

Methodological note

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1. Introduction

Collaborative working between Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs) has long been a positive driver for advancements in patient care and progression of innovative medicine. In order to ensure that such relationships do not improperly influence professional decisions, the European Federation of Pharmaceutical Industries and Associations (EFPIA) has established ethical standards and requirements in its Codes of Conduct. As a member company, we, Boehringer Ingelheim, have been following these Codes for a long time and support also EFPIA's latest initiative which sets out the expectation that financial interactions should be made transparent and comprehensible for the public.

The EFPIA Disclosure Code, which has been transposed into national codes, requires all pharmaceutical member companies to disclose information on certain payments and other transfers of value to Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs) from covered countries ¹(*) from 2016 onwards. In the countries, local Codes of Conduct contain all relevant rules and regulation regarding the disclosure.

This document is our methodological note specifying in detail the rules resulting from the Transparency Code. If local rules are stricter or differ from this Methodological Note, local rules prevail.

2. Definitions

2.1. Covered Recipients

Any HCP or HCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in a covered country. For detailed definition of HCP/HCO please refer to the section "Abbreviations".

2.2. Kind of ToVs

BI is disclosing the following ToVs to HCPs resp. HCOs (subject to local Data Protection Laws):

2.2.1. Transfers of Value to an HCP

¹ Covered Countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, Norway, Poland, Portugal, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and the United Kingdom

a. Contribution to costs related to Events

These costs can be divided into

- i. Registration fees; and
- ii. Travel and accommodation costs (to the extent governed by Article 10 of the EFPIA HCP Code)

Registration fees are disclosed separately from travel and accommodation costs.

b. Fees for Service and Consultancy

ToVs resulting from or related to contracts between BI and HCPs under which such HCPs provides any type of services. Fees, on the one hand, and on the other hand related travel and accommodation expenses.

c. Research and Development

All ToVs related to Research and Development as described in 2.2.1 and 2.2.2 are disclosed on aggregate level per recipient country, without specifying the cost category and the name of the recipients.

2.2.2. Transfers of Value to an HCO

a. Donations and Grants

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 HCPs and/or that provide healthcare and/or conduct research (therefore also HCOs per definition).

If BI made product donations to a HCO, the total value for all donated packages per HCO is disclosed. The value of a benefit in kind will be disclosed with the value mentioned in the contract (net sales price incl. wholesaler fee where applicable).

b. Contribution to costs related to Events

Contribution to costs related to Events, made through HCOs or third parties, e.g. congress organizers, 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 an Event; and
- iii. Travel and accommodation (to the extent governed by Article 10 of the EFPIA HCP Code)

c. Fees for Service and Consultancy

ToVs resulting from or related to contracts between BI and institutions, organizations or associations of HCPs under which such institutions, organizations or associations provide any type of services to BI RCV. Fees, on the one hand, and on the other hand related travel and

accommodation expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

d. Research and Development

All ToVs related to Research and Development are disclosed on aggregate level per recipient country, without specifying the name of the recipients.

2.3. General statements regarding ToVs

2.3.1. ToVs date

The reporting period is the calendar year. The data is disclosed until 30th June of the following calendar year. All ToVs falling in this reporting period are disclosed. BI will disclose the information for 3 years from first disclosing date onwards (please also see Data Protection Section). If local laws or codes required a longer or shorter disclosing period, these requirements prevail.

Nevertheless, there are situations where more than one reporting period needs to be considered. Following situations can occur:

- a) An event took place in year X but related ToV is paid in the following calendar year
- b) A contract is signed and a service is provided in year X but related ToV is paid in the following calendar year
- c) A frame contract is signed over more than one year e.g. consultancy agreement regarding consultancy in the period 2016 - 2026

BI RCV handles these situations as follows:

- a) An event took place in year X but the related ToV is paid in the following calendar year (year Y):**
Internal Cut-Off date: Payments which were made up to and including the internal cut-off date in year Y related to an event from the reporting period will be disclosed in the report released in year Y. All payments after that internal cut-off date will be captured in the report for the next reporting period.
- b) A contract is signed and a service is provided in year X but the related ToV is paid in the following calendar year (year Y)**
Internal Cut-Off date: Payments which were made up to and including the internal cut-off date related to an event from the reporting period will be disclosed in the report released in year Y. All payments after that internal cut-off date will be captured in the report for the next reporting period.
- c) A frame contract is signed over more than one year e.g. consultancy agreement regarding consultancy in the period 2016 - 20226**

ToV is published in accordance with internal accounting regulations in the reporting period in which ToV was actually granted to the HCP/HCO and recorded in the accounts.

2.3.2. Currency (local or if not, specify the exchange rate).

2.3.3. ToVs will be disclosed in local currency. If payments have been made in other than the disclosure currency, they have been converted with the annual average conversion rate.

2.3.4. VAT

Generally net amounts excluding VAT are disclosed. But where the invoice/document only shows the total amount including Value Added Tax, the total amount is reported.

2.3.5. Direct ToVs

Direct ToVs are those which are provided to the HCP/HCO directly without having any other party/person in between. These ToVs are disclosed under the relevant applicable categories as stated above under Sec. 2.2.

2.3.6. Indirect ToVs

Indirect ToVs are those which are not directly provided to an HCP/HCO, but through a third party being in between, e.g. congress organizer.

In this case ToVs are reported according to the “Follow the money principle”. Different scenarios may occur:

a) Event is organized by an HCO through an agency

In this case, ToVs are reported under the name of the HCO. HCPs may form a legal entity (HCO) if they have joined forces for a specific objective, are working for a certain period of time and appear under a certain name to the outside world.

b) Event is organized by several HCOs through an agency

In this case the whole amount of value is divided through the number of all HCOs and reported under the names of the HCOs in the same proportion.

c) Event is organized by a third party that is not a HCO

ToVs in this case are not reported at all as a third party (e.g. congress organizer, agency) is not an HCO.

2.3.7. ToVs in case of partial attendances or cancellation

If an HCP cancels his/her attendance for an event upfront, BI will only disclose ToVs that were actually received by the HCP and not refunded (e.g. where registration costs were paid but the HCP did not attend the congress, the registration fee will not be disclosed).

If an HCP attends only partially at an event (e.g. congress) we will disclose ToV that was actually paid. E.g. if registration fees and hotel accommodation was paid for two days, but the HCP attended for one day only, BI will nevertheless disclose the whole amount as not feasible to administrate otherwise.

2.3.8. Cross-border activities

ToVs are disclosed in the country of the Recipient's Principal Practice, (i.e. business address, place of incorporation or primary place of operation) irrespective of which BI entity actually paid resp. where the HCP/HCO was providing his services.

3. Disclosure's scope

3.1. Products concerned

Under the EFPIA Disclosure Code ToV are only covered in connection with prescription-only medications.

3.2. Excluded ToVs

The following ToV are excluded from the disclosure:

- solely related to over-the-counter medicines;
- provision of materials and objects of informative or educational character
- meals;
- samples;
- fees charged by logistics agencies assisting the signatories in organising travels and meetings;
- discounts, price reductions and other trading devices commonly used in the sale of medicinal products. Other e.g. parking costs, transportation costs under EUR 50 for more than 2 HCPs pre-paid by BI. If other local regulations exist, they prevail.

ToVs in connection with R&D activities are subject to aggregate disclosure. This includes ToVs related to non-clinical studies, clinical trials and non-interventional studies.

4. Specific considerations

4.1. Self-incorporated HCP

We treat self-incorporated HCPs as HCOs and disclose the ToV provided.

The same applies for HCPs who have joined forces in order to reach a specific goal/purpose or if an HCP is sole shareholder or partner of a legal entity. A self-incorporated HCP or individual companies, where the company's name indicates individual HCPs, will be considered as HCPs.

4.2. Movements of HCPs

HCPs who have moved meanwhile and are not located in their former country in time of reporting, we will still use the principal address at the time they received a ToV. E.g. in 2015 a HCP received a speaker fee for an engagement but moved to another country in May 2016. We will disclose the received amount under the address provided in the year 2015.

4.3. Multi-year agreements

For multi-year agreements please refer to Sec. 2.3.1.

5. Data protection and consent management

5.1. Legitimate Interests

According to the Data Protection Regulation Article 6(f) BI no longer collects consent to publish transfers of value to healthcare organization (hereinafter “HCO”) on an individual level. For the interactions initiated after the change of legal basis, publication at the individual level is based on BI's legitimate interest in increasing transparency and thereby strengthening and maintaining trust in the pharmaceutical industry and the cooperation between pharmaceutical companies and healthcare. It is also in the interests of third parties (especially patients, but there is also a wider social interest) to have the opportunity to look at cooperation and interests between pharmaceutical companies and healthcare organizations.

5.2 Consent for publication of data

Depending on whether individuals are protected with respect to their personal data under local data protection laws, HCPs will be asked for their consent for individual disclosure of their respective data for 3 years. If the consent is not provided by the HCP, BI discloses data on aggregated basis.

If an HCP does not respond at all, BI classifies this as a non-consenting party, meaning ToVs for that specific party will be disclosed on aggregated basis.

5.2.1 No “cherry picking”

BI follows the “no cherry picking” –rule. That means that HCPs can provide their consent resp. disagree with the disclosure regarding all ToVs only. It is “all or nothing”.

Example: BI pays HCP X for a speaker activity, and two months later for consultancy in an advisory board. HCP X wants to agree with the disclosure of the speaker fee, but not to the advisory board honorarium. This is not possible. BI will disclose all ToVs for HCP X on aggregated basis.

The same holds true for withdrawal of consent.

5.3. Management of recipient consent withdrawal

The “revocation process” is part of the “Declaration of Consent Process”. BI will process revocations immediately, within 5 business days. Therefore, if ToVs are already published, they will be removed from individual disclosure within 5 business days upon receipt of the revocation and transferred to the aggregated section. If the revocation was made before actual disclosure, the ToVs affected will be disclosed on aggregated basis from the beginning.

5.4. Management of recipient’s request

Requests of HCPs/HCOs regarding their published data will be handled within 3-5 business days. Upon request, HCPs/HCOs can also ask for a statement of accounts to be provided between 3-5 business days.

6. Disclosure form

The data is disclosed based on the template approved by the local EFPIA member association. Data will be disclosed according to the principle “one line per HCP/HCO”, as also listed in the standard template by EFPIA. This means that all payments from one and the same category will be aggregated (e.g. three advisory board honoraria will be displayed as one total amount under the category fee for service and consultancy)

6.1. Date of publication

The date of publication for the disclosure will be not later than June 30, of the following calendar year

6.2. Disclosure platform

The disclosure will be made under the webpage of BI (in countries where local webpages exist). For countries within the RCV Region where no local websites are established, BI in Vienna will make the disclosure.

6.3. Disclosure language

The disclosure language will be English and the respective local language.

6.4. Duration of publication

Please see Sec.2.3.1.

6.5. Abbreviations

HCP: Persons authorized to apply, administer or prescribe such as physicians, dentists, veterinary surgeons, dental practitioners, midwives, members of the nursing profession, medical laboratory services and paramedic and any other medical facilities, provided they require medicinal products to fulfil their tasks.

Therefore, BI RCV considers respiratory therapists as not being HCPs.

HCO: Any institution or organization, consisting predominantly of HCPs, providing healthcare or conducting research.

Therefore, BI RCV considers any commercial agency, e.g. event agencies, as not being HCOs.

Several HCPs may form an HCO, provided that they have joined forces for a specific scientific/medicinal objective for a certain period of time and act under a joint name, e.g. Central European Lung Cancer Initiative. ToVs provided to them are disclosed under the name of this formed HCO.

A self-incorporated HCP is also considered as an HCO, therefore, a covered recipient and ToVs are disclosed under the name of the corporation of the HCP. A self-incorporated HCP or individual companies, where the company's name indicates individual HCPs, will be considered as HCPs.

CRO: A 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. A CRO is not an HCO, therefore, not a covered recipient.