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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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) and Professional Congress Organisers ("PCOs") not considered to be Health Care Organizations ("HCOs") under the AIFP Code, 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 (AIFP), Novartis s.r.o. complies with the obligation to collect, disclose and report ToVs related to prescription-only medicines to HCPs/HCOs/ PCOs in accordance with the:

National transposition of the EFPIA Code of Practice[2]

AIFP Code of Practice (Approved by the AIFP general Assembly on 7th February 2025) and AIFP Methodology on Disclosure 2025
Novartis s.r.o. is working with HCP/HCO/PCO unique identifiers to ensure that the identity of the HCP/HCO/PCO benefitting from the ToVs is clearly distinguishable for each Novartis affiliate.
Local AIFP prepared the AIFP Methodology on Disclosure. The aim of this document is to provide readers of disclosed data with further information on the methodology used in disclosing Transfer of Values. As all data are disclosed on the central platform https://aifp.cz/cs/transparentni-spoluprace-3/, one common methodology covering all areas that need to be clarified was developed. However, some parts of the methodology, not strictly defined by this methodological note, may slightly differ among the companies and each company shall therefore issue its own methodology as well.

According to the AIFP Methodology on Disclosure, recipient is any HCP, HCO or PCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in the Czech Republic.

Note: Further details on the Novartis' position on transparency are given in chapter 3.

[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".*

2. Purpose of the Methodological Note

This document is intended to serve as supporting documentation for the 2025 Novartis s.r.o. Disclosure Report. Novartis s.r.o.'s position is based on the interpretation of the current version of the EFPIA Code aligned with AIFP Code of Practice.

The Methodological Note summarizes the disclosure recognition methodologies and business decisions as well as country specific considerations applied by Novartis s.r.o. 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/PCOs 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 s.r.o. Disclosure Report is following the disclosure standards pursuant to the EFPIA Code and AIFP Code of Practice. Subject to this disclosure report are all direct or indirect ToVs related to prescription-only medicines disclosed by Novartis s.r.o. 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 definition stated in local pharmaceutical regulation issued by State Institute for Drug Control. 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 s.r.o. Disclosure Report – AIFP Disclosure Report covers direct and indirect ToVs, payments, in kind or otherwise, made to HCPs/HCOs/PCOs 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 s.r.o. (Czech Republic) discloses the amounts of value transferred by type of ToVs with data coverage from January 1st 2025 to December 31st 2025. Novartis s.r.o. disclosure is performed for the full calendar year 2025.

Wherever possible, Novartis s.r.o. follows the principle of disclosure on individual HCP/HCO/PCO 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/PCO 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.

4.2 Self Incorporated HCP

This section outlines the reporting methodology for self-incorporated HCPs. This term refers to healthcare professionals who can be identified based on the registration number of the Czech Medical Chamber or Czech Chamber of Pharmacists and registered under this number as an HCP. IČ (IN) does not turn a physical entity into a legal entity.

5. Novartis' Disclosure Recognition Methodology and Related Business Decisions

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

Novartis s.r.o. applies the definition of the HCP/HCO/PCO as outlined in the EFPIA Code - pursuant to the AIFP Code of Practice.

Novartis s.r.o. has developed HCP/HCO/PCO unique identifiers to ensure that the identity of the HCP/HCO/PCO benefitting from the ToVs is clearly distinguishable for each Novartis affiliate.

In accordance with EFPIA Code and pursuant to the national AIFP Code of Practice, ToVs to an HCP/HCO/PCO are disclosed in the country where the Recipient's primary practice is located, independent of whether the ToVs occurred inside or outside that country. The physical address where the HCP has his primary practice or the principal address of an HCO/PCO is used as the deciding factor when determining in which country the data should be disclosed.

5.1 Definition of Direct and Indirect Transfer of Values

Novartis s.r.o. applies the EFPIA definition of ToVs as outlined in EFPIA Code Definitions pursuant to the definition in the AIFP Code of Practice.

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/PCOs.

- 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/PCO that benefits from the ToVs.
- Cross-border ToVs as being a Transfer of Value to an HCP/HCO/PCO 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.

In general, ToVs are reported at the level of the first identifiable Recipient which falls under the EFPIA definition of an HCP/HCO/PCO. To the extent possible, disclosure is made under the name of the individual HCP or at the HCO, PCO level, as long as this could be achieved with accuracy, consistency and compliance with the EFPIA Code and pursuant to the definition in the AIFP Code of Practice. Where a ToV was made to an individual HCP rendering services on behalf of an HCO indirectly via this HCO, such ToVs are only disclosed once on either Recipient level.

Generally, ToVs to HCPs via an HCO are disclosed at the first level Recipient (HCO), or exceptionally at second level Recipient, if a contract with an HCO specifies that part of the amount must be used to engage HCPs nominated by Novartis s.r.o. When a tripartite contract exists between Novartis s.r.o. an HCO and an HCP, with the HCP as benefitting party, ToVs are disclosed at HCP level. If Novartis s.r.o. holds a contract with a non-HCO Third-Party vendor acting on behalf of Novartis s.r.o. and who is contracting independent HCP/HCO to provide a reportable activity, ToVs are disclosed at the individual subcontracted HCP/HCO level, unless the HCP/HCO must remain unknown in order to comply with good market practices or Novartis internal rules.

ToVs from distributors of Novartis s.r.o. to HCPs/HCOs/PCOs whose primary practice is in an EFPIA country must be disclosed if the distributor is making a ToV on behalf of Novartis s.r.o. (influencing the promotional activities and selection of Recipient). ToVs made to HCPs and HCOs through Continuous Medical Education (CME) by a PCO provider are disclosable if the third-party CME provider is acting on behalf of Novartis s.r.o. and has influenced the choice of HCPs or faculty involved.

5.2 Transfer of Value Categories according to the EFPIA Code

Novartis s.r.o. applies the EFPIA definition of the ToVs categories as outlined in EFPIA Code Article 23.05 - pursuant to the definition in the AIFP Code of Practice.

The following categories constitute the EFPIA Disclosure Template for the **2025** Novartis s.r.o. Disclosure Report (AIFP Disclosure report):

- Non - Research and Development Categories
- Research and development

Details on the recognition methodology and business decisions affecting how the published ToVs data was constructed for each category can be found in the subsequent sub-chapters.

5.2.1 Transfer of Values Related to Non - Research and Development

Novartis s.r.o. applies the EFPIA definition of the ToVs categories as outlined in EFPIA Code Article 23.05 - pursuant to the AIFP Disclosure code.

The following categories constitute the EFPIA Disclosure Template for the 2025 Novartis s.r.o. Disclosure Report (AIFP 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

Payments and other benefits provided by the PCO are not divided into special categories for disclosure purposes. Member companies disclose sponsorships and contributions to event-related costs that have been negotiated in sponsorship agreements with PCOs.

5.2.2 Transfer of Values Related to Research and Development

Novartis s.r.o. 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 definition in the AIFP Code of Practice.

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.

- IIT (Investigator initiated trials) and IST (Investigator sponsored trials - since, although not initiated by Novartis s.r.o. they may benefit from Novartis s.r.o.).

- 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 Novartis s.r.o. 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 Novartis s.r.o. **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 and scientific meetings.

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 a 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 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.

5.3 Credit Notes

If Novartis s.r.o. 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 ToVs

This section refers to certain types of monetary or non-monetary ToV that are not subjected to disclosure under the EFPIA Code. Informational or educational materials and items of medical utility, Meals (Food and Beverages), Medical samples (all governed by AIFP Code); or are part of ordinary course purchases and sales of Medicinal products by and between Novartis and a HCP (such as a pharmacist) or a HCO do not fall within the scope of the disclosure obligation.

5.5 Non- Monetary ToVs

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.

Cancellation fees that a company pays for an HCP will not be disclosed as the Transfer of Value. Publication of cancellation fees for services that have not been consumed for e.g. illness of an HCP does not correspond to the purpose of the Disclosure Code.

In the case of earlier leaving from the sponsored event actually paid Transfers of Value shall be disclosure (e.g. full or partial payment of the registration fee, payment of fixed amounts – travel, accommodation etc.).

5.7 Multi-year agreements

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

6. Measures Taken to Ensure Compliance with Data Privacy Requirements

This chapter describes measures taken by Novartis s.r.o. 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.

Based on local AIFP Methodology and applicable data privacy and other legislation, the condition which is necessary for processing of personal data of the healthcare professionals in the EFPIA Disclosure includes obtaining the consent from the healthcare professional with processing of personal data or securing another title for the lawful processing of personal data.

Novartis s.r.o. is obtaining the consent from the Healthcare Professional and is also responsible for potential management of Healthcare Professionals' consent withdrawal or request as described in the AIFP Methodology as well.

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 s.r.o.. This data will be published for 3 years in public domain and stored for a minimum of 5 years on record by the Novartis s.r.o. (publishing affiliate). The disclosure of such personal information by Novartis s.r.o. 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 s.r.o. 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 internal data protection procedure/policy.

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 s.r.o. 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 aggregated/ anonymized 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 form.

[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 s.r.o. local data privacy laws.

6.2.1 Legitimate Interest

Any alternative way to manage individual publication of ToV (based on a different legal ground than consent, such as legitimate Interest) has to be discussed with and assessed by the local Data Privacy Head.

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 s.r.o. complies with the accounting principles and the financial disclosure methodology - pursuant to the definition in the AIFP Code of Practice.

Novartis s.r.o. 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.

Currency treatment – foreign currency ToVs will be converted using actual exchange rates in agreement with the accounting policy of the Novartis s.r.o. 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 5.1, 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.

When affiliate realizes that the published disclosure report is missing data, i.e., ToV has not been reported, missed ToV shall be reported in aggregate/ on individual level, based on consent level in a revised (updated) report in the same disclosure cycle. In case affiliate includes ToV from previous year in current year disclosure, this must be mentioned in the methodological note.

7.1 VAT

Novartis s.r.o. 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 s.r.o. on amounts earned by the HCP then the ToV will include these amounts.

8. Published Data

Novartis s.r.o. applies the EFPIA definition of “Form of Disclosure” as outlined in EFPIA Code Article 23.4 - pursuant to the definition in the AIFP Code of Practice.

Updates of published data are conducted on at least a quarterly basis to allow for reflection of data updates or consent withdrawal after disclosure submission.

HCP has a right to withdraw the consent in written to the common address **privacy-1.czech@novartis.com.** Consent withdrawal is with retroactive effect and Novartis s.r.o. has to change the Disclosure report at AIFP platform accordingly and as soon as possible. Novartis s.r.o consent withdrawal has been assessed according to the relevant applicable data privacy laws.

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.

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 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.