

## Celgene Sp. z o.o.

### Methodological Statement

*summarizing the methodologies used in preparing the disclosure of transfers of value to healthcare professionals and healthcare organisations pursuant to Article 6 sec. 2 of the INFARMA Disclosure Code 2015, the “Code”*

**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.

Celgene Sp. z o.o. (“*Celgene*” or “*Company*”) is responsible for promotion of Celgene medicinal products in Poland.

Celgene also collaborates both directly and through its parent company, Celgene Corporation<sup>1</sup>, in pre-clinical research and clinical trials in Poland.

In the course of these activities, Celgene engages with healthcare professionals<sup>2</sup> whose registered practice addresses are in Poland and with healthcare organisations<sup>3</sup> based in Poland.

The disclosures that Celgene has submitted to the Employer’s Union of Innovative Pharmaceutical Companies (INFARMA) represent the transfers of value that Celgene has made to such healthcare professionals and healthcare organisations during the course of 2017 insofar as those transfers of value fall within Celgene’s disclosure obligations as defined in Disclosure Code which defines the rules for providing information on cooperation between signatory companies and healthcare professionals and healthcare organisations (referred to jointly as the beneficiaries).

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<sup>1</sup> For the purposes of this document alone, the term “Celgene Corporation” refers to Celgene Corporation and all of its affiliates, sub-contractors and agents worldwide.

<sup>2</sup> as defined by Article 2 point 4 of the Disclosure Code.

<sup>3</sup> as defined by Article 2 point 3 of the Disclosure Code

## **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. Celgene has made its disclosures relating to direct transfers of value exclusive of all applicable taxes. It is possible, however, that some indirect transfers of value made by third party vendors have been reported to us inclusive of taxes.
- c. Celgene has made its disclosures in Polish zloty, using an average officially published monthly exchange rate with Polish zloty for those payments made in any other currency.

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

- a. Information on transfers of value to healthcare 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 healthcare 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 healthcare 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**

Celgene has made its disclosures relating to cash payments by reference to the payment date. In circumstances where transfers of value represent benefits in kind Celgene has made its disclosures by reference to the date of the event.

## **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.

Celgene has not identified any multi-year contracts that fall within its disclosure obligations for 2017.

## **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 an 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 healthcare 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 healthcare professionals in the event or services rendered by them (accommodation, transport).

### **b. healthcare professionals**

Transfers of value to individual healthcare 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 healthcare professional.

In the event that an entire or part of transfer of value is indirectly provided to healthcare 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 healthcare professionals within a sponsorship transfer of value to the healthcare organisation, the recommended solution includes making individual agreements with healthcare professionals for their attendance to the event.

Celgene has included in its contractual templates, on the basis of which it contracts with all third parties through which indirect transfers of value are made, a binding clause requiring the third party to notify

to Celgene all transfers of value made to healthcare professionals and healthcare organisations and to use its best efforts to obtain the consent of these entities for the public disclosure whenever such consent is required. Celgene has used its best endeavours to include all such transfers of value so notified within the scope of its disclosures to the INFARMA.

## **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 healthcare 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 healthcare 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 healthcare 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.

Celgene has used its best endeavours to seek consent from all healthcare professionals to disclosure on an individual basis, naming the recipient and identifying the value of the transfer. To this end, Celgene has incorporated a binding clause to this effect in its contractual templates on the basis of which, pursuant to Celgene's relevant policies, all such engagements should proceed.

In circumstances where a healthcare professional declines to give, or subsequently withdraws, consent to one or more transfers of value in the course of the 2017 reporting year, Celgene has disclosed all transfers of value made to that healthcare professional in aggregate.

## **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 healthcare professionals**

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

**10. Scope of transfers of value by category**

<b>Transfers of value received by healthcare 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 healthcare 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 healthcare professionals.

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

Cases of cross-border transfers of value to healthcare 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 healthcare 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 healthcare professional or a location of the healthcare organisation head offices).

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