Bristol-Myers Squibb (BMS) Methodology Document in support of the EFPIA transparency disclosure code for HCP/HCO transfers of value pertaining to 2017

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Introduction

The approach to timing, tax and currency aspects of Transfer of Value (ToV) disclosure are not defined by the EFPIA Code. Companies are free to define an appropriate methodology and are obliged to publish it as per the EFPIA Code, Article 3, Section 3.05. BMS, as a member of EFPIA, will fulfil this requirement by publishing this document alongside 2017 transparency disclosure reports where possible. All data in the disclosure report was correct at time of publication.

2017 transfers of value reported in 2018 are the first publication of Transparency data based on the Royal Decree of June 14, 2017 implementing the Sunshine Act.

Definitions

Recipients

BMS are fully aligned with HCP/ HCO scope, adjusted when necessary to accommodate country trade association definitions expected by the market.

HCO Any legal person (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations within the scope of the EFPIA PO Code) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.

HCP Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.

To ensure relevance of the HCP detailed definition

PO Patient organisations: a healthcare organisation that is responsible for patient representation.

Kind of Transfers of Value (ToVs)

1. Transfers of Value to an HCO, an amount related to any of the categories set forth below:

   a. Donations and Grants. Donations and Grants to HCOs that support healthcare, including donations and grants (either cash or benefits in kind) to
institutions, organisations or associations that are comprised of HCPs and/or that provide healthcare (governed by Article 11 of the HCP Code).

b. Contribution to costs related to scientific Events. Contribution to costs related to scientific Events, through HCOs or third parties, including sponsorship to HCPs to attend Events, such as:
   i. Registration fees;
   ii. Sponsorship agreements with HCOs or with third parties appointed by an HCO to manage a scientific meeting; and
   iii. Travel and accommodation (to the extent governed by Article 10 of the EFPIA HCP Code).

c. Fees for Service and Consultancy. Transfers of Value resulting from or related to contracts between Member Companies and institutions, organisations or associations of HCPs under which such institutions, organisations or associations provide any type of services to a Member Company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

2. Transfers of Value to an HCP:

a. Contribution to costs related to scientific Events. Contribution to costs related to scientific Events, such as:
   i. Registration fees; and
   ii. Travel and accommodation (to the extent governed by Article 10 of the EFPIA HCP Code).

b. Fees for Service and Consultancy. Transfers of Value resulting from or related to contracts between Member Companies and HCPs under which such HCPs provide any type of services to a Member Company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

c. Meals and drinks are excluded from reporting for EFPIA aligned countries.

d. Fees related to travel visas are not reportable.

3. Transfers of Value to an PO:

a. Fees for Service and Consultancy. Transfers of Value resulting from or related to contracts between Member Companies and POs under which such POs provide any type of services to a Member Company or any other type of funding. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

b. Financial or other support. This includes amongst others financial
support granted to a patient organisation for the organisation of a scientific event; to support disease awareness campaigns; to support the development of informative material for patients or a website for patients.

4. R&D transfers of value

R&D transfer include all TOVs related to pre-clinical and clinical development, paid to an HCO, PO or an HCP directly or indirectly (for example through a CRO or third party vendor)

All R&D TOVs are aggregated by country as a single number based on the recipient’s country principal practice address in the disclosure report.
Disclosure’s scope

TOV Timing Approach

1. Assumptions
   a. Timing of a ToV determines assignment to a disclosure period and the date required for value calculations (e.g. currency conversion, tax calculation)

2. Principles
   a. As actual values are relevant for disclosure reporting, the following dates are captured and transferred to the BMS reporting solution
      i. Financial Payments: Actual payment date
      ii. Transfer of Value:
          1. One-day interactions: Actual interaction date
          2. Multiple-day interactions: Actual interaction end date
   b. Above dates will be used for both:
      i. assigning any ToV to the relevant disclosure period
      ii. performing any ToV value calculations
   c. Multi-year contracts / R&D long term clinical trials: reporting of TOV’s related to the contract / trial follow the above rules.
   d. Congress closure
      i. For cases where the actual amount of a TOV has not been collected during the disclosure period, such payments will be attached to the next disclosure period

Reportable date:

The following rules have been used for the reportable dates relating to TOV’s in BMS.

- In Kind (travel, accommodation, registration fees): Event start date
- In Cash (sponsorship, donation, fee for service): Payment date
No Show / cancelation

If BMS made a TOV to an HCP who then was a no show or cancellation, those TOV’s will be excluded from all EU EFPIA aligned countries disclosure reports apart from Italy, where the TOV will be included as an aggregate amount in the disclosure report.

Cross-border activities

Where a TOV is made outside of the recipient’s country those TOV’s will be reported within the country disclosure report based on the recipient’s principal practice address.

Consent management

For countries where consent is required for individual publication at the named level of detail for HCP’s and HCO’s (for those countries where this is required), BMS has requested consent for disclosure to all recipients (HCPs, and HCOs where applicable).

BMS will only publish the individual recipient details where consent has been positively given (for those countries where consent is required). If an HCP or HCO (in those countries where consent is required) has not given consent or has not responded to the consent request, they will be considered to have not given consent and their data will be aggregated prior to publishing.

Publication

BMS will follow local country trade association procedures and legislation for reporting publication. When required, BMS will republish a disclosure report.

Date of publication

Publication of each country disclosure report will be aligned to the reporting dates provided by the associated country trade associations.

Disclosure platform

For markets with an external central platform: BMS will publish the disclosure report on the central platform. Where possible this methodology report will accompany the disclosure report.

For markets with no external central platform: BMS will publish the disclosure report on the country specific BMS website in a dedicated transparency section. This methodological note will be attached to this section.

Disclosure language

Disclosure language will be as determined by the country trade association.
Disclosure financial data

TOV Currency Approach

1. The disclosure report in any country will be submitted in the local currency of that country

2. Principles
   a. No currency conversion or translation is needed, if the transaction currency is the same as the one of the recipient’s country of practice (e.g. domestic payments)
   b. Otherwise currency conversion is required:
      i. the value of transaction currency is used for a currency conversion as follows:
         1. Financial Payments: the average monthly rate of the payment date is used for conversion
         2. Transfer of Value: the average monthly rate of the interaction date is used for conversion

VAT

A TOV will be calculated based on the actual amount received by a recipient, either in kind or in cash. The general approach is as follows:

- Including VAT for expenses such as travels, accommodations, Congress registration fees
- Excluding VAT for fees or contract based TOVs

Scientific Publications

BMS adheres to laws and industry standards for financial transparency reporting. External Authors of scientific publications receive an in-kind transfer of value when BMS pays a publication agency to provide medical writing and editorial services to the external authors at no cost to them. BMS will report funding for medical writing and editorial services, and payment of congress and journal fees.