

EXPLANATORY NOTE REGARDING THE DISCLOSURE OF TRANSFERS OF VALUE TO HEALTHCARE PROFESSIONALS AND ORGANIZATIONS IN 2016

BioMarin International (Moscow) LLC (hereinafter as “BioMarin”) was established in 2011 (Certificate of State Registration Series 77 No. 012131290 dated 09 December 2011), Taxpayer Identification Number (INN) 7704797321 / Tax Registration Reason Code (KPP) 770701001.

Business address: Bldg. 6, 16 Malaya Dmitrovka Street, Moscow 127006

The primary business activity of BioMarin International (Moscow) LLC is market research and analysis (OKVED Code 73.20.1). BioMarin specializes in marketing and consulting services aimed to promote pharmaceutical products and medical supplies in the Russian Federation and the CIS.

Involved in the research of rare diseases, BioMarin cooperates with healthcare organizations and professionals. Within the framework of such cooperation, BioMarin may perform transfers of value to or to the benefit of healthcare professionals and organizations.

As a member of the Association of International Pharmaceutical Manufacturers (AIPM), BioMarin is committed to disclosing information regarding transfers of value to healthcare professionals and organizations.

Starting from 2016, BioMarin publishes information on the transfers of value made to the benefit or healthcare professionals and organizations on its website. Disclosures will be made on an annual basis in a format and subject to the provisions of the Code of Practice of the Association of International Pharmaceutical Manufacturers (AIPM).

This Explanatory Note presents a general overview and (or) Russia-specific features defining the nature of relationships between the company and healthcare professionals and organizations, summarizes the methodologies used by BioMarin in preparing the disclosures and identifying transfers of value for each category, and describes other aspects of relations associated with the transfer reporting periods and amounts.

Definition of Healthcare Professionals

For the purpose of this disclosure, healthcare professionals mean 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.

Definition of Healthcare Organizations

For the purpose of this disclosure, a healthcare organization means 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.

Information subject to disclosure includes transfers of value to healthcare professionals and organizations in the following categories:

Categories	Transfers of value	
	Healthcare professionals	Healthcare organizations
Donations and grants	–	Either cash or benefits in kind
Events	1. Registration fees 2. Travel and accommodation	1. Sponsorship 2. Registration fees 3. Travel and accommodation
Service and consultancy	1. Fees for service and consultancy 2. Related expenses agreed in the fee for service or consultancy contract, including travel & accommodation relevant to the contract	
Research & Development	Transfers of value related to Research & Development	

Donations and grants

As a pharmaceutical company, BioMarin donates to non-profit organizations as part of its social responsibility, including contributions to the development and implementation of projects aimed to support the statutory activities of non-profit organizations and patients.

This category of transfers discloses donations and grants that are provided to healthcare organizations and 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.

Therefore, in this category BioMarin discloses information about the donations and grants paid to healthcare organizations to support healthcare, excluding donations and grants to patient organizations.

Information on transfers that fall within this category is included in the period in which the funds were actually transferred from BioMarin's bank account, regardless of the period in which such funds were disbursed by the recipient.

Contributions to costs related to events

For the purpose of raising the awareness of healthcare professionals about pharmaceutical products and/or supplying them with scientific or instructional information in healthcare or pharmaceuticals, BioMarin may cover costs related to scientific events (conferences, conventions, symposiums, etc.), and sponsor the participation of healthcare professionals by paying relevant registration fees, as well as travel, accommodation and other expenses.

Contributions to costs related to events include transfers of value to healthcare professionals and organizations, such as:

- 1) Registration fees;
- 2) Travel and accommodation;
- 3) Sponsorship agreements with healthcare organizations or with third parties appointed by a healthcare organization to manage an event.

Registration fees

Information about the registration fees paid by BioMarin for the participation of a healthcare professional or organization in scientific events is disclosed for each healthcare professional individually. These payments are also disclosed with a breakdown by healthcare organizations.

For example, if BioMarin supports the participation of a number of healthcare professionals from the same organization and this organization selects particular participants at its own discretion, in this case it is this organization that will be deemed as a recipient.

Travel and accommodation

Travel and accommodation expenses related to scientific and educational events include transfers of value to the benefit of healthcare professionals and organizations in the form of payments made for airfare, rail transport, taxi and hotel accommodation.

Collective travel is disclosed as an aggregate amount without specifying individual healthcare professionals if identification of the participants is not reasonable for organizational reasons.

Sponsorship agreements

Within this category, BioMarin discloses information on the amounts payable under negotiated arrangements (sponsorship agreements).

If a third party is appointed for the purpose of managing an event (an event manager) and the benefit is transferred to such third party, however the event is directly related to a healthcare organization, then information about such transfer of value is attributable to the healthcare organization that appointed the event manager. In this case, the total amount is subject to disclosure. A limited amount may only be disclosed if it is specifically mentioned that a limited amount was transferred to the healthcare organization.

If an event relates to several healthcare organizations and a particular transfer of value can be proportionately distributed among the organizations involved, information disclosed on such transfer of value is attributed to each of the organizations involved. If a transfer is not distributable, information is published as an aggregate amount.

The legal relations between a healthcare organization and an event manager must be supported by relevant documents, e.g. a trilateral agreement (between the company, the event manager and the healthcare organization). If the company enters into a sponsorship agreement with an event manager only, the legal relations between the event manager and the healthcare organization (if any) must be clarified in the provisions of the sponsorship agreement between the company and the event manager and supported by documents originating from the healthcare organization (for example, a letter written by the healthcare organization).

If the company fails to provide sufficient documentary evidence of the legal relations existing between a healthcare organization and an event manager, but it clearly understands or has indirect evidence proving that the beneficiary is a particular healthcare organization, BioMarin discloses such transfer of value in an aggregate form.

If the recipient of the value is not identifiable, BioMarin does not disclose such transfer of value.

Service and consultancy

The service and consultancy category includes any transfers of value (either monetary or non-monetary) made in consideration for the services provided by healthcare professionals or organizations.

BioMarin may hire healthcare professionals to make presentations or speak on a professional subject at a scientific event. The consent to such participation is documented in agreements that stipulate a speaker fee and the reimbursement of travel, accommodation and per diem expenses.

Research & Development

This category includes transfers of value made in connection with research and development (R&D). A transfer of value, regardless of the type of R&D activities, is reported as an aggregate amount without specifying the name of the recipient.

Confidentiality

BioMarin requests an approval from all healthcare professionals and healthcare organizations prior to the initiation of a transfer procedure. Being compliant with all existing privacy laws, BioMarin publishes information on the transfers of value in an aggregate form in the relevant section without specifying the names, addresses and other personal details of the covered persons and organizations. In case of written request to provide data on transfer of value from public authorities or other bodies having the right to request such information is received, and provided that there is a consent from the healthcare professional, BioMarin may disclose information on an individual basis.

VAT and other taxes

All amounts attributable to the transfers of value are reported as actual expenditures and include VAT.

Other taxes (e.g., personal income tax) are also included in the disclosed amounts.

Reporting period

In certain cases, the disclosure of transfers may involve more than one reporting period. The reasons behind this situation may be different.

For example, a healthcare professional gives his or her consent to participate in an event as a guest speaker and tickets to the venue of the event are purchased for this healthcare professional in the same period. However, the event is scheduled for a date that falls within the following reporting period.

Or, alternatively, a speaker participates in an event at the end of one reporting period, while the closing documents (a certificate of acceptance and a VAT invoice) are issued and the speaker fee is paid in the following reporting period.

Therefore, the event is funded in one reporting period, but refers to a date in another reporting period.

BioMarin publishes information on the transfers of value in accordance with the following rules.

If a transfer of value belongs to one of the categories below, it is included in the report for the period in which closing documents were received (a certificate of acceptance, a waybill and a VAT invoice):

- 1) Travel and accommodation
- 2) Fees under sponsorship agreements
- 3) Fees for service and consultancy
- 4) Research & Development

Transfers of value in the form of donations and grants, as well as registration fees for participation in events are included in the period in which the funds were actually transferred from the company's bank account.