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## **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”)<sup>1</sup> 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.

As a Novartis Company and member of the national KEFEA (Cyprus Association of R&D Pharmaceutical Companies), Novartis Pharma Services Inc. Representative Office Cyprus (NPhS CY) complies with the obligation to collect, disclose and report ToVs related to prescription-only medicines to HCPs/HCOs in accordance with:

- Section 23.05 of the EFPIA Code of Practice<sup>2</sup>
- The KEFEA Code of Practice Chapter 5 Articles 22 and 23 – Disclosure of ToVs to HCPs and HCOs (KEFEA Code).

NPhS CY 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.

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<sup>1</sup> A definition on the terms “HCP/HCO” and “ToVs” is provided in chapter 9 of this document.

<sup>2</sup> 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”.

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## 2. Purpose of the Methodological Note

This document is intended to serve as supporting documentation for the 2025 NPhS CY Disclosure Report. NPhS CY’s position is based on the interpretation of the current version of the EFPIA Code aligned with local transparency laws which locally transposed EFPIA disclosure code, i.e. the KEFEA Code.

The Methodological Note summarizes the disclosure recognition methodologies and business decisions as well as country specific considerations applied by NPhS CY in order to identify, collect and report ToVs for each disclosure category as described in Section 23.05 of the EFPIA Code and Section 23.04 of the KEFEA Code.

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### **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 CY Disclosure Report is following the disclosure standards pursuant to the local transposition EFPIA Code, namely the KEFEA Code. This disclosure report includes all ToVs made by NPhS CY, as described in Article 23 of the EFPIA Code and Article 23 of the KEFEA 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 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 and KEFEA Code.

In summary:

The 2025 NPhS CY 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 CY discloses the amounts of value transferred by type of ToVs with data coverage from January 1st 2025 to December 31st 2025. NPhS CY disclosure is performed for the full calendar year 2025. Wherever possible, NPhS CY 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. It is noted that the Disclosure Report includes a note on whether the relevant HCP has passed away or whether it is no longer an active HCP as they have retired from the exercise of their profession. 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.

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## 4.1 Voluntary disclosure

Not applicable

## 4.2 Self Incorporated HCP

Not applicable

# 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 CY applies the EFPIA definition of ToVs as outlined in EFPIA Code Definitions pursuant to the KEFEA Code set out below:

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.

It is clarified that the Disclosure Report identifies payments made to individuals HCPs, either directly to them or indirectly (i.e. in cases where both the HCP and the HCO are engaged but the payment for the services offered by the HCP is being made to the HCO).

## 5.2 Transfer of Value Categories according to the EFPIA Code

NPhS CY applies the EFPIA definition of the ToVs categories as outlined in EFPIA and Section 23.04 of the KEFEA Code.

The following categories constitute the EFPIA Disclosure Template (and are also reflected in the KEFEA Code Standardised Disclosure Template):

- Non - Research and Development Categories
- Research and development,

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The Standardised Disclosure Report is available on-line on the Novartis' website <https://www.novartis.com/healthcare-professionals/payments-healthcare-professionals>, at least as a machine-readable format, such as a searchable pdf in order to enable the location of a Recipient when searched by name. If possible, the file shall also be available in Excel format.

### **5.2.1 Transfer of Values Related to Non - Research and Development**

NPhS CY applies the EFPIA definition of the ToVs categories as outlined in EFPIA Code Article 23.05 - pursuant to the KEFEA Code.

The following categories constitute the EFPIA Disclosure Template for the 2025 NPhS CY 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 CY applies the EFPIA definition of the "Research and Development Transfers of Value" and the "Research and Development Transfers of Value" under the KEFEA Code, which provide that this definition captures Transfers of Value to HCPs or HCOs related to the planning or conduct of:

(i) non-clinical studies, as defined in the OECD Principles on Good Laboratory Practice, (ii) clinical trials as defined in Regulation 536/2014, and (iii) non- interventional studies regulated under Section 18 of the EFPIA Code and Section 18 the KEFEA 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 CY 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

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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**

Not Applicable

#### **5.6 ToVs for partial attendance or cancellations with refunds**

Not applicable

#### **5.7 Multi-year agreements**

Not applicable

### **6. Measures Taken to Ensure Compliance with Data Privacy Requirements**

This chapter describes measures taken by NPhS CY 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 CY. This data will be published for <3> years in public domain and stored for a minimum of <5> years on record by the NPhS CY (publishing affiliate). The disclosure of such personal information by NPhS CY 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

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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 CY country data protection authority (e.g. Information Commissioner).

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<sup>3</sup>. Consent management procedures were conducted in alignment with the KEFEA Code and the Cyprus Data Protection Act.

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 CY 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.

<sup>3</sup> 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 CY local data privacy laws (namely the Cyprus Data Protection Act) and the KEFEA Code.

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**

Not applicable

## **7 Financial Aspects**

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

NPhS CY complies with the accounting principles and the financial disclosure methodology - pursuant to the KEFEA Code.

NPhS CY 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

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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 CY discloses ToVs net amount only, except:

- if VAT cannot accurately be excluded, in which case the full ToV amount is disclosed; and
- where income tax or equivalent is withheld by NPhS CY on amounts earned by the HCP then the ToV will be disclosed in gross numbers and will include these amounts.

Currency treatment – foreign currency ToVs will be converted using actual exchange rates in agreement with the accounting policy of the NPhS CY ToVs will be disclosed in the local currency of the country where the disclosing entity is located. For direct and indirect ToVs, the foreign currency is converted to the local currency of the disclosing entity based on the transaction date. For cross-border ToVs, the foreign currency is converted to the local currency of the disclosing entity based on the average rate for the month in which the ToV occurred, using the Novartis Treasury rates.

In case of cross-border ToVs as defined in chapter 5.2, direct ToVs will be recognized when the payment has been cleared via the banking system and indirect ToVs will be related to the end date of the event.

In case of multi-year contracts, ToVs are recognized based on the date the payment has been cleared via the banking system.

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

## **7.1 VAT**

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

## **8 Published Data**

NPhS CY applies the EFPIA definition of "Form of Disclosure" as outlined in EFPIA Code Article 23.4 - pursuant to the KEFEA 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.

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## 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/> and the <http://kefea.org.cy/el/code-of-conduct/>