

Title: Novartis EFPIA Methodological Note

Doc. Version: 6.0

### **Novartis Methodological Note**

on Disclosure of Payments and other Transfers of Values to Health Care Professionals and Health Care Organizations following the 'EFPIA Code on Disclosure of Transfers of Value'

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**Division:** Sandoz

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# 1. Reference to National Transparency Laws and Regulations

Novartis supports laws and regulations that promote transparency around relationships between healthcare companies, Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs) associated with Transfers of Value (ToVs) related to prescription-only medicines by establishing a single, consistent transparency standard in Europe for disclosing ToVs across its divisions and European countries, by following the EFPIA transparency requirements and requirements set in local transparency laws.

As a Novartis Company which is an EFPIA member company, Sandoz nv-sa (hereafter Sandoz NV./SA) complies with the obligation to collect, disclose and report ToVs related to prescription-only medicines to HCPs/HCOs in accordance with the:

 National transposition of the EFPIA Code On Disclosure Of Transfers Of Value From Pharmaceutical Companies To Healthcare Professionals And Healthcare Organizations as of the Code of Deontology of pharma and the Code of Deontology of Association Pharmaceutique Luxembourgoise (APL). In Belgium the Royal Decree for the Sunshine Act was published on 23/06/2017 and the new regulation was applied for all ToV starting from 2017.

Sandoz NV./SA has developed HCP/HCO unique identifiers to ensure that the identity of the HCP/HCO benefitting from the ToVs is clearly distinguishable for each Novartis affiliate.

### 2. Purpose of the Methodological Note

This document is intended to serve as supporting documentation for the 2019 Disclosure Report of Sandoz NV./SA. Sandoz NV./SA's position is based on the interpretation of the current version of the EFPIA Disclosure Code aligned with local transparency laws and locally transposed EFPIA disclosure code where applicable.

The Methodological Note summarizes the disclosure recognition methodologies and business decisions as well as country specific considerations applied by Sandoz NV./SA in order to identify, collect and report ToVs for each disclosure category as described in Section 23.05 of the EFPIA Disclosure Code.





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## 3. Novartis' Commitment and Responsibility for Disclosure

Novartis supports laws and regulations that promote transparency around relationships between healthcare companies and HCPs/HCOs associated with ToVs related to prescription-only medicines.

Novartis establishes a single, consistent transparency standard for disclosing ToVs in all EFPIA countries.

## 4. Scope of the Novartis Disclosure on Transfers of Value

This 2019 Sandoz NV./SA Disclosure Report is following the disclosure standards pursuant to the local transposition of EFPIA Disclosure Code. Subject to this disclosure report are all direct or indirect ToVs related to prescription-only medicines disclosed by Sandoz NV./SA to or for the benefit of a Recipient made by any Novartis affiliate as described in Article 23 of the EFPIA Disclosure Code. Further details on the disclosure scope will be provided in chapter 4 of this document.

The legal definition of 'prescription-only medicine' is pursuant to the Medicines Law of March 25, 1964. ToVs related to a group of products that includes prescription-only medicines (e.g. combination products/diagnostics and medicinal products) are reported in total following the disclosure requirements of the EFPIA Disclosure Code.

#### In summary:

The 2019 Sandoz NV./SA Disclosure Report covers direct and indirect ToVs, payments, in kind or otherwise, made to HCPs/HCOs in connection with the development and sale of prescription-only medicinal products exclusively for human use, whether for promotional purposes or otherwise.

In this report, Sandoz NV./SA discloses the amounts of value transferred by type of ToVs with data coverage from January 1st 2019 to December 31st 2019. Sandoz NV./SA. disclosure is performed for the full calendar year 2019 once a year.

Whenever possible, Sandoz NV./SA follows the principle of disclosure on individual HCP/HCO level, to ensure that each Recipient is referred to in such a way that there is no doubt as to the identity of the HCP/HCO benefitting from the ToVs. Aggregate disclosure for non Research and Development ToVs is only used in exceptional cases, e.g. if consent could not be obtained despite best efforts or in case of withdrawal of consent.

No Transfer of Values are reportable for Sandoz Luxembourg for the disclosure cycle 2019.