
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: novartis.macedonia@novartis.com

Country: North Macedonia

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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 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 FARMABREND NOVA, (Association of representatives of foreign manufacturers of innovative medicines) Novartis Pharma Services AG Representative Office Skopje, North Macedonia (NPhS MK) 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
- *National transparency laws*

NPhS MK has developed unique HCP/HCO 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 2025 NPhS MK Disclosure Report. NPhS MK's position is based on the interpretation of the current version of the EFPIA Code aligned with local transparency laws and locally transposed EFPIA disclosure code (FARMABRAND NOVA (FBN) code for disclosing of ToV from Pharmaceutical companies to HCP and HCO).

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

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 "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".

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 NPhS MK Disclosure Report is following the disclosure standards pursuant to the local transposition of EFPIA Code (FBN code) and national transparency laws/regulations. Subject to this disclosure report are all direct or indirect ToVs related to prescription-only medicines disclosed by NPhS MK 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 reference to corresponding definition in local pharmaceutical regulation. 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 NPhS MK EFPIA 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, NPhS MK discloses the amounts of value transferred by type of ToVs with data coverage from January 1st, 2025 /personalize accordingly and/or product scope to December 31st, 2025. NPhS MK disclosure is performed for the full calendar year 2025.

Wherever possible, NPhS MK 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.

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

NPhS MK applies the EFPIA definition of ToVs as outlined in EFPIA Code Definitions pursuant to the following definition as per FBN code (paragraph "Transfer of values, pg 10): Direct and Indirect Transfers of Value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of generic or branded prescription-only Medicinal Products exclusively for human use.

Direct Transfers of Value are those made directly by FBN Member Company for the benefit of a Recipient. Indirect transfers of value are those made by a third party (such as contractors, agents, partners or affiliates – including foundations) on behalf of a FBN Member Company for the benefit of a Recipient, where the identity of such FBN Member Company is known to or can be identified by the Recipient.

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

NPhS MK applies the EFPIA definition of the ToVs categories as outlined in EFPIA Code Article 23.05 - pursuant to the FBN code.

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

NPhS MK applies the EFPIA definition of the ToVs categories as outlined in EFPIA Code Article 23.05 - pursuant to the FBN code.

The following categories constitute the EFPIA Disclosure Template for the 2025 NPhS MK EFPIA 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

NPhS MK 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 FBN Code.

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 EFPIA Code.

5.3 Credit Notes

NPhS MK 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. These exclusions are to be clearly defined and categorized in the Methodological Note to ensure transparency while maintaining focus on relevant reporting requirements. Examples: Meals/Food and Beverages etc.

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.

5.7 Multi-year agreements

As per the Global guidance, Payment date is considered based on Bank Clearing date. However, if there is any deviation locally, some explanation is necessary on how we are accurately disclosing the ToV for agreements where payments or benefits occur across multiple years

6. Measures Taken to Ensure Compliance with Data Privacy Requirements

This chapter describes measures taken by NPhS MK 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 NPhS MK. This data will be published for 3 years in public domain and stored for a minimum of 5 years on record by the NPhS MK (publishing affiliate). The disclosure of such personal information by NPhS MK 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 NPhS MK 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 applicable³. Consent management procedures were conducted in alignment with the the Law of data protection in Republic North Macedonia.

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.

NPhS MK 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 NPhS MK local data privacy laws, Law of data protection in Republic North Macedonia.

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.

6.2.1 Legitimate Interest

Legitimate interest is used lawfully to meet the requirements of the EFPIA Disclosure Code while respecting data protection laws. Ex: For few major markets the consent of the healthcare professionals is not required for the publication of individual data, in accordance with current data protection regulations, the HCP must be informed.

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.

NPhS MK complies with the accounting principles and the financial disclosure methodology - pursuant to the FBN code.

NPhS MK 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.

NPhS MK 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 NPhS MK 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

NPhS MK 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 NPhS MK on amounts earned by the HCP then the ToV will include these amounts.

8 Published Data

NPhS MK applies the EFPIA definition of "Form of Disclosure" as outlined in EFPIA Code Article 23.4 - pursuant to the FBN code.

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)