

Disclosure of Transfers of Value to Healthcare Professionals and Healthcare Organizations

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GENERAL

CSL Behring believes that interactions between the pharmaceutical industry and healthcare professionals have a profound and positive influence on the quality of patient treatment and the value of future research. There is a growing expectation that such interactions are transparent. Pursuant to the requirements set out by the AIPM Code of Practices, each pharmaceutical company, including CSL Behring, must document and disclose any transfers of value to healthcare professionals or healthcare organizations being the recipients of the said values. This methodology description defines the relevant types of transfers of value subject to disclosure, excluded types of transfers of value, and other relevant information that will help the reader understand how the branch of CSL Behring Biotherapies GmbH (hereinafter CSL Behring), being an AIPM member since 2017, in June 2018 shall publish information on payments made by the company to healthcare professionals or healthcare organizations in 2017. This information shall be posted on the company's website <http://www.cslbehring.ru/>. If you have any questions, you can send them to an email address Transparency.Russia@cslbehring.com.

Starting from 2018, disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year.

CSL Behring annually discloses TRANSFERS OF VALUE in Russian.

A disclosure report contains the following data:

- Data on healthcare professionals (HCPs) who have agreed to publish. In the absence or withdrawal of consent, disclosure of information on the transfer of values in favor of HCPs is carried out in a generalized form without specifying definite recipients of values, and
- data on healthcare organizations (HCOs) in whose favor the transfer of values is carried out, and the HCO is defined in such a way that there is no doubt about the identity of the organization. In the event that the HCO is not uniquely identified, the disclosure of information on the transfer is made in a generalized form without specifying definite recipients of values.

The Russian legislation on personal data processing also covers the processing of data on payments or transfers of value. Pursuant to the legislation, the subject's consent to data processing is required, and the subject may withdraw his/her consent at any time.

Requirements of Federal Law of July 27, 2006 No. 152-FZ "On Personal Data" shall be taken into consideration when disclosing payments or transfers of value to the benefit of HCPs. Pursuant to the said Law, personal data is any information related, directly or indirectly, to the identified or identifiable individual (the personal data subject). Thus, consent must be obtained for the processing of personal data related to individuals only.

CSLB Russia confirms its adherence to the principle that no interactions between a pharmaceutical company and HCPs should give rise to any conflict of interest for HCPs, in particular, between their professional duties and personal interests.

DEFINITIONS

Events – all meetings, congresses, conferences, symposia, and other similar promotional, scientific or professional events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and trainings, planning or investigator meetings for clinical trials and non-interventional studies) organized or sponsored by or on behalf of a pharmaceutical company.

Healthcare Organization (HCO) – any legal person 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 another educational institution (except for patient organizations) whose business address, place of incorporation or primary place of operation is in the Russian Federation, or through which one or more healthcare professionals provide services.

Healthcare Professionals (HCPs) – doctors and other medical staff, heads of healthcare organizations, pharmaceutical professionals, including pharmacists, heads of pharmacy organizations and other specialists whose professional activities cover pharmaceutical products, and

who, in the course of their professional activities, may prescribe, recommend, purchase, sell or administer pharmaceutical products and whose primary practice and principal professional address is in Russia. For the avoidance of doubt, the definition of Healthcare Professional includes: 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, but excludes employees of wholesalers or distributors of medicinal products.

Clinical Research Organization (CRO) – is an organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis. CRO is not HCO.

TRANSFER OF VALUE – direct and indirect transfer of value, whether in cash, in kind or otherwise, made in connection with the distribution and sale of prescription-only medicinal products exclusively for human use.

Direct TRANSFER OF VALUE is made directly by a pharmaceutical company for the benefit of HCP and/or HCO.

Indirect TRANSFER OF VALUE is made through a third party (such as contractor, event planning agency, logistic services agent, partner or associate) for the benefit of a Recipient on behalf of CSL Behring, where CSL Behring can identify the Healthcare Organization/Healthcare Professional that will benefit from the Transfer of Value. In this case, the Beneficiary is aware that the transfer is made on behalf of CSL Behring.

TRANSFER OF VALUE in the course of research works – a TRANSFER OF VALUE made for the benefit of HCO or HCP and connected with the planning or performance:

of preclinical studies; clinical studies; or (post-marketing) surveillance (non-interventional) studies that are prospective in nature and include collection of patients' data performed by individual healthcare professionals or groups thereof, or on their behalf, for the purpose of study.

When TRANSFER OF VALUE is made outside the country of residence/incorporation of the value recipient (HCO or HCP), CSLB shall disclose the TRANSFER OF VALUE to HCO and HCP based on the place of primary practice, principal professional address or place of incorporation which is in Russia.

DISCLOSURE. PURPOSES. PRINCIPLES. DESCRIPTION

Purpose of Disclosure. Timing Approach. Principles of Recognition of TRANSFER OF VALUE

The time of TRANSFER OF VALUE shall determine the disclosure period and the date necessary to calculate value (such as currency conversion, tax computation).

Since the time of Transfer of Value is essential for disclosure, CSL Behring Russia has adopted the following time frame for determining the time of Transfer of Value:

- For Grants, Donations: the Reporting Period shall be determined based on the date of payment,
- For payment of HCP's logistics expenses (including registration fees): the Reporting Period shall be determined based on the date of expense report confirmed in writing both by HCP and by the company's designated person,
- For fees for services and consultancy in favor of HCP – the Reporting Period shall be determined based on the date of signing a certificate of services rendered. The amounts of fees for services and consultancy in favor of HCP stated in the report shall include personal income tax (PIT) and exclude insurance premiums.
- For fee for the event paid to technical organizer – the Reporting Period shall be determined based on the date of event/date of signing the certificate of services rendered (the earliest known date), rather than the date of payments to technical organizer made by CSL Behring.
- For fee for the event in favor of HCO – the Reporting Period shall be determined based on the date of event/date of signing the certificate of services rendered (the earliest known date).

TRANSFER OF VALUE in case of partial attendance or cancellation. Since the information about TRANSFER OF VALUE is reported based on the payments made by CSL Behring, rather than based on the amounts received by the Recipient, in case of partial attendance information about the full amount paid by CSL Behring shall be reported. In case of cancellation and full refund to CSL Behring, TRANSFER OF VALUE shall not be disclosed. In case of partial refund, TRANSFER OF VALUE shall be disclosed to the extent of non-refundable amount.

Amounts paid in favor of HCO shall be specified inclusive of VAT.

Despite the fact that CSL Behring Russia is a branch of the international pharmaceutical company, and given the fact that it is located in the RF, the company shall only disclose payments in rubles.

This annual disclosure report shall cover all Transfers of Value to Russian HCOs and HCPs made by CSL Behring.

Actual value or actual cost provided by CSL Behring, rather than total income or revenue gained by HCO or HCP, shall be reported in the disclosure of TRANSFER OF VALUE.

Multi-year contracts. Disclosure shall be made based on the actual Transfers of Value made according to the certificates of executed works signed during the year, rather than pro rata to the amount of estimated total TRANSFER OF VALUE under the contract.

Types of Transfers of Value to be Covered by the Disclosure Report.

- I. Donations and Grants to HCOs 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.
- II. Contribution to costs related to events, through Healthcare Organizations or third parties, such as:
 - Registration fees;
 - Sponsorship fees under the agreements with Healthcare Organizations or with third parties engaged by a Healthcare Organization to manage an event; and
 - Travel and accommodation for HCP within the implementation of projects for further knowledge cascading.
- III. Fees for service and consultancy. Transfers of Value resulting from or related to contracts between pharmaceutical companies and Healthcare Professionals and/or Organizations under which such Healthcare Professionals and/or Organizations provide any type of services to a pharmaceutical company or any other type of funding not covered in the previous categories. Fees for services and consultancy, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written contract covering the activity shall be disclosed as two separate amounts
- IV. Research and development Transfers of Value.

Types of TRANSFERS OF VALUE Not Subject to Disclosure Within This Methodology

The following types of TRANSFERS OF VALUE must be excluded from the list of types of TRANSFERS OF VALUE subject to disclosure in accordance with the AIPM Code:

- i) that solely related to over-the-counter medicines;
- ii) that are part of ordinary course purchases and sales of medicines (e.g. between CSL Behring and a pharmacy);
- iii) medical samples, investigational drugs and biological samples for testing;
- iv) information or training materials and medical devices, and
- v) meals and drinks.

Disclosure of Transfers of Value to HCOs

The following types of TRANSFERS OF VALUE to HCOs shall be disclosed by CSL Behring:

1. i) donations and grants that support healthcare,
 - ii) contributions to costs related to Events, including direct and indirect sponsorship to HCPs to attend Events through HCOs, such as:
 - a. organization fees being part of a full package,

- b. sponsorship agreements with HCOs or with third parties (technical organizers) appointed by a HCO to manage the Events (such as reservation of a stand or show-floor, purchase of advertising space (on paper, in electronic or another format), management of satellite symposia during the congress, sponsor support to speakers or academic staff). Technical organizer undertakes to manage the event using the sponsorship fees received from the pharmaceutical company, including by renting premises for the event or any other event-related expenses for the benefit of the Healthcare Organization.

The sponsorship fee paid to technical organizer shall be disclosed as a Transfer of Value made in favor of the relevant Healthcare Organization, since the final beneficiary for the purpose of the said disclosure is the Healthcare Organization.

The disclosed amount may include any expenses for the event planning and conduct, as well as the contractor's (technical organizer's) remuneration.

Disclosure of Transfers of Value to HCPs

The following types of TRANSFERS OF VALUE to HCPs shall be disclosed by CSL Behring:

1. i) contributions to costs related to Events, such as:
 - a. organization (registration) fees, and
 - b. travel and accommodation expenses (such as: expenses for traveling by air, by train and by taxi, and hotel accommodation); as well as
2. ii) fee for services and consultancy (such as fees to speakers for public presentations, training of attendees, medical writing, data analysis, development of training materials, general consultancy and consultancy via advisory boards / expert forums). If any contingent expenses arising under a services agreement or consultancy services agreement (such as travel and accommodation expenses) are reimbursed, TRANSFER OF VALUE shall be disclosed in the corresponding category, and this type of TRANSFER OF VALUE shall not be a fee for services and consultancy.
3. Expenses for the maintenance of HCPs associated with the participation in training events for the purpose of further cascading of the knowledge gained.