

Methodological Note of Merck LLC

an affiliate of Merck KGaA, Darmstadt, Germany

1. Introduction

Relationships between Merck LLC and healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions shall be focused on informing healthcare professionals about our pharmaceutical products, providing scientific and educational information, and supporting medical research and education.

This Methodological note summarizes the methodologies used in preparing the company's disclosure according to the EFPIA Disclosure Code and AIPM Code of Practice identifying transfers of value, made directly or indirectly to or for the benefit of HCPs and HCO.

2. Definitions

Recipients

Any healthcare professional (HCP) or healthcare organization (HCO), whose primary practice, principal professional address or place of incorporation is in Russia.

HCO

Any legal entity (i) that is a healthcare, medical, pharmaceutical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution (except for patient organizations) whose business address, place of incorporation or primary place of operation is in Russia or (ii) which provides services through one or more healthcare professionals.

HCPs

Doctors and other medical professionals, heads of medical organizations, pharmaceutical professionals (including pharmacists), heads of pharmacy organizations, and other specialists the professional activity of which is concerned with pharmaceutical products and who in the process of their professional activity have the right to prescribe, recommend, purchase, supply, or administer pharmaceutical products.

Transfers of Value (ToVs)

Direct and indirect transfers of value, whether in cash, in kind or otherwise, made for the purposes allowed by the applicable legislation and in connection with the development and sale of prescription-only pharmaceutical products exclusively for human use. Direct transfers of value are those made directly by a pharmaceutical company for the benefit of a recipient. Indirect transfers of value are those made on behalf of a pharmaceutical company for the benefit of a recipient, or transfers of value made through an intermediate and where the pharmaceutical company knows or can identify the healthcare professional (HCP) or healthcare organization (HCO) that will benefit from the transfer of value.

Research and Development (R&D) ToVs

Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (ii) clinical trials (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.

3. Disclosure's scope

Excluded ToVs

Without limitation, transfers of value that (i) are solely related to over-the-counter pharmaceutical products; (ii) items of medical utility, meals and drinks, samples to the extent they are not restricted by applicable legislation and other transfers of value according to AIPM Code of Practice; or (iii) are part of ordinary course purchases and sales of pharmaceutical products by and between a pharmaceutical company and an healthcare professional or a healthcare organization, as relevant, do not fall within the scope of the disclosure obligation.

ToVs 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 disclosed.

Cross-border activities

a. Cases of cross-border ToVs to HCPs/HCOs, falling in the scope of obligatory disclosure, are disclosed in accordance with the recipient's country of practice (for HCP) or country of registration (for 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.

Self-incorporated HCP

A self-incorporated HCP, who is registered under legislation of the Russian Federation, constitutes a HCO.

Multiannual agreements and transfers of value in different calendar years

In case of multiannual agreements or other agreements, based on which the transfers of value are provided in different calendar years, the report is filled in with the information about sums, which were actually paid to the recipient in a given calendar year / reporting period.

Methodology for R&D spend documentation

Research and development (R&D) ToVs - transfers of value to healthcare professionals or healthcare organizations related to the planning or conduct of (i) pre-clinical studies; (ii) clinical trials; or (iii) post-registration observation (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, healthcare professionals specifically for the study. According to the EFPIA regulations, the volume of the company's R&D spending is determined on the basis of the company's regular internal expense reports on healthcare-related costs and allocations derived from clinical operations statistic.

4. Personal Data Protection

Disclosure of the ToVs is made in accordance with the Federal Law of July 27, 2006 No. 152-FZ "On Personal Data", Merck LLC's local act on data privacy considering compliance with other effective legislation on data privacy.

In accordance with sub-clause 7.3.4. of the AIPM Code of Practice, for transfers of value where certain information cannot be disclosed on an individual basis for legal reasons, a pharmaceutical company shall disclose the amounts attributable to such transfers of value in each reporting period on an aggregate basis. Such aggregate disclosure shall identify, for each category, (i) the number of recipients covered by such disclosure, on an absolute basis and as a percentage of all recipients, and (ii) the aggregate amount attributable to transfers of value to such recipients.

To comply with the requirements of the effective Russian data privacy legislation, Merck LLC discloses information on ToVs on the aggregate basis.

5. Disclosure Form

Date of publication

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

Disclosure platform

Disclosure report is published on the company's website.

Disclosure language

Report is published in English and Russian.

Currency

a. Total value of the ToVs is disclosed in Rubles (RUB) 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. Transfer rates are calculated on the basis of the company's internal exchange rate.

d. Transfer rate for R&D costs is calculated on the basis of the official exchange rate for Russian ruble (RUB) as of the last day of the year (31st of December).

VAT included or excluded

ToVs are disclosed with VAT included.

Calculation rules

a. ToVs effected in the reporting period are summed up according to the segmentation of the AIPM disclosure template requirements.

b. Only amounts of payments effected within the given calendar year (reporting period) are considered with the calculation.

c. Calculation is executed with amounts of harmonized (same) currency (see also note to Currency).