

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, *Representative Office of the Boehringer Ingelheim RCV GmbH & Co KG in Ukraine*, 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. For Ukraine, Art. 14 APRAD Code contains all relevant rules and regulation regarding the disclosure.

This document is our methodological note specifying in detail the rules resulting from the Transparency Code and the local implementation in the APRAD Code regarding publishing of information on the transfers of value (ToV) to HCPs and HCOs from BI RCV GmbH & Co KG in Ukraine.

If local associations in single countries have developed their own methodological notes these shall be taken into account as well.

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 Ukraine. For detailed definition of HCP/HCO please refer to the section “Abbreviations”.

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

2.2. Kind of ToVs

Representative Office of the BI RCV GmbH & Co KG in Ukraine is disclosing the following ToVs to HCPs resp. HCOs (subject to local applicable 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 HCP Code resp. Art. 14 APRAD 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 Representative Office of the BI in Ukraine 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 are disclosed on aggregate level per recipient, 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 RCV made product donations to a HCO, the total value for all donated packages per HCO may be 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 resp. Art. 14 APRAD Code).

c. Fees for Service and Consultancy

ToVs resulting from or related to contracts between Representative Office of the BI RCV in Ukraine 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, 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. 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 by 30th June of the following calendar year. All ToVs falling in this reporting period are disclosed. As Art 14.2.2 APRAD Code requires a disclosure for minimum 3 years, BI will disclose the information for 3 years from first disclosing date onwards unless it contradicts the requirements of the applicable legislation (please also see Data Protection Section).

2.3.2. Reporting data

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 (local or if not, specify the exchange rate)

ToVs will be disclosed in local currency, therefore in UAH. 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 RCV 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 RCV 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. Ukraine (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 and the APRAD Code, ToV are only covered in connection with prescription-only medications. In practice, however, such ToV may relate to a group of products made up of a combination of prescription-only and non-prescription pharmaceuticals and other products. In this case BI RCV allocates the full amount of ToV as relating to prescription-only pharmaceuticals and will publish it in the appropriate category.

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.

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.

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. 2.3.2.

5. Data protection of the HCPs, protection of confidential information and trade secrets of the HCOs, and consent management

5.1. General comments on data protection

According to Ukrainian Data Protection Law (June 01, 2010 N 2297-VI) in its applicable version, individuals as well as legal entities are protected with respect to their personal data. Therefore, HCPs will be asked for their consent in written form for individual disclosure of their respective data according to Art. 14 APRAD Code. If the consent is not provided by the HCP, BI RCV discloses data on aggregated basis.

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

5.2. General comments on protection of confidential information and trade secrets of the HCOs

According to Ukrainian Law “On Information” (October 10, 1992 N 2657-XII) in its applicable version, confidential information belongs to restricted information. Such access is restricted by a legal entity that owns it and can be disclosed only with the consent of such entity in the manner specified by it in accordance with the conditions set by it.

Similarly, according to the Civil Code of Ukraine (January 16, 2003 N 435-IV), commercial secrets are protected by public authorities from disclosure. Commercial secrets may include information of a technical, organizational, commercial, industrial or other nature, except those that, according to the law, cannot be classified as commercial secrets.

Therefore, HCOs will be asked for their consent for individual disclosure of their confidential information and/or trade secret according to Art. 14 APRAD Code in written form, stipulated in a separate document or in an agreement with BI RCV. If the consent is not provided by the HCO, BI RCV discloses data on aggregated basis.

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

5.3. No “cherry picking”

BI RCV 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 RCV 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 RCV will disclose all ToVs for HCP X on aggregated basis.

The same holds true for withdrawal of consent.

5.4. Management of recipient consent withdrawal

The “revocation process” is part of the “Declaration of Consent Process”. BI RCV 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.

5.5. 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 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 first disclosure will be not later than June 30, 2019.

6.2. Disclosure platform

The disclosure will be made under the webpage of Representative office of the BI RCV GmbH & Co KG in Ukraine, namely www.boehringer-ingenelheim.ua.

6.3. Disclosure language

The disclosure language will be Ukrainian and English.

6.4. Duration of publication

Please see Sec.2.3.1.

6.5. Abbreviations

HCP: According to the local APRAD Code: means any member of the regulatory authorities, medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product.

HCO: (for the purposes of Articles 14 of the Code) means any legal person irrespective of the legal or organizational form or its separate unit, aims at health care of patients and/or provision of medical services to the public based on appropriate licenses and professional activities of medical (pharmaceutical) workers. In addition, HCO includes: medical or scientific associations, learned society (except for patient associations), medical teaching institutions, healthcare foundations and other medical institution whose business address, place of incorporation or primary place of operation is in Europe.

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 HCPs, which duly formalized their legal status, are also considered as an HCO, therefore, a covered recipient and ToVs are disclosed under the name of the corporation of the HCPs. 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.