

## **Transparency Code**

### **Methodological Note template developed by the Employers' Union of Innovative Pharmaceutical Companies INFARMA (ZPIFF INFARMA)**

#### **INTRODUCTION**

Collaborative working between medical professionals and healthcare organisations has long been a positive driver for advancements in patient care and progression of innovative medicine. Medical professionals and organisations with whom they work provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and disease management experience. Furthermore, as the primary point of contact with patients, the medical professional can offer invaluable expert knowledge on patient outcomes and therapy management. This expert knowledge helps to adapt our products to better suit patients and thereby improve patient care overall.

Healthcare professionals and organisations should be fairly compensated for the services they provide to the pharmaceutical companies. The Transparency Code provides for accuracy and transparency in disclosing the scope and value of such collaborative work, and it becomes an important step towards building greater trust between the pharmaceutical industry, medical community and patients.

Pursuant to the provisions of the Transparency Code, its signatories, i.e. European Federation of Pharmaceutical Industries and Associations (EFPIA) member companies, are required to disclose all transfers of value such as support to attend medical education events, speaker fees and consultancy to medical professionals and healthcare organisations.

*This document is a methodological note specifying in detail the rules resulting from the Transparency Code regarding publishing of information on the transfers of value to medical professionals and healthcare organisations from innovative pharmaceutical companies. All companies signatory to this document have the obligation to develop their own methodological note and publish it along with the reports on the transfers of value.*

*The template developed by ZPIFF INFARMA specifies the minimum scope of information that needs to be included in the methodological note of each Signatory. It also makes reference to the areas that each company should determine individually in line with their internal policies.*

**1. Determination of the value transferred**

- a. Transfers of value are represented as the cost amount for the Company and not the Beneficiary's revenue,
- b. The Company specifies whether these are gross or net amounts,
- c. Total value of the transfers of value is disclosed in Polish zloty.

**2. Manner of disclosing transfers of value:**

- a. Information on Transfers of Value to Medical Professionals indicates the total amount of Transfers of Value in a given reporting period and is published on individual basis pursuant to the granted consent to disclose personal data,
- b. In the case of medical professionals who have not consented to disclose personal data, the following is published:
  - i. Information on transfers of value provided to them in an aggregate report indicating the total amount of Transfers of Value in a given reporting period and
  - ii. Information on their number expressed as an absolute value and as a percentage of all medical professionals who received Transfers of Value from the Company in a given reporting period.
- c. Information on transfers of value provided to Healthcare Organisations indicates the total amount of Transfers of Value provided to them in a given reporting period.

**3. Transfer of value date**

The moment of transfer of value to beneficiary:

- a. Contracts of mandate/for a specific task is the date of payment by the Company,
- b. In the case of events – the end date of a congress attended by a medical professional.

**4. Procedure in the case the transfer of value is not consumed (e.g. a doctor fails to attend the event)**

If value was not transferred, the information on the transfer of value is not subject to disclosure.

**5. Multiannual agreements and transfers of value in different calendar years**

In the case of multiannual agreements or other agreements based on which the transfers of value were provided in different calendar years, the Company included information in the Report about those which were effectively provided by the Company to the beneficiary in a given calendar year.

**6. Reporting indirect transfer of value to:**

- a. **Healthcare organisations**

In the case of transfers of value provided to healthcare organisations through an organiser of medical events, we shall report the healthcare organisation as beneficiary. This rule applies in the situation when a part or all transfers of value are provided to the accounts of so called logistic operators, such as for example event organisers.

Subject to disclosure are not only the transfers of value provided by the Company directly to the healthcare organisation, but also those transferred through entity acting on its behalf.

An example of such a situation includes an event organised by a company dedicated to conference organisation, and whose initiator and programme organiser is for example a scientific society. Without the support of a specialist company, the scientific society would have to carry out such activities on their own. The mere fact of existence of intermediary in the transfer of value (not only financial) to the end beneficiary does not exempt from the obligation to disclose the scope and value of collaborative work between companies and healthcare organisations.

In order to confirm the beneficiaries subject to disclosure, the Company may sign a relevant declaration with them.

The transfer of value amount provided to the healthcare organisation and allocated as benefits to individual medical professionals (e.g. as remuneration for: lecture, invitations to doctors, or to cover the costs of conference attendance) is broken down by categories and individual values are assigned to individual target beneficiaries, e.g.:

- PLN X on invitations to N doctors (personal information),
- PLN Y on professor's lecture (personal information),
- PLN Z on other logistics costs related to the participation of medical professionals in the event or services rendered by them (accommodation, transport).

#### **b. Medical professionals**

Transfers of value to individual medical professionals (e.g. invitations, covering travel or accommodation costs) do not constitute a part of sponsorship transfer of value to a healthcare organisation.

If the invitation unit value is not indicated, the organiser determines it so that the transfer of value could be disclosed as an individual transfer to a medical professional.

In the event that an entire or part of transfer of value is indirectly provided to medical professionals, a healthcare organisation should obtain their consent to disclose personal data. If it is not possible to determine an invitation unit value for individual medical professionals within a sponsorship transfer of value to the healthcare organisation, the recommended solution includes making individual agreements with medical professionals for their attendance to the event.

## **7. Rules regarding the consents to disclose personal data**

### **a. Consent for each agreement/Consent for the period of collaborative work**

Consent is obtained for each agreement or once for the period of time specified in the consent. Regardless of the adopted model, consent is granted by a medical professional in advance, i.e. at the moment of signing the first agreement with the Company that falls into the reporting period. The contents of the consent include information on the scope and aim of personal data processing and the right of access, as well as the voluntary nature of the consent.

### **b. Consent withdrawal procedure**

Upon demand of a medical professional – i.e. in the event of consent withdrawal – their personal data shall be removed from the disclosed Form without delay and no later than 14 days from submitting such a demand.

In the event of consent withdrawal by a medical professional, the Company's obligation to disclose the transfer of value continues to apply, but in this case it is disclosed in an aggregate manner (without disclosing the beneficiary's identity).

### **c. Selective consent** (consequences of granting consent to disclose data related to selected transfers of value)

Consent may not be partially withdrawn or granted for selected transfers of value in a given reporting period. Withdrawing consent to disclose part of the transfers of value or granting consent to disclose only part of the transfers of value will result in the revocation of the consent to disclose the remaining transfers of value in the reporting period.

## **8. Excluded disclosures**

The following transfers of value are excluded from the disclosure obligation:

- a.** Solely related to over-the-counter medicines;
- b.** Provision of materials and objects of informative or educational character (as per Art. 38 items 2 and 3 of the Pharmaceutical Industry Code of Good Marketing Practices);
- c.** Meals (as per Art. 27 of the Pharmaceutical Industry Code of Good Marketing Practices);
- d.** Samples (as per Art. 22 of the Pharmaceutical Industry Code of Good Marketing Practices);
- e.** Fees charged by logistics agencies assisting the Signatories in organising travels and meetings;
- f.** Discounts, price reductions and other trading devices commonly used in the sale of medicinal products;
- g.** Healthcare packages provided by private entities purchased by Signatories for their employees;
- h.** Related to anonymous marketing research;
- i.** Provided in connection to R&D activities are subject to aggregate disclosure, and thus they are excluded from reporting on individual basis.

**9. Qualification of legal entities owned by medical professionals**

A medical doctor conducting economic activity as a natural person is treated as a medical professional and not as a healthcare organisation. Regardless of the form of economic activity or form of employment, the agreements are signed directly with a given medical professional and not with an entity employing him/her on the basis of an employment contract or a civil law agreement.

All transfers of value provided to a medical professional (whether within economic activity or outside of it) are subject to disclosure in the report on the transfers of value to medical professionals. The Code obliges the Signatories to make the information on the end beneficiary public. Thus, if the medical professional does not consent to disclosure, his or her data will be collected as aggregated data concerning the medical professionals. The same rule applies to medical professionals who are partners in a civil law partnership.

## 10. Scope of transfers of value by category

<b>Transfers of value received by medical professionals</b>			
<b>Event-related costs</b>		<b>Remuneration for services provided</b>	
Registration fees	Travel and accommodation costs	Basic remuneration	Additional expenses
Costs of event attendance	Airline and railway tickets, taxis, car rental, parking fees, reimbursement for using own means of transport, visas, travel insurance (if such costs are directly related to travel), accommodation costs	Remuneration for: lectures and prelections, work on advisory teams (does not apply to R&D teams), medical studies, data analysis, educational materials preparation, post-marketing interviews, consultancy and advisory, speaker training (if a prelection is directly related to the lecture or prelection contract), participation in educational mentoring programmes.	Costs related to the services provided: airline and railway tickets, taxis, car rental, parking fees, reimbursement for using own means of transport, visas, travel insurance (if such costs are directly related to travel), accommodation costs

<b>Transfers of value received by healthcare organisations</b>					
<b>Donations</b>	<b>Event-related costs</b>			<b>Remuneration for services provided</b>	
	Registration fees	Travel and accommodation costs	Sponsorship agreement value	Basic remuneration	Additional expenses
Charity donations, scholarships, courses organised by healthcare organisations, lecturer fees classified as scholarships	Costs of event attendance	Airline and railway tickets, taxis, car rental, parking fees, reimbursement for using own means of transport, visas, travel insurance (if such costs are directly related to travel), accommodation costs	Costs of arranging exhibition or advertising space, costs of sponsoring logo or sponsoring product brand logo placement on the event programme or event invitation, costs of organising satellite symposium during congress, costs of event attendance by sponsor's representatives.	Remuneration for: lectures and prelections, work on advisory teams (does not apply to R&D teams), medical studies, data analysis, educational materials preparation, post-marketing interviews, consultancy and advisory, speaker training (if a prelection is directly related to the lecture or prelection contract), participation in educational mentoring programmes, facility rental.	Costs related to the services provided: airline and railway tickets, taxis, car rental, parking fees, reimbursement for using own means of transport, visas, travel insurance (if such costs are directly related to travel), accommodation costs

## **11. Scope of payments related to R&D activities**

All transfers of value related to R&D costs incurred by healthcare organisations or medical professionals, including clinical trials, R&D related events, non-interventional studies, operation of clinical trial data monitoring committees, clinical trials initiated by independent researchers, are disclosed in aggregate as a total amount without the breakdown on healthcare organisations and medical professionals.

## **12. Rules of disclosing cross-border transfers of value**

Cases of cross-border transfers of value to medical professionals or healthcare organisations, falling in the scope of the Transparency Code, are disclosed by the Company in accordance with the beneficiary's place of residence or head office location.

Cross-border transfers of value are included in the Company's local report regardless of the entity, belonging to the same capital group as the Company that organised and made transfer of value. For instance, US head office of EFPIA member company collaborating with a medical professional operating in Poland will be obliged to disclose the transfer of value in Poland (in accordance with the applicable law, provisions and code in the country of residence of the medical professional or a location of the healthcare organisation head offices).