 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. Such ToVs as a whole will then be disclosed in aggregated HCP category. ("All or nothing").

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.

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. ("All or nothing").

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/laakeyritysten-jaterveydenhuollon-ammattilaisten-yhteistyo

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) ofthe 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).