

Sandoz 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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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

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 and member of the national EFPIA Member Association, Malta Sandoz 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

In addition, Malta Sandoz is also disclosing ToVs related to OTC medicines and food supplements.

Malta Sandoz 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 2018 Malta Sandoz Disclosure Report. Malta Sandoz'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 Malta Sandoz 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

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 2018 Malta Sandoz 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 Malta Sandoz 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 the medical product which is a subject to a medical prescription. 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 2018 Malta Sandoz EFPIA Disclosure Report or local name of the 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.
- The 2018 Malta Sandoz report covers provision of funds for the support and the advancement of genuine medical education of HCP, patients and/or the public on clinical, scientific and/or health care topics relevant to the therapeutic areas as educational grants.

In this report, Malta Sandoz discloses the amounts of value transferred by type of ToVs with data coverage from January 1st 2018 to December 31st 2018. Malta Sandoz disclosure is performed for the full calendar year 2018

No Transfer of Values are reportable for Malta Sandoz for the disclosure cycle 2018.