

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

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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 and member of the national EFPIA Member Association KEFEA (Cyprus Association of Research and Development Pharmaceutical Companies), Sandoz Distributor Office Cyprus (“Sandoz Cyprus”) 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 Practice².
- the KEFEA Code on the Promotion of Prescription-only Medicines to interactions with Healthcare Professionals.
- National transparency laws.

¹ A definition on the terms HCP, HCO and ToVs is provided below:

- Healthcare Professional (HCP): Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or other organization (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practicing HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.
- Healthcare Organization (HCO): Any legal person (i) that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organizations within the scope of article 21 of the EFPIA Code) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCP provide services.
- Transfers of Value (ToVs): Direct and indirect transfers of value, whether payments, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only Medicinal Products <, OTC medicines and food supplements>exclusively for human use. Direct transfers of value are those made directly by a Member Company for the benefit of a Recipient. Indirect transfers of value are those made on behalf of a Member Company for the benefit of a Recipient, or transfers of value made through an intermediate and where the Member Company knows or can identify the HCP/HCO that benefit from the Transfer of Value.

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”.

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

Sandoz Cyprus 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 2021 Sandoz Cyprus Disclosure Report. Sandoz Cyprus' position is based on the interpretation of the current version of the EFPIA Code aligned with local transparency laws and locally transposed EFPIA Code, namely KEFEA Code.

The Methodological Note summarizes the disclosure recognition methodologies and business decisions as well as country specific considerations applied by Sandoz Cyprus 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, 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 2021 Sandoz Cyprus Disclosure Report is following the disclosure standards pursuant to the local transposition of EFPIA Code, namely KEFEA 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 and medical devices disclosed by Sandoz Cyprus 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 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:

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- (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 Code.

In summary:

The 2021 Sandoz Cyprus 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 Cyprus discloses the amounts of value transferred by type of ToVs with data coverage from January 1st 2021 to December 31st 2021. Sandoz Cyprus disclosure is performed for the full calendar year 2021.

No Transfer of Values are reportable for Sandoz Cyprus for the disclosure cycle 2021.