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

Contact: xpend.austria@novartis.com

Country: Austria

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Contents

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 affiliates and European countries, by following the EFPIA transparency requirements and requirements set in local transparency laws.

Novartis as a Company and member of the national EFPIA Member Association AB,

Novartis Pharma GmbH 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 Practice[2]
- Pharmig Code of Conduct, Article 9 on Transparency

Novartis Pharma GmbH 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.

Localization guidance:

- Pharmig Code of Conduct, Article 9 on Transparency

[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 Code) states in Section 23.05 *(Methodology)* that “e*ach 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”.*

2. Purpose of the Methodological Note

This document is intended to serve as supporting documentation for the 2025 Novartis Pharma GmbH Disclosure Report. Novartis Pharma GmbH's position is based on the interpretation of the current version of the EFPIA Code aligned with local transparency laws and Pharmig Code of Conduct, Article 9 on Transparency.

The Methodological Note summarizes the disclosure recognition methodologies and business decisions as well as country specific considerations applied by Novartis Pharma GmbH in order to identify, collect and report ToVs for each disclosure category as described in Section 23.05 of the EFPIA Code.

Localization guidance:

Pharmig Code of Conduct, Article 9 on Transparency

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

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 2025 Novartis Pharma GmbH Disclosure Report is following the disclosure standards pursuant to the local transposition of EFPIA Code and national transparency laws/regulations. Subject to this disclosure report are all direct or indirect ToVs related to prescription-only medicines disclosed by Novartis Pharma GmbH 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 Pharmig Code of Conduct, Article 9 on Transparency. 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 2025 Novartis Pharma GmbH 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 exclusively for human use, whether for promotional purposes or otherwise.

In this/these reports, Novartis Pharma GmbH discloses the amounts of value transferred by type of ToVs with data coverage from January 1st 2025 to December 31st 2025. Novartis Pharma GmbH disclosure is performed for the full calendar year 2025.

Wherever possible, Novartis Pharma GmbH 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 ToV is only used in exceptional cases, e.g. if consent could not be obtained despite best efforts or in case of withdrawal of consent.

This report also includes Transfer of Values made by ADACAP and Novartis Gene Therapies.

4.1 Voluntary disclosure

This section outlines the practices and commitments if a company decides to go beyond mandatory requirements. It covers disclosure beyond regulatory reporting, proactive reporting, supplementary efforts for member companies. It is not applicable in Novartis as the country follows the mandatory EFPIA reporting code or local code as applicable for reporting.

5. Novartis' Disclosure Recognition Methodology and Related Business Decisions

This chapter provides definitions, methodology and business decisions around ToV for public disclosure.

5.1 Definition of Direct and Indirect Transfer of Values

Novartis Pharma GmbH applies the EFPIA definition of ToVs as outlined in EFPIA Code Definitions pursuant to the Pharmig Code of Conduct, Article 9 on Transparency.

According to the EFPIA Code Definitions, the following definitions apply throughout this report:

- Direct ToVs are defined as those ToVs, payments or in kind, made directly by the Novartis affiliate to the benefitting HCPs/HCOs.

- Indirect ToVs are defined as those ToVs made through an intermediary (third party) on behalf of a Novartis affiliate for the benefit of HCP/HCO where the Novartis affiliate knows or can identify the HCP/HCO that benefits from the ToVs.

- Cross-border ToVs as being a Transfer of Value to an HCP/HCO that **occurred outside** the country where the Recipient has its primary practice, principal professional address or place of incorporation provided that this country is an EFPIA regulated country.

5.2 Transfer of Value Categories according to the EFPIA Code

Novartis Pharma GmbH applies the EFPIA definition of the ToVs categories as outlined in EFPIA Pharmig Code of Conduct, Article 9 on Transparency.

The following categories constitute the EFPIA Disclosure Template

- Non - Research and Development Categories
- Research and development

5.2.1 Transfer of Values Related to Non - Research and Development

Novartis Pharma GmbH applies the EFPIA definition of the ToVs categories as outlined in EFPIA Code Article 23.05 - pursuant to the Pharmig Code of Conduct, Article 9 on Transparency.

The following categories constitute the EFPIA Disclosure Template for the 2025 Novartis Pharma GmbH Disclosure Report:

- Donations and grants to an HCO
- Contribution to costs related to events to an HCO/HCP, such as:
  - Sponsorship agreements
  - Registration fees
  - Travel and accommodation
- Fees for service and consultancy to an HCO/HCP
  - Fees for service and consultancy and Related Expenses

5.2.2 Transfer of Values Related to Research and Development

Novartis Pharma GmbH applies the EFPIA definition of the “Research and Development” category as outlined in EFPIA Code – Definitions, the definition of non-clinical studies in the OECD Principles on Good Laboratory Practice, the definition of clinical trials and non-interventional studies (as defined in Regulation 536/2014 and Section 18 of the EFPIA Code) - pursuant to the Pharmig Code of Conduct, Article 9 on Transparency.

ToVs **related to the following Research and Development activities** are disclosed under the “Research and Development” category in aggregate form whenever they fall under the definition of Research and Development by the Pharmig Code of Conduct, Article 9 on Transparency.

5.3 Credit Notes

Novartis Pharma GmbH has processed a refund equivalent to the initial payment made to an HCP/HCO, neither transaction will be recorded since no actual value was transferred.

If a refund has been issued for a payment made in a year already published, the refunded amount will be subtracted from the HCP/HCO's total disclosed transfer value in the upcoming year. If the HCP/HCO received no payment the succeeding year, the disclosure report will display a negative value.

If the HCP has declined consent, the refund will subtract from the aggregate category totals.

5.4 Excluded ToV's

This section refers to certain types of monetary or non-monetary ToV that are not subjected to disclosure under the EFPIA Code.

5.5 Non- Monetary ToV's

Non-monetary transfers of value (ToV) under the EFPIA Code typically include items or benefits that are not direct monetary payments but still represent value provided by Company to HCPs or HCOs

5.6 ToVs for partial attendance or cancellations with refunds

Refunds for partial attendance or cancellations are typically handled within the broader framework of how transfers of value (ToV) are defined based on Payment date, FMV on actual participation accounted for, and disclosed.

6. Measures Taken to Ensure Compliance with Data Privacy Requirements

This chapter describes measures taken by Novartis Pharma GmbH to ensure compliance with data privacy regulations, rules on consent collection and managing of relevant information in compliance with relevant internal rules, data privacy laws and regulations.

6.1 Safeguarding Measures to Address Lawful Collection, Processing and Transfer of HCPs´ Personal Data

Data privacy refers to the individual's fundamental right to control the use of, access to and disclosure of information that describes or identifies the individual ("personal Information"). To fulfil the transparency disclosure requirements, it is necessary to collect, process and disclose such personal data within and outside of Novartis Pharma GmbH. This data will be published for 3 years in public domain and stored for a minimum of 5 years on record by the drw communication gmbh (publishing affiliate). The disclosure of such personal information by Novartis Pharma GmbH is at all times limited to the intended purposes.

In case personal data had to be transferred from countries to the central Novartis Transparency data repository manually (e.g. Excel) or via interfaces, applicable local regulations for the transfer were assessed at local level and managed accordingly. Where required, the transfer of data to a third country (outside the EU/EEA) was approved by the data controller´s Novartis Pharma GmbH country data protection authority (e.g. Information Commissioner).

6.2 Consent Collection

Consent for the publication of the ToVs was obtained and documented as such before disclosing the data on an individual HCP/HCO level where applicable[3]. Consent management procedures were conducted in alignment with the Pharmig Code of Conduct, Article 9 on Transparency.

Consent was obtained either on Recipient level for all ToVs during a given period of time not shorter than one full year or on spend level for each interaction or single ToVs.

Novartis Pharma GmbH does not accept partial consent or split disclosure.

In case consent was either not given by the Recipient or not documented sufficiently to prove the existence of consent, ToVs are disclosed on aggregate level only.

In the event of death of an HCP by the time of disclosure (by the publication date) the ToV is reported in aggregate.

[3] EU Regulation (GDPR) lays down rules relating to the protection of natural persons with regard to the processing of personal data.

HCP has a right to withdraw the consent. Consent withdrawal has been assessed according to the relevant Novartis Pharma GmbH local data privacy laws of Pharmig Code of Conduct, Article 9 on Transparency.

Any alternative way to manage individual publication of ToV (for example based on a different legal ground than consent like legitimate interest) is discussed with and assessed by the local Data Privacy Head.

HCOs are individually disclosed following the legal basis of legitimate interest according to § 1 Abs. 2 DSG and Art. 6 Abs. 1 lit f DSGVO.

6.2.1 Legitimate Interest

Legitimate interest is used lawfully to meet the requirements of the EFPIA Disclosure Code while respecting data protection laws.

7 Financial Aspects

This chapter focusses on the financial aspects related to recognition methodology and business decisions associated with the collection and disclosure of the ToVs information.

Novartis Pharma GmbH complies with the accounting principles and the financial disclosure methodology - pursuant to the Pharmig Code of Conduct, Article 9 on Tranparency.

Novartis Pharma GmbH decided to apply the following rules for ToVs payment dates based on type of ToVs: direct ToVs are disclosed based on the date the payment has been cleared via banking system. Indirect ToVs related to events such as attendance to scientific congresses for which the dates of (in kind) expenses differ from the date(s) the event took place, are disclosed using the date of the last day of the event.

Novartis Pharma GmbH discloses ToVs net amount only. If VAT cannot accurately be excluded, the full ToV amount is disclosed. Where income tax or equivalent is withheld by Novartis Pharma GmbH on amounts earned by the HCP then the ToV will include these amounts.

Currency treatment – Tov's reported in the ToV report are in local currency.

7.1 VAT

Novartis Pharma GmbH discloses ToVs net amount only. If VAT cannot accurately be excluded, the full ToV amount is disclosed. Where income tax or equivalent is withheld by Novartis Pharma GmbH on amounts earned by the HCP then the ToV will include these amounts.

8 Published Data

Novartis Pharma GmbH applies the EFPIA definition of "Form of Disclosure" as outlined in EFPIA Code Article 23.4 - pursuant to the Pharmig Code of Conduct, Article 9 on Transparency.

This data will remain published for 3 years in public domain and stored for a minimum of 5 years on record by the publishing affiliate.

9 Acronyms and Abbreviations

This chapter includes a list of acronyms, abbreviations and definitions for documentation purpose, based on Definitions in the EFPIA Code wherever possible.

Reference: https://www.efpia.eu/relationships-code/the-efpia-code/

- Contract Research Organization (CRO)
- Healthcare Professional (HCP)
- Healthcare Organization (HCO)
- Member Associations

- Member Companies
- Professional Conference Organizer (PCO)
- Recipient
- Research and Development ToVs
- Transfers of Value (ToVs)