

Novartis Methodological Note

On Disclosure of Payments and other Transfers of Values to Patient Organizations following internal Novartis codes, practices and guidelines, the interpretation of the current version of the EFPIA Disclosure Code aligned with local transparency laws.

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1. Reference to national transparency laws and regulations

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 centered. 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 open dialogue and transparent exchange of information with patient organizations. We see patient groups as a key partner in our decision-making throughout the medicines lifecycle. We believe that incorporating the patient perspective in our decision-making 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 [Commitment to Patients and Caregivers](#).

Novartis has adopted codes and guidelines in accordance to their Country legal and regulatory requirements to ensure that the interactions with patient organizations meet the high standards of integrity and transparency. Building greater transparency to the relationships between Pharma 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 and non-monetary support to patient organizations around the globe. For each organization we support, we disclose their name as well as the value and purpose of the funding, in full compliance with local laws and industry codes including the [European Federation of Pharmaceutical Industries and Associations \(EFPIA\) Code](#). This supplements the Novartis Commitment to Patients and Caregivers, recognizing the importance of transparency and reporting.

2. Purpose of the methodological note

This document is intended to serve as supporting documentation for the global patient organization Transfer of Value (ToV) report. Novartis's position is based on current internal [Novartis codes, practices and guidelines](#), the interpretation of the current version of the EFPIA Disclosure Code aligned with local transparency laws.

The methodological note summarizes the disclosure recognition methodologies and business decisions in order to identify, collect and report ToVs for each disclosure category

This document will be updated yearly in conjunction with the publication of the global patient organization ToV report to reflect current methodology of ToVs reporting.

3. Novartis' commitment and responsibility for disclosure

Novartis establishes a single, consistent transparency standard for disclosing ToVs worldwide. The global patient organization ToV report was introduced in 2012 to bring further transparency around our interactions with patient organizations at a global level.

Since its introduction, the global patient organization ToV report along with respective transparency reporting standards have undergone updates to ensure full adherence with Novartis's evolving [professional practices policy \(P3\)](#). Alignment is also maintained with the current EFPIA disclosure code and local transparency laws.

4. Scope of the Novartis' disclosure on transfers of value

In this report, Novartis discloses the amounts of value transferred by type with data coverage from January 1st 2018 to December 31st 2018.

Within each country, it is the Novartis business division providing support to a patient organization, which is responsible for the provision of the corresponding financial data for public disclosure. Any Novartis business division that provides support to an independent patient organization is known as a "reporting entity" throughout the global report.

Whenever possible, Novartis follows the principle of disclosure on an individual patient organization level, to ensure that each recipient is referred to in such a way that there is no doubt as to the identity of the patient organization benefiting from the ToVs.

Food and beverage has been deliberately excluded as the collection of this information results in additional effort not providing additional value for understanding payment transparency

5. Novartis' disclosure recognition methodology and related business decisions

This chapter provides information on the terminology definitions, recognition methodology and business decisions around ToVs for public disclosure.

5.1 Definition of direct, indirect and in-kind transfer of values

Based on the EFPIA Disclosure Code, the following Novartis definitions apply throughout this report:

- Direct ToVs are defined as those ToVs, payments, made directly by the Novartis division to the benefitting patient organizations.
- Indirect ToVs are defined as those ToVs made through an intermediary (third party) on behalf of a Novartis division for the benefit of patient organizations where the Novartis division knows or can identify the patient organization that benefits from the ToVs.
- In-Kind, defined as significant¹ non-monetary support provided to benefitting patient organizations.

In general, ToVs are reported at the level of the first identifiable recipient which falls under Novartis definition of a patient organization.

ToVs to individual patients who do not represent or are not hired through a patient organization are not subject to disclosure

For instance;

- Payments made to individual patients e.g. in a market research capacity
- A patient hired to create content

5.2 Definition of cross-border transfer of values

Novartis applies the EFPIA definition of cross-border ToVs as being a Transfer of Value to a patient organization that is registered **outside** the country where the Novartis division, who has provided the funding is based.

In general, where local law requires, such ToVs are disclosed in the country where the patient organization has been formally registered. In addition cross border ToVs made by Novartis to patient organizations are included on the global patient organization report, unless local law specifies otherwise.

¹ Significant value is pre-defined by national and local codes

5.3 Transfer of value categories according to Novartis policies

Novartis set out its minimum requirements for the interactions with patient organizations at a global/ cross divisional level in March 2018. All category of fundings that Novartis provide to patient organizations are detailed under [Novartis Codes, Policies and Guidelines](#).

Prior to March 2018, interactions with patient organizations were governed at a divisional level which have been retired and replaced by P3.

Within divisions, more stringent interaction requirements may apply according to local laws, regulations, and industry codes.

6. Measures taken to ensure compliance with data privacy requirements

This chapter describes measures taken by Novartis 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 patient organization 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"). In selected 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 had to be transferred from countries to the central Novartis Transparency data repository manually (e.g. Excel) or via interfaces; applicable local regulations for such a transfer would be assessed at local level and managed accordingly.

Where needed, consent for the publication of the ToVs 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 the existence of consent, ToVs are disclosed on aggregate level only.

7. Financial Aspects

This chapter focuses on the financial aspects related to recognition methodology and business decisions associated with the collection and disclosure of the ToVs information.

Novartis applied the following rules for ToV payment dates based on type of ToV:

- Direct ToVs are disclosed based on the date the payment has been cleared via the banking system.
- Indirect ToVs related to events or in kind/ non-financial support for which the dates of values differ from the date(s) the event took place, are disclosed using the date of the last day of the event.
- In case of cross-border ToVs as defined in chapter 5.2, 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.

ToVs included on the global patient organization ToV report will reflect the net amount. If VAT cannot accurately be excluded, the full ToV amount will be disclosed.

ToVs included in the global patient organization ToV report are collected with the local currency of the Division who provided the funding applied. Any currency conversions that are required are carried out using year-end target rates via Novartis Treasury rates.

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

8. Published Data

8.1 Updates to global published data

Updates of the global published data are conducted in the following circumstances;

- 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.

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.

8.2 Deviations between global and local publications

Novartis is committed to full transparency and have deemed all support provided to patient organizations as in scope for global publication which is in line with the Novartis commitment to patients and caregivers.

As global reporting standards have been defined by Novartis and local reporting standards are defined within Countries by local laws, regulations, and industry codes, it could occur that for any Country where local regulation differs to the global reporting position, deviations may occur between publications as a result.

9. Acronyms and Abbreviations

This chapter includes a list of acronyms, abbreviations and definitions for documentation purpose, based on Novartis P3.

Caregiver

Someone who participates in or makes 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.

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 Health Care Professionals (HCPs), volunteers and policy makers among their membership or leadership.