



Ethics, Risk & Compliance

# Third Party Code

Version: 4.0

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## 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.

The Novartis Third Party Code (the "Third Party Code") is based on the requirements in the United Nations Global Compact, the United Nations Guiding Principles on Business and Human Rights (UNGPs), the Pharmaceutical Supply Chain Initiative (PSCI) principles and other relevant international standards or accepted good practices.

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

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.

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.

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## Monitoring against our standards

Adherence to the standards and requirements 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 strive to prevent, mitigate, and remedy adverse human rights impacts throughout our workplace, business operations and in the communities in which we work. 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 value 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*”, Third Parties are required 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 (ILO) 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 decision-making and actions to mitigate the risks, tracking the effectiveness of these measures, and communicating 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 potential risk of human rights violation Third Parties are required to notify Novartis with the steps being taken to avoid or mitigate the risk. If prevention is not possible and the Third Party has caused or contributed to the violation, they must take corrective actions to address the impact. Notifications must be sent to [human.rights@novartis.com](mailto:human.rights@novartis.com).

### 2 Labor Rights

We are committed to supporting our Third Parties in enhancing labor conditions, health and safety, and environmental standards in the workplace. Our approach focuses on guiding Third Parties from basic compliance to industry-leading practices. This requires active engagement, listening to both Third Parties and their employees, and fostering collaboration. Through capability-building initiatives we aim to provide meaningful support to Third Parties to conduct business in a way that is fully consistent with the Third Party

Code.

Third Parties are expected to nominate dedicated personnel to oversee compliance with the human and labor rights standards of the Third Party Code

Third Parties are required to distribute or post the labor rights standards of the Third Party Code in a place frequented by all Workers in the local languages spoken by the Workers. Third Parties must undertake annual, documented training efforts to educate all Workers about the human and labor rights standards of the Third Party Code or equivalent standards. Third Parties must also ensure regular training on human and labor rights, including on relevant legal obligations, for their suppliers, and business partners.

Third Parties must address any gaps in compliance with the labor rights standards of the Third Party Code and implement sustainable management, reporting, and tracking systems to ensure ongoing adherence. Third Parties are required to provide documented proof of corrections for all non-compliances.

## 2.1. Forced Labor

**STANDARD** Third Parties must not use forced labor or engage in any form of modern slavery and human trafficking including the use of prison, bonded, indentured or other forms of forced labor (ILO Conventions 29, 105).

Upon request, the Third Party must provide written confirmation that their products and/or the materials used in their products or services that are supplied to Novartis are not manufactured with forced labor as assessed by ILO indicators; and comply with all relevant laws on forced labor and modern slavery. Third Parties are expected to cooperate fully with any investigations conducted by Novartis or relevant authorities concerning forced labor allegations.

## 2.2. Child Labor and Young Workers

**STANDARD** Third Parties must not employ any person who is less than fifteen (15) years old, or less than the age, for completing compulsory education in the country of operations (whichever is higher).

Young Workers below the age of 18 cannot be employed in hazardous or any kind of work that can harm their education, or physical and/or mental health nor be engaged in any form of heavy physical labor and night shifts (ILO Conventions 138 and 182).

If any child who is less than fifteen (15) years old, or less than the age for completing compulsory education in the country of operations (whichever is higher) is found to be working, or any child who is less than 18 years old is employed in hazardous work, Third Parties must 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 programs must conform to the provisions of the relevant ILO standards.

## 2.3. Discrimination

**STANDARD** Third Parties must ensure that all decisions about recruitment, hiring, compensation, benefits, training opportunities, role advancement, discipline, and termination, as well as any other terms, conditions and privileges of employment must not be on the basis of race, national origin, ethnicity, color, age, sex, sexual orientation, gender, gender identity or expression, social origin, physical or mental health and/or disability, medical condition, genetic information, religion, caste, political affiliation, union or association membership, pregnancy, marital status, family status or any other protected category as defined by local laws. All employment decisions must uphold the principle of equal employment opportunity, ensuring fair treatment for all Workers. Effective measures must be in place to prevent discrimination against migrant, temporary, or seasonal Workers who are legally eligible to work in their local jurisdiction (ILO Conventions 100 and 111).

## 2.4. Harassment

**STANDARD** Third Parties must treat Workers with respect and dignity. No Worker may be subjected to any physical, sexual, psychological or verbal harassment or abuse, or to fines or penalties as a disciplinary measure.

Management must be trained to enforce policies without harassment, discrimination, or abuse. Third Parties must not restrict Workers' freedom of movement, including access to canteens, breaks, restrooms, drinking water, or medical care, as a means of enforcing discipline.

Body searches and physical pat downs can only be undertaken when there is a legitimate and specific reason and upon consent of the Workers. They must be conducted by authorized personnel and done by the same sex as the Worker who is being searched. Third Parties must ensure that any private or public security forces they employ are properly trained and do not violate the rights and dignity of any Workers.

## 2.5. Fair Employment Practices

STANDARD

Third Parties must establish fair and transparent employment practices that respect Worker rights and comply with national and international labor laws, including the following:

- **Written contracts:** Employment must be based on legal written contracts in accordance with national laws and best industry practices, with terms clearly communicated in a language Workers understand before they commence employment.
- **Social security:** Third Parties must not circumvent labor or social security obligations through zero-hour, labor-only contracts, sub-contracting, home-working, apprenticeship schemes or excessive fixed-term contracts.
- **Employment and termination policies:** Clear policies and practices must be in place for recruitment, wages, training, performance reviews, workplace communication, grievance handling and termination with regular updates and Worker participation in reviews for all Workers – including contract, migrant, seasonal and temporary Workers. Workers must be free to leave employment with reasonable notice and receive full, timely wages upon departure.
- **Recruitment of Workers:** All Workers, especially vulnerable groups such as migrant Workers must be recruited responsibly, ensuring Workers do not pay recruitment fees, deposits or any potential wage deduction to secure their job, any employer-provided accommodation, or any training and equipment necessary to carry out their jobs (ILO convention 97). If a Worker has incurred illegal fees or costs related to the recruitment process in either the home or host country, the Third Party will ensure repayment of these costs to the Worker. Workers cannot be required to surrender personal and identification documents like passports unless legally mandated, and they must have access to them at all times. Third Parties must oversee all recruitment stages, provide accessible grievance mechanisms in Workers' languages, and guarantee a safe, dignified return to their home countries without fear of penalties or debt.
- **Freedom of movement:** Third Parties must ensure that all Workers – including temporary, contract, and migrant Workers – enjoy freedom of movement within the workplace and any provided accommodations. Workers must have unrestricted access to enter and exit the premises, with any limitations imposed only when necessary for health, safety, or security. Areas posing potential hazards must be accessible only to authorized, trained personnel through controlled access methods (e.g., badge recognition).
- **Protection during layoffs:** Workplace rules, compensation, and severance policies must be transparent and compliant with labor laws, with proper consultation during layoffs and restructuring. Third Parties must also provide Workers impacted by layoffs or restructuring with support for alternative employment opportunities where possible.

## 2.6. Wages and Benefits

STANDARD

All legal and contractual requirements relating to wages and benefits must be met. Wages and benefits for standard hours, excluding overtime, should meet or exceed national minimum requirements or the appropriate prevailing wages, whichever is higher. If wages and benefits fall short of meeting the Worker's and their family's Basic Needs, Third Parties must take steps to gradually enhance wages, benefits, and

overall living standards through improved pay structures, benefits, welfare programs, and support services (ILO Conventions 26 and 131).

Payment terms must be 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. Itemized pay slips must be provided to all Workers for each pay period.

Wage deductions as a disciplinary measure are not permitted.

## **2.7. Working Hours and Overtime**

**STANDARD** A standard work week must not exceed eight hours per day or 48 hours per week total (or 56 hours per week on average for shift work processes).

The sum of normal working time and overtime hours in a week must not exceed 60 hours or the maximum allowed by law in the country of operations, whichever is lower. Workers must have at least 24 consecutive hours of rest in every seven-day period and must be paid statutory leave and holidays (ILO Convention 1).

Overtime must be voluntary and not routinely requested. Overtime must be compensated at the rate legally required in the country of operations. In countries where such laws do not exist, Workers must be paid at a rate exceeding the regular hourly compensation rate by at least 125% (ILO Conventions 1 and 30).

Third Parties must implement a system to monitor working hours and wages paid to all Workers maintaining complete and accurate hours and payroll records for all Workers.

## **2.8. Freedom of Association and Collective Bargaining**

**STANDARD** Third Parties must respect the rights of Workers to freely form labor unions, seek representation and/or join associations of their own choice. Where legal restrictions exist, Third Parties must provide alternative means for independent representation. Where collective agreements are in place, they must be communicated to all Workers in a language they understand.

Third Parties must ensure effective and transparent communication channels between Workers, their representatives and management without threat of reprisal, intimidation or harassment (ILO Conventions 87, 98 and 135).

## **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 Compliance & 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 & 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 waste.



### 3.2. Risk 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 workplace and 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 a net-zero company by 2040. Our ambition is also to contribute to Nature Positive, defined as 'Halt and Reverse Nature Loss by 2030 on a 2020 baseline and achieve full recovery by 2050' by the Nature Positive Initiative based



on the Global Biodiversity Framework 2022. It is expected that Third Parties shall actively contribute and support us to achieve our environmental goals.

Third Parties shall continuously reduce their greenhouse gas (GHG) emissions in their own operations and across their value chain to meet their science-based targets aligned and validated by the Science Based Target Initiative (SBTi). Third Parties shall also aim to continuously reduce water withdrawals and waste throughout their own operations. Third Parties should adopt eco-friendly materials for products and/or services where feasible.

**Engagement:** Novartis together with Third Parties may establish a sustainability roadmap for products (goods and/or services) procured by Novartis, including goals and targets, particularly in terms of greenhouse gas (GHG) emissions reduction, water withdrawals reduction, 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 frameworks 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 (goods and/or 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 in line with science-based frameworks.

Third Parties shall also allow Novartis to report their environmental sustainability data related to products (goods 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 generation 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. Research with animals should be performed after consideration to replace animals, reduce the number of studies requiring animals or refine procedures to minimize stress. 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 Guide for the Care and Use of Laboratory Animals, The Guide for the Care and Use of Agricultural Animals in Research and Teaching, and the European ETS123. 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 (Refine, Reduce, Replace) 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 needed for research.
- Animals experience the minimum amount of discomfort, stress or pain and appropriate methods for sedation, analgesia or anesthesia are utilized whenever possible.
- Particular care and attention are 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 & 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 perceived to 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, Information Protection & Artificial Intelligence

### 7.1. 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 and Access 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 and data accesses, where applicable, including but not limited to the U.S. regulations addressing access to “bulk U.S. sensitive personal data” by “countries of concern” and “covered persons” found at 28 C.F.R. Part 202. Unless specifically approved in writing by Novartis, Third Parties shall not engage in or facilitate (i) “covered data transactions” (as defined in 28 C.F.R. § 202.210) involving Novartis Covered Data, nor (ii) any other activity involving transfer of, or making available, Novartis Covered Data to a “country of concern” or “covered person” regardless of bulk data volumes or purpose.

**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.

### 7.2. Artificial Intelligence

**STANDARD** Third Parties shall establish and maintain responsible business conduct and adopt ethical and responsible Artificial Intelligence (AI) governance and practices when using, developing, making available and/or managing AI. Third Parties are expected to impose on their own suppliers and sub-contractors standards that cover the same principles and content as in this Third Party Code.

Third Parties shall operate in a way that is consistent with OECD (Organization for Economic Co-operation and Development) AI principles for responsible stewardship of trustworthy AI, the Novartis commitment to ethical and responsible use of AI available at [this link](#), and the current and upcoming applicable AI legislation, regulation, guidelines and case law.

#### REQUIREMENTS Third Parties shall:

**Governance and Risk management:** Have an appropriate organizational structure, processes and procedures to ensure that they remain in compliance with current and upcoming applicable AI laws, regulations and industry standards.

**Operationalization:** Implement the above processes and procedures, maintaining relevant and updated documentation and ensure monitoring to detect and mitigate risks arising throughout the entire lifecycle of the AI System.

## 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 & Export Controls

**STANDARD** Third Parties shall identify and comply with applicable trade sanctions and export control laws, including but not limited to US, EU, UK, and Swiss legislation. Novartis does not engage with 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; the UK Sanctions List; 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;
- Not circumvent applicable export controls in their dealings with Novartis entities;
- Immediately inform Novartis by email (using the mail address: [ctc.coe@novartis.com](mailto:ctc.coe@novartis.com)) if during the course of dealings with Novartis: (i) they, their affiliated 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 Whistleblowing | Grievance Mechanism

**STANDARD** Third Parties are expected to implement a whistleblowing or grievance mechanism through which their Workers can raise complaints directly with such Third Party anonymously and without fear of retribution or losing their jobs. Third Parties must publicize and enforce a non-retaliation policy. All complaints must be recorded and acted upon, and the anonymity of Workers must be protected. 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 from 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 Third Party’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 Workers 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.

**AI System:** a machine-based system that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments. Different AI Systems vary in their levels of autonomy and adaptiveness after deployment. (*definition from the Organization for Economic Co-operation and Development as in "OECD, Recommendation of the Council on Artificial Intelligence, OECD/LEGAL/0449"*)

**Basic Needs:** as outlined by the ILO encompasses essential resources required for a Worker and their dependents to maintain a decent standard of living, including food, safe drinking water, clothing, shelter, energy, transportation, education, sanitation, healthcare, and provisions for unexpected events. The Anker Research Institute has further developed methodologies to estimate living wages based on these basic needs, ensuring that compensation allows Workers to afford a decent standard of living for themselves and their families.

### **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.

**Novartis Covered Data:** Novartis or Novartis affiliates' U.S. sensitive personal data or U.S. government-related data, regardless of bulk volume and regardless of whether it is encrypted, pseudonymized, anonymized or de-identified, as such terms are used and defined in U.S. regulations at 28 C.F.R. Part 202.

**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. All types of suppliers of goods or services
  - ii. Contract Manufacturing Organizations (CMOs)
  - iii. 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)
  - iv. 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
  - v. 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- or out-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).
- **All other legal entities,** such as Healthcare Organizations (hospitals, clinics, etc.), pharmacies, non-governmental organizations (NGOs), non-commercial organizations (NCOs), patient organizations, and any other entity.

**Worker:** Any employee, director, officer, staff or personnel engaged or employed by a Third Party, including young workers, migrant workers, seasonal workers, contingent workers, agency workers, whether on a permanent, temporary or casual basis.

## References & 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.

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

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