

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: Iceland

Division: SANDOZ

Last Update: April, 2016

Version: 1.0

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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) 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.

Sandoz A/S (“Sandoz Iceland” for ToV on Iceland) covers Iceland. As a Novartis Company, Sandoz Iceland 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 in Iceland is also disclosing ToVs related to OTC medicines and food supplements.

2. Purpose of the Methodological Note

This document is intended to serve as supporting documentation for the EFPIA disclosure report of Sandoz in Iceland. Sandoz Iceland’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 Iceland in order to identify, collect and report ToVs for each disclosure category as described in Section 3.01 of the EFPIA Disclosure Code.

These disclosure recognition methodologies and business decisions include but are not limited to:

- Scope of Sandoz in Iceland’s disclosure on ToVs (Chapter 4)

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

No Transfers of Values occurred in 2015 and thus no Transfers of Values are reportable for the disclosure cycle 2016 for Sandoz Iceland.

Scope overview in case Transfers of Values would occur:

This 2016 Sandoz Iceland 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 Iceland to or for the benefit of a Recipient made by any Novartis affiliate as described in Article 3 of 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 2016 Sandoz Iceland 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.

Excluded from disclosure are items such as items of medical utility (governed by Article 9 of the EFPIA HCP Code), meals and drinks (governed by Article 10, especially Section 10.05 of the EFPIA HCP Code), medical samples (governed by Article 16 of the HCP Code) or which are part of ordinary course purchases and sales of medicinal products by and between a Member Company and HCP or HCO.

Sandoz Iceland disclosure is performed for the full calendar year 2015.