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’

Country: Malta

Division: Sandoz

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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..........................................................3
4. Scope of the Novartis’ Disclosure on Transfers of Value............................................................4
5. Acronyms and Abbreviations......................................................................................................20
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, Sandoz Malta complies with the obligation to collect, disclose and report ToVs related to prescription-only medicines to HCPs/HCOs in accordance with the:

- **EFPIA Code On Disclosure Of Transfers Of Value From Pharmaceutical Companies To Healthcare Professionals And Healthcare Organizations**
- In addition, Sandoz Malta is also disclosing ToVs related to OTC medicines and food supplements.

Sandoz Malta 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 EFPIA disclosure report of Sandoz in Malta. Sandoz Malta’s position is based on the interpretation of the current version of the EFPIA Disclosure Code, aligned with local transparency laws.

The Methodological Note summarizes the disclosure recognition methodologies and business decisions as well as country specific considerations applied by Sandoz Malta in order to identify, collect and report ToVs for each disclosure category as described in Section 3.01 of the EFPIA Disclosure Code.

3. Novartis’ Commitment and Responsibility for Disclosure

1 A definition on the terms “HCP/HCO” and “ToVs” is provided in chapter 9 of this document.
Novartis supports laws and regulations that promote transparency around relationships between healthcare companies and HCPs/HCOs associated with ToVs related to prescription-only medicines, OTC medicines and food supplements.

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 <2017 Sandoz Malta Disclosure Report is following the disclosure standards pursuant to the local transposition of EFPIA Disclosure Code and national transparency laws/regulations. Subject to this disclosure report are all direct or indirect ToVs related to prescription-only medicines, OTC medicines and food supplements disclosed by Sandoz Malta to or for the benefit of a Recipient made by any Novartis affiliate as described in Article 3 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 EFPIA Disclosure Code. 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, this <2017 Sandoz Malta Disclosure EFPIA 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 OTC medicines and food supplements exclusively for human use, whether for promotional purposes or otherwise.

In this report, Sandoz Malta discloses the amounts of value transferred by type of ToVs with data coverage from <January 1st 2016/personalize accordingly per division and/or product scope> to December 31st 2016. Sandoz Malta disclosure is performed <for the full calendar year 2016/twice a year/personalize accordingly>. <update entire paragraph with disclosure dates for more affiliates if applicable.>

Whenever possible, Sandoz Malta 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 Malta for the disclosure cycle 2017.