
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 (ToV)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, UIPL complies with the obligation to collect, disclose and report ToV related to prescription-only medicines to HCPs/HCOs in accordance with the:

- *National transposition of the EFPIA Code of Practice*²

Code of Conduct of Research-based medicine Producers (UIPL) Law on Medicines and Medical Devices (Official Gazette of the BiH No. 58/2008)

http://www.almbih.gov.ba/_doc/regulative/zakon_o_lijekovima_bih_bo.pdf Law on Protection of Personal Data (Official Gazette of Bosnia and Herzegovina 49/06, 76/11)

http://www.azlp.ba/propisi/Default.aspx?id=5&langTag=en_US&template_id=149&pageIndex=1

Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina 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.

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 Pharma Services Inc. Representative office in Bosnia and Herzegovina. The Representative office in Bosnia and Herzegovina'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.

The Methodological Note summarizes the disclosure recognition methodologies and business decisions as well as country specific considerations applied by Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina to identify, collect and report ToV 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 related to prescription-only medicines

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

4. Scope of the Novartis Disclosure on Transfers of Value

This 2025 Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina 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 related to prescription-only medicines disclosed by Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina 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 Act on Medicines and Medical Devices (Official Gazette of BiH, No. 58/08). ToV 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 Inc. Representative office in Bosnia and Herzegovina Disclosure Report covers direct and indirect ToV, 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, Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina discloses the amounts of value transferred by type of ToV with data coverage from January 1st, 2025, to December 31st, 2025. For Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina disclosure is performed for the full calendar year 2025.

Wherever possible, Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina 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 ToV. 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.

5. Novartis' Disclosure Recognition Methodology and Related Business Decisions

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 data was established for each category of the disclosure report.

5.1 Definition of Direct and Indirect Transfer of Values

Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina applies the EFPIA definition of ToV as outlined in EFPIA Code Definitions pursuant to the Code of Conduct for Innovative Pharmaceutical Manufacturers.

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

- Direct ToV are defined as those ToV, payments or in kind, made directly by the Novartis affiliate to the benefitting HCPs/HCOs.
- Indirect ToV are defined as those ToV 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.

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- Cross-border ToV 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 Inc. Representative office in Bosnia and Herzegovina applies the EFPIA definition of the ToV categories as outlined in EFPIA Code Article 23.05 - pursuant to the Code of Conduct for Innovative Pharmaceutical Manufacturers.

The following categories constitute the EFPIA Disclosure Template for the 2025 Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina 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
 - Expenses related to fees for service and consultancy
- Research and development

Details on the recognition methodology and business decisions affecting how the published ToV 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 Pharma Services Inc. Representative office in Bosnia and Herzegovina applies the EFPIA definition of the ToV categories as outlined in EFPIA Code Article 23.05 - pursuant to the Code of Conduct for Innovative Pharmaceutical Manufacturers

The following categories constitute the EFPIA Disclosure Template for the 2025 Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina 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 Inc. Representative office in Bosnia and Herzegovina 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 Code of Conduct for Innovative Pharmaceutical Manufacturers.

ToV **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 <select/adjust as required>

5.3 Credit Notes

Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina will process 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.

5.4 Excluded Tov

Not Applicable – Complete alignment to EFPIA transparency requirements and requirements set in local transparency laws

5.5 Non-Monetary ToV

Not Applicable

5.6 ToV for partial attendance or cancellations with refunds

Not Applicable - Payments were based on bank clearing dates and actual participation.

5.7 Multi Year agreements

Not Applicable

6. Measures Taken to Ensure Compliance with Data Privacy Requirements

This chapter describes measures taken by Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina 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 Inc. Representative office in Bosnia and Herzegovina. 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 Inc. Representative office in Bosnia and Herzegovina (publishing affiliate).

The disclosure of such personal information by Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina 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 Inc. Representative office in Bosnia and Herzegovina country data protection authority (e.g. Information Commissioner).

6.2 Consent Collection

Consent for the publication of the ToV was obtained and documented as such before disclosing the data on an individual HCP/HCO level where applicable.

Consent management procedures were conducted in alignment with the Act on Protection of Personal Data ("Official Gazette of BiH" No. 49/06, 76/11 and 89/11).

Consent was obtained either on Recipient level for all ToV during a given period of time not shorter than one full year or on spend level for each interaction or single ToV. Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina 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, ToV 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 HCP has a right to withdraw the consent. Consent withdrawal has been assessed according to the relevant Act on Protection of Personal Data ("Official Gazette of BiH" No. 49/06, 76/11 and 89/11).

Any alternative way to manage individual publication of ToV (for example based on a different legal ground than the consent) is discussed with and assessed by the local Data Privacy Head.

³ EU Regulation (GDPR) lays down rules relating to the protection of natural persons with regard to the processing of personal data.

6.2.1 Legitimate Interest

Not Applicable

7 Financial Aspects

Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina complies with the accounting principles and the financial disclosure methodology - pursuant to the Code of Conduct for Innovative Pharmaceutical Manufacturers.

Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina decided to apply the following rules for ToV payment dates based on type of ToV: direct ToV are disclosed based on the date the payment has been cleared via banking system.

Indirect ToV 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.

Where income tax or equivalent is withheld by Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina on amounts earned by the HCP then the ToV will include these amounts.

Currency treatment – foreign currency ToV will be converted using actual exchange rates in agreement with the accounting policy of the Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina.

ToV will be disclosed in the local currency of the country where the disclosing entity is located. For direct and indirect ToV, the foreign currency is converted to the local currency of the disclosing entity based on the transaction date.

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

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

7.1 VAT

Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina discloses ToV net amount only. If VAT cannot accurately be excluded, the full ToV amount is disclosed.

8 Published Data

Novartis Pharma Services Inc. Representative office in Bosnia and Herzegovina applies the EFPIA definition of “Form of Disclosure” as outlined in EFPIA Code Article 23.4 - pursuant to the Code of Conduct for Innovative Pharmaceutical Manufacturers.

Updates of published data are conducted on a quarterly basis to allow for reflection of data updates or consent withdrawal after disclosure submission. HCPs who signed consents for individual disclosure are informed on the ToV planned to be disclosed (“pre-disclosure”) in written at latest 1 month before the publication date, with the intention to ensure the correctness of the data. Potential disputes or consent withdrawals are handled by the local program management. All requests are processed in the shortest possible time and reflected in the disclosure report.

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 Page 15 Title: EFPIA Methodological Note Doc. Version: 11 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 ToV: ToV 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 (ToV): 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.