

Disclosure Code

Methodology Note to the Disclosure Report - Boehringer Ingelheim Sp. z o.o.

This document is a methodology note which details the rules set forth in the Disclosure Code for disclosure of transfers of value (ToV) to healthcare professionals and healthcare organisations by innovative pharmaceutical companies. Each company, Signatory of this document, is obliged to prepare its own methodology note to be published with reports on transfers of value.

INTRODUCTION

For a long time now cooperation between healthcare professionals and healthcare organisations has been the driving force of the development of patient care and innovative medicine. Healthcare organisations and cooperating organisations support the pharmaceutical industry with valued, independent and specialist knowledge based on clinical experience and practice in the disease treatment. Moreover, a healthcare professional, as the primary point of contact with the patient, has invaluable expertise in terms of treatment outcomes and patient management. This expertise supports us in an even better adjustment of products to the needs of patients, thus in the improvement of comprehensive patient care.

Employees and healthcare organisations should receive suitable remuneration for their work and services provided to healthcare companies. The Disclosure Code allows for a reliable and transparent reporting of the extent and value of this interaction and is an important step towards building trust between the pharmaceutical industry, medical community and patients.

Pursuant to the Disclosure Code, the signatories, i.e. member companies of the European Federation of Pharmaceutical Industries and Associations (EFPIA) are obliged to disclose all transfers of value to healthcare professionals and healthcare organisations, such as contribution to costs related to attendance at medical educational events, speakers' fees and consulting services.

1. ToV [transfer of value]

- a. ToV disclosures reflect the actual value or cost provided by the Company and not the resulting income or benefit to the Beneficiary.
- b. Disclosed transfers of value are reported as net values (i.e. excluding VAT), with the exception for lodging costs, which are reported as gross value, and in the event the invoice or other document confirming the transfer of value includes solely the total amount including VAT.
- c. All disclosed transfers of value are reported in Polish zlotys converted from foreign currency at the average annual exchange rate of EURO at 4,29753 PLN.

2. ToV Disclosure Form:

- a. Transfers of value to healthcare professionals are reported as total ToV in a given reporting period and published on individual disclosure basis provided the consent to disclose personal information has been given.
- b. For healthcare professionals who did not consent to disclose personal information:
 - i. the ToVs will be reported on aggregate basis presenting a total ToV amount in a given reporting period and
 - ii. information on the total number and percentage of non-consenting healthcare professionals who received ToVs from the Company in a given reporting period
- c. Information on ToVs to healthcare organisations represent a total ToV value in a given reporting period.

3. ToV Recognition Date. Date of publication. Disclosure language and platform.

The reporting period is from 01.01.2019 to 31.12.2019. All ToVs will be disclosed which were made during this period, including ToVs for 2020 if the event took place in 2019.

The information will be disclosed not later than June 30, 2020 on BI website in Polish at www.boehringer-ingelheim.pl and in English at www.boehringer-ingelheim.at

BI will keep the disclosed information available for 3 years after first disclosure.

4. Transfer of Value in case of partial attendances or cancellation (e.g. HCP did not attend the event)

In the case the transfer of value has not been made, there is no disclosure of ToV.

If a healthcare professional cancels his/her attendance for an event upfront, BI will only disclose ToVs that were actually received by the HCP and not refunded.

If a healthcare professional attends only partially at an event we will disclose ToV that was actually paid.

5. Reporting of indirect ToV made to:

a. healthcare organisation

In the case of transfers of value to a healthcare organisation through a professional conference organiser, the healthcare organisation is reported as beneficiary. This rule applies when part of or all transfers of value are made to intermediaries, such as professional conference organisers.

Transfers of value by the Company directly to a healthcare organisation as well as to an intermediary acting on behalf of that organisation are disclosed.

An example would be an organisation of an event by a professional conference organiser, for which the initiator and programme organiser is e.g. a scientific society. Without the support of a professional organiser, it would be up to the scientific society to carry out all these activities. The fact that the transfer of value (also non-financial) to the final beneficiary is made through an intermediary does not waive the obligation to disclose information on the extent and value of the interaction with healthcare organisations.

The transfer of value to a healthcare organisation intended for individual healthcare professionals (e.g. fees for: lecture, invitations for physicians or contribution to conference attendance related costs) is divided into categories and specific amounts are allocated to individual healthcare professionals.

b. healthcare professionals

Transfers of value to individual healthcare professionals (e.g. invitations, contribution to costs of travel or accommodation) are not a part of the sponsorship transfer of value to a healthcare organisation.

6. Consent to disclosure of personal information

Pursuant to regulations regarding the personal data protection, personal information of natural persons is subject to protection.

Healthcare professionals have been asked to provide consent to individual disclosure of transfers of value for 2019.

The declaration of consent includes information on the scope and purpose of personal information processing, according to the article 13 of the regulation of the European Parliament [2016/679 of 27/Apr/2016] regarding personal data protection and to repeal the directive no 95/46/EC [following the GDPR].

If a healthcare professional did not respond at all and has failed to return the consent form, BI classifies this as a non-consenting party, meaning transfers of value for that specific healthcare professional will be disclosed on aggregated basis.

At the request of the healthcare professional – in the event of consent withdrawal – his/her information will be removed from the disclosed Form without delay, and not later than within 14 days from filing the request.

In the event of withdrawal of consent by the healthcare professional, the Company is nevertheless obliged to disclose the transfer of value, which is then reported on aggregated basis (without identification of the beneficiary).

The consent cannot be withdrawn in part or in relation to some transfers of value made in a given reporting period. Withdrawal of consent to disclosure of some transfers of value or consent to disclosure of some transfers of value is equivalent to withdrawal of consent to disclosure of remaining transfers of value made in the reporting period.

6.1 Special situation due to COVID-19 pandemic.

The extraordinary situation caused by the COVID-19 pandemic has limited the possibility of obtaining all declarations of consent to disclose personal data for the previous calendar year. Therefore, the percentage of individual disclosure is lower than it would have been if HCPs with whom BI cooperated in 2019 were available in March-May 2020. In the situation when the HCPs have not been available, the ToVs will be disclosed on aggregate basis respectively.

7. Excluded transfers of value

The following transfers of value are excluded from disclosure:

- a. solely related to over-the-counter medicines activities;
- b. transmission of informational or educational materials or objects (referred to in Art. 38, paragraph 2 and 3 of the Pharmaceutical Industry Code of Good Practices);
- c. meals (referred to in Art. 27 of the Pharmaceutical Industry Code of Good Practices);
- d. samples (referred to in Art. 22 of the Pharmaceutical Industry Code of Good Practices);
- e. commissions paid to event agencies cooperating with signatories in organising travels and meetings;
- f. discounts, deductions and other sales tools that are part of ordinary course of purchases and sales of medicinal products;
- g. medical packages provided by private entities to employees of Signatory companies;
- h. related to anonymous marketing research;
- i. made in relation to research and development activity are subject to aggregate disclosure and are therefore excluded from individual reporting.

8. Classification of businesses owned by healthcare professionals

A healthcare professional conducting his/her activity as natural person is regarded as healthcare professional and not a healthcare organisation. Irrespective of the legal entity or the employment form, agreements are concluded directly with a specific healthcare professional and not the employing or contracting entity.

9. Classification of Transfers of Value

Transfers of Value to healthcare professionals			
Costs related to events		Fees for services	
Registration fees	Travel and accommodation costs	Fees for services and consultancy	Related expenses
Event related expenses.	flight, train, taxi, car rental (only when these costs are directly related to travel), accommodation.	fees for: lectures and speeches, advisory boards (excluding research and development), medical writing, data analysis, development of educational materials, consulting and advising, speaker training (if speech is related directly to contract for speech or lecture), participation in individual development programs.	Service related costs, i.e. flight, train, taxi, car rental (only when these costs are directly related to travel), accommodation.

Transfers of Value to healthcare organisations					
Donations	Costs related to events			Fees for services	
	Registration fees	Travel and accommodation costs	Value of Sponsorship agreements	Fees for services and consultancy	Related expenses
donations covering statutory aims, medical equipment, diagnostics, educational grants, courses provided by healthcare organisations.	event related expenses	flight, train, taxi, car rental (only when these costs are directly related to travel), accommodation.	costs of exhibition and advertising space, costs related to placement of a sponsoring company logo or brand logo in a conference program or invitation communication, costs of a satellite symposium at a congress, costs of attendance of sponsor's representatives at an event.	fees for: lectures and speeches, advisory boards (excluding research and development), medical writing, data analysis, development of educational materials, consulting and advising, speaker training (if speech is related directly to contract for speech or lecture), participation in individual development programs, space rentals.	service related costs, i.e. flight, train, taxi, car rental (only when these costs are directly related to travel), accommodation.

10. Research and Development Transfers of Value

Transfers of Value related to expenses of healthcare organisations or healthcare professionals on research and development, including clinical trials, research and development related events, non-interventional studies, data monitoring committees related to clinical trials, investigator initiated trials are disclosed on an aggregate basis, and reported as total amount, without allocation to healthcare organisations and healthcare professionals.

11. Disclosure of cross-border transfers of value

Cross-border transfers of value to healthcare professionals or healthcare organisation that fall within the scope of the Disclosure Code are disclosed by the Company in the country where the Beneficiary has their place of residence or registered office.

Cross-border transfers of value are disclosed in the local report of the Company, irrespective of which of the entities of the capital group, to which the Company belongs, has arranged and made the transfer of value.