

EFPIA Disclosure in Luxembourg

Methodology Note - Boehringer Ingelheim

1. Introduction

Collaborative working with HealthCare Professionals (HCP) and HealthCare Organizations (HCO) 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, Boehringer Ingelheim has been following these Codes as well as EFPIA's 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 defined Transfers of Value (ToV) from the pharmaceutical industry to HCP and HCO, and this from 2016 onwards.

For Luxembourg, the Deontological Code of APL, Chapter 5bis on 'Transparency', Art. 44bis contains all relevant rules and regulations regarding the disclosure in Luxembourg.

This document is a methodology note specifying in detail the rules resulting from the Deontological Code and the local implementation in Boehringer Ingelheim Belgium/Luxembourg (BIBE), regarding the disclosure of information on Transfers of Value to Luxembourgian HCP and HCO.

2. General Methodology

2.1. Covered Recipients

'Covered recipients' are any HCP or HCO, whose primary practice, principal professional address or place of incorporation is in Luxembourg. For detailed definitions of HCP/HCO we refer to the section "Abbreviations".

According to EFPIA, the recipient of ToV needs to be "clearly identifiable", that means that there cannot be any doubt about the identity of the HCP/HCO receiving ToV. As EFPIA did not develop unique identifiers for HCP/HCO in Europe, BIBE used the Veeva ID as country unique identifier for HCP/HCO.

2.2. Types of Transfer of Value

BIBE is disclosing the following ToV to HCP and HCO, according to EFPIA Disclosure Code and local Data Protection Laws:

2.2.1. ToV to an HCP

a. Contribution to costs related to Events

These costs can be divided into

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

b. Fees for Service and Consultancy

It consists of ToV resulting from or related to contracts, between BIBE and a HCP, under which the HCP provide any type of services to BIBE. Fees or honoraria on the one hand, and on the other hand ToV relating to expenses agreed in the written agreement covering the activity, are disclosed as two separate amounts.

2.2.2. ToV to an HCO

a. Donations and Grants

Donations and Grants to HCO that support healthcare or to organizations that consist of HCP and/or that provide healthcare and/or conduct research.

b. Contribution to costs related to Events

Contribution to costs related to Events, through HCO or third parties, e.g. congress organizers including sponsorship to HCP to attend Events, such as:

- Registration fees;
- Sponsorship agreements with HCO or with third parties appointed by an HCO to manage an Event; and
- Travel and accommodation (to the extent governed by Article 10 of the EFPIA HCP Code)

c. Fees for Service and Consultancy

ToV resulting from or related to contracts, between BIBE, and institutions, organizations or associations of HCP, under which such institutions, organizations or associations provide any type of services to BIBE.

Fees or honoraria on the one hand, and on the other hand ToV relating to expenses agreed in the written agreement covering the activity, will be disclosed as two separate amounts.

3. Specific Methodology

3.1. ToV period

- a) Generally, ToV from one yearly reporting period are disclosed. This reporting period is from 01.01.2017 – 31.12.2017.
- b) ToV are published for all events that took place in 2017 and were paid in 2017 (as of 1Feb2017 due to change in cut-off date).
- c) Events with start date 2017 but payment done in 2018 will be captured in the 2019 report.
- d) Outstanding events with start date 2015 or 2016 not included in report 2017 for which invoices have been paid in 2017 are also captured in this report.
- e) ToV are published 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.
- f) According to the EFPIA disclosure Code, BIBE will disclose this information for 3 years from first disclosing date onwards.

3.2. Direct ToV

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

3.3. Indirect ToV

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

In this case ToV are reported according to the “Follow the money principle”. The following scenarios may occur:

- a) Event is organized by an HCO (or a group of HCP forming an HCO) through an agency.
In this case, ToV are reported under the name of the HCO.
- b) Event is organized by a third party that is neither HCP nor HCO but an agency as actual initiator.
In this case, ToV are not reported as the third party (e.g. congress organizer, agency) is not an HCO.

3.4. ToV in case of partial attendances or cancellation

If an HCP cancelled his/her attendance prior to an event, ToV are not reported unless payments for registration or hospitality already occurred and are not refundable.

If an HCP attended only partially an event (e.g. congress), all ToV that were actually paid by BIBE are reported.

3.5. Cross-border activities

ToV are disclosed in the country of the Recipient`s Principal Practice (i.e. business address, place of incorporation or primary place of operation in Europe). Therefore, any ToV that fall

within the scope of the EFPIA HCP/HCO Disclosure Code that are paid to a Luxembourgian HCP/HCO are disclosed in Luxembourg, irrespective of where the ToV was actually paid or where the HCP/HCO was engaged.

BIBE has opted to disclose 1 EFPIA report for LUX for ToV paid by the Belgian (or International- if any) affiliate to Luxembourgian HCP/HCO.

The EFPIA report is available on the appropriate platform (see 6.2)

3.6. Self-incorporated HCP

A legal entity of which a HCP is the Sole Shareholder has been considered as an (self-incorporated) HCP and therefore the provided ToV are disclosed following the consent management procedure (see item 5).

A legal entity consisting of ≥ 2 HCP who have joined forces in order to reach a specific goal/purpose (Group Practice under BVBA/SPRL, vzw/asbl ...) has been considered as an HCO and therefore the provided ToV are disclosed.

3.7. Longer term (> more than 1 year) agreements/projects

For activities that occurred in 2017 only the ToV provided to HCP/HCO based on the payments done in 2017 are disclosed.

3.8. Research & Development (R&D)

ToV related to R&D activities are subject to aggregate disclosure.

This involves

- ToV related to non-clinical studies, clinical trials and non-interventional studies
- Research grants to HCO (institutions, organizations or associations that support healthcare and conduct research)
- Mdeon costs for investigator meetings

4. Disclosure's scope

4.1. Products concerned

Under the EFPIA Disclosure Code only ToV related to prescription-only medicinal products for human use are covered.

4.2. Excluded ToV

The following ToV are excluded from the disclosure:

- Items of medical utility or informational or educational material
- Meals and drinks
- Samples

- Support to Patient Organizations
- Fees charged by logistics agencies assisting BIBE in organising congresses and events

5. Consent management

Each HCP as well as legal entities with a single HCP shareholder have been asked for their consent for individual disclosure of their respective data. If the consent was not provided by the HCP, data are being disclosed on aggregated basis.

BIBE collected the consents for the disclosure in 2018 of ToV from the reporting period 01.01.2017 – 31.12.2017, at the time of the first service agreement concluded for activities started in 2017. We provided each HCP with a Declaration of Consent Form (DoC) together with the contract (that also includes a transparency clause).

HCP had two different options when filling in the DoC:

- Consent with individual disclosure
- No consent with individual disclosure

A reminder letter was sent if no response of the HCP was obtained. If finally no response was obtained, it was considered as ‘no consent’ and therefore ToV were disclosed on aggregated basis.

Consent is valid for the whole disclosure period and for all applicable ToV.

BIBE will process consent revocations as long as the revocation is obtained before actual disclosure. The ToV affected will then be disclosed on aggregated basis.

Upon request, data corrections are possible 3 and 6 months after first publication. Once published, consents provided for that publication period of 3 year cannot be revoked.

6. Disclosure Form

6.1. Date of publication

The date of publication is July 2018 in Luxembourg.

6.2. Disclosure platform

The disclosure in Luxembourg is available via a link from APL website to the company transparency web page.

6.3. Disclosure language

The disclosure language in Luxembourg is in French.

6.4. Duration of publication

3 years as of date of first publication.

7. Disclosure financial data

7.1. Currency

ToV are disclosed in local currency, therefore in EUR.

If applicable other currencies were converted into EUR, taking into account the exchange rate of March 21st, 2018.

7.2. Value Added Tax (VAT) included or excluded

Generally BIBE disclosed net amounts, VAT excluded.

However, where the invoice only showed the total amount VAT included, the total amount is reported.

8. Abbreviations

BIBE: Boehringer Ingelheim Belgium/Luxemburg with legal entity ‘SCS Boehringer Ingelheim Comm. V.’

CRO: Clinical research organization or organization that provides support to the pharmaceutical, biotechnology and medical device industries in the form of research services outsourced on a contract basis

DoC: Declaration of Consent

EFPIA: European Federation of Pharmaceutical Industries and Associations

HCO: ‘Healthcare Organisation’.

Any legal person (i) that is 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 healthcare professionals provide services.

HCP: ‘Healthcare professional’.

Any natural person who 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 healthcare professional 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, recommend or administer medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practising healthcare professional, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.

R&D: Research & Development

ToV: Transfers of Value

VAT: Value Added Tax