

Novartis Global Policy



# Professional Practices Policy (P3)

Novartis Global Policy

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 **NOVARTIS**



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# 1 Introduction

## Purpose

Novartis' vision is to be a trusted leader in changing the practice of medicine. Consistent with this vision, Novartis is committed to the same high standard of ethical business conduct wherever it does business. Novartis has therefore adopted a single set of ethical principles that should be applied in daily decision-making by all Novartis Associates in any customer interaction and professional practice-related activity, including those not specifically covered by this Policy or related documents.

## Scope and applicability

This Policy applies to all Novartis Associates as well as all professional practice-related activities conducted by third parties on behalf of Novartis. All such activities must be conducted in accordance with local laws, regulations and industry codes, which may be more stringent than the requirements outlined in this Policy.

This Policy serves as the foundation for P3 Guidelines ("Guidelines") and local standard operating procedures ("SOPs") all of which provide additional requirements for expected behaviors. As a result, this Policy should be read and applied in conjunction with the Guidelines and other references included in [Section 5](#) of this document.

This Policy is effective as of March 1, 2018 and must be implemented by all Novartis affiliates. It replaces the existing versions of the divisional Professional Practices Policies.

The owner of this Professional Practices Policy (P3) is Group Integrity & Compliance

## 2 Principles

### Put patients first

All interactions with our customers must ultimately benefit patients by enhancing the standard of care, raising awareness about diseases and their treatment options, or otherwise contributing to the ethical delivery of healthcare.

We will treat patient information with respect, protect confidentiality, where required obtain informed consent, and be transparent with patients at all times.

We must protect patient safety. If an Associate becomes aware of a product-related risk or complaint (e.g., adverse event, manufacturing defect or product failure) related to Novartis products (approved or investigated) it must be reported in a timely manner.

### Fund responsibly

External funding, including grants, donations and sponsorships, must only be given to legitimate organizations and provided in a way that protects our reputation, aligns with society's expectations, and is consistent with the Novartis Mission to discover new ways to improve and extend people's lives.

The same rules apply for external in kind support.

### Act with clear intent

As trusted partners in healthcare, all of our activities must have clear and transparent objectives that are accurate, truthful, not misleading, and appropriate for their intended context.

Novartis may conduct promotional and non-promotional activities throughout the product lifecycle. These activities ensure that products are developed to meet the needs of patients, to advance scientific understanding of disease, including disease management and treatment outcomes, and to discuss the appropriate use of products.

Non-promotional activities should never be conducted in a way that are intended or perceived to be promotional.

### Engage appropriately

Associates must not offer, approve, or provide anything of value with the intent or consequence of inappropriately influencing or rewarding our customers for the use of Novartis products.

Novartis may choose to engage healthcare professionals or other customers to provide necessary and legitimate services to help us research, develop, and/or promote our products. Any compensation must be for a bona fide service, consistent with fair market value, properly documented and accounted for, and disclosed where required.

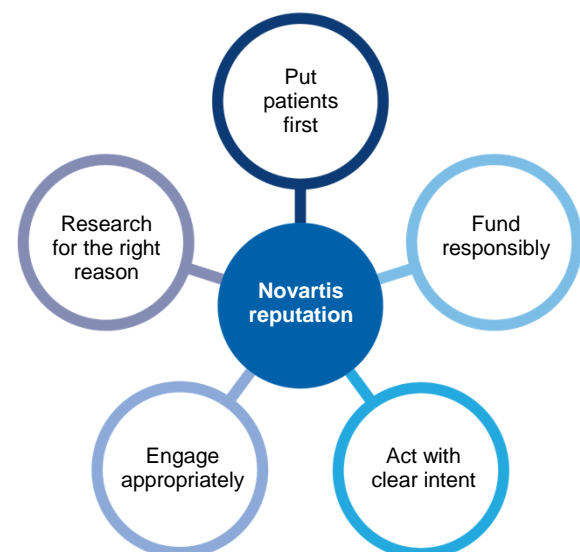
Allowable items of value, when provided to customers, must be modest, reasonable, infrequent, free from actual and perceived conflicts of interest, and disclosed where required.

### Research for the right reason

Research and development must only be conducted to address valid medical or scientific questions aimed at enhancing patient care. We must always respect and protect the rights, safety and well-being of patients and animals and safeguard the integrity and validity of the data obtained.

Research and development activities must follow established ethical and scientific standards and be conducted by qualified investigators.

Research and development activities must never be promotional in nature.



## 3 Policy

### 3.1 Clinical Research

Novartis must conduct clinical **research for the right reasons**. Research must be conducted only if it is scientifically valid and designed to answer relevant medical, scientific, or health economic questions. It must follow the *Novartis Position on Clinical Study Transparency* and the *Novartis Quality Manual*.

Novartis Associates must always **put patients first** and protect their safety; if an Associate becomes aware of an adverse event related to any study or product, he/she must report it according to *Novartis Global Adverse Event Reporting Standard*.

Novartis supports the publication of study results in a timely manner and must not withhold or suppress data. We must protect confidential and/or patentable information, and personal information. Where required by local laws, regulations and/or industry codes, Novartis must disclose and report any payments or transfer of value made to HCPs and/or their institutions for research studies and third party medical writing support for publications. All publications must follow *Novartis Guidelines for the Publication of Results from Novartis-Sponsored Research*.

### 3.2 Pricing and Market Access

Novartis may interact with individuals, including HCPs, involved in recommending or deciding product reimbursement or purchase of Novartis products. However, these **interactions must not interfere with their independent judgment** or be perceived as improperly influencing them. Interactions may include proactive discussions to understand the needs of governments, payers and public health organizations (e.g., budgetary impact of new therapies) or responding to specific request for information (e.g., providing economic data or pipeline information that is in the public domain). All such discussions must be truthful and accurate. If these interactions are with public officials they may be subject to additional laws, regulations and industry codes. Engagement of HCPs for professional services who are formulary committee members must be disclosed according to local laws, regulations and industry codes. Discounts, rebates and other payments must be accurately and appropriately recorded in our books and records.

### 3.3 Pre-Approval Communication and Scientific Exchange

Products must only be **promoted consistent with approved labeling**.

Novartis supports the right of the scientific community and the public to be informed concerning scientific and medical progress. Therefore, where allowed by local laws, regulations and industry codes, Novartis may exchange scientific information. This may include communications at scientific events, public disclosure of information to investors/ shareholders, governments, reimbursement agencies or their agents and public health organizations.

Novartis may receive unsolicited requests for information on unapproved drugs and indications (off-label) from HCPs, patient organizations, and other stakeholders. Only the Medical function may provide such information in response to these requests. Novartis Associates who receive unsolicited requests for off-label information must forward such requests to the Medical function. The response provided by the Medical function, including any materials, must be accurate, not misleading, not promotional in nature, related solely to the subject matter of the request, and in compliance with local laws, regulations and industry codes. The Medical function should maintain written documentation of unsolicited requests and responses.

Novartis Medical Scientific Liaisons (MSLs) may interact with HCPs throughout the lifecycle of a product for the purpose of exchanging scientific information. Interactions must not be promotional in any way, and must have **clear intent and transparent objectives**.

### 3.4 Promotional Interactions

Upon receipt of marketing authorization, Novartis may interact with customers, either directly or via a third party, to promote Novartis products, related features, and benefits. All interactions must have **clear intent, transparent objectives**, and must not interfere with the independence of customers.

Products must only be promoted consistent with approved labeling, as approved by the local regulatory authorities. Anyone promoting a Novartis product must be trained and have sufficient knowledge of the product to provide full and accurate product information.

Any materials used for purposes of the interaction must be approved in accordance with the *P3 Guideline on Promotional and Non-Promotional Materials* and local laws, regulations and industry codes.

### 3.5 Promotional Content

Novartis may produce and disseminate content (printed, electronically, and orally) to inform, educate, or promote its products. All content **must be accurate, fair, balanced, truthful and not misleading**, based on adequate substantiation and consistent with the scope of the relevant product's marketing authorization. Content must be reviewed, approved and updated, as required in accordance with the *P3 Guideline on Promotional and Non-Promotional Materials* and local laws, regulations and industry codes.

### 3.6 Items of Medical Utility and Cultural Acknowledgements

Novartis must **engage appropriately with all customers**. Where permitted by local laws, regulations, and industry codes, items of medical utility and cultural acknowledgements may be offered or provided to HCPs if such items are modest, reasonable in value, offered on an occasional basis and according to the *P3 Guideline on Items of Medical Utility and Cultural Acknowledgements*.

Gifts (including personal gifts) or promotional aids, whether branded or unbranded, must not be provided to HCPs or their family members. This includes payments in cash or cash equivalents (such as gift certificates). Items made available to HCPs for use during Novartis meetings (such as pens and note pads) must not include any Novartis product or company branding.

Novartis Associates must not use their own personal funds to provide gifts to HCPs.

### 3.7 Samples, Demonstration and Evaluation Devices

Where permitted by local laws, regulations, and industry codes, free samples of Novartis pharmaceutical products may be provided to HCPs authorized to prescribe that product in order to **enhance patient care** or provide experience with the product. Pharmaceutical samples must be permanently labeled as samples, and managed with systems of control and accountability. They must never be resold or otherwise misused.

Over the counter (OTC) product samples may be distributed directly to customers where permitted by local laws, regulations, and industry codes.

Demonstration and evaluation devices may be provided free of charge to an HCP or HCO for a limited and agreed-upon duration. Devices provided must be labeled appropriately and must not be provided prior to receipt of marketing authorization for their intended use in that market. Title to the device must remain with Novartis for the entire duration of the evaluation and devices must not be stored at any HCP or HCO facility when not under evaluation.

### 3.8 Events

Novartis may organize events or fund events organized by third parties throughout the product lifecycle with the objective to provide scientific information or educate customers about our products or applicable disease areas. All events must have clear objectives, be **funded responsibly** and aligned with Novartis' mission, in a way that meets societal expectations.

Events must have **clear purpose and be transparently conducted**. If the purpose of the event is non-promotional we must not use materials with brand colors and logos or any promotional content, and avoid any perceptions of disguised promotion.

Common types of events organized or funded by Novartis are:

- Promotional **speaker programs** to educate HCPs on Novartis products or applicable disease areas.
- **Scientific meetings** to facilitate legitimate scientific debate, gain or provide scientific or medical educational information
- **Disease awareness programs** to increase knowledge and education about diseases and their management.
- **Investigator meetings** to initiate, update, or close-out Novartis sponsored or supported studies. Such meetings must be managed in accordance with the requirements of the relevant investigator study.
- Novartis **site visits** for customers or regulatory authorities. Such visits must be coordinated with the local site management.
- **Third party congress or symposia** to provide medical education.

Novartis Associates should organize events in accordance with the *P3 Guideline on Events and Professional Meetings*.

### 3.9 Venue, Travel, and Hospitality

All events, meetings, or activities must be held in a venue appropriate for scientific or educational exchange and in accordance with local laws, regulations, and industry codes. Novartis must avoid venues that may be perceived as extravagant or applying inappropriate influence. For Novartis-organized events, refreshments and/or meals incidental to the main purpose of the event may be provided, however no entertainment or other leisure/social activities should be provided or paid for by Novartis. Interactions with public officials may be subject to additional laws, regulations and industry codes.

Where permitted locally, Novartis may fund HCPs to attend events in their country of practice (or home country). However, Novartis does not fund HCPs to attend international events with the exception of HCPs who are providing a service to Novartis. International travel may be funded only under certain circumstances where HCPs are engaged by Novartis to provide professional services. In all instances, we must ensure that event funding does not interfere with HCP independence.

### 3.10 Fees for Service

Novartis may engage with HCPs and HCOs for professional services, either directly or via a third party. Such services may include the engagement of HCPs as **speakers for promotional speaking programs, scientific standalones, or other events, consulting engagements, advisory boards** and/or **market research**. Irrespective of direct engagement or via a third party, Novartis is responsible for **engaging appropriately** and without the intent, perception or consequence of inappropriately influencing HCPs or HCOs for the use of our products.

All engagements must be based on a legitimate need for the service. Any HCP or HCO engaged by Novartis must have the necessary experience and/or capabilities to provide the services. The engagement must be confirmed in a written agreement signed by both parties before commencing any services. Compensation for services must be reasonable and at fair market value in relation to the services rendered. Engagement of HCPs who are public officials may be subject to additional laws, regulations and industry codes.

Cross-country engagements of HCPs must be approved by qualified Novartis Associates from the HCP's practicing country for compliance with local laws, regulations and industry codes. Compensation for services must be paid into the HCP's practicing country.

Novartis Associates must follow the *P3 Guideline on HCP and HCO Engagement*.

### 3.11 Interactions with Patients and Patient Organizations

Novartis may interact with patients, caregivers, and patient organizations to understand their perspective and provide knowledge regarding diseases, treatments, and its care. All interactions must be ethical, transparent, non-promotional, and consistent with Novartis' mission and **maintain the independence of the patient and patient organizations**.

Novartis must treat **patient information with respect and protect confidentiality**. We must not accept any patient or caregiver information from third parties unless the patient or caregiver has provided explicit consent for the provision of the information to Novartis.

In most markets, interactions with patients are non-promotional activities and must not be used for, or mixed with, promotional purposes. Promotion of prescription-only products to patients (direct-to-consumer promotion, "DTC") is not allowed in most countries. Where such promotion is allowed, it must strictly follow the applicable local laws, regulations and industry codes. Advertisements for patient recruitment in public media, where permitted, must not be misused for promotion of a product.

Novartis may engage with patients or patient organization for services, such as participation in **patient advisory boards**. All engagements must be based on a legitimate need for the service and confirmed in a written agreement signed by both parties before commencing any services. Compensation for services must be reasonable in relation to the services rendered.

Novartis may also provide financial and other support to patients and patient organizations. Such support may be in the form of **Patient Support Programs** ("PSPs"), **Patient Assistance Programs** (PAPs), funding to support/establish patient organizations, etc.

Novartis Associates must follow the *P3 Guideline on Interactions with Patients and Patient Organizations*.

### 3.12 External Funding

Novartis may provide funding or other support to external organizations. This includes **grants, donations**, funding for medical education such as **preceptorship programs**, and **sponsorships**. We must **fund responsibly**, in a manner that maintains our reputation, aligns with our mission to discover new ways to improve and extend people's lives, advance medical or scientific knowledge, and supports communities where Novartis Associates live and work.

External funding or support must only be given to legitimate organizations, never to individuals, and in accordance with the *P3 Guideline on External Funding*. It must have a clear and defined purpose. Funding must be reasonable and legitimate in light of the activity being funded and properly tracked, documented, reported, and accounted for, as required by local laws, regulations and industry codes. Where applicable, funding must follow the *Novartis Anti-Bribery Policy*.



## 4 Definitions

### Adverse Event

An adverse event is any unfavorable medical occurrence or unintended sign (including an abnormal laboratory finding), symptom, disease or injury temporally associated with the use of a medical device, medicinal or investigational product, in patients, users, or other persons, whether or not it is considered to be related to or due to the product.

### Customer

Defined broadly as:

- Patients and patient organizations
- Healthcare partners, including but not limited to, healthcare professionals, healthcare organizations, payers, third party distributors/wholesalers, suppliers, intermediaries
- Non-HCP Retailers.

### 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.

### Disease Awareness Programs

A program intended to provide information, awareness, or education regarding health and diseases and their management to the general public, potential patients, or HCPs.

### Over the Counter (OTC) Product

A product marketed for use by consumer without the intervention of a HCP in order to obtain the product.

### Cultural Acknowledgements

An inexpensive item, not related to the practice of medicine (also referred to as 'Courtesy Gift'), involving the HCP or their immediate family members to acknowledge significant national, cultural or religious holidays or events.

### Donation

Benefit granted by Novartis to legitimate organizations for an altruistic and specified purpose, where Novartis does not expect to receive any benefit, consideration or service in return.

### Event

A conference, congress, symposium, or any other meeting of a scientific, educational, or professional nature organized or funded partially or fully by Novartis or a third party to disseminate knowledge enhancing information, increase knowledge of Novartis products, provide scientific, educational and/or professional information.

### Gifts

Benefits of any kind given to someone as a sign of appreciation or friendship without expectation of receiving anything in return.

### Grant

Independently requested contribution conveyed to a legitimate organization for a specified purpose without agreement or intent to receive any tangible benefit (a measurable or quantifiable and objective benefit).

### 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, 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.

### **Items of Medical Utility**

Items given to HCPs that (1) are intended for the direct education of HCPs or patients, or are for use by patients to assist them in the administration of their treatment or management of their conditions, and (2) do not have value to HCPs outside of the scope of their practice and educational need.

### **Medical Services**

Performing or ordering any examination, test, or procedure to diagnose or treat any medical or health-related issue, or filling a prescription for a pharmaceutical or device product that is eligible for payment by someone (whether payor is public or private) other than a patient/consumer.

### **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.

### **Patient Support Program**

A program that involves direct or indirect interactions with a patient or patient's caregiver implemented by Novartis or a third-party on behalf of Novartis. Examples include helping patients manage medication administration and adherence, provide disease management support or provide or arrange for financial assistance for patients who cannot afford medications.

### **Pharmaceutical Samples**

Free pharmaceutical products supplied to HCPs authorized to prescribe that product in order to enable HCPs and their patients to gain experience in dealing with the product.

### **Promotional Aid**

Non-monetary items that are branded or include minimal information intended to promote Novartis or its products. Examples of Promotional Aids include pens, mousepads, and microfiber cloths.

### **Public Official**

- Any elected or appointed officer or employee of a government or government department, government agency, or of a company owned or partially owned by a government. Medical and scientific personnel qualify as public officials when they work at a hospital, clinic, university or other similar facility owned or partially owned by a government.
- Any elected or appointed officers or employees of public international organizations, such as the United Nations

- Any person acting in an official capacity for or on behalf of a government or a government department, government agency, or of a public international organization
- Politicians and candidates for a political office
- Any other person who is considered to be a public official according to applicable laws, regulations and industry codes

### **Research and development activities**

Activities conducted to obtain scientific and clinical knowledge in order to address unmet medical needs. These activities include clinical and non-clinical studies, exploratory early stage research, investigator meetings, studies in human subjects or involving human/patient data, and animals or biological materials.

### **Scientific Exchange**

Collection, publication, distribution and communication of scientific knowledge (knowledge related to, derived from or used in science for sharing), which may include information concerning a Novartis product.

### **Sponsorship**

Agreement by which Novartis, for the mutual benefit of Novartis and the sponsored party, provides funding to establish an association between the Novartis' image, brands, or services and a sponsored event, activity, or organization.

## 5 References

- P3 Guideline on Items of Medical Utility and Cultural Acknowledgements
- P3 Guideline on Market Research
- P3 Guideline on Interactions with Patients and Patient Organizations
- P3 Guideline on External Funding
- P3 Guideline on Events and Professional Meetings
- P3 Guideline on HCP and HCO Engagements
- P3 Guideline on Promotional and Non-Promotional Materials
- Novartis Anti-Bribery Policy
- Novartis Position on Clinical Study Transparency
- Novartis Guideline for the Publication of Results from Novartis-Sponsored Research
- Novartis Quality Manual
- Novartis Global Adverse Event Reporting Standard
- Novartis Third Party Guideline

## 6 Implementation

### Training

Associates must familiarize themselves with this Policy and the relevant Guidelines referred to in this Policy. Associates must be trained in line with the Novartis-wide compliance training curriculum. Additional training requirements for Associates and third parties conducting business on behalf of Novartis may be defined in local SOPs.

### Third parties

Third parties involved in conducting activities covered by this Policy and on behalf of Novartis are expected to comply with this Policy, applicable laws and to adhere to ethical business practices. Novartis Associates contracting third parties are ultimately responsible for how third parties conduct these activities on behalf of Novartis.

### Breach of this policy

Failure to comply with this Policy may lead to disciplinary and other actions, up to and including termination of employment.

### Reporting potential misconduct/non-retaliation

Any Associate with knowledge of suspected misconduct must report his or her suspicion promptly in accordance with the Business Practices Office (BPO) process. Associates who report potential misconduct in good faith or who provide information or otherwise assist in any inquiry or investigation of potential misconduct will be protected against retaliatory action.

### Exceptions

No exceptions can be granted from compliance with applicable laws, regulations and industry codes. The Compliance Leadership Team (CLT) will review exceptions related to this Policy.

### Responsibilities

It is the responsibility of every Novartis Manager to adhere to this Policy within his or her area of functional responsibility, lead by example, and provide guidance to the Associates reporting to him or her. All Associates are responsible for adhering to this Policy.