

Title: EFPIA Methodological Note

Doc. Version: 9.0

Novartis Methodological Note

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

Contact: transparency.belgium@novartis.com

Country: Luxembourg

Division: Sandoz NV

Last Update: 03/04/2023

Version: 9.0; this document replaces previous drafts and editions.



Title: EFPIA Methodological Note **Doc. Version:** 9.0

Table of Contents

1.	Reference to National Transparency Laws and Regulations	.3
2.	Purpose of the Methodological Note	.3
3.	Novartis' Commitment and Responsibility for Disclosure	. 4
4.	Scope of the Novartis Disclosure on Transfers of Value	. 4



Title: EFPIA Methodological Note

Doc. Version: 9.0

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) ¹ 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, Novartis Pharma nv-sa (hereafter Novartis Pharma BeLux) 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 of Practice ² for Transfers Of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations
- Disclosure of Transfers Of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations, as laid down in Chapter 5bis of the Code of Deontology of Association Pharmaceutique Luxembourgoise (APL).

Novartis Pharma BeLux 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 2022 Disclosure Report of Novartis Pharma BeLux. Novartis Pharma Belux's position is based on the interpretation of the current version of the EFPIA Code aligned with local transparency laws and locally transposed EFPIA where applicable.

The Methodological Note summarizes the disclosure recognition methodologies and business decisions as well as country specific considerations applied by Novartis Pharma

 1 A definition on the terms "HCP/HCO" and "ToVs" is provided in chapter 9 of this document.

² The 2019 EFPIA Code of Practice (in short: EFPIA Code) states in Section 23.05 (Methodology) that "each Member Company must publish a note summarizing the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category described in Section 23.05. The note, including a general summary and/or country specific considerations, must describe the recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Transfers of Value for purposes of this Code, as applicable".



Title: EFPIA Methodological Note

Doc. Version: 9.0

BeLux in order to identify, collect and report ToVs for each disclosure category as described in Section 23.05 of the EFPIA Code.

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 2022 Novartis Pharma BeLux Disclosure Report is following the disclosure standards pursuant to the local transposition of EFPIA Code and national transparency laws/regulations. Subject to this disclosure report are all direct or indirect ToVs related to prescription-only medicines and OTC medicines disclosed by Novartis Pharma BeLux to or for the benefit of a Recipient made by any Novartis affiliate as described in Article 23 of the EFPIA Code. Further details on the disclosure scope will be provided in chapter 0 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 Code.

In summary:

The 2022 Novartis Pharma BeLux 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 and OTC medicines exclusively for human use, whether for promotional purposes or otherwise.

No Transfer of Values are reportable for Sandoz Belux for the disclosure cycle 2022.