

Novartis Methodological Note for Patient Organizations

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 aligned with local transparency laws.

Country: Global

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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 patients 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 stakeholders in the healthcare community including pharmaceutical companies. Joint projects may relate to informing the development process for a new medicine, the gathering of information on diseases, treatments and available clinical trials, or the development of patient support programs.

Novartis is committed to an open dialogue and transparent exchange of information with patient organizations. We see patient organizations 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 intentions we have set out in our Code of Ethics related to Patient Engagement, effective November 2021.

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 to the relationships between pharmaceutical companies and patient organizations aims to build a better understanding of the collaboration and recognition of its value to patient care.

Novartis annually discloses monetary and non-monetary Transfer of Value (ToV) as well as non-monetary support to patient organizations around the globe. For each organization we support, we disclose the name as well as the value and purpose of the ToV, in full compliance with local laws and industry codes including the European Federation of Pharmaceutical Industries and Association (EFPIA) [Code of Practice](#).¹ 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 (the ToV Report). Novartis methodology is based on current internal [Novartis codes, practices and guidelines](#), as well as the interpretation of the current version of the EFPIA Code aligned with local transparency laws.

¹ 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”

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

The note will be 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 evolving [professional practices policy \(P3\)](#) (within Ethics and Compliance). Alignment is also maintained with the current EFPIA Code and local transparency laws.

The ToV Report discloses the amounts of value transferred by category with data coverage from January 1, 2021 to December 31, 2021. Each reporting entity is accountable for the disclosure of the corresponding Patient Organization ToV.

Any Novartis division providing support to an independent patient organization is reported as a 'reporting entity' throughout the global report.

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 patient organization benefiting from the ToV.

Food and beverage 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 benefitting patient organizations.
- **Indirect ToV:** ToV made through an intermediary (third party) on behalf of Novartis for the benefit of patient organizations and where the organization can be clearly identified.
- **In-Kind:** significant 2 non-monetary support provided to the benefitting patient organizations.
- **Cross-border ToV:** ToV to a patient 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 patient organization has been formally registered. In addition, cross border ToV made by Novartis to patient 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.

4.2 Novartis funding categories

Novartis goes beyond reporting obligations and publishes a global report for Patient Organization ToV. Novartis set out minimum requirements to fund engagements with patient organizations in March 2018. All funding categories Novartis provided to patient organizations are detailed under [Professional Practices Policy \(P3\)](#) (within Ethics and Compliance).

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 organization 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

² Significant value is pre-defined by national and local codes

Novartis. The disclosure of such personal information by Novartis is at all times limited to the intended purposes.

In case personal data has to be transferred from countries to the central Novartis Transparency data repository manually (e.g., Excel) 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 patient 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 only.

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.

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 collected in local currency. Any currency conversions that are required are carried out using year-end target rates.

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

7. Published Data

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

7.1 Updates to global published data

Global data updates are conducted in the following instances:

- when local publications are updated (to ensure consistency)
 - when significant funding is identified after publication; significant funding corresponds to funding exceeding 10% of overall reported value for that same year
- Updates, when identified, will occur in the same reporting year.

7.2 Deviations between global and local reporting

Novartis is committed to full transparency and publishes a global report including all support provided to patient organizations. This is in line with the [Novartis Commitment to Patients and Caregivers](#) as well as the [Novartis Code of Ethics](#) (23rd commitment to Patient Engagement).

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 [Professional Practices Policy \(P3\)](#) (within Ethics and Compliance).

- **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.
- **Healthcare Organizations (HCOs):** Any legal entity (such as a company, partnership, or healthcare institution), whether public or private, that offer/provide Medical Services to patients and may prescribe, order, dispense, recommend, purchase, supply, administer, lease, and use Novartis products, and all members of their office staff, and medical associations or organizations.
Examples of HCOs include physician practices, hospitals (including university hospitals), ambulatory surgical centers, and pharmacies, clinics, nursing facilities, managed care entities, group purchasing organizations (GPOs), specialty pharmacies, medical societies, and businesses owned by an individual or group of HCPs.
- **Healthcare Professional (HCP):** Any member, student, or researcher of the medical, dental, optometry, opticianry, pharmacy, or nursing profession or any other person, social workers, clinical psychologists, formulary committee members, and pharmacy & therapeutics (P&T) committee members who in the course of his or her professional activities provides medical services and may prescribe, order, dispense, recommend, purchase, supply, administer, lease, or use pharmaceutical products and/or medical technologies, and all members of their office staff.
- **Patient:** Any person who may receive a prescription for, and/or are treated with a pharmaceutical product and/or medical technology for his or her individual needs. A

person with personal experience of living with a disease. Their main role is to contribute with their subjective disease and treatment experience. Patient involved in a clinical trial are not in scope for the document and the ToV report.

- **Patient Organization:** Independent organization which has the goal of providing direct support to people affected by an illness or advocating for, among other things, patients' rights, disease awareness and patient information in one or more therapeutic areas. Such organizations are often established by patients, their family members and caregivers but may also include HCPs, volunteers and policy makers among their membership or leadership.

9. References

- Novartis Commitment to Patients and Caregivers:
<https://www.novartis.com/patients-and-caregivers/novartis-commitment-patients-and-caregivers>
- EFPIA Code:
<https://www.efpia.eu/relationships-code/the-efpia-code>
- Patient Organization ToV disclosure on Novartis.com:
<https://www.novartis.com/esg/reporting/transparency-and-disclosure/patient-organization-funding>
- Novartis Codes and Policies – Professional Practices Policy (P3) and Code of Ethics (within Ethics and Compliance)
<https://www.novartis.com/esg/reporting/codes-policies-and-guidelines>