

## White Paper on the Corporate Sustainability Due Diligence Directive

### AT A GLANCE

Due diligence on human rights and environmental sustainability is strongly embedded into Novartis' business. Novartis calls for a risk-based approach to due diligence in the legislative framework, to allow companies to effectively allocate resources to due diligence, thereby addressing the greatest risks while remaining competitive. Clearly defined terms such as "business relationships" and "third-party actors" are necessary to delineate the scope of company obligations and create a feasible and proportional due diligence framework. Requirements for civil liability must be clarified to harmonize with existing Directives and Regulations regarding corporate civil liability, e.g., use familiar concepts of direct causation and negligence to avoid unnecessary and unpredictable liability. The legislative framework should align with existing industry initiatives, creating a harmonised due diligence framework that limits administrative burden to companies and ensures implementation of due diligence measures to the expected standard.

### NOVARTIS IS A GLOBAL PLAYER

Novartis is a leading player in the European and worldwide pharmaceutical market. Over 140 nationalities are represented within Novartis and Novartis products reach nearly 800 million people throughout the world. In Europe, across 80 sites – from R&D to manufacturing to commercial – and 45,000 employees (10,000 in R&D), Novartis invests over EUR 4 billion in R&D in the European market alone. Ethics and sustainability are embedded in our company culture and operations globally. In 2021, Novartis obtained 21 major approvals in the US, EU Japan and China, while achieving a reduction in greenhouse gas emissions by 34%.

### NOVARTIS ACTIVITIES ON DUE DILIGENCE

Novartis conducts due diligence across the entire business to identify, address, evaluate and communicate the risks of involvement with adverse human rights and environmental impacts. Novartis updated its [Human Rights Commitment Statement](#) and [Environmental Sustainability Strategy](#) in 2022. These documents detail the approach taken to embedding respect for human rights and consideration for environmental sustainability across the company. They outline priority areas for human rights and environmental action based on ongoing due diligence and stakeholder engagement and enable the company to continue making investments to implement these commitments. With regards to third party due diligence, Novartis has established the [Third Party Risk Management](#) (TPRM) programme, which ensures that expectations for human rights, labour rights, health and safety, environmental standards, and anti-bribery and corruption, and other related management systems are addressed at the earliest stages of the third-party selection process. In this scope, since 2017, Novartis has completed deep-dive assessments in eleven countries and labor rights teams continue to investigate deeper concerns in supply chains. Included within the TPRM programme, the [Third Party Code](#) further reflects Novartis' ambition to be a leader in corporate responsibility, including to third parties.

### KEY ASKS ON CORPORATE SUSTAINABILITY DUE DILIGENCE

#### Allow for a risk-based approach to due diligence

Novartis welcomes European legislation on due diligence to address and mitigate human rights and environmental impacts. However, the implementation approach must be feasible to achieve the shared goal of mitigating the greatest risks, while effectively allocating resources and remaining competitive in Europe and the world.

Novartis supports a risk-based approach to due diligence that prioritizes prevention and mitigation strategies based on the severity of harm and likelihood of adverse impacts. Conducting due diligence across all parts of the business, even those which do not carry a significant high human rights and/or environmental risk, would strain resources and limit the impact on the most significant risks. A risk-based approach, on the other hand, would allow for a more streamlined process and targeted allocation of resources across the company operations, without diluting capacity on due diligence in lower risk areas. This approach is in line with the principles laid out by the UN [Guiding Principles on Business and Human Rights](#) and the OECD [Guidelines for Responsible Business Conduct](#).



### **Clarify supply chain due diligence requirements**

Ensuring the concepts of business relationships and third-party actions are clearly defined is essential to delineate the scope of companies' due diligence obligations and to create a framework that is sustainable, easy to implement and does not stifle business operations.

Novartis supports an approach which clarifies the definitions of 'indirect' and 'direct' business partners, as well as clearly identifies the activities considered in-scope. Extending due diligence obligations to cover the activities of all third parties with an 'established business relationship,' would result in an unrealistic screening, auditing and remediating process requiring significant resources. This approach is neither proportional nor feasible. Rather, it would mean pulling resources away from efforts which could have a substantial positive impact on human rights and/or the environment. Furthermore, company liability for operations conducted outside the EU could pose a significant threat to European businesses. Engaging with business partners in third countries where human rights and environmental protection standards are significantly lower than in the EU, could place an unreasonable burden on companies and could ultimately lead to disengagement and more risk-averse business strategies. It could even result in smaller companies opting to leave European markets for other geographies.

### **Provide certainty in administrative and civil liability**

Administrative and civil liability requirements must be **clear and proportionate**. Novartis supports a liability framework which rests on a **link of direct causation** between the adverse impacts on human rights and/or the environment and the conduct of the parent company. An **element of negligence** should be included in the assessment of the company's liability. This would avoid liability for adverse impacts that occurred for no direct fault of the company in question.

In the European Parliament and Council, the concepts of 'intentionality' and 'negligence' have been raised, in order to clarify the conditions under which companies can be held to civil liability. Novartis supports an approach which establishes a clear causation link between the company's conduct and the alleged damage, to prevent exposing companies to frivolous litigation and, consequently, extensive compensation costs and reputational damage. According to the proposed framework, national administrative authorities could be asked to open investigations into a company's conduct not only by allegedly damaged parties, but also by any party having reason to believe a violation of due diligence obligations has occurred. Liability for actions of business partners across the value chain beyond what can be reasonably foreseen and prevented, could impose a significant burden and create uncertainty in the conduction of business operations. This could cause companies to disengage from business operations in order to avoid legal exposure.

### **Consider industry frameworks in the legislative framework**

Ensuring alignment between the new legislative framework and existing industry initiatives will create a clear and harmonized due diligence framework. This will limit excessive administrative burden to ensure that all companies are able to conduct due diligence to the expected standard.

Discussions and proposed amendments in the European Parliament to the current legislative proposal have called for further recognition of the existing industry initiatives and frameworks that aim to address and mitigate adverse human rights and environmental effects. Novartis welcomes a clear and predictable due diligence framework that can be implemented in practice. It should therefore take into consideration and complement the existing industry activity in the area. Ensuring that the new legislative framework is aligned with existing industry initiatives, such as the Task Force on Climate-related Financial Disclosures ([TCFD](#)) which Novartis supports, will be crucial to ensure that all companies are able to conduct due diligence to the expected standard. It will also ensure that European competitiveness is maintained. In particular, alignment is necessary on the definition of what constitutes a human right and/or environmental adverse impact, to ensure coordination with conducts being scrutinized under national laws and with existing industry frameworks for due diligence processes.