

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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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 also a member of the national EFPIA Member Association PRIMA (Pharmaceutical Research-based Industry Malta Association), Sandoz Malta 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 Organizations².
- the PRIMA Code on the Promotion of Prescription-only Medicines to, and interactions with Healthcare Professionals [PRIMA code].

In addition, Malta Sandoz 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 2019 Sandoz Malta Disclosure Report. Sandoz Malta's position is based on the interpretation of the current version of the EFPIA Disclosure Code aligned with local transparency laws and the locally transposed EFPIA disclosure code, namely PRIMA code.

The Methodological Note summarizes the disclosure recognition methodologies and business decisions as well as country specific considerations applied by Sandoz Malta in

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 Disclosure 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".

order to identify, collect and report ToVs for each disclosure category as described in Section 23.05 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 and medical devices.

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 Malta Disclosure Report is following the disclosure standards pursuant to the local transposition of EFPIA Disclosure code, PRIMA code. Subject to this disclosure report are all direct or indirect ToVs related to prescription-only medicines, OTC medicines and food supplements and medical devices disclosed by Sandoz Malta 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 medicinal product subject to a medicinal prescription. Medicinal products shall be subject to medical prescription where they:

- (a) Are likely to present a danger either directly or indirectly, even when used correctly, if utilized without medical supervision, or
- (b) Are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, or
- (c) Contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation, or
- (d) Are normally prescribed by a doctor to be administered parenterally.

As per the definition of the Medicinal Products for Human Use Laws 70(I) 2001.

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 Malta 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 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 2019 to December 31st 2019. Sandoz Malta disclosure is performed for the full calendar year 2019.

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