

BioMarin Europe Limited

ABPI Transparency Report

Methodological Note for 2019 Transfers of Value (reported 2020)

1. Introduction

Statement for the disclosure of 2019 data during the COVID-19 pandemic in 2020

As part of the pharmaceutical industry's annual disclosure of transfers of value to HCPs, ORDMs, and HCOs via the Disclosure UK platform and in order to ensure accuracy of the published date, the ABPI writes to all the HCPs, ORDMs, and HCOs name in companies' disclosure data ahead of its publication on Disclosure UK at the end of June. (over 20,000 in June 2019).

Given the unprecedented pressure on the NHS and health care professionals in responding to the COVID-19 pandemic, in April 2020 the ABPI and PMCPA agreed that it would not be appropriate for the industry to write to HCPs, ORDMs or HCOs to request that disclosure data be reviewed. Doing so would add additional work to NHS professionals at this time. To avoid this, and in line with guidance provided by the ABPI, BioMarin's 2019 transfer of value data has been published on Disclosure UK in aggregate.

Commitment to transparency

The pharmaceutical industry is committed to preserving the integrity of Disclosure UK and transparency in our interactions with HCPs, ORDMs, and HCOs. The ABPI continues to explore how the full disaggregated 2019 data can be submitted to Disclosure UK in line with data from previous years.

This methodological note, which accompanies the Report, summarises BioMarin's approach in calculating and reporting the figures stated in the ABPI central platform submission. This note shall be published together with the Report. The reason for publishing this note is to better inform external recipients and readers of the Report and enable them to understand the data contained in the Report and how this data was collected.

2. Terminology and Definitions

BioMarin defined relevant terms according to Clause 1, including but not limited to the definition of a healthcare professional (HCP), other relevant decision makers (ORDMs), healthcare organisation (HCO) and transfer of value (ToV).

2.1.1. Definition of an HCP

The term health professional (HCP) includes members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine. Disclosure will also apply to other relevant decision makers (ORDMs), this includes those with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who are not HCPs.

2.1.2. Definition of an HCO

A healthcare organisation (HCO) is either a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university whose address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more health professionals or other relevant decision makers provide services.

2.1.3. Definition of a Transfer of Value (ToV)

A Transfer of Value (ToV) can be a salary, fee or remuneration for a service provided by a HCP, ORDM or HCO to BioMarin. Expenses incurred during the execution of a service (e.g. travel and accommodation) are also considered ToV. Donations and sponsorships provided to HCPs or HCOs are also considered to be ToV. Direct ToV are those made directly by BioMarin for the benefit of a recipient and indirect ToV are those made on behalf of BioMarin for the benefit of a recipient, or ToV made through an intermediate and where BioMarin knows or can identify the HCP/HCO that will benefit from the ToV.

2.1.4. Grants and Donations

A grant or donation is a ToV made to a HCP or HCO without consideration or any kind of return in exchange for such payment for an educational, scientific or a charitable purpose.

2.1.5. Sponsorship

BioMarin may sponsor HCPs to attend congresses or events to enhance their medical and/or scientific knowledge, and their use of medicines. In this context, the sponsorship covers congress registration, travel, accommodation and meals. The HCP does not receive any compensation, as no service is provided from the HCP.

BioMarin may also sponsor a third-party event in exchange for services such as an exhibition booth or satellite symposium.

2.1.6. Registration fees

BioMarin supports continuous medical education and may provide support to HCPs or HCOs to cover the costs of registration fees for HCPs to attend certain independent congresses as part of this support. All arrangements are generally paid directly to travel or logistics third party.

Travel and Accommodation

BioMarin pays for or reimburses HCPs for reasonable and documented expenses. Travel costs would include flight, train, car hire, parking and mileage reimbursement and accommodation would be any hotel or lodging required. Such costs may be associated with either a sponsorship arrangement or a fee for service engagement.

2.1.7. Fee for Service remuneration

BioMarin engages HCPs or HCOs in exchange for monetary compensation and/or a benefit in kind for purposes such as:

- Consulting or advising services
- Speaker activities
- Medical writing (e.g. editorial support for scientific publications).

Service Agreements' related transfers of value may include fees or honoraria, but also expenses incurred in the course of the provision of the services, such as travel and accommodation.

2.1.8. Research and Development

Research and Development activities are those undertaken to discover and develop new therapies to treat patients suffering from severe diseases, such as but not limited to, clinical trials designed to verify or study the clinical effects of one or more medicinal product(s) and identify any adverse reactions in order to ascertain its (their) safety and/or efficacy, or partnerships with both academia and leading drug discovery foundations.

3. Scope and Content of the ABPI Disclosure

Reporting Format and Reporting Period

BioMarin's Report has been prepared using the reporting template provided by the ABPI. Reports are made publicly available on the Disclosure portal at the end of June each year and capture ToVs that were provided during the previous calendar year. The Report is available here: <http://www.abpi.org.uk/ethics/ethical-responsibility/disclosure-uk/>

The disaggregated report can be found on <http://www.bmrnsunshinereports.com/>.

Consent

BioMarin has used its best endeavors to seek consent from all HCPs to report on an individual basis, naming the HCP and identifying the ToV. To this end, BioMarin has incorporated a binding clause to this effect in its contractual templates and has obtained consents on a per activity basis.

In the event that a HCP declines to give, or subsequently withdraws consent to report, BioMarin has disclosed all ToV made to that HCP in aggregate.

In the UK HCOs are reported without the need for consent as they are legal entities.

Disclosure in aggregate

BioMarin works in a limited capacity in the United Kingdom with respect to its research and development activities and discloses transfers of value in an aggregate fashion as required by Clause 23.2.

BioMarin is aware of one HCP who has opted out from the individual disclosure. All other HCPs and ORDMs have been disclosed on the basis that permission from these individuals was obtained, prior to disclosing personal data such as TOV, through contractual terms.

Meals

ToV related to meals (food and beverages) are not disclosed in the Report pursuant to Clause 24, but said meals complied with the limitations set forth in Clause 22.

Currency

Disclosure is made in British Pounds. Where ToVs were made in any other currency the exchange rate used is based on the payment date for direct payments or date of the event for indirect payments.

Value Added Tax (VAT) and other taxes

VAT is not included in the report, but taxes (e.g. local tax) relating to accommodation and travel are included.