

Novartis Norge AS Transparency Act Statement 2022

This Statement is made in accordance with the Norwegian Transparency Act (Transparency Act) relating to enterprises' transparency and work on fundamental human rights and decent working conditions. It covers the reporting period January 1, 2022 to December 31, 2022.

Novartis Norge AS is part of the Novartis Group, a medicines company, whose ultimate parent company is Novartis AG headquartered in Switzerland. Unless expressly stated otherwise, references to 'we', 'us' and 'our' refer to the Novartis Group as a whole.

We are committed to respecting human rights throughout our value chain in accordance with the United Nations Guiding Principles on Business and Human Rights (UNGPs) and the Organization for Economic Co-operation and Development (OECD) Guidelines for Multinational Enterprises.

Our commitment embraces all internationally recognized human rights, including those contained in the International Bill of Human Rights, consisting of the Universal Declaration of Human Rights (UDHR), the International Covenant on Civil and Political Rights (ICCPR), and the International Covenant on Economic, Social and Cultural Rights (ICESCR); and the International Labour Organization's (ILO) Core Labour Rights Conventions. We are also signatories to the United Nations Global Compact (UNGC) and report annually on our progress.

A. General description of Novartis Norge AS company structure, operations, guidelines and procedures for handling actual and potential adverse impacts of fundamental rights and decent working conditions

Novartis is a medicines company. We use innovative science and technology to address some of society's most challenging healthcare issues. We discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible. Worldwide, our medicines reached 743 million people in 2022.

In Norway, our medicines cover the following key therapeutic areas: oncology (solid tumors and hematology), cardiovascular, immunology and neuroscience. Our activities in Norway are restricted solely to the sale of prescription pharmaceuticals and participation in clinical trials and studies on behalf of Novartis AG; performed at Norwegian hospitals and clinics.

We distribute our products through local wholesalers and distributors. We use local warehouse and transport services third parties for the delivery of our pharmaceutical products. In addition, we use local suppliers for facilities management in our Oslo office related to general services such as security, catering, car lease for employees, travel agency, banking and insurance. Local procurement is governed by the same global policies and procedures as outlined in this report.

As of December 31, 2022, Novartis Norway has a headcount of 111 employees. For more information on our global business structure, workforce, and operations see page 10 of [Novartis in Society Integrated Report 2022](#)

Guidelines and procedures for handling actual and potential adverse impacts of fundamental rights and decent working conditions

We are committed to addressing the actual and potential adverse impacts of fundamental rights and decent working conditions in our own operations and supply chain. We have clear and well-defined global policies, guidelines and standards in place co-sponsored by the Chief Ethics, Risk and Compliance Officer (CERCO) and Chief Legal Officer. These are regularly updated to ensure alignment with our human rights and decent working commitments and are binding on all Novartis employees globally.

In addition, Novartis Norway independently evaluates the need for additional local guidelines or standards. We have reviewed relevant local and global governing documents and determined that these are aligned with the expectations in the Transparency Act.

Policies

- [Novartis Code of Ethics](#) which sets out our commitment to conduct business in a manner that respects the rights and dignity of all people.
- [Novartis Human Rights Commitment Statement](#) which sets out our commitment to implementing the UNGPs and identifies labor rights (including decent working conditions) in our own and third party operations as one of our salient human rights issues.
- [Global Guideline on People and Organizational Principles and Labor Right Practices](#) which sets out our commitment to respect decent working conditions in our own operations.
- [Third Party Code](#), which sets out our commitment to ensure that third parties adhere to our human rights and decent working conditions requirements.

Governance

Overall accountability for implementation of our human rights program, sits with Novartis CERCO who is a member of the Executive Committee of Novartis. The Environmental Social & Governance (ESG) Committee, an executive-level body chaired by the Chief Executive Officer has endorsed our overall approach to managing human rights, including fundamental rights and decent working conditions.

A dedicated Human Rights team sits within the global Ethics, Risk and Compliance (ERC) function and is responsible for the implementation of Novartis human rights strategy in tandem with a dedicated Third Party Risk Management (TPRM) labor rights team.

All global governing documents are embedded in the Norwegian organization through management and Board of Directors.

We welcome the right to information under the provisions of the Transparency Act. Contact information for Novartis Norway AS is available on www.novartis.no

TPRM framework

Our overall approach to labor rights management including fundamental rights and decent working conditions in our supply chain is through our risk based TPRM program. For further information on how we work with our third parties to mitigate adverse human rights impacts see Section C below.

Training and capability building

We seek to empower our employees through formal and informal training and capability-building on human rights and decent working conditions.

- All employees including those in Norway are required to complete an annual training on our [Code of Ethics](#), which includes our ethical commitment to human rights. In 2022, 98% our employees globally completed the training.
- In November 2022, we launched a mandatory TPRM e-training on the importance, scope and responsibilities associated with regard to the management of Third Party risks. By Dec 31, 2022, 62% of our employees completed the training.
- We have an active Human Rights Ambassador Network globally that meets every quarter to discuss existing and emerging human rights risks. In 2022, 57 employees joined the network bringing the total to 137 employees globally. The Norwegian Head for ERC is an ambassador in this global network and participates in these discussions.

- In 2022, we launched a targeted human rights masterclass for employees from the ERC function. We also held a human rights webinar for over two hundred employees including our ERC and Legal teams from Norway; to educate and raise internal awareness on this critical topic. Going forward we aim to offer quarterly webinars expanding the reach beyond ERC to include relevant functions across the organization.
- The importance of patient safety, which we take seriously, was highlighted in our [2021 materiality assessment](#). In full alignment with Novartis global policies on pharmacovigilance, all employees in Norway are trained in adverse event reporting and quality complaints. We have a medical information service for health care professionals and the general public. We monitor all Novartis Norway social media accounts to ensure information is handled correctly.

Grievance mechanism and remediation

The Novartis SpeakUp Office is our confidential grievance mechanism for global and local Norwegian employees and third parties to report misconduct, including related to human rights and decent working conditions. The web-based and telephone channels are operated by an independent third party available 24 hours a day, 7 days a week.

We follow a clear process to manage all allegations raised. Reported misconduct is investigated and substantiated cases are escalated to management for appropriate action



In 2022, our SpeakUp Office received a total of 2 569 complaints of alleged misconduct, none of which were received from Novartis Norway.

We are currently in the process of enhancing the SpeakUp reporting tool to improve its visibility and make the process of reporting a human rights grievance easily accessible to third parties.

B. Information regarding actual adverse impacts and significant risks of adverse impacts identified through due diligence

Since 2017, we have conducted targeted human rights assessments across the business in our priority areas. These human rights assessments take a variety of forms:

- **In Country-Assessments:** We conduct in-country assessments to understand our potential human rights risks and impacts across our business operations in high-risk operating environments. Since 2017, we have conducted eight in-person country human rights assessments, and three remote assessments. Countries are selected for an assessment based on a Human Rights Country Risk Assessment tool we developed, incorporating 14 publicly available human rights risk indicators, and the size of our operational footprint in the market. In 2019, we redesigned our human rights assessment program to include direct engagement with suppliers, communities, and civil society actors.
- **Business-Unit Assessments:** We conduct targeted business-unit assessments to understand how human rights risks may arise in a particular part of the business, regardless of the geography. Since 2018, we have completed assessments of our risk exposure in the procurement of raw materials, our main grievance mechanism (SpeakUp), procurement of human biosamples, the global policy framework for our clinical trials division, and other business unit areas. In 2022, we carried out an assessment of our global health programs to ensure compliance with international human rights standards. This assessment applied to specific functions within our global

health programs and was based on the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, issued in 2008 by the UN Special Rapporteur on the right to health. Our overall finding was that our global health programs are broadly aligned with the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicine, which is consistent with our high score on the Access to Medicines Index.

- **Rapid response "hot spot" assessments:** We conduct rapid human rights assessments in response to emergency or "hot spot" issues that may arise where our business may potentially be exposed to human rights risks or impact. These have included, for example, assessments and responses to the Covid-19 health crisis and various geopolitical issues arising over the last several years.
- **Business Development & Licensing (BD&L) Deal Review:** In partnership with our third-party labor rights colleagues, we review potential labor and human rights risks of potential in-scope partners in merger, acquisition, licensing, or other corporate deal structures.

Identifying salient risks

Using the UNGPs Scope, Scale and Remediability principles we periodically conduct a risk saliency exercise¹ to identify those risks that are most severe and that present the greatest risk to the greatest number of people.

We have identified the following four areas which may involve the most severe actual or potential negative human rights impacts.

- **Right to Health** - Every person has a right to the highest attainable standard of mental and physical health, as articulated in Article 25 of the UDHR and Article 12 of the ICESCR. Our commitments in this area relate to access to medicine, safe and ethical clinical trials, product quality, and falsified medicines.
- **Labor Rights** - We commit to respect international labor rights as articulated in Articles 23 and 24 of the UDHR, Articles 6-11 in the ICESCR, Article 8 of the ICCPR, and the ILO Core Labour Rights Conventions in our own operations and contractually with our third parties through the Novartis Third Party Code.
- **Human Rights and the Environment** - We commit to minimize the environmental impact of our operations and products over their lifecycle, particularly where the harm impacts on the livelihoods of people and communities. We apply measures in our own operations and expect our third parties to do the same through our Third Party Code. For further information see our Environmental Sustainability Strategy.
- **Human Rights and Technology** - We recognize that all people have privacy rights and freedoms as articulated in Article 12 of the UDHR and Article 17 of the ICCPR. We are committed to responsibly use personal information to protect the privacy of our employees, patients, physicians and other stakeholders as outlined in our Global Privacy Policy. We are committed to design, implement and deploy artificial intelligence (AI) systems in a manner that respects the human rights of affected rightsholders including the right to non-discrimination and is transparent, responsible, accurate and appropriate for its intended context. Further information can be found in our Commitment to Ethical and Responsible Use of AI.

In 2022, we updated our Human Rights Commitment Statement, endorsed by the executive-level ESG Committee explaining the 4 human rights focus areas we've identified and outlining our methodology to embedding human rights throughout our business. For more information on our Human Rights Commitments, see our [Human Rights Commitment Statement](#).

Maturity of routines and procedures in assessing third party risks

¹ At the time of publishing this report, our global risk saliency exercise is underway.

We assess risks in our supply chain by considering two factors: procurement category risk and country risk factors. The TPRM framework assigns all third parties a high, medium or low labor rights risk through an automated tool based on the above two factors.

A negative media screening is conducted for low risk third parties which considers allegations relating to human rights risks. If red flags are identified, third parties are required to complete a Third Party Risk Questionnaire (TPQ) and may be required to implement Corrective and Preventative Action Plans (CAPAs) should serious risks be identified.

Medium and high-risk third parties are required to complete a TPQ. TPQs include specific human rights questions ranging from responsible recruitment practices, verification of workers' ages, compensation for overtime work, and policies relating to labor practices. We review the completed TPQ and if areas of non-conformance with our Third party Code are identified, the third party will be engaged to develop a time bound CAPA. CAPAs may be completed before contracting with a third party as well as after they are on-boarded. CAPAs are monitored by the TPRM labor rights team to track and record evidence of remediation. Enforcement actions including termination may be applied to third parties that are unable to meet the requirement set out in a plan. In some cases, CAPAs are complemented by on-site auditing and monitoring activities as determined necessary by the TPRM team. CAPAs may also be generated based on audit findings.

We have identified the following potential risk areas by evaluating our procurement activities against data generated from several sources, including: outputs from our TPRM due diligence framework, participation in external working groups such as the Pharmaceutical Supply Chain Initiative (PSCI) Human Rights and Labor Subcommittee and the Business for Social Responsibility (BSR) Human Rights Working Group; and publicly available sources including the annual U.S. Department of State Trafficking in Persons Report, resources from organizations such as Walk Free and the Business and Human Rights Resource Center, and regular media scans for emerging risks.

The risk areas are (in no particular order):

- Contract Manufacturing Organizations
- Labor supply involving the use of recruitment agencies
- Facility services (catering, construction) involving informal, short-term and low skilled labor
- Packaging
- Raw material agricultural inputs used to manufacture our medicines
- Transport, logistics and warehousing service supply

We have identified 21 specific raw materials used in our manufacturing processes with a heightened risk of adverse human rights impacts at the source level, which is typically 3 to 5 tiers below our direct suppliers. We engaged with our PSCI peers on certification mapping for key high-risk raw materials and have jointly developed a responsible certification assessment tool covering the ILO's Core Labour Standards. We have initiated a process to integrate responsible raw material certification requirements into our existing TPRM framework.

Potential risks for Novartis Norway

Through our third party risk assessment process, we have identified transport and logistics procurement as a category that presents potential risks related to labor rights for Novartis Norway, including low wages, long working hours and social dumping. We conducted a desktop review of our key supplier that provides road transport, sea freight, air freight and logistics services. The outcome of the review was satisfactory as we determined that the supplier has the requisite routines and procedures in place to respect human rights. We will continue to engage closely with this supplier through quarterly meetings on several topics including respecting our human rights obligations.

C. Information regarding measures to cease actual adverse impacts or mitigate risks of adverse impacts, and the results or expected results of these measures

Policies

Our Third Party Code is incorporated into our standard supplier contract terms with third parties, regardless of whether the third party is low-, medium-, or high-risk. These contractual terms give us the right to conduct an audit to monitor compliance with the Third Party Code, as well as the right to immediately terminate an agreement for non-compliance with the Third Party Code (whether identified in an audit or otherwise).

In 2022 we updated our Third Party Code to clarify our human rights due diligence expectations including a clear expectation that our suppliers broadly adopt the same principles with their own suppliers.

Governance

In Q2 2022, we undertook an external human rights program gap assessment to assess our compliance with and readiness for existing and emerging business and human rights laws including the Norwegian Transparency Act. Representatives from the Legal and ERC function in Norway and the global Human Rights and TPRM teams have collaborated through 2022 to analyze reporting requirements in light of the Transparency Act, ensure information sharing and reviewed internal guidelines and process adaptations with respect to the Act.

TPRM framework

In 2022, TPRM screened 11 097 third parties of which 5 379 were screened for labor rights risks. Of these 5 379 third parties, 482 third parties were classified as medium and high risk based on country and procurement category risks. None of these were from Novartis Norway. All 482 third parties were further assessed through the TPQ. Potential exploitative labor practices related to excessive working, overtime, lack of labor policies, lack of anti-discrimination policies were identified, resulting in 308 follow-up activities (e.g., risk mitigation actions and audits). In all relevant cases, CAPAs were initiated and follow up activities by the third parties have resulted in the creation of standalone policies and changes to processes in order to mitigate the identified risks.

High risk mitigation projects

We recognize that foreign migrant workers are vulnerable to exploitation through the payment of excessive recruitment fees leading to situations of forced labor and in worse cases debt bondage. In 2022, we undertook a global risk mapping of our foreign migrant worker footprint and have identified a relatively low foreign migrant labor population in specific high-risk countries in Asia and the Americas. Through our TPRM framework we are in the process of engaging third parties identified as high risk to support their development of appropriate management systems for the responsible recruitment and treatment of foreign migrant workers.

In 2022, we ended our relationship with a Brazilian raw material supplier for carnauba wax (used for coating and binding medicine tablets) due to non-conformance with international human rights standards and switched to a different socially compliant supplier.

Grievance mechanism and remediation

We conducted a targeted human rights assessment of our SpeakUp grievance mechanism against the UNGPs and identified the absence of a standalone policy on non-retaliation as a potential risk that may prevent people from raising concerns. To mitigate this risk, in 2022 we codified our commitment to protecting any employee who speaks up with our standalone policy on non-retaliation.

In 2022 we updated our Third Party Code requiring our third parties to implement a mechanism through which workers can raise complaints directly with the Third Party without fear of retribution, including providing access to remedy for foreign migrant workers in a language they understand.