

Organizations **Version:** 11.0

# Novartis Methodological Note for Global Patient Organization Transfer of Value (ToV) Report

On disclosure of payments and other Transfer of Values (ToV) to Patient Organizations following Novartis codes, practices and guidelines, as well as the interpretation of the EFPIA Code of Practice.

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Version: 11.0, this version replaces all previous versions.



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#### 1. Introduction

As an important voice of patients around the world, patient organizations have expanded and evolved the active role of the patient community in the healthcare ecosystem. By drawing upon the unique expertise and experiences of the patients they serve, patient organizations are a key driving force in making healthcare more patient centric. To this end, patient organizations partner with a number of different stakeholders of the healthcare community including pharmaceutical companies. Joint projects may relate to informing the development process for a new medicine, gathering information on diseases, treatments and available clinical trials, or development of patient support programs.

Novartis is committed to an open dialogue and transparent exchange of information with patient organizations. We see them as a key partner in our decision-making throughout the medicine lifecycle. We believe that engaging patients consistently and systematically across the medicines lifecycle ultimately allows us to develop better medicines for the benefit of patients with unmet needs. This reflects the commitments we have set out in our Code of Ethics and in our Commitment to Patients and Caregivers.

Novartis has developed codes and guidelines in accordance with legal and regulatory requirements to ensure that the interactions with patient organizations meet high standards of integrity and transparency. Building greater transparency in the relationships between pharmaceutical companies and their partners aims to build a better understanding of the collaboration and recognition of its value to patient care.

Novartis annually discloses monetary Transfer of Value (ToV) as well as non-monetary support to patient organizations around the globe in the Global Patient Organization Transfer of Value (ToV) Report. For each organization we support, we disclose the name as well as the value and purpose of the ToV, in full compliance with industry codes including the European Federation of Pharmaceutical Industries and Associations (EFPIA) <a href="Code of Practice.">Code of Practice.</a><sup>1</sup> This supplements the Novartis Commitment to patients and caregivers, recognizing the importance of transparency and reporting.

## 2. Purpose of the Methodological Note

This note serves as supporting documentation for the global patient organization ToV report. Novartis methodology is based on current internal <u>Novartis codes</u>, <u>practices and guidelines</u>, as well as the interpretation of the current version of the EFPIA Code

The methodological note summarizes the methodologies and business decisions implemented to identify, collect and report ToVs for each disclosure category.

<sup>1</sup> The 2019 EFPIA Code of Practice (in short: EFPIA Code) states in Section 24 (Methodology) that "each Member Company must publish the methodologies used by it in preparing the disclosures and identifying supports and services provided"

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The note is updated annually in conjunction with the publication of the ToV report to reflect the latest ToV reporting methodology.

## 3. Novartis commitment to and responsibility for ToV reporting

Novartis has established a single and consistent transparency standard for ToV to patient organizations. Since 2012, the company publishes a ToV report with the intent to increase transparency on our interactions with patient organizations at a global level.

Since its introduction, the ToV report along with respective transparency reporting standards have undergone updates to ensure full adherence with Novartis <u>Doing Business Ethically Policy</u>. Alignment is also maintained with the current EFPIA Code.

The ToV report discloses the amounts of value transferred from January 1, 2024, to December 31, 2024. Any Novartis subsidiary providing support to an independent patient organization is reported as a 'funding entity' throughout the global report. Each funding entity is accountable for the disclosure of the corresponding ToV.

Whenever possible, Novartis ensures that each patient organization is referred to in such a way that there is no doubt as to the identity of the organization benefiting from the ToV.

Food and beverages have been deliberately excluded as the collection of this information results in a considerable effort not providing additional value for the understanding of the ToV report.

## 4. Novartis disclosure methodology and related business decisions

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

### 4.1 Direct, indirect, in-kind and cross-border ToV

The following definitions apply throughout the ToV report:

- Direct ToV: ToV, payments made directly by Novartis to the benefiting organization.
- Indirect ToV: ToV made through an intermediary (third party) on behalf of Novartis for the benefit of an organization and where the organization can be clearly identified.
- **In-Kind**: non-monetary support provided to the benefiting organization.
- Cross-border ToV: ToV to an organization registered outside of the country where Novartis subsidiary providing the funding is based. Where local law requires, such ToV is disclosed in the country where the organization has been formally registered. In addition, cross-border ToV made by Novartis to organizations are included in the ToV report unless local law specifies otherwise.

ToV to an individual patient who does not represent or is not hired through a patient organization is not subject to disclosure, e.g.: payments made to individual patients in a market research capacity, a patient hired to create content.



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### 4.2 Novartis funding categories

Novartis meets reporting obligations by publishing a global report for patient organization ToV which includes all the funding categories as per EFPIA code.

#### 4.3 Credit Notes

If Novartis has processed a refund equivalent to the initial payment made to a patient organization, 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 patient organization's total disclosed ToV in the upcoming year. If the patient organization received no payment in the succeeding year, the ToV report will display a negative value.

## 5. Data privacy

This chapter describes measures taken by Novartis to ensure compliance with data privacy regulations, rules on consent collection and management of relevant information in compliance with internal rules, data privacy laws and regulations.

## 5.1 Measures to address collection, processing and transfer of patient organizations data

Data privacy refers to the individual fundamental right to control the use of access to and disclosure of information that describes or identifies the individual (personal information). In some countries, this also applies to patient organizations. To fulfil the transparency disclosure requirements, it is necessary to collect, process and disclose such data within Novartis. The disclosure of such personal information by Novartis is at all times limited to the intended purposes.

In case personal data must be transferred from countries to the central Novartis transparency data repository manually or through local systems, applicable local regulations for such transfer would be assessed at local level and followed accordingly.

Where applicable, consent for the publication of the ToV is obtained and documented within the underlying contract before disclosing the data on an individual organization level. In case consent was either not given by the recipient or not documented sufficiently to prove its existence, ToVs are disclosed on an aggregated level.

## 6. Financial Aspects

Novartis applies the following rules for ToV payment dates based on different ToV categories:

- Direct ToV payment date is the clearing date via the banking system.
- Indirect ToV related to events or in kind/non-financial support payment date is the date of the last day of the event.
- In case of cross-border ToV as defined in chapter 4.1, direct ToV payment date is clearing date via the banking system and indirect ToV payment date is end date of the event.



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ToVs reported in the ToV report reflect the net amount. If VAT cannot accurately be excluded, the full ToV amount will be disclosed.

ToVs reported in the ToV report are in local currency.

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

Multiple ToVs for the services covered under the same contract will be consolidated and reported together.

#### 7. Published Data

Data will remain published for three years in the public domain (<u>Patient Organization</u> <u>Funding | Novartis</u>) and stored for a minimum of five years by the publishing Novartis subsidiary.

### 7.1 Deviations between global and local reporting

Local reporting requirements based on country regulations may differ from Novartis global reporting requirements; deviations may occur between publications as a result.

#### 8. Definitions

This chapter includes a list of definitions per **Doing Business Ethically Policy** 

- Caregiver: A person who helps a patient with daily activities, healthcare, or any other activities that a person is unable to perform him/herself due to illness or disability. This person may also participate in or make medical decisions for a patient. Examples of caregivers include parents or legal guardians, spouses or partners, adult children, relatives, or other friends.
- Patient: A person with personal experience of living with a disease. Their main role is to contribute with their subjective disease and treatment experience.
  - Patients involved in a clinical trial are not in scope for the document and the ToV report.
- **Patient Organization:** A not-for-profit institution that primarily represents the interests and needs of patients, their families and/or caregivers.

#### 9. References

- Novartis Commitment to Patients and Caregivers:
   <a href="https://www.novartis.com/patients-and-caregivers/novartis-commitment-patients-and-caregivers/novartis-careg
- EFPIA Code: https://www.efpia.eu/relationships-code/the-efpia-code
- Patient Organization ToV disclosure on Novartis.com: <a href="https://www.novartis.com/esg/reporting/transparency-and-disclosure/patient-organization-funding">https://www.novartis.com/esg/reporting/transparency-and-disclosure/patient-organization-funding</a>
- Novartis Codes and Policies Doing Business Ethically Policy and Code of Ethics <a href="https://www.novartis.com/esg/reporting/codes-policies-and-guidelines">https://www.novartis.com/esg/reporting/codes-policies-and-guidelines</a>