Merck Methodological Note

Merck Czech Republic
an affiliate of Merck KGaA, Darmstadt, Germany

on Disclosure of Payments and other Transfers of Values to Health Care Professionals and Health Care Organizations following the 'EFPIA Code on Disclosure of Transfers of Value'

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1. Introduction

This Methodological Note refers to the Transparent Cooperation Initiative which is a Europe-wide project dealing with disclosure of Transfer of Values between the pharmaceutical industry and healthcare professionals/organizations. In the Czech Republic, this obligation is regulated by the Czech Disclosure Code and this methodological note is issued based on its Section 3.05. The aim of this document is to provide readers of disclosed data with further information about methodologies used when disclosing Transfer of Values, made directly or indirectly to or for the benefit of a Recipient.

2. Purpose

This document is intended to serve as supporting documentation for the 2021 Merck spol. s.r.o. (herein after as "Company"). Disclosure Report based on AIFP procedural requirements. The interpretation is based on the current version of the EFPIA Disclosure Code/ AIFP Disclosure Code.

The Methodological Note summarizes methodologies and business decisions as well as country specific considerations applied byCompany in order to identify, collect and report ToVs for each disclosure category in compliance with EFPIA Disclosure Code/ AIFP Disclosure Code.

3. Definitions

Recipients

Any HCP or HCO, whose primary practice, principal professional address or place of incorporation is in Czech Republic.

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 AIFP Code of relationships between Pharmaceutical industry and Patient Organizations) whose business address, place of incorporation or primary place of operation is in Europe or

(ii) (ii) through which one or more HCPs provide services.

The healthcare organization is also the company or other legal entity established by another healthcare professional who might also be its employee.

Healthcare Professional (HCP)

Any person entitled to either prescribe or dispense a medicine. This definition follows the legal definition of HCP in the Czech Advertising Regulation Act. With regards to this legal definition, transfers of values to other healthcare professionals, e.g. nurses, do not fall within the scope of the disclosure obligation.

Kind of Transfer of Values (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 Company for the benefit of a Recipient.
- **Indirect ToVs** - transfers of value made on behalf of Company for the benefit of a Recipient, or transfers of value made through an intermediate and where Company 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).

4. Disclosure's scope

This 2021 Company Disclosure Report is following disclosure standards pursuant to the EFPIA Disclosure Code / AIFP Disclosure Code. Subject to this disclosure report are all direct or indirect ToVs related to prescription-only medicines disclosed by Company to or for the benefit of a Recipient as described in Article 23 of the EFPIA Disclosure Code.

In this report, Company discloses the amounts of value transferred by type of ToVs with data coverage from January 1st 2021 to December 31st 2021, so it means that disclosure is covering full calendar year 2021.

Note: 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.

Products concerned

Prescription-only medicine.

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. healthcare packages provided by private entities purchased by Signatories for their employees;
h. 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 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 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 AIFP disclosure template.
- If the disclosure 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 AIFP disclosure template.

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

5. Specific considerations

Country unique identifier

In the Czech Republic, a doctor's unique identifier is a registration number assigned by the Czech Medical Chamber; for pharmacists it is a registration number assigned by the Czech Chamber of Pharmacists. The unique identifier of a Healthcare Organisation is IČ (IN).

Self-incorporated HCP

HCP – physical entity – who can be identified based on the registration number of the Czech Medical Chamber will be registered under this number as an HCP. IČ (IN) does not turn a physical entity into a legal entity.

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.

6. 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)

R+D related ToVs will be disclosed in the home country of the investigator!

Non-interventional studies that are retrospective in nature will be disclosed under the individual HCO spend category.

IST related payments do fall within the R+D aggregate amount.

The determination of R+D spend according to EFPIA regulations is based on Company Healthcare's regular internal expense reporting and allocations derived from Clinical Operations Statistic.

7. 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 according to the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data .

Management of recipient consent withdrawal

a. If the consent to disclose individual data and transfer of value is withdrawn, the data controller (Company) and data processor (AIFP as a Database provider) shall terminate the processing operations pertaining to the respective personal data and withdraw corresponding personal data from its website and/or destroy any such personal data unless legislation imposed upon the data controller/processor prevents it from destroying all or part of the personal data processed. Individual data are removed from the disclosed form within a period of 14 days 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.

Management of recipient's request

Requests and/or complaints by Recipients may be lodged with Company. and Company 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.

8. Disclosure Form

Date of publication

Disclosure will be made within six months after the end of the reporting period (30th June).

Disclosure platform

Disclosures shall be made on the central platform provided by AIFP on www.transparentnispoluprace.cz.

Disclosure language

Disclosures shall be made in Czech and English.

9. Disclosure of financial data and calculation rules

Currency

a. Total value of the transfers of value is disclosed in CZK 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. For calculation of R+D spend is used currency rate of Czech National Bank of the last day of reported calendar year (December 31).

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 AIFP 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).

10. Queries

Definition

For the purposes of this Regulation a specific question means a public inquiry seeking to clarify a single published information regarding a healthcare professional (HCP), healthcare organization (HCO) or pharmaceutical company and/or provided transfers of value.

For the purposes of this Regulation a general question means a public inquiry on the Disclosure project generally such as the rules of disclosure, orientation in the database of the Disclosure project, implemented rules for protection of personal data, classification of disclosure, etc.

Technical measures

AIFP as the founder and administrator of the database where the data of the Disclosure project will be disclosed (hereinafter as the "Database") is obliged to take such technical and personal measures which help timely answer general and specific questions from the public.

The following measures are especially concerned:

a. Creating a signpost for the purpose of classification of inquiries to general, regarding the project as such and its rules which will be answered directly by AIFP, and the specific questions relating to single published information which will be automatically sent to involved pharmaceutical companies;

b. Creating an electronic form for public inquiries that can be accessed directly in the Database and that will contain the following mandatory items which must be completed: name and surname of the enquirer (phone, email), field to indicate the inquiry addressee, i.e. a pharmaceutical company whose data the question concerns (by selecting from the list of pre-defined subjects) for the case of specific questions, or designation of AIFP for the case of general questions, and the place to fill in the question;

c. Ensuring the system of sending inquiries to the appropriate recipients in real time;

d. Ensuring archiving of inquiries in the Database with limited access for the employees of AIFP. The purpose of archiving is to find a question in the case that the enquirer completed the field "Addressee" incorrectly, and its immediate sending to the correct addressee (at least within 48 hours/2 working days).

The technical measures implemented to ensure answering the questions described in Section 2.1 are the only one possible way how the specific questions will be answered via AIFP; in the case that the enquirer asks AIFP by phone, email or in an alternative way he will be asked to use the electronic form for public questions that is available in the Database. The general questions answered directly from AIFP can be received by AIFP in a different form.

Protection of personal data

The public inquiries regarding specific disclosed information can be answered only by the person who was given consent with processing of personal data from the respective subject (= a healthcare professional whose data is disclosed) i.e. the administrator of personal data (= a relevant pharmaceutical company). AIFP in the position of a processor of personal data is not entitled to answer this type of questions concerning a particular pharmaceutical company or single published payments.

Since archiving of all inquiries will be performed, AIFP, as the founder and administrator of the database, will be in the position of administrator of personal data of the inquirers.