

Doing Business Ethically (DBE)

External Partner Training
V1_November 2024



Disclaimer

For the purpose of this course only, the terms “people” and “employee” or “we”, are used to also describe external partner employees, working at, or on behalf of Novartis.

Your participation in this course does not indicate that you are an employee of the Novartis Group of Companies, and by continuing you hereby acknowledge that any such claim will constitute a breach of your services agreement.

This course **aims to share Novartis' ethical standards with our external partners** however, the external partner must comply with local regulations and laws, their own processes, and industry codes for the proper execution of related activities under the agreement with Novartis.

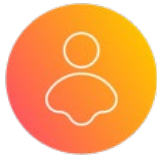
Introduction

Welcome to the Novartis' Doing Business Ethically External Partner Training

As part of Novartis' commitment to ethical business practice and compliance with national and international laws, Novartis aims to work with external partners who share our values and ethical principles.

Our success depends on strong, reliable, and reputable partners. They help us build trust with all stakeholders by living up to the same standards.

Purpose:



This training is intended for **external partners interacting with External Stakeholders on behalf of Novartis.**

This module will help you understand and comply with applicable Novartis policies.

Scope:



This Training covers:

- General Anti-Bribery/Anti-Corruption
- Key Novartis Requirements from Doing Business Ethically Policy and External Partner Code (Anti-Bribery)
- Interactions with External stakeholders with specific focus on HCPs and GOs

Anti-Bribery and Anti-Corruption Training Module

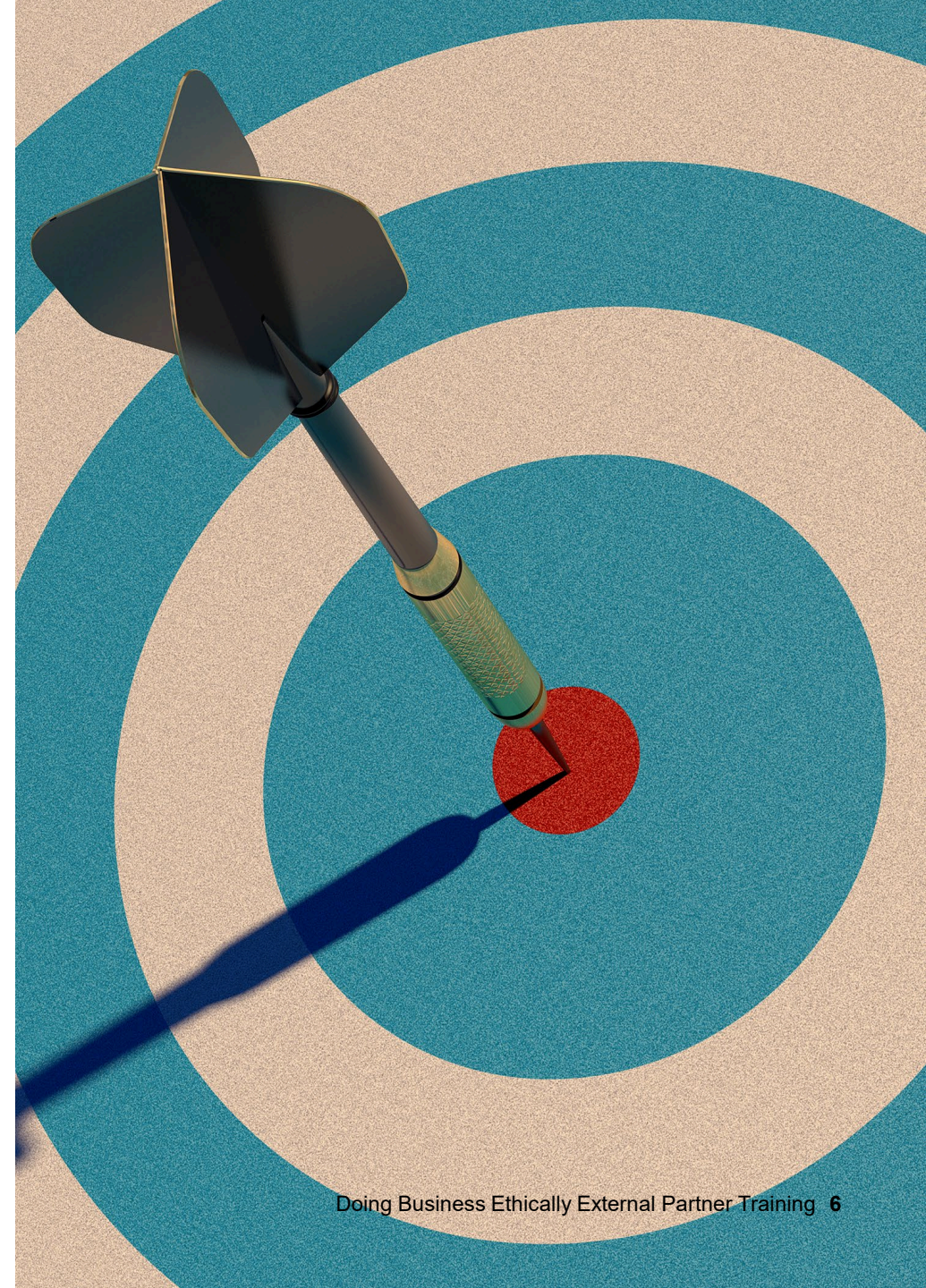


Anti-Bribery and Anti-Corruption Training Module

Learning Objectives:

By the end of this course, you should be able to:

- Describe the compliance obligations of Novartis and their external partners regarding anti-corruption and anti-bribery laws
- Explain key anti-bribery and anti-corruption concepts
- Recall Novartis policy requirements and expectations for external partners with regards to Anti-Bribery/Anti-Corruption



Why are you receiving this training?

Novartis' Obligations:



Under anti-bribery and anti-corruption laws, Novartis may be held responsible if an external partner:

- **Offers or pays a bribe, or**
- **Gives, offers, or promises to give anything of value for the purpose of improperly influencing any decision**

Novartis and its Affiliates do not tolerate any form of bribery or corruption. External partners must not bribe, and they must not use intermediaries, such as agents, consultants, advisers, distributors or any other external partners to commit acts of bribery.

Novartis' Expectations:



Novartis expects that the external partners that they work with to:

- **Comply with the law**
- **Adhere to ethical business practices**
- **Observe our standard requirements, as per the external partner Code**

Novartis' Anti-Corruption Commitment

Our Commitment

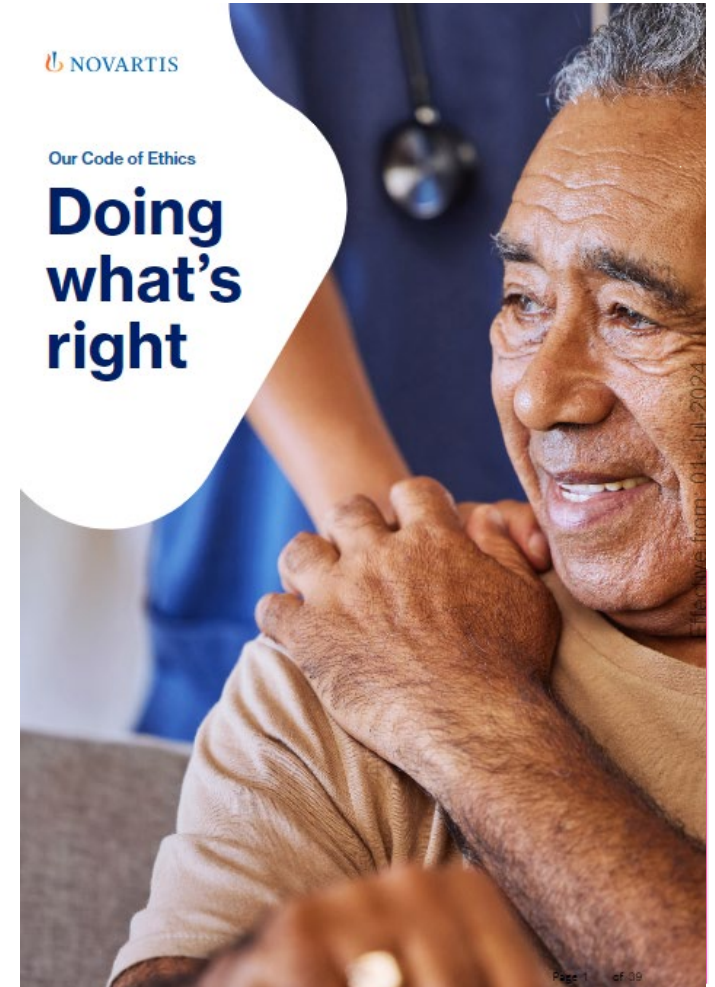
To have zero tolerance for bribery or corruption in any form

We will not give, offer or promise to give anything of value or accept, request or agree to receive anything of value for the purpose of improperly influencing any decisions. **We will not** use external parties to commit acts of bribery or corruption.

Why it matters:

To improve access to medicine we need to address corruption. It erodes trust in both governments and businesses, and reduces access to public services including health and education

To learn more about Novartis' Code of Ethics ([click here](#))



What is Bribery?

A bribe is:

Offering, giving or promising – or authorizing someone else to offer, give, or promise – an improper benefit directly or indirectly, with the intention of influencing or rewarding the behavior of someone to obtain or retain a commercial advantage.

Bribery can take a variety of forms, for example (but not limited to):



- Facilitation payments
- Gifts, hospitality and expenses
- Employing relatives
- Benefits and perks to relatives



- Charitable contributions & sponsorships
- Political donations
- Lobbying
- Agents



How is bribery being confronted?

Example of International and local regulations:

US Foreign Corrupt Practices Act (FCPA) (1977)

“Many companies doing business ... retain a local individual or company to help them conduct business... Companies should be aware of the risks involved in engaging third-party agents or intermediaries. The fact that a bribe is paid by an external partner does not eliminate the potential for criminal or civil FCPA liability.”

UK Bribery Act (2010)

...where an organization fails to prevent bribery by persons associated with it, it is a defense for an organization “to prove that despite a particular case of bribery it nevertheless had adequate procedures in place to prevent persons associated with it from bribing”.

Examples of Domestic Regulations:

Countries have stepped up in their fight against corruption. These include, but are not limited to:

Year	Law
1977	United States: Foreign Corrupt Practices Act (FCPA)
1997	China: Criminal Law of the People's Republic of China
1999	Canada: Corruption of Foreign Public Officials Act (CFPOA)
2010	United Kingdom: Bribery Act 2010
2013	India: Prevention of Corruption (Amendment) Bill 2013
2014	Brazil: Clean Company Act
2015	Spain: 2015 Organic Law
2016	Switzerland: Swiss Criminal Code (current version)
2016	India: Lokpal and Lokayukta (Amendment) Act 2016
2016	South Korea: Kim Young-ran Law
2016	France: Sapin II
2017	Mexico: The General Law of the National Anti-Corruption System

Test your knowledge

Let's have a look at the following situations and determine if this is a bribe:

	A bribe	Not a bribe
Buying travel packages for your client and family members for a tour after you won business locally.	<input type="checkbox"/>	<input type="checkbox"/>
Charitable donations given with the intention of influencing business.	<input type="checkbox"/>	<input type="checkbox"/>
Meeting with potential business partner who hands you over a luxurious branded pen as a gift.	<input type="checkbox"/>	<input type="checkbox"/>
Paying an "express fee" to a customs officer to process customs clearance more quickly for a product delivery to a hospital.	<input type="checkbox"/>	<input type="checkbox"/>

Test your knowledge

See the correct answers below:

Buying travel packages for your client and family members for a tour after you won business locally.



Charitable donations given with the intention of influencing business.



Meeting with potential business partner who hands you over a luxurious branded pen as a gift.



Paying an “express fee” to a customs officer to process customs clearance more quickly for a product delivery to a hospital.



Anti-Bribery and Anti-Corruption - Remember...

- ✓ Bribery payments **can be disguised** as entertainment and used as a bribe to secure a business deal.
- ✓ **Charitable donations, sponsorships and other contributions** can also be used as bribes and are especially problematic when given to public officials.
- ✓ You should **never receive anything of value in return for business**. If you encounter this situation, you should politely decline the gift.
- ✓ **Facilitation payments** to a public official in order to speed-up an official process, regardless of the amount, **should not be made or tolerated**.

! Ensure that you have read and adhere to the Third Party Code throughout your engagement with Novartis



Some scenarios that could potentially raise a red flag

- ✓ **Items of significant value** requested in return for preferential treatment
- ✓ **Commission payments or extra fees** required for carrying out normal work
- ✓ **Invoices inflated** in value after the contract is agreed on
- ✓ Requests for foreign travel for **family members**
- ✓ **Charity donations** required in exchange for business contracts
- ✓ Requests for money transfers to **external partner accounts** or different countries
- ✓ Connections to **public officials**
- ✓ **Atypical requests** for anonymity or confidentiality in business deals



Summary

Zero Tolerance for bribery or corruption

Novartis and its Affiliates do **not tolerate any form of bribery** or corruption.

External partners must not bribe, and they must not use intermediaries, such as agents, consultants, advisers, distributors or any other business external partners to commit acts of bribery.

Novartis does not distinguish between public officials and employees of private sector organizations so far as bribery is concerned; bribery is not tolerated, regardless of the status of the recipient.

Novartis will not engage any external partners who commit acts of bribery or corruption.

More information on our [Code of Ethics](#)



Handling concerns of misconduct

External partners are expected to implement a complaint mechanism.

All external partner employees should be encouraged to raise complaints without fear of retaliation.

- External partners shall investigate potential bribery or corruption and take corrective action if needed.
- All external partner employees may also report any concern about work being done on behalf of Novartis via the confidential web-based reporting platform or the phone hotline accessible through the Novartis SpeakUp Office line.

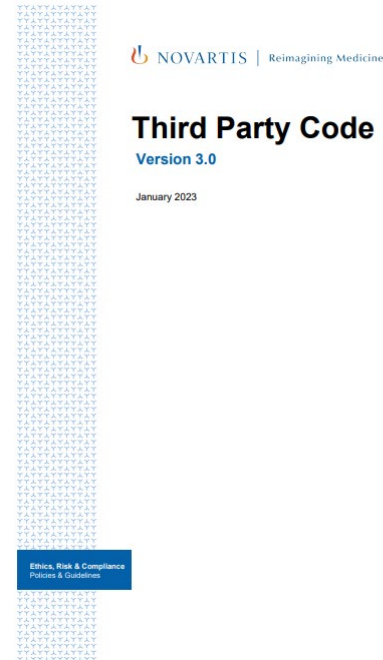
More information on our [SpeakUp hotline](#)



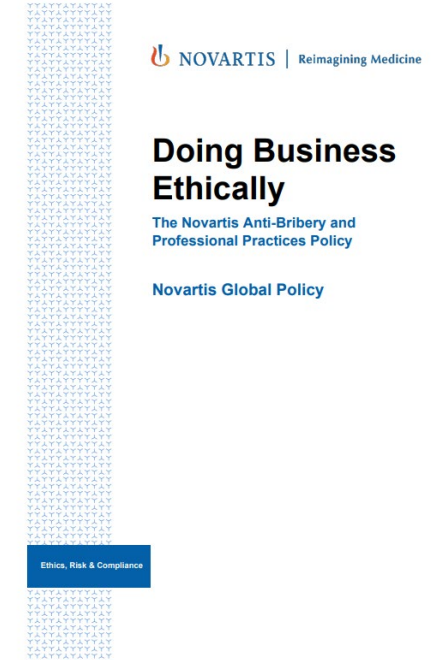
References



For more information on
our [Code of Ethics](#)



For more information on
our [Third Party Code](#)



For more information on
our [Doing Business Ethically Policy](#)

Interactions with External Stakeholders

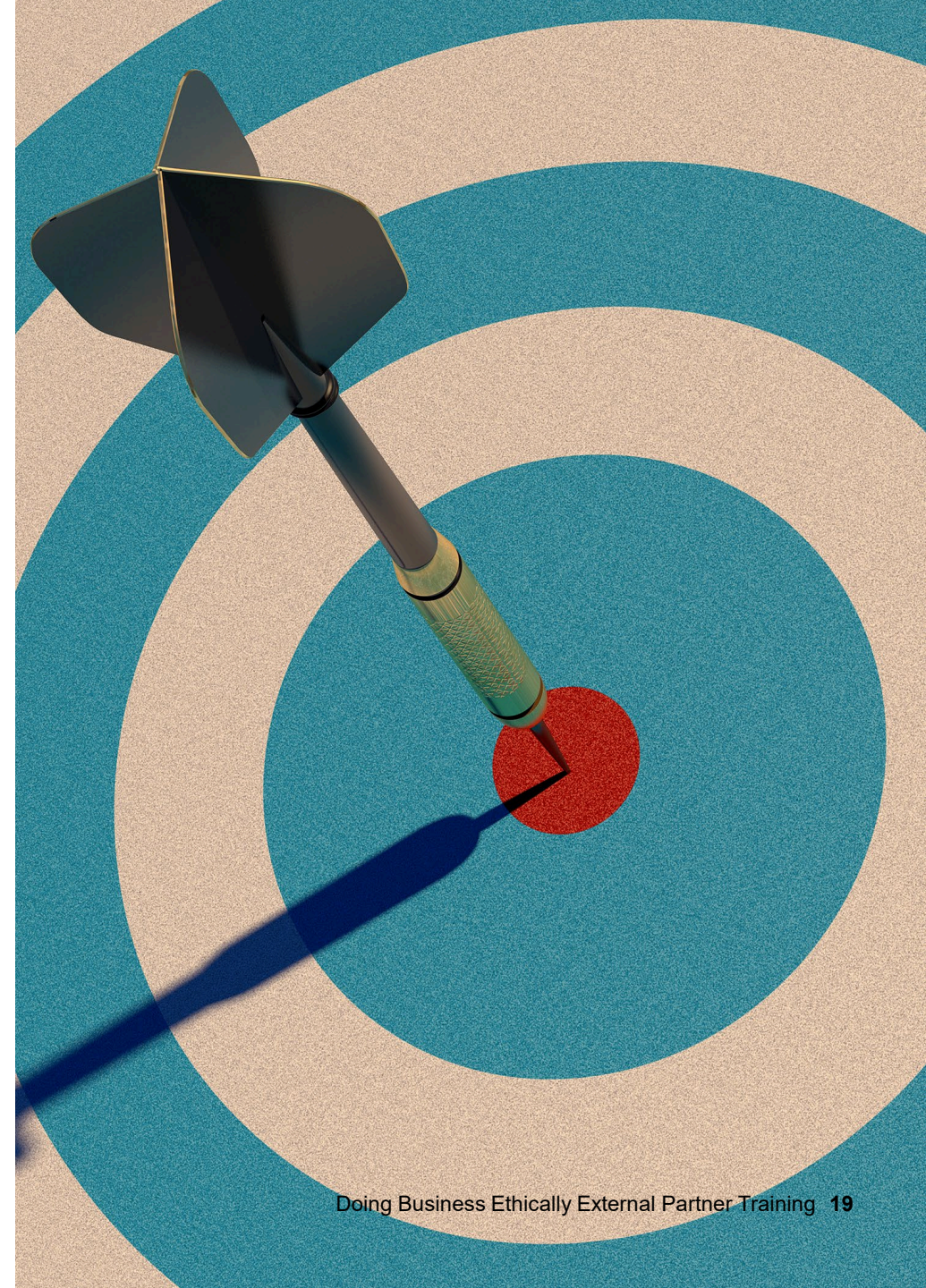


Interactions with External Stakeholders

Learning Objectives:

By the end of this section, you should be able to:

- List Novartis policy requirements for external partners that interact with external stakeholders
- Identify GOs and HCPs
- Recall key points of Novartis DBE Policy regarding common interactions between TPs and external stakeholders:
 - Professional Services
 - Events and Professional Meetings
 - Gifts, Samples, and other Items
 - Standards of Information and Materials



Novartis' Professional Practices Commitment

Our Commitment

To conduct business ethically, and in compliance with laws and regulations.

We are committed to the same high standards of ethical business conduct wherever we do business. We will adhere to our “Doing Business Ethically” policy, which helps to guide our daily decision making

Why it matters:

Interacting in an ethical manner and operating with integrity has a profound impact on finding new ways to expand patient access to our treatments and building trust with society

To learn more about Novartis' Code of Ethics ([click here](#))

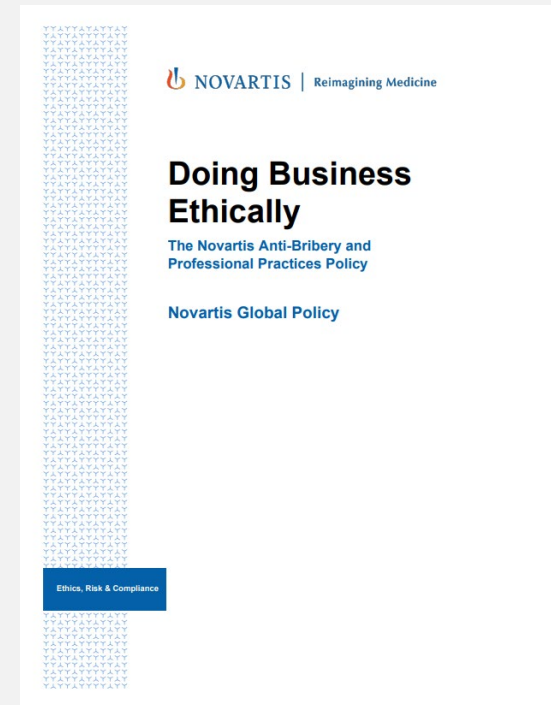


Interactions with External Stakeholders

When interacting with external stakeholders on behalf of Novartis, we expect from you as an external partner to apply high standards of ethical business conduct:

- Adhere to all **legal and regulatory requirements** and comply with relevant **industry codes**.
- Engage with our stakeholders in a **responsible, ethical and transparent** manner.
- Ensure that your interactions have **clear, truthful, transparent, and appropriate objectives**.
- Treat stakeholders with **mutual respect** and **avoid** the creation of any actual, potential or perceived **conflict of interest**.
- Determine **fair, appropriate, and objective compensation** for the services provided by stakeholders and **disclose transfers of value**.
- Value and **respect** the **independent decision-making** undertaken by our stakeholders
- Safeguard the **integrity and validity of the data** obtained during research, and respect and protect the **rights, safety, and well-being** of patients and animals.
- Do not seek or knowingly accept any information that would violate **confidentiality and / or privacy rights** of any of our stakeholders.

For more information, visit our [Doing Business Ethically Policy](#)



Who are External Stakeholders?

Examples:

- Health Care Professionals (HCPs) and Health Care Organizations /HCOs)
- Patients, Caregivers and Patient Organization (PO)
- Government Officials (GO), payers
- academic and scientific Institutions
- wholesalers and distributors, suppliers,
- non-governmental organizations (NGO)
- Media Representatives and Social Media Influencers

What are the types of interactions?

Interactions with External Stakeholders may take various forms:



Engagement

Novartis works with reputable External Stakeholders that have the necessary experience and capabilities to provide the services requested

(e.g. Research, Professional Services, Events, Learning and Education, Public Policy Engagement, Patient Engagement, Patient Support Programs, Social Media etc.)



Funding & Collaboration

Novartis collaborates with or provides funding to reputable External Stakeholders to improve healthcare, advance scientific/medical knowledge, or support the communities where we live and work.



Gifts, Samples, and other Items

Novartis never promises, offers, or provides anything of value with the intent of influencing the recipient to do something favoring Novartis, to reward such behavior, or to refrain from doing something disadvantaging Novartis.

Let's look at some External Stakeholders in more detail...

- **Health Care Professionals (HCPs)**
- **Government Officials (GOs)**

Healthcare Professional (HCPs)



A Healthcare Professionals (HCP) is:

- Any member of the **medical, dental, pharmacy or nursing professions**
- Or any other persons who during their professional activities **may prescribe, recommend, purchase, supply, sell or administer a pharmaceutical product.**
- Some HCPs are also considered Government officials (GO).

Our Guiding Principles



- HCPs have a **professional duty of care** and need to make **independent decisions** in the patient's best interest.
- Our interactions might potentially be perceived as **inappropriately influencing** the HCPs' independent decision making, in favor of their own personal and/or Novartis' interests rather than serving the patient's best interest



When we act with HCPs and other external stakeholders, we commit to **act responsibly, ethically, transparently, and professionally.** Irrespective of how we engage, we interact appropriately, and **without** the intent, perception, or consequence of **inappropriately influencing any decision of our stakeholders**, including the recommendation, purchase, prescription, or use of our products.

Government Official (GOs) / Public Official (POs)



Government Officials (GOs)/Public Officials (POs) are:

- 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 government 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 a **government official according to applicable laws, regulations, and industry code**

Our Guiding Principles



Interactions with government and public officials may be subject to **additional laws, regulations, and industry codes**. Some medical and scientific personnel qualify as government and public officials, for example **HCPs in public hospitals**. We can engage these stakeholders in their capacity either as medical and scientific personnel or as government and public officials only and different guidelines apply to each case.

Identifying HCPs and GOs



Let's determine which of the following individuals is a Health Care Professional (HCP) and/or a Government/Public Official (GO):

	HCP	GO
A pharmacist working at a private hospital	<input type="checkbox"/>	<input type="checkbox"/>
A customs agent	<input type="checkbox"/>	<input type="checkbox"/>
A physician working in a public hospital	<input type="checkbox"/>	<input type="checkbox"/>



Identifying HCPs and GOs

Let's determine which of the following individuals is a Health Care Professional (HCP) and/or a Government/Public Official (GO):

See the correct answer(s) below.

	HCP	GO
A pharmacist working at a private hospital	<input checked="" type="checkbox"/>	<input type="checkbox"/>
A customs agent	<input type="checkbox"/>	<input checked="" type="checkbox"/>
A physician working in a public hospital	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Feedback:

- Pharmacists are Healthcare professionals, as they may prescribe, recommend, purchase, supply, sell or administer a pharmaceutical product.
- Customs agents are government officials, as they are acting in an official capacity for or on behalf of a government.
- Some medical and scientific personnel qualify as government and public officials, for example HCPs in public hospitals. Additional laws, regulations, and industry codes may apply.

Interactions with HCPs and GOs - Remember...

Whenever interacting with a Healthcare professional or a Government Official on behalf of Novartis, we expect you to:

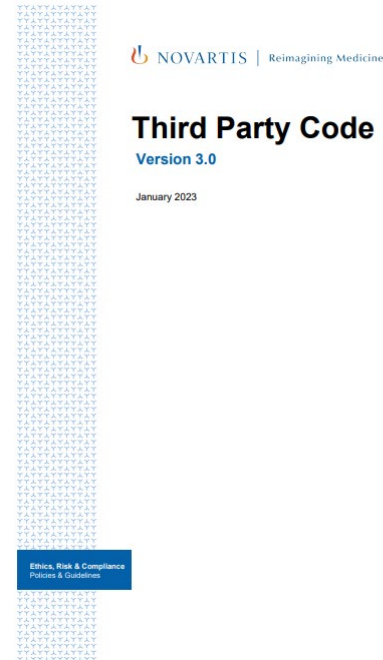
- ✓ Interact appropriately **without** the intent, perception, or consequence of **inappropriately influencing** any decision of our stakeholders, including the recommendation, purchase, prescription, or use of our products.
- ✓ Adhere to all applicable **laws, regulations, and industry codes**.
- ✓ Be aware that some **medical and scientific personnel** qualify as **government and public officials**, for example HCPs in public hospitals and follow the appropriate guidelines.
- ✓ Ensure that the interaction does not create an **actual, potential, or perceived conflict of interest**.



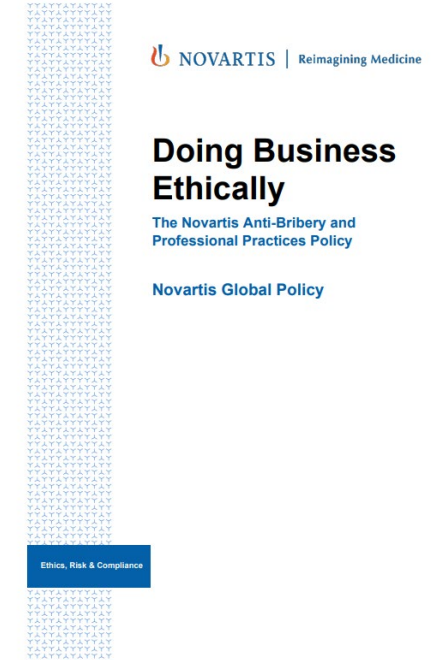
References



For more information on
our [Code of Ethics](#)



For more information on
our [Third Party Code](#)



For more information on
our [Doing Business Ethically Policy](#)

Let's look at some interactions in more detail...

- Professional Services
- Events & Professional Meetings
- Gifts, Samples & other Items
- Standards of Information and Materials

Interaction with External Stakeholders

Professional Services

Engagements of External Experts, who have specialist knowledge or expertise in a particular area, to provide consultancy, advisory, speaking, or similar services related to healthcare.



Scenario 1a – Speaker engagement with an HCP

Let's look at a scenario where Novartis has asked you to line up a healthcare professional to act as a program speaker. What do you think are valid reasons for engaging the HCP to be a speaker?

Select all that apply.

- ☐ The HCP has the necessary experience and capabilities to speak on that topic.
- ☐ You want to encourage the HCP to promote Novartis products among his/her peers.
- ☐ You want to recognize the HCP for being a high prescriber for Novartis products.
- ☐ There is a legitimate need for the HCP's speaking service.



Scenario 1a – Speaker engagement with an HCP

Let's look at a scenario where Novartis has asked you to line up a healthcare professional to act as a program speaker. What do you think are valid reasons for engaging an HCP to be a speaker?

See the correct answer(s) below.



The HCP has the necessary experience and capabilities to speak on that topic.



You want to encourage the HCP to promote Novartis products among his/her peers.



You want to recognize the HCP for being a high prescriber for Novartis products.



There is a legitimate need for the HCP's speaking service.

Feedback:

When engaging external stakeholders we need to have a legitimate need and they need to have the necessary experience and capabilities to provide the services requested. We do not engage them to inappropriately influence their independent decision making, including the recommendation, purchase, prescription, or use of our products.



Scenario 1b – Speaker engagement with a GO

You would like to engage a government official who is a member of the National Reimbursement Committee to speak at an event.

Which questions should you ask yourself?

Select all that apply.

- ☐ Is there a legitimate need for this engagement?
- ☐ Am I sure no actual, potential, or perceived conflicts of interest could arise?
- ☐ Is my interaction transparent?
- ☐ Am I sure that the interaction won't be perceived as trying to inappropriately influence the government official?
- ☐ Have I considered all applicable laws, regulations and rules?



Scenario 1b – Speaker engagement with a GO

You would like to engage a government official who is a member of the National Reimbursement Committee to speak at an event.

Which questions should you ask yourself?

See the correct answer(s) below.



Is there a legitimate need for this engagement?



Am I sure no actual, potential, or perceived conflicts of interest could arise?



Is my interaction transparent?



Am I sure that the interaction won't be perceived as trying to inappropriately influence the government official?



Have I considered all applicable laws, regulations and rules?

Feedback:

All these questions are important to ask yourself and answer with YES before interacting with government officials. Paid Professional Services must not be obtained from a government and public official who has direct / actual position to influence Novartis business e.g., as a decision maker on a committee approving products listings or providing market authorization.

Professional Services – Remember...

When you engage external stakeholders for professional services on behalf of Novartis, we expect from you:

- ✓ Only engage external stakeholders for a **legitimate need**.
- ✓ Work with **reputable External Stakeholders** that have the necessary **experience and capabilities** to provide the services requested.
- ✓ Document the paid services to be performed in a **written agreement** before the services are started.
- ✓ Do not pay for services without **adequate evidence** of performance.
- ✓ **Interact appropriately** without the intent, perception, or consequence of inappropriately influencing any decision of the stakeholder, including the recommendation, purchase, prescription, or use of our products.
- ✓ Do not engage GOs for paid professional services if they have a **direct/actual position to influence Novartis business**.
- ✓ Follow all **additional laws, regulations, and industry codes** when engaging HCPs, scientists, and academics, who fall under the definition of a GO.
- ✓ Payments made must be fair market value and reasonable.



Interactions with External Stakeholders

Events and Professional Meetings

Organization of events and professional meetings, or funding of third-party organized events and professional meetings for scientific, educational, policy, promotional, or other professional purposes. Such events may be conducted physically or virtually.





Scenario 2a – Event Location

You were asked to organize a local diabetes symposium for 50 HCPs. One of the HCPs recommends a 5-star Hilton Golf and Beach resort as the venue.

What should you do?

Select the correct answer.

- ☐ Go with the recommendation and organize the event at the 5-star resort.
- ☐ Look for a less extravagant venue.
- ☐ Tell them that the company will pay for the 5-star hotel and inclusive of two rounds of golf, if they ensure to prescribe your new medicine.
- ☐ Stop the engagement with the HCP immediately.



Scenario 2a – Event Location

You were asked to organize a local diabetes symposium for 50 HCPs. One of the HCPs recommends a 5-star Hilton Golf and Beach resort as the venue.

What should you do?

See the correct answer(s) below.

- ☐ Go with the recommendation and organize the event at the 5-star resort.
- ☒ Look for a less extravagant venue.
- ☐ Tell them that the company will pay for the 5-star hotel and inclusive of two rounds of golf, if they ensure to prescribe your new medicine.
- ☐ Stop the engagement with the HCP immediately.

Feedback:

Events organized on behalf of Novartis must be conducted in a venue that is conducive for the purposes of the exchange, may not be perceived as extravagant or inappropriate, and in accordance with local laws, regulations, and industry codes.

Scenario 2b – Event Purpose

You are planning a speaker event for HCPs to learn about a new Novartis product.

What is a legitimate purpose to organize such an event?

Select the correct answer.

☐

Because it is a great opportunity to build relationships with potential future prescribers.

☐

Because the event meets an educational need that the HCPs have to learn about new treatment options.

☐

Because it is a great opportunity to bring together medical experts.



Scenario 2b – Event Purpose

You are planning a speaker event for HCPs to learn about a new Novartis product.

What is a legitimate purpose to organize such an event?

See the correct answer(s) below.



Because it is a great opportunity to build relationships with potential future prescribers.



Because the event meets an educational need that the HCPs have to learn about new treatment options.



Because it is a great opportunity to bring together medical experts.

Feedback:

Events organized on behalf of Novartis must have a clear and justifiable purpose and the event must be conducted transparently.

Novartis events must not be initiated to purely build relationships.

Scenario 2c – Concert

You are planning a training session for Healthcare Professionals. The event agency informs you that there is a classical concert of a famous orchestra in town. You ask yourself if this could be a nice event to invite the HCPs to after the training session.

Should you invite the HCPs to the concert?

Select the correct answer.

- ☐ Yes, this is a good idea. The HCPs would keep this concert event in good memories which might encourage them to prescribe our products.
- ☐ Yes, as long as the concert is not longer than the duration of the training event, it is okay to invite them.
- ☐ No, you should not invite the HCPs to the concert.
- ☐ Yes, it is okay to invite the HCPs, but you should not put the concert on the training event agenda.



Scenario 2c – Concert

You are planning a training session for Healthcare Professionals. The event agency informs you that there is a classical concert of a famous orchestra in town. You are thinking that this could be a nice event to invite the HCPs to after the training session.

Should you invite the HCPs to the concert?

See the correct answer(s) below.

- ☐ Yes, this is a good idea. The HCPs would keep this concert event in good memories which might encourage them to prescribe our products.
- ☐ Yes, as long as the concert is not longer than the duration of the training event, it is okay to invite them.
- ☒ No, you should not invite the HCPs to the concert.
- ☐ Yes, it is okay to invite the HCPs, but you should not put the concert on the training event agenda.

Feedback:

No, you should not invite the HCPs to the concert. We do not provide entertainment to any HCP attending Novartis business meetings, congresses or comparable events.

Events and Professional Meetings

When organizing events and professional meetings on behalf of Novartis, we expect you to...

- ✓ Have a **clear and justifiable purpose** for the event, conduct it transparently, and in a **venue that is conducive for the purposes** of the exchange, may not be perceived as extravagant or inappropriate, and in accordance with local laws, regulations, and industry codes.
- ✓ Provide hospitality only to the participants in the form of refreshments and/or meals, which are **moderate, reasonable, and incidental to the main purpose** of the event.
- ✓ **Not provide entertainment to any HCP**. For other stakeholders provide entertainment only if it is an appropriate, incidental part of such events, allowed under local laws and regulations. Do not pay for side or extended trips.
- ✓ Do **not pay** for entertainment, hospitality, or travel costs of **anyone who accompanies an invitee** to a Novartis meeting.



Interactions with external stakeholders

Gifts, Samples, and other items

Never promise, offer, or provide anything of value with the intent of influencing the recipient to do something favoring Novartis, to reward such behavior, or to refrain from doing something disadvantaging Novartis.



Scenario 3a – Small gift for an HCP

You are going to visit an HCP on behalf of Novartis. There is an upcoming holiday in the HCP's country and it's the local custom to give a small gift around this holiday. You'd like to give him something.

What do you need to consider?

Select the correct answer.

- ☐ The gift should be valuable enough to impress the HCP.
- ☐ The gift should be modest and reasonable.
- ☐ It is not allowed to provide gifts to Healthcare Professionals.



Scenario 3a – Small gift for an HCP

You are going to visit an HCP on behalf of Novartis. There is an upcoming holiday in the HCP's country and it's the local custom to give a small gift around this holiday. You'd like to give him something.

What do you need to consider?

Select the correct answer.

- ☐ The gift should be valuable enough to impress the HCP.
- ☐ The gift should be modest and reasonable.
- ☒ It is not allowed to provide gifts to Healthcare Professionals.

Feedback: It is not permitted to provide **ANY** gifts of any kind including personal gifts, Cultural Acknowledgements or promotional aids, whether branded or unbranded, to **HCPs, Healthcare Organizations, Patient Organizations, or patients** and their family members.

Scenario 3b – Small gift for a GO

You are going to visit the Minister of Finance on behalf of Novartis. There is an upcoming holiday in the GO's country and it's the local custom to give a small gift around this holiday. You'd like to give him something.

What do you need to consider?

Select the correct answer.

- ☐ Is the gift modest, reasonable, infrequent and given in a transparent way?
- ☐ Are gifts to GOs permitted under the local laws, regulations, and applicable internal policies?
- ☐ Do we make sure not to provide gifts to GOs who can make a decision about Novartis?
- ☐ Could the gift give rise to a real or perceived conflict?
- ☐ Would not providing such a token cause embarrassment or be perceived as disrespectful in the context of local customs?



Scenario 3b – Small gift for a GO

You are going to visit the Minister of Finance on behalf of Novartis. There is an upcoming holiday in the GO's country and it's the local custom to give a small gift around this holiday. You'd like to give him something.

What do you need to consider?

Select the correct answer.

- ☒ Is the gift modest, reasonable, infrequent and given in a transparent way?
- ☒ Are gifts to GOs permitted under the local laws, regulations, and applicable internal policies?
- ☒ Do we make sure not to provide gifts to GOs who can make a decision about Novartis?
- ☒ Could the gift give rise to a real or perceived conflict?
- ☒ Would not providing such a token cause embarrassment or be perceived as disrespectful in the context of local customs?

Feedback: All these questions should be considered. Giving gifts to government and public officials is discouraged. Gifts are only allowed, if all questions above are answered with YES.

Gifts

When interacting with external stakeholders on behalf of Novartis, we expect from you...

- ✓ **Never promise, offer, or provide anything of value** with the intent of influencing the recipient to do something favoring Novartis.
- ✓ **Do not provide** entertainment, **any gifts of any kind** including personal gift, cultural acknowledgements, or promotional aids, whether branded or unbranded, **to HCPs, HCOs, PO or patients** and their family members.
- ✓ **Do not provide cash** and gifts that are cash equivalent to any External stakeholder
- ✓ **Gifts** to Government/Public Officials, media and other external stakeholders (not mentioned above) **are discouraged**.



Scenario 3c – Samples

Dr Rogers is a leading local cardiologist in an emerging market. You plan on offering samples of a recently launched drug to familiarise her with the product. This high-cost product has high efficacy rates in treating heart disease which could benefit Dr Rogers' patients.

Which questions should you ask yourself, when receiving such a request?

Select all that apply.

- ☐ Is it permitted by local laws, regulations, and industry codes to provide free samples of pharmaceutical products?
- ☐ Could this be perceived as an inducement to increase the prescription, selling or administering of our drug?
- ☐ Are the samples marked as samples to prevent resale or any other misuse?
- ☐ Is the main purpose of the samples to familiarize the HCPs and patients with the product, with the ultimate purpose of enhancing patient care?



Scenario 3c – Samples

Dr Rogers is a leading local cardiologist in an emerging market. You plan on offering samples of a recently launched drug to familiarise her with the product. This high-cost product has high efficacy rates in treating heart disease which could benefit Dr Rogers' patients.

Which questions should you ask yourself, when receiving such a request?

See the correct answer(s) below.

- ☒ Is it permitted by local laws, regulations, and industry codes to provide free samples of pharmaceutical products?
- ☒ Could this be perceived as an inducement to increase the prescription, selling or administering of our drug?
- ☒ Are the samples marked as samples to prevent resale or any other misuse?
- ☒ Is the main purpose of the samples to familiarize the HCPs and patients with the product, with the ultimate purpose of enhancing patient care?

Feedback: We must always ask ourselves if the provision of such samples could be considered an inducement to increase the use of a Novartis product. Samples must not be used in Market Access and/or Patient Support Programs (PSPs). All local laws, regulations and industry codes need to be followed.

Samples

When providing Samples to HCPs, we expect you to...

- ✓ Comply with **local laws, regulations, and industry codes** with regards to provision of free samples
- ✓ When providing samples (where permitted):
 - ❖ Do **not provide** them **as an inducement** to recommend and/or prescribe, purchase, supply, sell or administer Novartis products.
 - ❖ Distribute over the counter product samples directly to patients, only where permitted by local laws, regulations, and industry codes.
 - ❖ Ensure they are **marked as samples** to prevent resale or any other misuse.



Scenario 3d – Medical Book

The cardiologist Dr. Miller asks if you can provide to him a very expensive medical book outlining the anatomical basics for optical diseases for medical practice.

What should you do?

Select the correct answer.

☐

As it is a medical book, it is okay to provide it to Dr. Miller.

☐

You should not provide the book to Dr. Miller.



Scenario 3d – Medical Book

The cardiologist Dr. Miller asks if you can provide to him a very expensive medical book outlining the anatomical basics for optical diseases for medical practice.

What should you do?

See the correct answer below.



As it is a medical book, it is okay to provide it to Dr. Miller.



You should not provide the book to Dr. Miller.

Feedback:

Educational items may only be provided, where permitted by local laws, regulations, and industry codes and must be intended for the direct education of HCPs or patients and the value must be reasonable.

There does not seem to be a legitimate need for providing this book to doctor Miller, as it is very expensive and it is not within his area of expertise.

Items of Medical Utility and Educational Items

When providing Items of Medical Utility and Educational Items to HCPs, we expect you to...

- ✓ Where permitted by **local laws, regulations, and industry codes**, we may offer or provide items of medical utility to HCPs if **modest, reasonable in value**, and offered on an **occasional basis**.
- ✓ When providing items of medical utility (where permitted), they must:
 - ❖ Be **intended for the direct education of HCPs, or patients**, or to assist patients in the administration of their treatment, or management of their conditions.
 - ❖ **Not offset normal operating costs** or routine business expenses or have a personal benefit to the HCP.
 - ❖ **Not use product branding** (no product logo), unless branding is essential for the correct use of the item by the patient, or required by local law, regulation, or industry code.
 - ❖ The value of books and subscriptions must be **reasonable**, Other educational items must be of **modest value**.
- ✓ When providing devices to HCPs/HCOs for limited and agreed-upon duration
 - ❖ Consider potential **transfer of value**, ensure appropriate labelling, and do not provide them prior to receipt of the marketing authorization for their intended use in that market
 - ❖ Ensure the ownership of the device remains with Novartis for the entire duration of the evaluation and that the devices are not stored at any HCP/HCO facility when not being evaluated.



Interactions with External Stakeholders

Standards of Information and Materials

Sharing with stakeholders information that is accurate, clear, fair, balanced, truthful, and not misleading.



Scenario 4a – Off-label question

Dr Scott heard about the use of breast cancer treatment drug Oculonova in pregnant women in a small-scale study. Dr Scott has a patient, who might benefit from the drug, as she is not responding to her current treatment. Dr Scott asks you as the Sales Rep for any information on it. This indication is not in the approved label.

How should you respond?

Select the correct answer.

- ☐ Share with Dr. Scott the latest Oculonova study.
- ☐ Tell her about the outcome of the study, but do not share the respective article.
- ☐ Tell her that you are not in a position to respond to her question, but that you will send your Medical colleague to discuss this with her.



Scenario 4a – Off-label question

Dr Scott heard about the use of breast cancer treatment drug Oculonova in pregnant women in a small-scale study. Dr Scott has a patient, who might benefit from the drug, as she is not responding to her current treatment. Dr Scott asks you as the Sales Rep for any information on it. This indication is not in the approved label.

How should you respond?

See the correct answer(s) below.

- ☐ Share with Dr. Scott the latest Oculonova study.
- ☐ Tell her about the outcome of the study, but do not share the respective article.
- ☒ Tell her that you are not in a position to respond to her question, but that you will send your Medical colleague to discuss this with her.

Feedback: You may receive unsolicited requests for information on unapproved drugs and indications (off-label) from HCPs and other stakeholders. Only certain representatives from Medical or any other function with assigned authority may provide such information reactively.

Standards of Information and Materials

When providing information and materials on behalf of Novartis, we expect you to...

- ✓ Share information that is **accurate, clear, fair, balanced, truthful, and not misleading**
- ✓ Only promote products in alignment with the **approved label** and upon receipt of **marketing authorization**.
- ✓ Only use information in a promotional context that is substantiated either by reference to the **approved label** or by **scientific evidence**.
- ✓ If you receive unsolicited requests for information on **unapproved drugs and indications (off-label)** from HCPs, patient organizations, and other External stakeholders, make sure that only **representatives** from Medical or other functions **with assigned authority** provide such information reactively.
- ✓ Do not use materials with any promotional content in any non-promotional context to **avoid** and perception of **disguised promotion**.
- ✓ If applicable, follow **additional Novartis guidelines** provided to you.



For any interaction with external stakeholders, always remember to ask yourself:

- 1 **What is the intent of your interaction...**
 - Does it serve a legitimate and unmet need?
 - Does it respect the stakeholders' independent decision-making?
 - Does it benefit patients, the practice of medicine, overall healthcare systems?
- 2 **Have you assessed the risks of the interaction and taken relevant mitigating actions to avoid the**
 - Risk of actual, potential, or perceived bribery
 - Risk of inappropriate influence
 - Risk of disseminating misleading information
- 3 **Is your activity being executed in a manner that**
 - It is ethical
 - Avoids the identified risks
 - Is in compliance with local laws, regulations and industry codes

Thank you