Methodological note

Content

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 (Schweiz) GmbH 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 the countries, local Codes of Conduct contain all relevant rules and regulation regarding the disclosure.

In the case of Switzerland the code of conduct of the pharmaceutical industry in Switzerland on cooperation with healthcare professional circles and patient organizations (Pharma Cooperation Code/ https://www.scienceindustries.ch/_file/24292/pharmakodex-version-april-2019-d.pdf) puts into concrete terms for Switzerland the codes of the international associations (e.g. EFPIA) of the pharmaceutical industry, insofar as they relate to cooperation with healthcare professionals nd healthcare organisations and patient organisations, together with the disclosure of pecuniary benefits which the healthcare professionals and healthcare organisations, as well as patient organisations, receive from pharmaceutical companies.

This document is our methodological note specifying in detail the rules resulting from the Code of Practice and the Swiss Pharma Cooperation Code. If local rules are stricter or differ from this Methodological Note, local rules prevail.

[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

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 Switzerland. For detailed definition of HCP/HCO please refer to the section "Terms and 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.

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 Code of Practice)

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

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 and the Swiss Pharma Cooperation 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 retrospective 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. 2.3.2.

4.4. Special situation due to COVID-19 pandemic

Due to the COVID-19 crisis and the related lock-down, BI Switzerland was facing difficulties collecting the individual consents. The process of collecting consents had to be interrupted when the crisis and respective lock downs started. Therefore, the percentage of individual disclosure is lower than expected.

5. Data protection and consent management

5.1. General comments on data protection

Depending on weather individuals as well as legal entities are protected with respect to their personal data under local data protection laws, 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.

5.2. No "cherry picking"

Boehringer Ingelheim (Schweiz) GmbH 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: Boehringer Ingelheim (Schweiz) GmbH 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 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 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 30thof the following calendar year

6.2. Disclosure platform

The disclosure will be made under the webpage of BI-Switzerland: https://www.boehringer-ingelheim.ch/de.

6.3. Disclosure language

The disclosure language will be German and French.

6.4. Duration of publication

Please see Sec.2.3.1.

6.5. Terms and abbreviations

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.

Events: events which are organised or conducted by a pharmaceutical company or in its name or financially or otherwise supported by it, such as symposia or congresses, meetings of healthcare professionals, advisory bodies or bodies for the planning of clinical trials or non-interventional investigations or for the training of testers for clinical trials, visits and inspections of research and manufacturing establishments of pharmaceutical companies,

together with events held by or with patient organisations for their purposes or in their interest.

HCP: physicians, dentists and pharmacists who are working in particular in a practice or hospital, together with pharmacists active in retail businesses, and persons who are authorised by Swiss law on therapeutic products, to prescribe, deliver or use prescription-only medicinal products for humans.

HCO: institutions, organisations, associations or other groups of healthcare professionals which provide healthcare services or consultancy tasks or other services in healthcare (e.g. hospitals, clinics, foundations, universities or other educational establishments, scientific societies or professional associations, community practices or networks, but not patient organisations).

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.

Medicinal products: medicinal products for humans within the meaning of the Swiss law on therapeutic products; this Code applies solely to prescription-only medicinal products (original preparations and generics).

Pharmaceutical companies: companies which manufacture or distribute prescription-only medicinal products for humans by way of business in Switzerland.

Patient organisations: not-for-profit organisations (including the organisations to which they are affiliated) based or active in Switzerland, which consist primarily of patients or their carers and which represent or support the needs of patients or their carers.

Pecuniary benefits (general): in cash, as non-cash contributions, donations, grants or payments made either directly or indirectly in some other form for consultancy tasks or services, research and development, advertising, sales or other purposes, always in connection with medicinal products within the meaning of Section
Direct pecuniary benefits are those which a pharmaceutical company provides directly for a particular recipient. Indirect pecuniary benefits are those which a third party (e.g. supplier, agent, partner, subsidiary company or foundation) provides for a recipient in the name or on

behalf of a pharmaceutical company, the identity of the pharmaceutical company being known or recognisable to the recipient.
Pecuniary benefits for research and development services: benefits in connection with the planning or conduct of non-clinical studies (in compliance with GLP standards), clinical studies (compliant with GCP standards) and non-interventional studies.
Recipients of pecuniary benefits: healthcare professionals or healthcare organisations together with patient organisations whose primary practice or determining business address or registered place of business are in Switzerland.

ToV: Transfer of value