

Methodological Note

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

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 irrespective of its legal or organizational form, individual entrepreneurs (i) that are a healthcare organization or association, or a medical, pharmaceutical or scientific organization or association, for example, a hospital, clinic, foundation, university or other teaching institution (except for patient organizations) location or primary place of operation of which is within the Russian Federation 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 (ToV)

Transfers of value - direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for the purposes permissible by the applicable legislation and by this Code in connection with the development and sale of exclusively prescription-only pharmaceutical products for human use.

Direct ToV are those made directly by a pharmaceutical company for the benefit of a recipient.

Indirect ToV are those made on behalf of a pharmaceutical company for the benefit of a recipient, or ToV made through an intermediate (e.g., event organizing agency) and where the pharmaceutical company knows or can identify the healthcare professional/healthcare organization that will benefit from the transfer of value.

Research and Development ToV

ToV 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; Post-registration clinical (interventional) study - a study of a pharmaceutical product conducted in the Russian Federation by its developer or manufacturer, including with the involvement of a contracted research organization, for the purpose of gathering additional data on the efficacy, safety, and tolerability of the relevant pharmaceutical product after its state registration, in the course of which the studied pharmaceutical product is prescribed according to the terms of its registration in the country, while the specific therapy, diagnostic and monitoring procedures are conducted in strict compliance with the relevant study protocol.

3. Disclosure's scope

ToV categories for disclosure

1. Donations and grants to healthcare organizations that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organizations or associations that are comprised of healthcare professionals and/or that provide healthcare.
2. Contribution to costs related to events. Contribution to costs related to events, through healthcare organizations or third parties such as:
 - Registration fees;
 - Sponsorship fees under agreements with healthcare organizations or with third parties appointed by a healthcare organization to manage an event; and
 - Travel and accommodation.
3. Fees for service and consultancy. ToV resulting from or related to contracts between pharmaceutical companies and healthcare professionals and/or healthcare organizations under which such healthcare professionals and/or healthcare organizations provide any type of services to a pharmaceutical company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand ToV relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.
4. Contribution to costs related to events and participation of healthcare professionals therein:
 - Registration fees;
 - Travel and accommodation.
5. Research and development ToV.

Travel and accommodation expenses under "Fees for service and consultancy" category

In accordance with sub-clause 7.3.3 of AIPM Code of Practice, ToV relating to expenses agreed in the written agreement covering the activity shall be disclosed under the category "Fees for service and consultancy".

Due to the absence of travel and accommodation expenses in the service agreement, such ToV are disclosed on an aggregate basis.

ToV not within the scope of disclosure

The following ToV made in accordance with effective legislation and AIPM Code of Practice should not be disclosed:

1. ToV that are solely related to over-the-counter pharmaceutical products;
2. ToV that are not listed in the answer to the question 11 (eleven) of AIPM Code of Practice, such as:
 - items of medical utility,

- meals and drinks,
 - samples of the pharmaceutical products; or
3. ToV that are part of ordinary course purchases and sales of pharmaceutical products by and between a pharmaceutical company and a healthcare organization, as relevant.

ToV in case of partial attendances or cancellation

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.

If no value was transferred, the information on the transfer of value is not part of disclosure.

Cross-border activities

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

If one HCP/HCO has several countries of practices / registration the country in which context the assignment took place discloses the ToV.

Multiannual agreements and ToV in different calendar years

In case of multiannual agreements or other agreements based on which the ToV are provided in different calendar years, the information is included in the report about those which were effectively paid to the recipient in a given calendar year / reporting period.

4. Personal Data Protection

Disclosure of the transfer of values is made in accordance with the Federal Law of July 27, 2006 No. 152-FZ "On Personal Data", Data Privacy Policy of Merck LLC and other applicable privacy laws and industry codes.

In accordance with sub-clause 7.3.4. of AIPM Code of Practice, for ToV where certain information cannot be disclosed on an individual basis for legal reasons, a pharmaceutical company shall disclose the amounts attributable to such ToV in each reporting period on an aggregate basis.

To comply with the requirements of the current Russian legislation on the protection of personal data, Merck LLC discloses information on ToV on an aggregate basis.

5. Disclosure form

Date of publication

Disclosure is made on an annual basis for the preceding calendar year no later than 6 months after the end of the relevant reporting period (within the period from June 20 to June 30).

Disclosure platform

Disclosure report is published on the Company's website.

Disclosure language

Disclosure is provided in Russian.

VAT and other taxes

Amounts of ToV include applicable taxes (VAT and Personal Income Tax).