NOVARTIS

Anti-Bribery Third Party Guideline

Novartis Global Guideline for engaging Third Parties

Effective: May 1, 2017

Version GIC 100.18.V3.EN

Group I&C

Contents

Glossary

Associate – Directors, officers, managers, and employees of Novartis AG and its affiliates.

Business Owner - The person from the business unit who requests or sponsors the engagement of a Third Party and who is responsible for the business impact of such engagement.

Compliance Confirmation – A Compliance Confirmation is an attestation requested from the Third Party to confirm their compliance with the law and to confirm the validity of the information collected as part of the due diligence. A template for the Compliance Confirmation is attached to Annex 5 of this Guideline.

Due Diligence Checklist – The Due Diligence Checklist is a document that is designed to help the Due Diligence Coordinator to conduct and document the efforts related to the due diligence. This checklist (issued by Group I&C) is not an exhaustive list but ensures that the main sources of information will be collected.

Due Diligence Coordinator – The person who receives the request to perform the risk-based Due Diligence on the prospective Third Party.

Executive Summary – The Executive Summary is a document that captures and summarizes the information collected during the due diligence process, the identified Red Flags, the proposed measures to address the risks identified with the proposed Third Party engagement, and the decision whether or not to engage the prospective Third Party.

Guideline – The term Guideline refers to this Anti-Bribery Third Party Guideline.

Material Change to the Structure of the Third Party – A material change to the structure of a Third Party covers the following two situations:

(a) **Change in ownership/control:** the Third Party or any person who Controls the Third Party has a change of Control. "Control" in this context means the direct or indirect ownership of more than 50% of the equity interest or voting rights in a corporation or business entity, or the ability in fact to control the management decisions of such corporation or business entity (e.g., by the appointment of a majority of the directors or management or otherwise); or

(b) **Change to membership of the executive body of the Third Party:** there is a change to the membership of the executive body of the Third Party. For example, a change to the **executive** management of the Third Party (e.g., CEO, N-1 to CEO).

Questionnaire for Third Parties – The Questionnaire is designed to assist the Due Diligence Coordinator to gather information from the Third Party amongst others about their business, their ownership and structure, government relations, compliance with laws and commercial references.

Red Flag – A Red Flag is information that indicates an increased risk of corruption or another potential issue with a Third Party, such as any undesirable characteristic that pertain to a company's ownership, business structure or relationships and/or compliance with laws.

Third Party – The term Third Party is defined in Section 2.8 of the Anti-Bribery Policy as any natural person or legal entity with whom Novartis interacts and who poses, due to the nature of their business, a particular level of bribery risk. Section 1.4 of this Guideline sets out the specific types of services that pose a bribery risk.

List of Acronyms

DDC – Due Diligence Coordinator

Group I&C – Group Integrity & Compliance

LCO – Local Compliance Officer

PEP – Politically Exposed Person

RCO – Regional Compliance Officer

1 Introduction

1.1 Purpose

Our continued commitment to ethical business conduct is central to earning and maintaining the trust and support of our key stakeholder groups and realizing our aspiration to be a trusted leader in changing the practice of medicine.

To achieve this aspiration, it is essential that Novartis only engages Third Parties that are suitable from an anti-bribery perspective. We expect Third Parties with whom we work to comply with bribery and corruption laws and to observe our requirements concerning anti-bribery.

This Guideline elaborates on section 2.8 of the Novartis Anti-Bribery Policy, and gives Associates instructions as to the requirements for the management of Third Parties from an Anti-Bribery perspective.

1.2 Scope and Applicability

This Guideline applies to all Associates.

It enters into force as of May 1, 2017 and replaces the previous version of the Novartis Third Party Guideline dated March 1, 2012.

This Guideline is not intended to override or supersede more restrictive laws relating to bribery. In addition to this Guideline, other Novartis principles and practices or equivalent documents may apply to the engagement of Third Parties (e.g. professional practices and procurement rules).

1.3 Roles and Responsibilities

The **Business Owner** has ultimate responsibility for managing and mitigating the bribery risks associated with Third Parties and must:

- confirm the legitimate need for the goods and/or service provided by the Third Party
- identify whether a Third Party falls within the scope of this Guideline
- ensure that the Due Diligence Coordinator (DDC) is provided with all necessary information to fulfill the requirements outlined in this Guideline
- validate the information captured in the Executive Summary and decide on the engagement of the Third Party
- ensure that the Agreement covers the content of the clauses listed in Section 2.2.1
- monitor the Third Party in adherence to the contract and in accordance with the measures identified in the Executive Summary
- define an audit plan, if necessary, for the Third Party in consultation with LCO and Legal

Procurement shall appoint DDCs in the relevant market, where possible cross-divisionally, and shall communicate the appointment.

The **DDC** is responsible for:

- Performing the due diligence or ensuring that it is performed for all new Third Parties or existing Third Parties who fall within the scope of this Guideline by virtue of the provision of a new service (see sections 2.1.1 and 2.1.2)

- Supporting the Business Owner in making an informed decision about the engagement of the Third Party (see section 2.1.3)
- Monitoring and performing any subsequent assessments after the Third Party has been engaged (see section 2.2.2)

If the Third Party is domiciled in a different country to the Novartis contracting entity, the DDC of the contracting entity may decide to request support from the DDC of the country in which the Third Party is domiciled. If such a request is made, the DDC in that country is obliged to provide support.

The **Local Compliance Officer** (LCO) is responsible for advising the Business Owner and the DDC. The LCO must approve any decision to pursue the engagement of any Third Party that is classified as medium or high risk.

Legal is responsible for supporting the Business Owner, as requested, when engaging the Third Party, including but not limited to the overall adequacy of the contract and inclusion of all necessary clauses.

The **Head Legal** of the local division or unit must approve any decision to pursue the engagement of any Third Party that is classified as high risk.

Group Integrity & Compliance (Group I&C) provides resources supporting the rollout of this Guideline (e.g., guidance, communication toolkits). They are responsible for keeping a central repository of these resources. A database of appointed DDCs is also maintained by Group I&C.

1.4 Third Parties Subject to this Guideline

A Third Party is subject to this Guideline if they engage in any of the activities specified below:

- Sell or resell or assist in selling or reselling Novartis products, through demand generation and/or active promotion of a Novartis product
- Act on behalf of Novartis or assist Novartis in dealing with government agencies to obtain permits, licenses, visas, regulatory approvals, pricing, reimbursement, participation in tenders, etc.
- Act on behalf of Novartis or assist Novartis in dealing or interacting with health care professionals
- Conduct clinical trials on behalf of Novartis

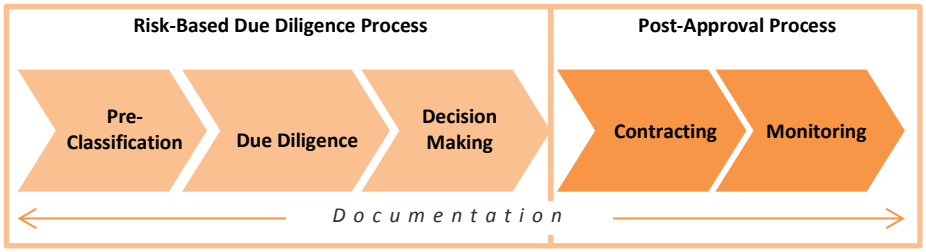
Further guidance to support the identification of Third Parties that fall within the scope of this Guideline can be found in Annex 6.

Due diligence on Third Parties that are selected as mandatory global providers for one or more of the activities listed above must be undertaken at the global level. Local organizations engaging such mandatory global providers for the activities that are subject to global due diligence are not required to perform a separate due diligence.

2 Anti-Bribery Third Party Risk Management

The management of Third Parties requires the identification, assessment, mitigation and monitoring of the risk associated with the engagement of Third Parties.

The following risk based due diligence and post-approval processes must be implemented to ensure that the risk is adequately managed:



2.1 Risk Based Due Diligence Process

2.1.1 Pre-classification of Third Party

Before the commencement of the due diligence, the Third Party must be pre-classified as ”low”, “medium” or “high” risk using the Novartis Risk Classification Methodology as per the Responsible Procurement Risk Assessment Process. This provides an indication of the risk-adjusted efforts required for each step of the management of the Third Party (e.g., due diligence, decision making, contracting and monitoring). Risk pre-classification is based on risk-related factors such as the geography, the type of services provided and background of Third Party.

2.1.2 Due Diligence

The purpose of the due diligence is to:

- Confirm the pre-classification through the collection and verification of due diligence process relevant information relating to the Third Party
- Identify and assess specific areas of elevated risk and seek to mitigate those risks

For all Third Parties, information on the Third Parties’ business, ownership & management, government relations, compliance with laws, licenses, registrations, and certifications (such as licenses to trade) and commercial references must be collected. An essential component of this exercise is the full and accurate completion of the Novartis Anti-Bribery “Questionnaire for Third Parties” (Questionnaire) by the Third Party.

Depending on the Third Party risk pre-classification, the following due diligence activities must be completed.

Risk Classification	Minimum Activities Required
Low	Basic Due Diligence: • Verification of Questionnaire responses • Global screening of Third Party (sanctions and watch lists, etc.) • Conduct adverse internet & media search of Third Party in local language(s) and/or English
Medium	Mid-Level Due Diligence: • All low-risk due diligence activities plus: • Screening of key individuals [sanctions and watch lists, Politically Exposed Person list (PEP), etc.] • Conduct adverse internet and media searches of key individuals in the local language(s) and/or English
High	Enhanced Due Diligence: • All low and medium-risk due diligence activities plus: • Local public database searches focusing on in-country public records including litigation, regulatory, criminal, bankruptcy and directorship role of the Third Party • Verification of references collected in Questionnaire

Group I&C identifies external vendors that will provide the activities listed above.

Where the outcome of the due diligence is unclear due to conflicting or inadequate information, the DDC must conduct further investigation. This may require communication with the Third Party to clarify and validate the information collected, or to gather additional information. The DDC should discuss and align with Legal and/or the Local Compliance Officer as to whether further investigation by Global Security is needed.

Where Red Flags have been identified, mitigating and monitoring measures (if available) must be proposed to address the associated risks.

To conclude the due diligence, the DDC must prepare an Executive Summary of the information collected and verified during the due diligence; the Executive Summary must include:

- a final risk classification (i.e., low, medium or high risk)
- any Red Flags identified
- any proposed mitigating measures and monitoring activities

In order to support an informed decision, the DDC must send the Executive Summary to the Business Owner. In cases where the Third Party is classified as medium or high risk the Executive Summary shall also be sent to the LCO (for medium and high risk) and the Head Legal (for high risk only) of the local division or unit.

2.1.3 Decision Making

The Business Owner is responsible for deciding whether or not to engage the Third Party based on the results of the concluded due Diligence. For Third Parties that are classified as medium risk, the LCO has to approve the engagement. For Third Parties that are classified as high risk, the LCO and the Head Legal of the local division or unit have to approve the engagement.

Depending on the risk classification of a Third Party, the following functions and roles must be involved:

Risk Classification	**Decision**	**Consultation**	**Escalation in case of disagreement about**	
			Risk Classification, Mitigation and/or Monitoring	**Third Party Engagement**
Low Risk	Business Owner	DDC	LCO	-
Medium Risk	Business Owner & LCO	DDC	*Regional Compliance Officer (RCO) & next level manager of the Business Owner*	-
High Risk	Business Owner, LCO & Head Legal of the local division or unit	DDC	*Regional Compliance Officer (RCO) & Divisional Country Head*	

Legal, Finance, Integrity & Compliance, and other functions should be consulted by the Business Owner as appropriate.

The decision concerning the engagement of a Third Party must be documented in the Executive Summary. The concluded Executive Summary must be signed by the representatives of the functions involved.

Where Red Flags have been identified during the due diligence that could not be fully resolved (e.g. due to incomplete information), the Business Owner can only proceed if the other functions involved in decision making approve the engagement, and specific monitoring measures are documented in the Executive Summary.

Any due diligence that has been concluded may later be used by other Business Owners (from the same or another Novartis division or unit), provided that (i) the nature of the service remains the same (ii) the due diligence is not older than 3 years, and (iii) there is no Material Change to the Structure of the Third Party and there are no grounds to believe that the risk classification of the Third Party has increased.

A new due diligence may be conducted for any Third Party that failed to be approved after a prior Novartis due diligence if there are reasonable grounds to believe that the risk associated with the Third Party has decreased.

2.2 Post Approval Process

2.2.1 Contracting

Before a Third Party can be engaged by Novartis, or receive any payment from Novartis, a written contract or another written document with a similar legally binding effect (hereinafter referred to as "Agreement") must be concluded and must have come into effect. The Agreement must clearly describe the subject matter (e.g. goods and/ or services to be performed), and the terms of remuneration.

Clauses that address the following concepts must be included in each Agreement with a Third Party:

- An unequivocal statement that they will not promise, offer, pay, cause to pay, accept payment or induce payment or take any action that could be considered a bribe, and any such action will be grounds for immediate termination
- An unequivocal statement, agreeing to comply with the law, including those related to bribery and corruption such as the US Foreign Corrupt Practices Act, UK Bribery Act
- No sub-contracting of the services without Novartis prior written consent
- No assignment of the Agreement without Novartis prior written consent
- Obligation to inform Novartis of any Material Change in the Structure of the Third Party
- The right to terminate the Agreement upon occurrence of any of the following events (to the extent permitted under local law):
    - If the Third Party breaches the "Compliance with Law" clause
    - In the event of any material omission or misrepresentation of information provided by the Third Party in the due diligence
    - In the event of a material delay (at least thirty days) or failure to provide a Compliance Confirmation (where applicable)

  The termination right should be immediate where permitted under local law.

For Third Parties that pose a medium or high risk, the following additional concepts should be included in the Agreement:

- Right to audit the Third Party
- Refusal by the Third Party to be audited may result (subject to local law) in immediate termination of the Agreement by Novartis
- Responsibility to deliver during the term of the Agreement a Compliance Confirmation for each calendar year. The Compliance Confirmation shall be delivered during the first quarter of the year following the end of the calendar year to which the Compliance Confirmation relates
- Responsibility to provide training to the personnel of the Third Party or assign responsibility for such training to Third Party personnel according to the *Compliance Training Guideline for Externals Part 2: Companies and External Service Providers*

Examples of clauses that capture the aforementioned concepts are included in Annex 4 of this Guideline. Legal counsel shall have the authority to draft their preferred contract language which still adequately addresses the above concepts. Furthermore, some of these concepts may be covered by appropriate language in the Novartis Supplier Code if the Novartis Supplier Code is referenced in the Agreement with the Third Party.

2.2.2 Monitoring

The Third Party must be monitored on an on-going basis by the Business Owner and the respective DDC. The monitoring must be appropriate to the risk classification.

(a.) Event Triggered Monitoring Activities:
In instances where there is a change in circumstances (e.g., a Material Change to the Structure of a Third Party or newly identified Red Flags), the impact on the decision to continue to engage the Third Party and any possible mitigating and monitoring measures must be assessed. The Executive Summary must be updated accordingly.

This requires that the DDC and Business Owner work closely to inform each other of any relevant information that they become aware of that may have a negative impact on the risk classification of the Third Party.

(b.) Renewal of the Due Diligence:
The due diligence process must be renewed in line with the Novartis contract life and in any case at least every three years.

(c.) Pre-Defined Monitoring Activities:
An annual “Compliance Confirmation” shall be provided to Novartis by all Third Parties classified as medium and high risk. An example of such confirmation is included in Annex 5 of this Guideline.

The Business Owner in consultation with the LCO and Legal must define, if necessary, an appropriate audit plan for the Third Party.

3 Sub-Contracting and Assignment of Rights and Obligations

Any subcontracting of the services contracted by Novartis is subject to prior written approval in line with the Decision Making process defined in section 2.1.3. The risk classification of the Third Party applies to its sub-contractor.

Clauses that are materially equivalent to those that have been inserted into the Agreement with the Third Party as a result of applying section 2.2.1 should be included in the contract between the Third Party and its sub-contractor.

The requirements relating to sub-contracting also apply to any assignment of rights or obligations by the Third Party.

4 Record Keeping

Documentation related to the engagement of the Third Party must be retained to demonstrate that Novartis has taken reasonable precautions to avoid involvement in corrupt activities or with corrupt actors by providing evidence of credible due diligence, decision making, contracting and monitoring. The relevant documents should at a minimum include:

Due Diligence Process Documentation:

- Completed “Questionnaire for Third Parties” including any documentation provided by the Third Party
- Results of the Basic, Mid-Level or Enhanced Due Diligence
- Results of investigations performed by Global Security, if requested
- Completed “Due Diligence Checklist”
- Executive Summary of due Diligence
- Decision by the Business Owner, by the LCO (for medium or high risk Third Parties), and by Head Legal of the local division or unit (for high risk Third Parties); this should be shared across business units / divisions through the DDC

Contract Related Documentation:

- Agreement (e.g., Contract, Purchase Order, and evidence of relevant documentation required by Procurement)
- Documentation to support the conclusion that services and goods are priced at no more than market value (e.g., a fair market value analysis or the results of a procurement bidding process)
- Evidence of the transfer of value and/or proof the services or products were delivered (e.g. invoices)

Monitoring Related Documentation (as applicable based on Guideline):

- Documentation of training as defined by the Compliance Training Guideline for Externals Part 2: Companies and External Service Providers
- Evidence of an annual “Compliance Confirmation” by any medium or high risk Third Party
- Evidence of the results of any Third Party Audit, where performed
- Evidence of any additional local monitoring, where performed

All relevant documents should be made available at country level.

5 Implementation

5.1 Training

Associates must familiarize themselves with this Guideline. They must be trained in line with the Novartis-wide compliance training curriculum and the *Integrity & Compliance Training for Novartis Internal Associates Framework Guideline*. Additional training requirements may be defined in local company procedures.

Group I&C and/or divisional I&C provide the respective training tools.

The local compliance organization performs training about this Guideline. Procurement provides training about the systems and tools used to execute this Guideline.

5.2 Breach of this Guideline

Breaches of this Guideline will not be tolerated and can lead to disciplinary and other actions up to and including termination of employment.

5.3 Responsibilities with regard to the implementation of this Guideline

Subject to local adaption, every Novartis manager must implement this Guideline 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 the principles and rules set out in this Guideline.

The owner of this Anti-Bribery Third Party Guideline is Group I&C. They will prepare a high-level plan for the rollout of this Guideline which shall also define roles and responsibilities.

Any questions should be addressed to a representative from Integrity & Compliance or Legal.

Annexes

1. Questionnaire for Third Parties
2. Due Diligence Checklist
3. Executive Summary
4. Sample Clauses
5. Sample Compliance Confirmation
6. Guidance to support the identification of Third Parties that fall within the scope of the Anti-Bribery Third Party Guideline