Methodological Note

- Merck AB Sweden –

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1. Introduction

This Methodology note summarizes the methodologies used in preparing the company's disclosure according to the EFPIA HCP/HCO Disclosure Code and local Swedish Association of the Pharmaceutical Industry (LIF) Code of Ethics (LER), and identifying Transfers of Value, made directly or indirectly to or for the benefit of a Recipient.

All the company 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.

Healthcare Professional (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

[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.

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 Values (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 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. ("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.

LER
Ethical Rules for the Pharmaceutical Industry in Sweden / Läkemedelsbranschens etiska reglerverk, http://www.lif.se/etik/filer--mallar/

3. Disclosure's scope

Products concerned

Prescription-only medicine.

The company have not had any OTC interactions.

Included Transfer of Value

When consented by HCP diclosed ToVs for Individual HCP include:

a. HCP's name and address, city and country of principal practice
b. Fee for service and consultancy (as defined in LER chapter 2, section 1, article 5) 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 (LER chapter 2, section 1, article 10)
c. Sponsorships for meeting arrangement (LER chapter 2, section 1, article 4b) when the company gets in return e.g. an exhibition stand or booth, advertising space or timeslot for satellite symposium.
d. Financial support to meeting arrangements organized in collaboration with healthcare (LER chapter 2, section 1, article 4), e.g. venue costs, speaker fees, study materials, moderate working meals.
e. Fee for service and consultancy (LER chapter 2, section 1, article 5) with related travel and accommodation costs when relevant to the contract.

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). In the company no OTC interactions;
b. Provision of materials and objects of informative or educational character;
c. Meals in connection to HCP/HCO meetings (if not part of financial support to meeting arrangements);
d. Medical 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. Healthcare packages provided by private entities purchased by Signatories for their employees;
h. Related to anonymous ("double-blinded") marketing research

Transfer of value date

- Date of Transfer of Value is the date of the effective payment to the recipient.
- 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.

  Note. *No sponsorship of HCP/HCO to attend medical/scientific meetings/events (registration fees, travel and accommodation costs) allowed in Sweden since 01 Jan 2015.* (LER chapter 2, section 1, article 4b)

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

- 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.
- Transfers of value to individual HCPs executed by a third party company are reported with the individual HCPs as recipient.
- 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 engagement or cancellation

a. In case of partial engagement, already transferred value is disclosed according to applicable consent status.
b. In case of cancellation of engagement, when no benefit received by HCP/HCO, already transferred value is disclosed in

aggregated category if ToV not refundable for the company, e.g. cancelled Speaker's travel bookings without refund.

c. 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 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.

b. Disclosure of aggregated data:

i. Transfers of value to recipients from which consent declaration could not be obtained or is later withdrawn are disclosed on an aggregated basis.
ii. 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 Code ("All or nothing").
iii. The aggregated details shall, for each category, include (i) the number of recipients which are comprised by the details, expressed as a number and a percentage of the total number of recipients, and (ii) the aggregated amount for the transfer of value which is not disclosed on an individual level.

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

Unique Country Local Identifier (e.g. a professional code). This is voluntary information in Sweden, not collected by the company.

Self-incorporated HCP

A self-incorporate HCP constitutes a HCO (see above section 'Definition of HCO'). Note. In Sweden disclosure consent has to be collected from self-incorporated HCPs too.

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 category.

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

In Sweden, according to the local law and codices in the country of practice/registration of the recipient, disclosure consent declaration is obtained with each assignment accordingly.

Management of recipient consent withdrawal

a. If the consent to disclose individual data and transfer of value is withdrawn the individual data are removed from the individual 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").

New General Data Protection Regulation (GDPR)

The General Data Protection Regulation will become effective on 25 May 2018. All Personal Data which will be processed on that date and onwards shall comply with the new regulation including also the data already disclosed on Efpia Reports.

Because of this new Regulation and because LIF's previous Consent form (according to LIF's legal counsel DLA) will not be compliant with GDPR, LIF's board recommends that all Companies shall aggregate the data disclosed 2016 and 2017 as follows:

- The data governed by PUL/GDPR on the Reports shall be disclosed on an aggregated basis.
- Important though is that the company shall do this adjustment during 1-24 May 2018. During that period the earlier Reports can be non- accessible for the public.

Note. Report which will be disclosed on 31 May 2018 (2017 Transfers of Value) shall be disclosed according to Efpia Code based on the Disclosure Consent compliant with GDPR.

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 Sweden the disclosure will take place each year on the 31st of May.

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's local website http://www.merck.se/sv/responsibility/transparency/transparency.html

Legal Stipulations in some countries require disclosure on an external central platform run by the government or a regulatory authority or Industry association. In Sweden the company will provide a link to LIF Cooperation Database where the disclosure report is also published: http://www.lif.se/etik/samarbetsdatabaser/

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 (SEK) 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 (SEK) of the 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).