NOVARTIS | Reimagining Medicine

Third Party Code

Version 3.0

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Ethics, Risk & Compliance
Policies & Guidelines

Contents

Introduction

While the Novartis purpose - to reimagine medicine to improve and extend people's lives - drives our values and defines our culture, our ethical principles guide us in our everyday decision-making and ensure we act with integrity and do what's right.

Novartis promotes the societal and environmental values of the United Nations Global Compact and United Nations Guiding Principles on Business and Human Rights to its Third Parties and uses its influence where possible to encourage their adoption. The Novartis Third Party Code (the "Third Party Code") is based on the United Nations Global Compact, the United Nations Guiding Principles on Business and Human Rights, and other international standards or accepted good practices. The Third Party Code is aligned with the Novartis Code of Ethics which is binding for all Novartis associates.

Novartis requires its Third Parties to comply with the standards defined in the Third Party Code. Furthermore, our Third Parties are expected to adopt standards that cover the same principles and content included in our Third Party Code with their own suppliers and to perform beyond legal compliance.

Being a member of the Pharmaceutical Supply Chain Initiative (PSCI), Novartis aligns the Third Party Code with the Pharmaceutical Industry Principles for Responsible Supply Chain Management for ethics, human rights, labor rights, health and safety, environment and related management systems.

Novartis believes that society and business are best served by responsible business behaviors and practices. Fundamental to this belief is that business should not only operate in compliance with applicable laws, rules and regulations, but that our behaviors address underlying societal concerns. Novartis is aware that differences in local operating environments and laws create challenges in applying our standards as defined in the Third Party Code globally. Novartis also believes that our standards are best implemented through a continual improvement approach that advances Third Party performance over time.

The Third Party Code does not replace local law or labor agreements. Novartis expects Third Parties to operate in compliance with applicable laws, rules, regulations and collective bargaining agreements, in addition to the standards contained herein. Where compliance with the Third Party Code would violate local law or collective bargaining agreements, Third Parties are expected to comply with local requirements while seeking to uphold the principle underpinning the relevant Third Party Code standard.

Steffen Lang, Ph.D.
President, Novartis Operations

Klaus Moosmayer, Ph.D.
Chief Ethics, Risk & Compliance Officer

Links referenced on this page and a glossary of terms used can be found at the end of this document.

Monitoring against our standards

Adherence to the standards contained in this Third Party Code is one of the criteria used in the Novartis Third Party selection and evaluation process.

Novartis expects Third Parties to adhere to applicable legal standards and any higher standards contained herein. Under some circumstances, where the Third Parties have shown and continue to show a material commitment to improvement, Novartis is willing to work with them to bring about improvements through engagement and collaboration. This may include audits, development, and progress monitoring of corrective action plans, referring Third Parties to external experts, and other reasonable improvement plans.

Novartis Third Party Standards

1 Human Rights

Novartis is committed to conducting our business in a manner that respects the rights and dignity of all people. We will strive to prevent, mitigate, and remedy adverse human rights impacts throughout our workplace, business operations and in the communities in which we work. In order to fulfil this commitment, and in accordance with the United Nations Guiding Principles on Business and Human Rights (UNGPs), Novartis is required to identify, assess, and address any human rights risks or impacts in its operations and supply chains.

Novartis is committed to working with Third Parties who operate in a manner that is consistent with our values and ethical principles, including respect for human rights. In addition to the specific requirements set out under "*Section 2. Labor Rights – Fair Employment Practices*", Third Parties are expected and strongly encouraged to conduct human rights due diligence, as set out in the UNGPs, on all internationally recognized human rights, and at a minimum, those expressed in the International Bill of Human Rights (i.e., the Universal Declaration of Human Rights, International Covenant on Civil and Political Rights, and International Covenant on Economic, Social and Cultural Rights) and the principles concerning fundamental rights set out in the International Labor Organization's Declaration on Fundamental Principles and Rights at Work.

Human rights due diligence is the ongoing process through which Third Parties can "know and show" that they respect human rights. This includes assessing risks to human rights, integrating the findings into its decision-making and actions to mitigate the risks, tracking the effectiveness of these measures, and communicating its efforts internally and externally. The UNGPs recommend that all companies, regardless of size, sector or operational context, conduct human rights due diligence in order to prevent or mitigate any risks to human rights that they cause, contribute to or are directly linked to their operations, products or services through their business relationships; and to participate in the remediation, in whole or in part, of human rights impacts which they cause or contribute to.

In case of a perceived risk of a violation of human rights, Third Parties are required to notify us of this, and the steps being taken to avoid or mitigate such a breach, and where this is not possible, for the Third Party to provide for the remediation of the adverse human rights impact where they have caused or contributed to this. Any notification shall be sent to human.rights@novartis.com.

2 Labor Rights – Fair Employment Practices

Third Parties shall be committed to uphold human rights for Workers, as set out in the International Bill of Human Rights, and to promote decent work and the four pillars of the International Labor Organisation's Decent Work Agenda.

Third Parties are expected to nominate dedicated personnel with responsibility for Human Resources to oversee compliance with the labor elements of the Third Party Code.

Novartis expects Third Parties to implement a risk evaluation process for their own supply chain in line with the standards defined herein and to communicate the Third Party Code to its own suppliers and partners. Third Parties are expected to have visibility over their own supply chain and implement responsible sourcing and purchasing practices.

The Third Party Code is applicable to all stakeholders in the Novartis supply chain; including Workers onsite and offsite, directly employed by Third Parties or by agencies and other intermediaries.

2.1 Employment shall be freely chosen

STANDARD

Third Parties shall not use or engage in any form of Modern Slavery, including any form of prison labor.

Workers are free to leave their jobs after reasonable notice and are paid their wages on time and in full upon leaving.

Workers are not required to hand over original versions of their personal documents to secure employment, unless permitted or required by local law. In any such event Workers must have access to their papers at all times.

Workers can freely move to and from their employment or residence at all times and are not controlled by security guards.

Workers do not pay recruitment fees or deposits to secure their job, their employer-provided accommodation, or any training and equipment necessary to carry out their jobs.

Third Parties must recruit foreign migrant labor responsibly:

- No Worker should pay recruitment fees or deposits to secure a job.
- Third Parties shall oversee all steps of the recruitment process and carry out due diligence at every stage of the labor migration process.
- Third Parties shall ensure foreign migrant Workers have access to grievance mechanisms in a language they understand throughout the entire labor migration process that give effective access to remedy.
- Third Parties shall ensure the safe and dignified return of migrant Workers to their countries of origin at any time, without fear of reprisal or penalties and without incurring extraordinary debt.

Third Parties shall ensure that private or public security forces engaged by Third Party for security or other purposes shall not violate the human and labor rights of any Worker.

2.2 There shall be no Child Labor

STANDARD

Children below the local minimum working age, the age of compulsory education or the ages set out in the International Labor Organization Core Conventions (whichever is higher) shall not be employed.

No young Worker below the age of 18 shall be employed in hazardous or night work or any form of forced labor. Young Workers must be above a country's legal age for employment and the age established for completing compulsory education.

If Children are found engaged in prohibited Child Labor, Third Parties shall put in place a suitable plan to support the child, which may involve removing the child from the workplace while continuing to pay salary and the cost of formal or vocational training, accommodation or other costs as necessary, to the child until adulthood. These policies and programmes shall conform to the provisions of the relevant ILO standards.

2.3 There shall be no Discrimination

STANDARD

Discrimination at any time from recruitment to leaving employment for reasons such as race, national or ethnic minority status, ethnicity, color, age, sex, sexual orientation, gender, gender identity or expression, social origin, disability, religion, political affiliation, union or association membership, pregnancy, marital status, family status or any other protected category as defined by local laws is not tolerated.

Disciplinary and grievance procedures to deal with discrimination are in place and all Workers are made aware of how they can report incidences of discrimination or any unfair employment practices. Third Parties must enforce a non-retaliation policy that permits Workers to express their concerns about the workplace without fear of retribution or losing their jobs.

2.4 Fair Treatment must be given

STANDARD

Third Parties shall treat Workers with dignity and respect and provide a workplace free of harassment and with no threat of harsh and inhumane treatment. Workers neither face nor are threatened with bullying, sexual harassment, corporal punishment, any verbal, sexual, physical or psychological abuse or coercion of any kind.

Workers understand disciplinary and grievance procedures, and fines imposed on Workers as part of a disciplinary action are legal and fair. Supervisors, managers or co-Workers found abusing Workers are disciplined accordingly.

Workers are not subject to unreasonable body searches.

Physical security searches are only carried out by authorized bodies, according to local legal standards, and by same-sex security guards.

Workers do not have to pay supervisors, managers or co-Workers to avoid victimization or receive preferential treatment.

2.5 Regular Employment shall be provided

STANDARD

Employment relationships should be established through contract on the basis of national law and best industry practice. Employment terms are communicated to Workers in writing (paper or electronically) in a language they understand before they commence employment.

Obligations to employees under labor or social security laws and regulations arising from the regular employment relationship shall not be avoided through the use of labor-only contracting, sub-contracting, or home-working arrangements, or through apprenticeship schemes where there is no real intent to impart skills or provide regular employment, nor shall any such obligations be avoided through the excessive use of fixed-term contracts of employment.

2.6 Fair Wages and Benefits shall be paid

STANDARD

Wages and benefits should be fair and adequate. Wages and benefits for standard hours, excluding overtime, should meet national minimum requirements or industry benchmarks, whichever is higher. We strongly encourage all Third Parties to pay workers a living wage, benchmarked in the local market.

Payment terms are communicated to Workers in writing (paper or electronically) in a language and format they understand before they commence employment and each time they are paid.

Deductions as a disciplinary measure are only taken in accordance with local law.

Equal pay for equal work must be ensured – temporary Workers, contractors or Workers on probation shall be entitled to the same compensation as their directly employed, permanent peers.

Overtime shall be compensated at a premium rate, in accordance with national law or collective agreements. Where these do not exist, overtime pay shall be no less than 1.25 times regular pay.

2.7 Working Hours must not be excessive

STANDARD

Third Parties shall have a system in place to monitor the hours and wages paid to all staff, and complete hours and payroll records must be kept for all Workers.

Standard working hours shall not exceed eight hours per day or 48 hours per week (or 56 hours per week on average for shift work processes).

Overtime hours shall not exceed the limits established in national law or under collective agreements, whichever offers more protection to the Worker. Where these do not exist, overtime hours shall be limited to the degree necessary to ensure the health and safety of Workers. All overtime work must be consensual and not used to replace regular employment.

Workers are given time off, breaks and appropriate leaves in accordance with local laws, ILO standards, collective agreements and/or industry benchmarks, whichever offers more protection to Workers.

2.8 The right to Freedom of Association and Collective Bargaining must be respected

STANDARD

Third Parties shall respect the rights of Workers to freely form labor unions, seek representation and/or join Workers' councils of their own choosing. Workers understand how to raise issues if they wish. Where collective agreements are in place, they are communicated to all Workers in a language they can understand.

Workers and representatives shall be able to communicate openly with management regarding working conditions without threat of reprisal, intimidation, or harassment. Workers are able to bargain collectively and understand how to raise issues if they wish. Where collective agreements are in place, they are communicated to all Workers in a language they can understand.

Where the right to freedom of association and collective bargaining is restricted under law, the employer facilitates, and does not hinder, the development of parallel means for independent and free association, bargaining and grievance raising.

Health & Safety and Environmental Compliance & Sustainability

Given the breadth, complexity and size of the Novartis supply chain, the standards outlined in sections 3 and 4 for Health, Safety and Environmental Sustainability (HSE) provide Third Parties with basic standards and concepts that Novartis expects adherence to throughout its supply chain.

Novartis expects each Third Party to understand the applicable HSE standards for its specific products or services and to augment these standards with the additional product/service-specific standards as necessary. The effectiveness of the protection needs to be verified by trained and experienced or certified subject matter experts.

3 Health and Safety

Third Parties shall comply with all applicable health and safety laws and regulations by providing a safe and healthy working environment and, if applicable, safe and healthy company living quarters. The health and safety elements include:

3.1 Hazard Information

STANDARD

Third Parties shall have programs and systems in place to provide Workers with safety information relating to hazardous materials and education to protect them from potential hazards. Hazardous materials can include but are not limited to raw materials, isolated intermediates, products, solvents, cleaning agents and wastes.

3.2 Risks and Process Safety

STANDARD

Third Parties shall have systems and programs in place to identify both occupational and process hazards as well as potential impacts on surrounding communities. They should quantify such

hazards, define the risk levels appropriately and have programs and systems in place to prevent or mitigate these risks (e.g., catastrophic releases of chemicals, fumes, dust).

3.3 Worker Protection

STANDARD

Third Parties shall provide sufficient training to its Workers, establish preventive measures to avoid physical or mental fatigue and have systems and processes in place to protect Workers from exposure to chemical, biological and physical hazards (including physically demanding tasks) in the workplaceand company-provided living quarters.

3.4 Emergency Preparedness and Response

STANDARD

Third Parties shall develop and distribute emergency plans across their facilities and company-provided living quarters and surrounding communities. Third Parties should minimize the potential impact of any emergency by implementing suitable emergency plans and response procedures.

4 Environmental Compliance & Sustainability

Third Parties shall comply with all applicable environmental laws and regulations. They are expected to act beyond legal compliance and actively minimize the environmental impact of their activities and products over their lifecycle:

4.1 Environmental Compliance

STANDARD

Environmental Authorizations: Third Parties shall have processes and systems to conform with applicable environmental laws and regulations. Required environmental permits, licenses, information, registrations and restrictions shall be obtained, and their operational and reporting requirements followed.

Spills and Releases: Third Parties shall have processes and systems in place to prevent and mitigate any spills and releases to the environment which substantially impair the natural foundations for the preservation and production of food or prevent access to clean drinking water, impede or destroy the access to sanitary facilities or harm the health of a person. They shall remedy any impacts that are caused.

Water Quality: Third Parties who manufacture or formulate Active Pharmaceutical Ingredients (APIs) and/ or drug substances shall manage manufacturing effluents to avoid any water quality impacts on the receiving aquatic environment. Such Third Parties shall be required to demonstrate safe discharge levels for releases to the aquatic environment in accordance with local regulatory requirements and conform to the AMR Industry Alliance Manufacturing Framework. Third Parties supplying API shall also be required to demonstrate water quality performance to Novartis through disclosure of mass balance and/or analytical monitoring results.

Waste and Emissions: Third Parties shall have processes and systems in place to ensure safe handling, movement, storage, recycling, reuse, or management of waste. Any generation and disposal of waste, emissions to air and discharges to water, with the potential to adversely impact human health or the livelihoods or way of life of surrounding communities or the environment (giving priority to Active Pharmaceutical Ingredients) shall be appropriately minimized, properly managed, controlled and/or treated prior to release into the environment.

4.2 Environmental Sustainability

STANDARD

Targets: As a leading pharmaceutical company, our ambition is to be a catalyst for change. We are driving sustainability through our own operations as well as across Third Party operations to become carbon neutral in the value chain by 2030 and net-zero by 2040. Our ambition is also to become plastic neutral and water sustainable by 2030. It is expected that Third Parties shall actively contribute and support us to achieve our environmental targets.

Third Parties shall ensure that all products and/or services procured by Novartis are carbon neutral by 2030. Third Parties shall also ensure that water is used responsibly, and waste is reduced continuously throughout their operations. Third Parties should adopt eco-friendly materials for

products and/or services where feasible.

Engagement: Third Parties shall establish a sustainability roadmap for products and/or services procured by Novartis, goals and targets, particularly in terms of greenhouse gas (GHG) emissions reduction, responsible use of water, waste reduction and the use of eco-friendly materials. As part of this roadmap, Third Parties shall define baselines, set milestones to track their performance, and identify improvement opportunities to reduce their environmental footprint.

Third Parties shall align their emission reduction targets with and have them approved by the Science Based Targets initiative (SBTi). Third Parties shall be transparent about their environmental practices and performance via established global reporting framework or platforms. Third Parties shall also ensure similar standards are followed by their suppliers and overall supply chain.

Third Parties shall be required to make available Novartis product/ service specific environmental sustainability data to track their performance. Upon request from Novartis, Third Parties shall have the relevant environmental data assured by an independent third party.

Third Parties shall engage with their suppliers to actively minimize the environmental impact of their supply chain.

Third Parties shall also allow Novartis to report their environmental sustainability data related to products and/or services procured by Novartis to independent third-party platforms in an anonymized form, as may be required for the purposes of external reporting, benchmarking and auditing.

Sustainability and Resource Efficiency: Third Parties shall have processes and systems in place to strive for a positive effect on climate, by reducing their carbon footprint, waste and water usage and making efficient use of natural resources. As members of society, we have to protect the environment for future generations. Where surrounding communities rely on ecosystem services for their sustenance or livelihoods, Third Parties shall ensure that their use of natural resources does not adversely impact community members' rights to water and an adequate standard of living and they shall remedy any impacts that are caused.

Eviction and unlawful deprivation: Third Parties shall refrain from the unlawful eviction and the unlawful deprivation of land, forests and waters in the acquisition, construction or any other use of land, forests and waters, the use of which secures the livelihood of a person.

5 Animal Welfare

STANDARD

Animals shall be treated respectfully, with pain and stress minimized. Animal testing should be performed after consideration to replace animals, reduce the numbers of animals used or refine procedures to minimize distress. Alternatives should be used wherever scientifically valid and acceptable to regulators.

REQUIREMENTS

Novartis is committed to globally achieving high standards of Animal Welfare whenever animals are involved in a Novartis study or procedure. The Novartis Animal Welfare Standard applies to all internal and Novartis external animal studies. It corresponds with the US regulations, namely the AW Act (USC 7; 1966) and Regulations, and the US Guides for the Care and Use of Laboratory and Agricultural Animals (including all vertebrates). More stringent criteria apply for Non-Human Primates.

Third Parties are required to comply with all applicable local and national laws and regulations relating to Animal Welfare. In addition, they are required to comply with the following key principles, which embody the Third Party requirements of the Novartis Animal Welfare Policy (where local/national laws and regulations impose stricter requirements, the stricter requirements shall be followed):

- The welfare of animals is of primary concern.
- The 3Rs (Replace, Reduce, Refine) are applied.

- Studies are carried out by well-trained, competent and experienced personnel.
- Finished cosmetics and their ingredients will not be tested on animals.
- Only animals specifically bred for research purposes are purchased and used, except for some farm animals, companion animals used in clinical studies and fish.
- Animals are treated respectfully and cared for in accordance with the particular needs of the given species and individual, as defined by current veterinary care and practice guidelines for animals used in experiments.
- Animals experience the minimum amount of discomfort, distress or pain and appropriate methods for sedation, analgesia or anesthesia are utilized whenever possible.
- Particular care and attention is paid to the transportation of animals, including use of appropriate and adequate devices and/or facilities for transport in accordance with applicable guidelines and legal requirements.
- The principles and requirements apply to Novartis-initiated studies performed at Third Party facilities (e.g., contract research organizations, universities and other companies).

6 Anti-Bribery and Fair Competition

6.1 Anti-Bribery

STANDARD

Third Parties shall not bribe any public official or private person and shall not accept any bribes. No intermediaries, such as agents, advisers, distributors or any other business partners, shall be used to commit acts of bribery.

Third Parties shall comply with applicable laws and regulations and industry standards related to anti-corruption.

REQUIREMENTS

Facilitation Payments: Novartis prohibits any facilitation payments being made in the context of any Novartis business.

Gifts, Hospitality and Entertainment: Gifts, hospitality and entertainment will not be given, offered or promised to be given to receive anything of value for the purpose of improperly influencing any decisions concerning the Third Party and/or Novartis. The Third Party will not use other third parties to commit acts of bribery or corruption. Gifts, hospitality and entertainment are modest, reasonable and infrequent, so far as any individual recipient is concerned. However, no gifts of any kind including personal gifts or promotional aids, etc., whether branded or unbranded, can be provided to HCPs or their family members. This includes payments in cash or cash equivalents (such as gift certificates).

Grants, Donations and Sponsorship: Grants and donations are only given if the Third Party and/or Novartis do not receive, and are not to be perceived to receive, any tangible consideration in return. Grants and donations must never reward, or be perceived to reward, any tangible consideration. Sponsorship is not to be used (or perceived to be used) to receive an improper commercial advantage in return. Sponsorship must never reward (or be perceivedto reward) an improper commercial advantage.

Political Contributions: If the Third Party chooses to make political contributions, they must be made in compliance with all applicable laws, regulations and industry codes and standards, and must not be made with the expectation of direct or immediate return for the Third Party or Novartis.

Lobbying: Lobbying is not to be misused for any corrupt or illegal purposes, or to improperly influence any decision.

Public Officials: Any relationship between the Third Party and public officials is in strict compliance with the rules and regulations to which they are subject (i.e., any applicable rules or regulations in the particular country relating to public officials or that have been imposed by their employer). Any benefit conveyed to a public official is fully transparent, properly documented and accounted for.

6.2 Fair Competition

STANDARD

Third Parties shall conduct their business consistent with fair competition. They shall employ fair business practices, including accurate and truthful advertising.

Third Parties shall comply with all fair competition and antitrust laws and regulations.

7 Data Privacy and Information Protection

STANDARD

Third Parties shall establish and maintain adequate personal data and information security protection for the information that they, and any third parties acting on their behalf, process.

Third Parties shall operate in a manner that is consistent with applicable data protection/privacy laws and aligned with industry standards for the protection and security of all information, including Personal Information.

REQUIREMENTS

Proper Protection of Personal Information: Third Parties shall have the proper organizational structure, processes and procedures to ensure the protection, confidentiality, integrity and availability of information against accidental, unauthorized or unlawful loss, destruction, alteration, disclosure, use or access.

Proper Security Measures: Third Parties must have adequate policies and procedures in place, which address technical and organizational security, and take reasonable steps to stay current and to confirm on a periodic basis, compliance with those. Such policies and procedures must include for Suppliers only, at minimum, the Minimum Information Security Controls for Suppliers, available at this link.

Compliance with Cross-Border Transfer Restrictions: Third Parties must have adequate safeguards, rules and procedures to ensure that they remain in compliance with all applicable laws that govern cross-border data transmissions, where applicable.

Data and/or Information Breach Notification: Third Parties shall notify Novartis for any suspected or actual data breach concerning the services/deliverables/goods provided. Third Parties shall appropriately assist Novartis in any investigations in response to a data or information breach.

8 Responsible Minerals

STANDARD

Third Parties shall support Novartis commitment to seek to identify, reduce and, where possible, eliminate the use of certain minerals known as 3TG that have been identified as included in Novartis products and that have been determined to have directly or indirectly financed or benefitted armed groups in the Democratic Republic of Congo (DRC) or its adjoining countries.

REQUIREMENTS

Third Parties shall:

- Help identify the source of 3TGs in products, components or materials supplied to Novartis by Third Parties (including the smelter or refiner where such 3TGs were processed and the country of origin of the 3TGs where possible through reasonable means)
- Cooperate with Novartis in its due diligence process and in responding to its requests for information relating to minerals used in our products
- Provide, upon request, reasonable evidence of the Third Party's performance of similar due diligence with respect to any of their suppliers or sub-contractors involved in the production of the materials or products supplied to Novartis or any components of those materials or products
- Work with Novartis to assess opportunities for alternative sources where 3TG responsible minerals are identified.

9 Quality (Good Manufacturing Practices)

STANDARD

Third Parties shall ensure that they are providing materials, products and services that comply with applicable laws, regulations, health authority standards, industry guidance and any additional customer requirements.

Third Parties shall, where applicable, abide by the Quality Contract in place governing Good Manufacturing Practices (GMP) activity, expectations and requirements.

REQUIREMENTS

Third Parties that are subject to GMP requirements shall:

- Hold and maintain the necessary manufacturing licenses, permits and registrations (or comparable authorizations) in respect of the materials, products and/or services supplied to Novartis and for the relevant facility issued by relevant regulatory authorities
- Ensure that all data relevant for any activities conducted to provide materials, products and/or services to Novartis, is accurate, controlled, safe from manipulation or loss and compliant with all health authority standards and industry expectations for data integrity
- Take measures to ensure security and integrity of the supply chain, including but not limited to measures for anti-tampering, anti-counterfeiting and product serialization requirements, etc.
- Cooperate with Novartis in implementing new or changed health authority standards or expectations in time for regulatory implementation.

10 Trade Sanctions and Exports Control

STANDARD

Third Parties shall identify and comply with applicable trade sanctions and export control laws, including but not limited to US, EU and Swiss trade sanctions laws. Novartis does not engagewith persons or companies that have been placed by governments on sanctioned party lists.

REQUIREMENTS

Third Parties shall:

- Confirm that neither they nor their affiliated companies, shareholders or directors have been previously, or are currently, placed on one of the following restricted parties lists: the U.S. List of Specially Designated Nationals (“SDNs”) and Blocked Persons, maintained by the U.S. Treasury Department Office of Foreign Assets Control; the Debarred List and non-proliferation sanctions lists maintained by the U.S. State Department; the EU Consolidated List of Designated Parties; and the Sanctions Embargoes List of Switzerland;
- Confirm they are not currently owned 50% or more, individually or in the aggregate, by one or more SDNs;
- Shall immediately inform Novartis by email (using the mail address: ctc.coe@novartis.com) if during the course of dealings with Novartis: (i) they, theiraffiliated companies, shareholders or directors are placed on one of the restricted parties lists referenced above; or (ii) they become owned 50% or more, individually or in the aggregate, by one or more SDNs.

11 Identification of Concerns

STANDARD

Third Parties are expected to implement a complaint mechanism through which their Workers can raise complaints directly with such Third Party without fear of retribution or losing their jobs. In addition, Workers can report actual and / or potential violations of this Third Party Code, the Human Rights Commitment Statement (HRCS) and other relevant policies or applicable human rights and environmental laws and regulations in their country and/or Novartis countries of operation through our Speak Up Office available here.

12 Management Systems

Third Parties shall use management systems to facilitate continual improvement and compliance with these standards. Elements of the management systems include:

12.1 Commitment and Accountability

STANDARD

Third Parties shall demonstrate commitment to the concepts described in this document by allocating appropriate resources.

12.2 Legal and Customer Requirements

STANDARD

Third Parties shall identify and comply with applicable laws, regulations, standards and relevant customer requirements.

12.3 Risk Management

STANDARD

Third Parties shall have mechanisms to determine and manage risk in all areas addressed by this document.

12.4 Third Party Relationships

STANDARD

Third Parties do not sub-contract or otherwise engage with third parties on behalf of Novartis or represent Novartis to third parties, without the prior written consent of Novartis. Similarly, there is no assignment of the contract, without prior written consent of Novartis.

12.5 Audit Right

STANDARD

Novartis may audit (or engage a third party to audit on their behalf) the Third Party at any time upon reasonable prior notice, to ensure its compliance with the standards in the Third Party Code, and to confirm all payments made by Novartis and to third parties on behalf of Novartis. Supplemental audit provisions may also apply as agreed between the parties.

12.6 Documentation

STANDARD

Third Parties shall maintain documentation necessary to demonstrate conformance with these standards and compliance with applicable regulations.

REQUIREMENTS

Third Parties shall prepare and maintain books and records that document accurately and in reasonable detail all matters related to business with Novartis, accounting for all payments (including gifts, hospitality and entertainment, or anything else of value) made on behalf of Novartis, or out of funds provided by Novartis.

“Off-the-books” accounts and false or deceptive entries in the Third Party’s books and records are prohibited. All financial transactions must be documented, regularly reviewed and properly accounted for. A copy of this accounting is available to Novartis upon request.

Third Parties shall ensure that all relevant internal financial controls and approval procedures are followed and that the retention and archive of books and records is consistent with the ThirdParty’s own standards and tax and other applicable laws and regulations. More specific record retention requirements may be agreed between the parties.

12.7 Training and Competency

STANDARD

Third Parties shall educate their employees to make ethical decisions in compliance with laws, regulations and contract requirements. If requested by the Third Party, Novartis has the right to train.

12.8 Continual Improvement

STANDARD

Third Parties are expected to continually improve by setting performance objectives, executing implementation plans and taking necessary corrective actions for deficiencies identified by internal or external assessments, audits, inspections and management reviews.

12.9 Business Continuity Management

STANDARD

Third Parties that are involved in the manufacturing, storage and/or logistics of Novartis products or products/materials/devices used in Novartis products (or the provision of services relating to or supporting any of the above activities), will ensure they have and keep up to date, business

continuity plans and disaster recovery plans (periodically tested) sufficient to minimize the possibility of any interruption in the supply of products, devices, materials and related services and allow the rapid restoration of supply and/or services should they, nonetheless, have a disruptive incident. Such Third Parties will provide a copy of the business continuity plan and testing results to Novartis on request.

All other Third Parties shall consider having Business Continuity measures in place for products and services being provided to Novartis in the case of disruptive incident.

Acknowledgement

The Third Party acknowledges that their engagement is not used by Novartis to create an incentive or reward for prescribing Novartis products or to secure any improper business advantage for Novartis.

Disclaimer

Novartis may, in its sole discretion, provide guidance, documents, information, advice, best practice sharing, know-how, insights and/or examples ("**Guidance**") to the Third Party for the purpose of its compliance with this Third Party Code. The Third Party acknowledges and agrees that any such Guidance is provided by Novartis for information purposes only and is not a substitute for professional advice and/or compliance with applicable legal requirements. The Third Party places reliance on Novartis Guidance at its own risk and any consequences of decisions relating to, or the implementation of, such Guidance are the sole responsibility of the Third Party. Novartis does not warrant and makes no representations as to the accuracy or completeness of such Guidance and will not be held responsible by any person, including the Third Party, in any manner whatsoever, for any consequences of the Third Party's reliance on or implementation of such Guidance.

Glossary of Terms

3TG: Tin (Cassiterite), Tantalum (Coltan, Columbite-Tantalite), Tungsten (Wolframite) and Gold as defined in the 2010 Dodd-Frank Act, Section 1502.

Child Labor:
Any young person below 15 years of age (or 14 years of age in countries with a derogation in accordance with Article 2 of ILO Convention 138 (Minimum Age Convention, 1973).
Any young person below the local legal minimum working age where this is higher than 15 years of age.
Any young person below the age of local legal compulsory education where this is higher than 15 years.

Data Protection Laws/Legislation:
a. The General Data Protection Regulation (2016/679)
b. All other existing or new applicable laws/regulations relating to or impacting on the processing of Personal Data of a data subject and/or its privacy.

Donation: Benefit granted by Novartis to legitimate organizations for an altruistic and specified purpose, where Novartis does not expect (and there is no agreement or intention) to receive any benefit, consideration or service in return.

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

GMP (Good Manufacturing Practices): System for ensuring that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification.

Healthcare Professional (HCP): Any member, student, or researcher of the medical, dental, optometry, opticianry, pharmacy or nursing profession, or any other persons, 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.

Human Trafficking: The transporting, harboring, recruiting, transferring or receiving of persons by means of threat, force, coercion, abduction or fraud, for labor or services.

Modern Slavery: Modern slavery is an umbrella term encompassing the risks posed by forced labor, prison labor, indentured labor, bonded labor, debt servitude, state-imposed forced labor and the worst forms of trafficking where coercion, threats or deception are used to intimidate, penalize or deceive Workers thereby creating situations of involuntary work and exploitation. Modern slavery may also be associated with the worst forms of Child Labor.

Personal Data/Personal Information:
a. Any information relating to an identified or identifiable person, including without limitation electronic data and paper-based files that contain information such as name, home address, office address, e-mail address, age, gender, family information, profession, education, professional affiliations or salary
b. Non-public personal information, such as national identification number, passport number, social security number, driver's license number
c. Health or medical information, such as insurance information, medical prognosis or treatment, diagnosis information or genetic information; and including coded clinical trial patient data
d. Sensitive personal information, such as race, religion, disability, trade union memberships or sexuality
e. Any data or information that is qualified as Personal Information or Personal Data under the applicable Data Protection Legislation.

Quality Contract: A quality contract is a legal agreement that helps to assign the quality assurance responsibilities between the contract giver and contract acceptor for current GMP requirements and compliance, details any specific requirements regarding the product provided via written

specifications, establishes the expectations for providing acceptable services, quality processes, analysis and/or products and ensures the agreed upon quality activities between the parties involved are carried out.

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.

Standards: Collectively, the standards and corresponding requirements set out in this Third Party Code.

Third Party/Third Parties: For the purpose of the scope of the Third Party Code, this means the following third parties:

- **Suppliers:** An external natural or legal person/entity outside the Novartis Group from whom Novartis sources goods or services. This includes, for example:
  i. Contract Manufacturing Organizations (CMOs)
  ii. Institutions and collaborators carrying out research for or on behalf of Novartis, where Novartis is acting as the sponsor and paying for the research, including collaborators of both Contract Research Organizations (CROs) and Academic Research Organizations (AROs)
  iii. Third Parties that handle or distribute Novartis products (i.e. logistics services) where the ownership of the products is not transferred to the Third Party service provider
  iv. HCPs acting as "third parties" only, i.e. where they provide goods or services against a fee for a service beyond their profession as an HCP, such as app developers or commercial/marketing consultants, etc. (otherwise HCPs are out of scope).
- **Business Development & Licensing (BD&L):** Any Third Party with whom a product in-licensing agreement has been contracted with Novartis.
- **Distributors and Wholesalers:** Any Third Party that imports and/or resells for its own business purposes Novartis Products (whether or not they provide promotion services for the specific Novartis Products on behalf of Novartis).

Worker: Any employee, director, officer, staff or personnel engaged or employed by a Third Party, including agency Workers, whether on a permanent, temporary or casual basis.

References and Bibliography

The following references are included for information. They are not intended to create any additional obligations beyond this Third Party Code. Novartis is not responsible for the content on external links below and within this TPC.

General References	Novartis Code of Ethics Pharmaceutical Supply Chain Initiative United Nations Global Compact Universal Declaration of Human Rights United Nations Guiding Principles on Business and Human Rights
Labor Rights	ILO Decent Work Agenda **Freely Chosen Employment** International Labor Organization ("ILO") Conventions 29 and 105 **Child Labor** ILO Conventions 138 and 182 **Non-Discrimination** ILO Conventions 111 and 100 International Convention on the Elimination of All Forms of Racial Discrimination Convention on the Elimination of All Forms of Discrimination Against Women: **Violence and Harassment** ILO Convention 190 and Recommendation 206 **Wages, Benefits and Working Hours** ILO Conventions 131, 95, 14 and 1 **Freedom of Association** ILO Conventions 87 and 98
Health, Safety & Environment	OHSAS 18001 ISO 14001 Environmental Management Systems standard ISO 50 000 Energy Management Systems standard Forest Stewardship Council Sustainable Palm Oil AMR Industry Alliance Manufacturing Framework
Animal Welfare	Guide for the Care and Use of Laboratory Animals, 8th Edition (©2011) National Research Council (NRC), Washington DC, USA Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, 3rd Edition (2010), Federation of Animal Science Societies (FASS), Champaign IL, USA European Directive 2010/63/EU (PE-CONS 37/10) of the European Parliament and of the Council of he European Union on the Protection of Animals used for Scientific Purposes (2010)
Anti-Bribery	UN Convention Anti Bribery OECD Anti-Bribery Convention US Foreign Corrupt Practices Act 1977 UK Bribery Act 2010

Novartis International AG, P.O Box CH-4002 Basel, Switzerland
Tel: +41 61 324 11 11 | www.novartis.com

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