

Methodological note

Content

- 1. Introduction
- 2. Definitions
- 2.1. Covered Recipients
- 2.2. Kind of ToVs
- 2.2.1. Transfers of Value to an HCP
- 2.3. General statements regarding ToVs
- 2.3.1. ToVs date
- 2.3.2. Reporting period.....
- 2.3.3. Currency (local or if not, specify the exchange rate)
- 2.3.4. VAT.....
- 2.3.5. Direct ToVs
- 2.3.6. Indirect ToVs.....
- 2.3.7. ToVs in case of partial attendances or cancellation
- 2.3.8. Cross-border activities.....
- 3. Disclosure’s scope
- 3.01. Products concerned.....
- 3.02. Excluded ToVs
- 4. Specific considerations.....
- 4.01. Self-incorporated HCP
- 4.02. Movements of HCPs.....
- 4.03. Multi-year agreements
- 5. Data protection and consent management.....
- 5.01. General comments on data protection
- 5.02. No “cherry picking”.....
- 5.03. Management of recipient consent withdrawal.....
- 5.04. Management of recipient’s request.....
- 6. Disclosure form
- 6.01. Date of publication
- 6.02. Disclosure platform
- 6.03. Disclosure language.....
- 6.04. Duration of publication.....
- 6.05. Abbreviations.....

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, in charge for North Macedonia as well the local association Pharma brand-Nova,- PNB, as member of EFPIA, 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 Code of Practice, 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 Republic of North Macedonia, the local Code for disclosure of transfer of values from pharmaceutical companies to Health Care Professionals and Health Care Organisations, contain all relevant rules and regulation regarding the disclosure.

This document is our methodological note specifying in detail the rules resulting from the Code of Practice. 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 Europe. 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

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 Code of Practice)

Registration fees are disclosed separately from travel and accommodation costs.

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

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. 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 Code of Practice)

d. Fees for Service and Consultancy

ToVs resulting from or related to contracts between BI (via Demano HR Consultancy for the needs of Boehringer Ingelheim RCV GmbH & Co KG in North Macedonia) 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.

2.3 General statements regarding ToVs

2.3.1 ToVs date

The reporting period is the calendar year. Relevant for the reporting period is when the transfer of value to the HCP/HCO has been granted. If for example an HCP provided a service in the year X, which was remunerated in year Y, the transfer of value is relevant for the year Y's disclosure.

The data is disclosed until 30th June of the following calendar year. All ToVs falling in the 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.

2.3.2 Reporting period

Services provided in more than one year

In case a frame contract for more than one year is concluded, e.g. a consultancy agreement for several years (eg. 2015-2025), the ToV are disclosed in accordance with internal accounting regulations in the reporting period in which ToV were actually granted to the HCP/HCO and recorded in the accounts.

2.3.3 Currency

ToVs will be disclosed in local currency. If payments have been made in other than the disclosure currency, they have been converted, in denars under National Bank of the Republic of North Macedonia conversation 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

3.01 Products concerned

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

3.02 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 prospective *non-interventional studies*.

4. Specific considerations

4.01 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.

4.02 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.

4.03 Multi-year agreements

For multi-year agreements please refer to Sec. 2.3.2.

5. Data protection and consent management

5.01 General comments on data protection

In accordance with Law on Personal Data Protection (Official Gazette of the Republic of N. Macedonia No 7/2005, 103/2008, 124/2008, 124/2010, 135/2011, 43/2014, 153/2015, 99/2016 и 64/2018), with all current and further changes, individuals are protected with respect to their personal data. HCPs as well as HCOs will be asked for their consent for individual disclosure of their respective data. If the consent is not provided by the HCP/HCO, BI discloses data on aggregated basis.

If an HCP/HCO 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.

5.02 “No cherry picking”

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

Example: BI pays HCP 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.

5.03 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.

5.04 Management of recipient’s request

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

June, 2023

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)

6.01 Date of publication

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

6.02 Disclosure platform

The disclosure will be made under the webpage of BI, BI RCV GmbH & CO KG: www.boehringer-ingelheim.com

6.03 Disclosure language

The disclosure language will be English and Macedonian language

6.04 Duration of publication

Please see Sec.2.3.1.

6.05 Abbreviations

HCP: Every physical person member of medical, dental, pharmaceutical or close profession or other person during professional activities is authorized to prescribe, purchase or apply medical products, and whose basic practice, business address or place of registration is in Europe. To be avoided any suspicion, definition for HCP includes: (i) all governmental employees or other organization members (no matter public or private sector) who can prescribe, purchase, deliver or took prescribed doctors products and (ii) every employee person of company –member who's basic work is as HCP, with an exception of (x) all other employees at company member and (y) wholesalers or distributors of medical productions.

HCO: All legal entities as associations or organizations providing healthcare, nursing or science (no matter whether in a legal or organizational manner), as hospitals, clinics, foundations, universities or other educational institution (except patient organizations in framework of PNB Code for patient organizations), whose primary practice, principal professional address or place of incorporation is Europe or under which association more HCP's are providing services.

In accordance with CODE OF PHARMA BRENDA-NOVA (PNB) for disclosure of transfer of values from pharmaceutical companies to HCP'S and HCO'S.

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