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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.

Novartis as a Company and member of the The Innovative Pharmaceutical Industry Association (IFPIA), SIA Novartis Baltics Lithuania Branch 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*

SIA Novartis Baltics Lithuania Branch 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 SIA Novartis Baltics Lithuania Branch Disclosure Report. SIA Novartis Baltics Lithuania Branch position is based on the interpretation of the current version of the EFPIA Code aligned with local transparency laws and Lithuania IFPA ethical code.

The Methodological Note summarizes the disclosure recognition methodologies and business decisions as well as country specific considerations applied by SIA Novartis Baltics Lithuania Branch 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

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 SIA Novartis Baltics Lithuania Branch Disclosure Report is following the disclosure standards pursuant to the Lithuania IFPA ethical code. Subject to this disclosure report are all direct or indirect ToVs related to prescription-only medicines disclosed by SIA Novartis Baltics Lithuania Branch 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 Lithuanian Pharmaceutical Law. 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 SIA Novartis Baltics Lithuania Branch 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, SIA Novartis Baltics Lithuania Branch discloses the amounts of value



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transferred by type of ToVs with data coverage from January 1st 2025 to December 31st 2025. SIA Novartis Baltics Lithuania Branch disclosure is performed for the full calendar year 2025.

Wherever possible, SIA Novartis Baltics Lithuania Branch 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

SIA Novartis Baltics Lithuania Branch applies the EFPIA definition of ToVs as outlined in EFPIA Code Definitions pursuant to the Lithuania IFPA ethical code.

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

SIA Novartis Baltics Lithuania Branch applies the EFPIA definition of the ToVs categories as outlined in EFPIA Code Article 23.05 - pursuant to the Lithuania IFPA ethical 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

SIA Novartis Baltics Lithuania Branch applies the EFPIA definition of the ToVs categories as outlined in EFPIA Code Article 23.05 - pursuant to the Lithuania IFPA ethical code.

The following categories constitute the EFPIA Disclosure Template for the 2025 SIA Novartis Baltics Lithuania Branch EFPIA Disclosure Report:

- Donations and grants to an HCO

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- 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

SIA Novartis Baltics Lithuania Branch 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 Lithuanian IFPA ethical 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, for example:

- Activities related to the planning or conduct of non-clinical studies, clinical trials or prospective non-interventional studies and that involve the collection of patient data from or on behalf of individual, or groups of HCPs specifically for the study (Section 15.01 of the HCP Code).
- IIT (Investigator initiated trials) and IST (Investigator sponsored trials - since, although not initiated by SIA Novartis Baltics Lithuania Branch they may benefit from SIA Novartis Baltics Lithuania Branch
- Post marketing trials, investigator meetings - in which case the total ToV amount is disclosed and in case of participating HCP from other countries, the total actual cost per meeting (incl. infrastructure, travel, logistic and with exclusion of meals whenever possible) is divided by the number of participants per country of practice
- Activities contracted to CROs, where SIA Novartis Baltics Lithuania Branch makes indirect ToVs to HCPs/HCOs falling under the definition of Research and Development
- ToVs related to early stage research if falling under the definition of Research and Development in the EFPIA Code

In case ToVs relating prospective and retrospective non-interventional studies cannot be distinguished, all non-interventional studies are disclosed on an individual basis.

ToVs made by or on behalf of SIA Novartis Baltics Lithuania Branch **related to consultancy 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: consultancy activities related to the planning/conduct of non-clinical studies, clinical trial or prospective non-interventional studies, ethics committees, steering committee and advisory board activities related to the planning or conduct of non-clinical studies, clinical trial or prospective non-interventional studies, adjudication committees, speaker programs, scientific meetings.

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ToVs related to **licensing fees** paid for the use of Clinical/Health Economics and Outcomes Research questionnaires and tools, if the questionnaires and tools are intended for use with an Research and Development project/study are reported in aggregate form under the “Research and Development” category.

The following instances of medical writing and editorial support (as defined in chapter 5.3.3) are covered under the “Research and Development” category: investigator’s brochure (trials), clinical study report (trials), clinical report, safety report; generally all types of medical writing related to clinical trials or related to Research and Development activities, patient narrative writing - only if not disclosed under the “Fees for Service and Consultancy” category by SIA Novartis Baltics Lithuania Branch, consensus report - only if not disclosed under the “Fees for Service and Consultancy” category by SIA Novartis Baltics Lithuania Branch.

### 5.3 Credit Notes

SIA Novartis Baltics Lithuania Branch 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. Scope of the Lithuania transparency report is per the EFPIA Code. No additional exclusions have been applied. F&B is not in scope.

### 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

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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

Multi Year agreements are not in scope for Novartis Lithuania however we follow a consistent Methodology where the bank clearing date is applied as the payment date for all the disclosure purposes.

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

This chapter describes measures taken by SIA Novartis Baltics Lithuania Branch 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 SIA Novartis Baltics Lithuania Branch. This data will be published for 3years in public domain and stored for a minimum of 5 years on record by the SIA Novartis Baltics Lithuania Branch (publishing affiliate). The disclosure of such personal information by SIA Novartis Baltics Lithuania Branch 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 SIA Novartis Baltics Lithuania Branch 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<sup>3</sup>. Consent management procedures were conducted in alignment with the local data privacy requirements of the publishing affiliate's jurisdiction.

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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.

SIA Novartis Baltics Lithuania Branch 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 SIA Novartis Baltics Lithuania Branch local data privacy laws.

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. Not in scope.

## 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.

SIA Novartis Baltics Lithuania Branch complies with the accounting principles and the financial disclosure methodology - pursuant to the Lithuania IFPA ethical code.

SIA Novartis Baltics Lithuania Branch 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.

SIA Novartis Baltics Lithuania Branch discloses ToVs in their total value included all applicable taxes.

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

Currency treatment – foreign currency ToVs will be converted using actual exchange rates in agreement with the accounting policy of the SIA Novartis Baltics Lithuania Branch. 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.

## 7.1 VAT

SIA Novartis Baltics Lithuania Branch 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 SIA Novartis Baltics Lithuania Branch on amounts earned by the HCP then the ToV will include these amounts.

## 8 Published Data

SIA Novartis Baltics Lithuania Branch applies the EFPIA definition of “Form of Disclosure” as outlined in EFPIA Code Article 23.4 - pursuant to the Lithuanian IFPA ethical code.

Updates of published data are conducted on a quarterly basis to allow for reflection of data updates or consent withdrawal after disclosure submission. All claims will be accepted via [disclosure.questions@novartis.com](mailto:disclosure.questions@novartis.com) email and resolved not later than within one calendar month.

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.

Member Companies shall be able to modify, delete or in any way alter their disclosures at any time before or after the time of publication. The information disclosed shall remain in the public domain for 3 years after the time such information is first published.

## 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.

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

- **Contract Research Organization (CRO):** an organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.
- **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.
- **Member Associations:** as defined in the EFPIA Statutes, means an organisation representing pharmaceutical manufacturers at national level whose members include, among others, research-based companies. Collectively, the national Member Associations or their constituent members, as the context may require, are bound by the EFPIA Code.
- **Member Companies:** as defined in the EFPIA Statutes, means research-based companies, developing and manufacturing Medicinal Products in Europe for human use.
- **Professional Conference Organizer (PCO):** a company which specializes in the organization and management of congresses, conferences, seminars and similar events.
- **Recipient:** Any HCP or HCO/PCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Europe.
- **Research and Development ToVs:** ToVs to HCPs or HCOs related to the planning or conduct of (I) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Directive 2001/20/EC); or (iii) non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study.
- **Transfers of Value (ToVs):** Direct and indirect transfers of value, whether payments, in kind or otherwise, made, whether for promotional purposes or otherwise, in

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connection with the development and sale of prescription-only Medicinal Products 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.