
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: office.romania@novartis.com

Country: Romania

Division: Novartis Pharma Services Romania SRL

Version: 12; this document replaces previous drafts and editions.

Contents

1.	Reference to National Transparency Laws and Regulations	3
2.	Purpose of the Methodological Note	4
3.	Novartis' Commitment and Responsibility for Disclosure	4
4.	Scope of the Novartis Disclosure on Transfers of Value	4
4.1	Voluntary disclosure.....	5
4.2	Self Incorporated HCP	5
5.	Novartis' Disclosure Recognition Methodology and Related Business Decisions	5
5.1	Definition of Direct and Indirect Transfer of Values.....	6
5.2	Transfer of Value Categories according to the EFPIA Code	6
5.2.1	Transfer of Values Related to Non - Research and Development	6
5.2.2	Transfer of Values Related to Research and Development	7
5.3	Credit Notes.....	7
5.4	Excluded ToV's.....	7
5.5	Non- Monetary ToV's	7
5.6	ToV's for partial attendance or cancellations with refunds	8
5.7	Multi-year agreements.....	8
6.	Measures Taken to Ensure Compliance with Data Privacy Requirements	8
6.1	Safeguarding Measures to Address Lawful Collection, Processing and Transfer of HCPs Personal Data	8
6.2	Consent Collection.....	9
6.2.1	Legitimate Interest.....	9
7	Financial Aspects.....	9
7.1	VAT	9
8	Published Data	9
9	Acronyms and Abbreviations	10

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 (ToV's)¹ related to prescription-only medicines by establishing a single, consistent transparency standard in Europe for disclosing ToV's 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 Services Romania SRL complies with the obligation to collect, disclose and report ToV's related to prescription-only medicines to HCPs/HCOs in accordance with the:

- EFPIA Code of Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations ²
- And national transparency laws

Novartis Pharma Services Romania SRL has developed HCP/HCO unique identifiers to ensure that the identity of the HCP/HCO benefitting from the ToV's is clearly distinguishable for each Novartis affiliate.

Localization guidance:

- Law no. 95/2006 regarding the healthcare reform;
- Order no. 194/2015 approving the Norms for Evaluation and Endorsement the Drug Advertising;
- Order no. 874/2015 for approving the disclosure forms of sponsorship activities within the field of medical devices and sanitary materials;
- ARPIIM Transparency Code;
- EFPIA Board Decision dated 14 April 2016 approving that Romanian disclosure will be made on local format and such reporting is consistent with the EFPIA Disclosure Code.

¹ A definition on the terms "HCP/HCO" and "ToV's" 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 done by Novartis Pharma Services Romania SRL. The company position is based on the interpretation of the current version of the EFPIA Disclosure Code, aligned with focal transparency laws and locally transposed EFPIA disclosure code which is aligned with the local transparency law (i.e. - Order no. 194/2015 approving the Norms for Evaluation and Endorsement the Drug Advertising).

The Methodological Note summarizes the disclosure recognition methodologies and business decisions as well as country specific considerations applied by Novartis Pharma Services Romania SRL in order to identify, collect and report ToV's 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 ToV's related to prescription-only medicines

Novartis establishes a single, consistent transparency standard for disclosing ToV's in all EFPIA countries.

4. Scope of the Novartis Disclosure on Transfers of Value

This 2025 Novartis Pharma Services Romania SRL Disclosure Report is following the disclosure standards pursuant to the local transposition of EFPIA Disclosure Code and national transparency laws/regulations. Subject to this disclosure report are all direct or indirect ToV's related to prescription-only medicines disclosed by Novartis Pharma Services Romania SRL to or for the benefit of a Recipient made by any Novartis affiliate as described in Article 23 of the EFPIA Disclosure 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 Law no. 95/2006 regarding the healthcare reform. ToV's 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 Services Romania SRL Disclosure Report covers direct and indirect ToV's, 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 report, Novartis Pharma Services Romania SRL discloses the amounts of value transferred by type of ToV's with data coverage from January 1st 2025 to Dec 31st 2025. Novartis Pharma Services Romania SRL disclosure is performed for the full calendar year 2025.

Wherever possible, Novartis Pharma Services Romania SRL follows the principle of disclosure on individual HCP/HCO/ Self Incorporated HCP 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/ Self Incorporated HCP benefitting from the ToV's, based on the contract. 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, or for indirect cost for participants at events organized by Novartis Pharma Services Romania SRL, as company guests, and are not included in sponsorship activities.

This report also includes Transfer of Values made by Advanced Accelerator Applications 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 (such as a doctor, nurse practitioner) who has established themselves as a legal business entity rather than operating as a sole proprietor or a direct employee of a hospital.

5. Novartis' Disclosure Recognition Methodology and Related Business Decisions

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

This chapter represents the central pillar of this Methodological Note. It provides comprehensive information on the terminology definitions, recognition methodology and business decisions that affected how the published ToV's data was established for each category of the disclosure

report.

5.1 Definition of Direct and Indirect Transfer of Values

Novartis Pharma Services Romania SRL applies the EFPIA definition of ToV's as outlined in Law no. 95/2006 regarding the healthcare reform, Order 194 I 2015 and Order no. 874/2015.

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

- Direct ToV's are defined as those ToV's, payments or in kind, made directly by the Novartis affiliate to the benefitting HCPs/HCOs.
- Indirect ToV's are defined as those ToV's 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 ToV's.
- Cross-border ToV's 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 Services Romania SRL applies the EFPIA definition of the ToV's categories as outlined in EFPIA Code Article 23.05 - pursuant to the Law no. 95/2006 regarding the healthcare, Order 194/2015, and Order no. 874/2015.

The following categories constitute the EFPIA Disclosure Template

- Non - Research and Development Categories
- Research and development (reported as aggregate data)

5.2.1 Transfer of Values Related to Non - Research and Development

Novartis Pharma Services Romania SRL applies the EFPIA definition of the ToV's categories as outlined in EFPIA Code Article 23.05 - pursuant to the Law no. 95/2006 regarding the healthcare reform, Order 194/2015 and Order no. 874/2015.

The following categories constitute the EFPIA Disclosure Template for the 2025 Novartis Pharma Services Romania SRL 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

Novartis Pharma Services Romania SRL 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 national disclosure code .

ToV's 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 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.

ToV's 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.

5.3 Credit Notes

Novartis Pharma Services Romania SRL 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 ToV's 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

Novartis Pharma Services Romania SRL decided to apply the following rules for ToV's payment dates based on type of ToV's: direct ToV's are disclosed based on the date the payment has been cleared via banking system. Indirect ToV's related to events such as 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.

6. Measures Taken to Ensure Compliance with Data Privacy Requirements

This chapter describes measures taken by Novartis Pharma Services Romania SRL 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 Services Romania SRL. This data will be published for 3 years in public domain and stored for a minimum of 5 years on record by the Novartis Pharma Services Romania SRL (publishing affiliate). The disclosure of such personal information by Novartis Pharma Services Romania SRL is always 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 Services Romania SRL country data protection authority (e.g. Information Commissioner).

6.2 Consent Collection

No consent collection was required since Novartis Pharma Services Romania SRL pursues the disclosure based on local transparency laws during the 2025 disclosure cycle for these ToV categories.

As disclosure is mandatory by law, consent is not legally required.

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 ToV's information.

Novartis Pharma Services Romania SRL complies with the accounting principles and the financial disclosure methodology - pursuant to the Order 194/2015 and Order no. 874/2015.

Novartis Pharma Services Romania SRL decided to apply the following rules for ToV's payment dates based on type of ToV's: direct ToV's are disclosed based on the date the payment has been cleared via banking system. Indirect ToV's 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 Services Romania SRL discloses ToV's net amount only. If VAT cannot accurately be excluded, the full ToV amount is disclosed.

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

7.1 VAT

Novartis Pharma Services Romania SRL discloses ToV's 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 Services Romania SRL on amounts earned by the HCP then the ToV will include these amounts.

8 Published Data

Novartis Pharma Services Romania SRL applies the EFPIA definition of "Form of Disclosure" as outlined in EFPIA Code Article 23.4 - pursuant to the Order 194/2015 and Order no. 874/2015.

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.

This 2025 Novartis Pharma Services Romania SRL Disclosure Report has been sent to the national drug and medical devices agency in accordance with local transparency requirements and will be officially published on a further date which was not made public. Disclosures are made on an annual basis on March 31st of each year, for the full previous calendar year. Publication is made via the following disclosure platform: ANMDM platform and local Novartis Romania website.

The platform chosen fulfils the recommendation of the EFPIA Disclosure Code as being a platform accessible in the country where the Recipient has the primary practice and following the local laws or regulations of the country where the Recipient has their practice. All EFPIA Disclosure Reports published by Novartis Pharma Services Romania SRL and any other Novartis affiliate in Romania are published on the same platform: Novartis.com.ro .

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)
- Healthcare Professional (HCP)
- Healthcare Organization (HCO)
- Member Associations
- Member Companies
- Professional Conference Organizer (PCO)
- Recipient
- Research and Development ToV's
- Transfers of Value (ToV's)