# Celgene International S.a.r.l.

# **Methodological Statement**

summarizing the methodologies used in preparing the disclosure of transfers of value to health professionals and healthcare organisations pursuant to Clauses 1-3 of the Annex D "HCP/HCO Disclosure Code" of the Code of Ethics for Pharmaceutical Marketing, the "Code"

#### Introduction

Celgene International S.a.r.l. ("*Celgene*") is responsible for the sales and marketing of Celgene medicinal products in Lithuania.

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

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

The disclosures that Celgene has submitted to the Innovative Pharmaceutical Industry Association ("*IFPA*") represent the transfers of value that Celgene has made to such health professionals and healthcare organisations during the course of 2015 insofar as those transfers of value fall within Celgene's disclosure obligations as defined in Clauses 1-3 of the Annex D "HCP/HCO Disclosure Code" of the Code.

# Methodology

The data upon which Celgene's disclosures are based has been collected and compiled by Celgene Corporation's Spend Transparency Office based in Summit, New Jersey. The Spend Transparency Office is responsible for the disclosure of transfers of value to health professionals and healthcare organisations made by any Celgene Corporation affiliate worldwide in accordance with relevant local laws and codes of practice.

In order to prepare for compliance with Clauses 1-3 of the Annex D "HCP/HCO Disclosure Code" of the Code, the Spend Transparency Office first identified all of the possible sources of information within the

<sup>&</sup>lt;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>&</sup>lt;sup>2</sup> As defined by Schedule 1 of the Annex D "HCP/HCO Disclosure Code" of the Code and including "other relevant decision makers" as defined by Schedule 1 of the Annex D "HCP/HCO Disclosure Code" of the Code.

<sup>&</sup>lt;sup>3</sup> As defined by Schedule 1 of the Annex D "HCP/HCO Disclosure Code" of the Code.

Celgene Corporation finance system and held by third party vendors that could identify any and all payments made by Celgene. Using information supplied by IMS Health, verified and supplemented by various commercial operations resources within Celgene and Celgene Corporation, publically available information and information from third party vendors, the Spend Transparency Office narrowed down the list of payees to those that fell within the definitions of health professional, other relevant decision makers and healthcare organisation, as set out in Clauses 1-3 of the Annex D "HCP/HCO Disclosure Code" of the Code. Celgene used the IMS OneKey Code as a unique identifier of any given health professional.

On the basis of these data Celgene has used its best endeavours to disclose to the IFPA for publication on its central platform all direct and indirect transfers of value made between 1 January 2015 and 31 December 2015 inclusive that fall within its disclosure obligations as set out in Clauses 1-3 of the Annex D "HCP/HCO Disclosure Code" of the Code, applying the relevant definitions contained therein. Celgene undertakes to submit promptly to the IFPA any corrections or additions that may be required as a result of knowledge acquired after the date the disclosures are submitted.

## Third parties

Celgene has included in its contractual templates, on the basis of which it contracts with all third parties, a binding clause requiring the third party to notify to Celgene all transfers of value made to health professionals<sup>4</sup> and healthcare organisations. Celgene has used its best endeavours to include all such transfers of value so notified within the scope of its disclosures to the IFPA.

#### **Distributors**

Celgene does not market its products through a distributor in Lithuania.

# **Cross border transactions**

Celgene Spend Transparency Office has worked with all of Celgene's functions and affiliates worldwide to capture data relating to transfers of value made by them to health professionals with their practice address in the Lithuania and healthcare organisations based in Lithuania. Celgene has used its best endeavours to include all such transfers of value within its disclosures to the IFPA.

#### Consent

Celgene has used its best endeavours to seek consent from all health 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 the event that a health professional has declined to give their consent to such individual disclosure, the Vice President, General Manager of Celgene, or his designee, has considered in each case whether

<sup>&</sup>lt;sup>4</sup> Hereafter the phrase, "health professionals", includes other relevant decision makers as defined by Schedule 1 of the Annex D "HCP/HCO Disclosure Code" of the Code.

there is an overriding need to pursue the potential engagement with the result that any transfer of value may only be disclosed in aggregate pursuant to Clause 3 of the Annex D "HCP/HCO Disclosure Code" of the Code. Factors that are relevant to this consideration include whether the health professional has special knowledge and skills that are not available to Celgene from another health professional willing to give consent to individual disclosure.

In circumstances where a health professional declines to give, or subsequently withdraws, consent to one or more transfers of value in the course of the 2015 reporting year, Celgene has disclosed all transfers of value made to that health professional in aggregate.

## Disclosure in aggregate

Where the recipients of transfers of value cannot be disclosed for legal reasons, including where a health professional has declined to give consent to disclosure on an individual basis, Celgene has disclosed those transfers of value on an aggregate basis.

Celgene has also disclosed on an aggregate basis transfers of value falling within the definition of "Research and Development Transfers of Value" pursuant to Clause 3.04 of the Annex D "HCP/HCO Disclosure Code" of the Code.

### **Currency**

Celgene has made its disclosures in euros, using a published monthly average exchange rate with euros for those payments made in any other currency.

#### Tax

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.

## Date methodology

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.

### Multi-year contracts

Celgene has not identified any multi-year contracts that fall within its disclosure obligations for 2015.

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