

# Global Materiality Assessment 2021

**Results Report** 



### **Table of Contents**

| ^X<br>X<br>^X   | Letter from the President, Global Health & Sustainability   | 3  |
|---|---|----|
| ××  | About this Report   | 4  |
| ××<br>××<br>××  | Key Takeaways   | 5  |
| XX<br>XX  | Background  | 6  |
| ××<br>××  | Why Novartis Conducts Materiality Assessments               | 6  |
| ××  | Materiality Approach at Novartis                            | 6  |
| ÂX<br>X   | How Novartis Defines and Measures Material Topics           | 8  |
| ^X<br>^X<br>^X  | Strategic Objectives of the Novartis Materiality Assessment | 8  |
| ××<br>××<br>××  | Results   | 9  |
| ÂX<br>XX  | Sample Size   | 9  |
| ××<br>××  | Materiality Assessment Results                              | 11 |
| ××  | Priority Impact Topics                                      | 13 |
| ^^<br>^X<br>XX  | Comparison vs. Previous Years                               | 29 |
| ^X<br>^X<br>^X<br>*X  | Strategic Implications                                      | 30 |
| ××<br>××<br>××  | Next Steps  | 31 |
|   | Stakeholder Dialogue  | 31 |
| \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\  | External Support  | 32 |
| ××<br>××  | Appendix  | 33 |
| ××  | Impact Topic List and Definitions                           | 33 |
| ^X<br>^X<br>^X<br>^X<br>^X<br>^X<br>^X<br>^X<br>^X<br>^X<br>^X<br>^X<br>^X<br>^ | Glossary  | 37 |

### Letter from the President, Global Health & Sustainability



**Lutz Hegemann,**President, Global Health & Sustainability

Dear Reader,

As a global medicines company, our purpose is inherently a social one – to reimagine medicine to improve and extend people's lives. We use innovative science and technology to address some of society's most challenging healthcare issues. Yet, we realize that our impact extends far beyond the patients and healthcare professionals we serve, to other stakeholders such as policymakers, investors, and our own associates, as well as the communities in which we operate. It is therefore important that we understand all their needs if we are to deliver on our purpose and ensure we create a positive impact on those around us. Materiality assessments play a critical role in helping us accomplish this goal.

Since we began these assessments in 2006, they have helped us learn about the Environmental, Social and Governance (ESG) topics that matter most to our stakeholders, as well as assess stakeholder expectations. They have also helped us understand how our stakeholders perceive our performance in these areas, and, importantly, where and how we can improve.

The 2021 Novartis Materiality Assessment is our fourth and represents the most robust piece of employee and stakeholder engagement we have carried out to date. The results show that both internal and external stakeholders are aligned in prioritizing four main areas: patient health and safety, access to healthcare, innovation, and ethical business practices. While all the topics we discuss in this assessment are important, it is these four themes that have been identified as being the most material globally for our company.

As we work to further evolve our ESG strategy and to make progress toward our vision to become the most valued and trusted medicines company in the world, listening to our stakeholders and ensuring our efforts are in step with their insights and needs has never been more important.

On behalf of Novartis, I would therefore like to thank everyone who has taken the time to participate in this assessment and look forward to continuing this constructive dialogue in the months and years ahead.

Sincerely,

Lutz Hegemann,

President, Global Health & Sustainability

### **About this Report**



At Novartis, we believe focusing on material ESG topics will drive financial performance and deliver meaningful impact for society. As a company, we constantly evaluate the impact we're having on the world to make good on the social contract we have with countries and patients."

Vas Narasimhan,

Chief Executive Officer



This report summarizes the results of the 2021 Novartis Materiality Assessment, as well as the methodology used. This assessment is undertaken every four years and is critical for embedding materiality at the core of our business. This systematic approach enables us to assess both our stakeholders' views on the impacts Novartis has on society and the environment, and the potential impact of outside events on our business. Materiality assessments therefore constitute a valuable management tool for our company.

While a number of best practice guidelines from international standard setters exist, none of them outline how to actually undertake such an exercise. Through our materiality assessment, and by incorporating the latest thinking about the topic into our methodology, we therefore aim to set the standard for what constitutes best practice when it comes to embedding stakeholders' views about materiality into a company's processes.



The Novartis Materiality Assessment is a valuable tool because it enables us to take onboard the perspectives of a wide range of stakeholders on how we can improve our impact on society."

Joerg Reinhardt,

Chairman of the Board of Directors



The materiality analysis helps us identify focus areas for the company, which the Board of Directors oversees through its committees. This exercise truly contributes to creating an environment of accountability within Novartis."

**Andreas von Planta,** Member of the Board of Directors and the Governance, Sustainability and Nomination Committee

### Key Takeaways

On Patient Health & Safety and Pharmacovigilance in particular, the performance of Novartis was widely seen as strong. Internal stakeholders viewed the use of cutting-edge tools, including Artificial Intelligence, as key to sustaining the company's performance in this area. External stakeholders considered that pharmacovigilance was the topic where Novartis could have the most impact as, unlike health education, it was among the company's core responsibilities. The topic of diversity in clinical trials has also risen to prominence in this year's edition.



Stakeholders expressed concerns around Access to Healthcare topics including Pricing and Intellectual Property, due

at least in part to strained healthcare budgets in the wake of the COVID-19 pandemic. While some pointed to value-based pricing as the way forward, others highlighted that, in certain cases, healthcare systems may not all be able to support this pricing model. Internal and external interviewees pointed out that Sandoz could help improve overall affordability and accessibility of medicines.



Regarding the topic of Innovation, stakeholders focused on the activities of Novartis in delivering transformative

therapies to patients, with some concerns expressed around the lack of accessibility. Others pointed to the need for a greater focus on addressing disease areas where the burden is greatest. At the same time, the capacity of Novartis to deliver life-changing innovation for patients was widely recognized.

When it came to **Ethical Business** Practices, stakeholders generally held the view that controversies resulting in negative media coverage have largely receded. This was mainly because of a perceived recent cultural change in relation to integrity and ethics within the company. Novartis associates emphasized the importance of cascading communication on these topics from leadership to employees on the ground, to ensure consistency and local ownership.

On the topic of **People & Culture**, stakeholders noted that there was still room for Novartis to improve its performance in terms of employee attraction & retention. Interviewees also mentioned that ensuring that social rights standards and benefits for the external workforce (contractors) were on a par with those for Novartis employees would build trust.



Overall, stakeholders held the view that the company's performance on Good Governance - and Corporate

Governance in particular - was robust. More specifically, the rationale in decision-making was often deemed to be both clear and transparent. When it came to **Supply Chain Management** however, many investors said they would welcome more openness and transparency.

Moving on to the topic of **Sustainable** Financial Performance, investors generally believed Novartis to be a

financially healthy company. However, concerns remained across different stakeholder groups that profit margins and dividends were having an adverse impact in low- and middle-income countries, with some arguing that profit margins can stand in the way of volume pricing.

Some thought that Environmental Sustainability was less of an issue in the pharmaceutical sector compared to other

industries, as the sector is not perceived as a major contributor to global warming. Nonetheless, the ambitious goals set by Novartis, including the target to become fully carbon-neutral by 2030 and achieve net zero by 2040, went a substantial way toward building trust in its efforts to reduce its environmental footprint.

### **Novartis ESG Impact Clusters**

**External and internal perspective** 



**Internal View** 

Please see the Novartis in Society Integrated Report for more information on how we create value for society as a company.

### **Background**

### Why Novartis Conducts Materiality Assessments

Businesses face ever-increasing demands – from consumers, politicians, regulators, investors and others – that they create value in society that goes far beyond simply producing products, employing staff and rewarding shareholders. They face calls to address society's challenges, reduce inequalities and contribute to the communities in which they operate. In turn, businesses are also increasingly entrusted to play their part in resolving the issues faced by the society they are a part of.

As a global medicines company, Novartis welcomes this shift. We have long been committed to using innovative science and technology to address some of society's most challenging healthcare issues. Understanding the effects of the actions we take is embedded in our strategic thinking. We view this

as essential both for our continued success as a business and to ensure we always impact society in the most positive way we can.

We conduct global materiality assessments every four years to help determine which Environmental, Social and Governance (ESG) topics are most important for the company's internal and external stakeholders. These allow us to look at how our ESG impacts are perceived along our value chain, and how they translate today and in the future into both opportunities and risks for the company. Materiality assessments also contribute to building trust with key stakeholders, by enabling a dialogue to take place that ensures their views and priorities are considered and reflected in our strategy.

### **Materiality Approach at Novartis**

### **How We Define Materiality**

ESG topics are considered to be material to Novartis if they have a substantial likelihood of influencing the judgment and decisions of key stakeholder groups and significantly impacting overall business performance. There are a number of different materiality definitions within a range of global sustainability frameworks and guidelines which have provided input to our own. In addition, Novartis determines materiality in accordance with standards set forth by the United States' Security and Exchange Commission (SEC), since Novartis reports under the Generally Accepted Accounting Principles (GAAP), which consider both material externalities and dependencies.

### **Double Materiality and Why We Measure it**

At their core, companies exist to perform business activities such as manufacturing goods or providing services. In doing so, they have an impact on society and the environment. At the same time, changes in society and the environment can affect a company's activities. This two-way relationship is called 'Double Materiality.'

Impacts by the company on society and the environment are commonly referred to as externalities because they affect stakeholders beyond the business.

Some impacts are unintended, and potentially negative: for example, impacts on the environment. But externalities can be positive too, for example skills that employees learn through company training can be used outside the company itself, to the benefit of society as a whole.

By contrast, potential impacts on the company are commonly referred to as dependencies. They include topics which affect a company's ability to deliver medicines and treatments, such as its potential vulnerabilities to a disruption of the supply of natural resources or changes to its operating ecosystem.

### **Financial vs. Non-Financial Materiality**

While sustainability and ESG are often thought of as being non-financial, they can have indirect financial implications for businesses too. For example, ethical misconduct or product recalls can translate into fines, while pandemics or other extreme weather events can disrupt our ability to manufacture our products. Issues like these will eventually be internalized in our financial statements. However, the impact of the material event may be complex and may take time to appear on financial statements. This means we need to be forward-looking when it comes to assessing the potential effects of ESG topics.

### The Changing Nature of Materiality

Nothing remains static in our world. What is relevant and pressing today may no longer be an issue in the future. In contrast, what seems unimportant today may be business-critical in the months or years ahead. We therefore need to view our analysis as a constantly evolving process, rather than a one-off exercise, and examine a series of possible future scenarios.

#### Global vs. Local Relevance

When conducting assessments, it is important to ensure they are relevant not just at a global level, but at a local level too. Different aspects of materiality might be priorities in different parts of the world at different times. So, tailoring the findings from our materiality exercises to the places in which we operate is critical to ensure they are relevant for our activities. Only then are we in a position to listen to the stakeholders of the communities within which we operate.

#### An Established Practice Since 2006

Materiality assessments have been an established practice at Novartis since 2006, when we first evaluated what matters to our stakeholders and our impacts on them. In 2013, a regular cycle began, with global assessments carried out every four years. While this may seem like a significant time lapse, this time is necessary both to allow Novartis to fully implement the actions resulting from the materiality assessment as well as to give time for our stakeholders to become aware of these changes. Between each edition, the methodology used is refined and updated, as topics change or become more relevant. Beyond the corporate assessment Novartis country organizations across the globe also conduct their own materiality assessments to help them define strategic areas of focus and integrate their findings into their business priorities in line with local stakeholder expectations.

### **Enterprise Risk Management (ERM)**

As we learn how we best create value, we also shed light on opportunities and risks. We look at these in different ways. While opportunities are considered as part of our ESG strategy, risks are compared against the company's strategic, operational, and emerging risk management. If the risks we find are lacking from our mapping, they are then considered within the enterprise risk management (ERM) process to ensure it is responsive to stakeholder perceptions and remains forward-looking.

### **Impact Valuation**

The Novartis Materiality Assessment helps us understand how our impacts are perceived by society and what stakeholders expect of us. However, it does not measure our actual performance. In order to do so, performance metrics are needed that can reflect how value is created, sustained or destroyed.

We therefore operate with impact valuation metrics, taking into account benefits and costs to society in monetary terms. The results of the 2017 assessment were used to inform the initial set of impact valuation metrics. In turn, the results of the 2021 assessment will be used to identify gaps in our performance measurement and consider impacts against which we do not yet report systematically.

# **Continuous Monitoring: Leveraging the Latest Technology**

Society and the environment in which Novartis operates are constantly in flux. In order to ensure we address all the value creation opportunities that are relevant to our activities as quickly as possible, we continuously monitor the concerns and expectations of our stakeholders. One effective way of undertaking such monitoring is through leveraging artificial intelligence (AI).

Through the use of such technology, we are able to review our stakeholders' public statements in order to improve our understanding of their perspectives. The use of such AI solutions can therefore help us monitor materiality topics in real time and ensure we are aware of how our stakeholders' priorities and views on ESG topics change over time.

# Forward-looking Deep-Dives (Scenario Analysis)

Real time monitoring is not enough to understand our ever-changing world. It can be helpful to think about the future and how we can pursue our purpose not only tomorrow, but also 10 years from now. But how do we account for the multitude of different events that may occur over that period?

The use of forward-looking deep dives on future scenarios (also known as Scenario Analyses) can be a way of addressing these uncertainties and deciding on plans for the years ahead. In addition, they can identify topics that may become material in the future. In order to ensure that Novartis conducts meaningful and engaging scenario analyses, we are currently experimenting with a number of different methodologies to assess the contribution they could make.

# **How Novartis Defines & Measures Material Topics**

The company's systematic approach to materiality enables us to assess both our stakeholders' views on the impacts we make on society and the environment, and the potential effect of outside events on our business. Measuring these helps Novartis identify potential vulnerabilities that could affect its ability to deliver medicines and treatments, while also enabling the company to manage its impacts and be more aware of how it is perceived by stakeholders.

In addition, materiality assessments help us understand topics such as any potential contributions to climate change through our emissions and, in turn, the impact of any such change on our future business.

Our materiality assessment follows a multi-step process, including desk research, stakeholder identification, online survey and in-depth interviews.





### Strategic Objectives of the Novartis Materiality Assessment

The 2021 materiality assessment has been specifically developed with three sets of objectives in mind:

#### Aligning our strategy, operations and resource allocation with societal expectations, business needs and market developments by: Informing the strategic Informing our Informing our priorities of Novartis risk management divisional and



(including our ESG strategy)



process



functional processes

### Intensifying engagement with our key stakeholders to:



**Build trusted** relationships so we receive candid feedback



Align company objectives with the priorities and expectations of society



Co-create inclusive solutions to resolve societal challenges

### **Creating a standardized and holistic reporting process that:**



Ensures transparency for management decisions



Ensures external transparency for our stakeholders

### **Results**

### Who we surveyed globally

Both the quantitative and the qualitative results of the Novartis Materiality Assessment 2021 (MA21) process relied on robust participant samples. An overview of the participants is presented below:

### **Quantitative Assessment**

While securing larger numbers of internal participants to take part in the survey was easier, as might be expected, an unprecedented number of external participants was also secured for our quantitative

assessment. The following infographics provide further details on the sample population for the quantitative component of our MA21 research:

### Sample size

#### **Internal Assessment**

• Survey period: February 8, 2021 - March 17, 2021

Invited: 158,797Participants: 19,753

Response rate: Global: 12.4%
Included surveys: 12,555
Completion rate: 63.3%

Response rate: Number of responses/Total invited.
Completion rate: Included surveys/Participants

#### **External Assessment**

• Survey period: February 8, 2021 - June 22, 2021

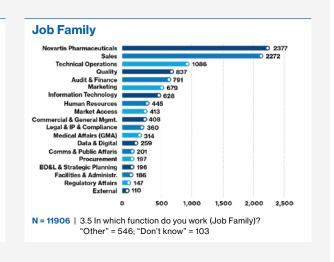
Invited: 3,583 + ~500\*
Participants: 1,439
Response rate: 35.2%
Included surveys: 538
Completion rate: 37.4%

\*3583 stakeholders received it from the central stakeholder database + stakeholders who received the survey link directly from internal contact owners (no option to trace back the exact number [-500 additional contacts])

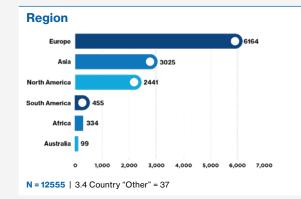
### **Breakdown of participants**

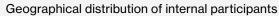
### Internal Stakeholders **Division** Novartis Business Services Sandoz D 1522 artis Technical Operations Novartis Oncology NIBR = Novartis Gene Therapy 243 Group - Finance 149 Group - P&O ■ 104 Group - Legal & Public Affairs ■ 86 oup - Ethics, Risk & Compl. Group - Comms & Advocacy | 57 Group - Digital | 35 oup - Gl. Health & Corp, Resp. NBAA 134 N = 12555 | 3.2 Your Division/Organization Unit

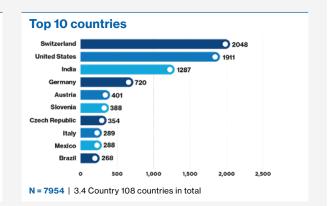
Distribution of internal participants by department



#### Internal Stakeholders



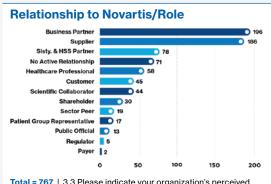




#### **External Stakeholders**



Distribution of external participants by category



Total = 767 | 3.3 Please indicate your organization's perceived relationship(s) to Novartis. 2.x Are you a Healthcare Professional/Public Official/Patient Group Representative? Multiple selections were possible.

### **Qualitative Assessment**

Complementing our quantitative assessment, a series of qualitative interviews were conducted among a group of 140 internal (73) and external (67) stakeholders, who were asked to provide more context around their survey responses.

The sample was as comprehensive and representative as possible, including stakeholders from the following categories:

- Governments and regulatory, political and economic stakeholders
- Representatives from nongovernmental organizations (NGOs), non-profit organizations (NPOs) & charitable organizations
- Advisory & other groups
- Financial market participants, comprising mostly of Novartis investors
- Healthcare providers & industry representatives
- Academia
- · Novartis associates across divisions and functions

### **Materiality Assessment Results**

### **Overview of Impact Topics**

The overall objective of the materiality assessment results is to enable Novartis to assess the value that we create, sustain or erode, and incorporate it in our decision-making process. Before diving into the more detailed findings later in this section, you will find below a chart providing a high-level overview of the different ESG topics where Novartis has an impact and how significant this impact is.



#### **How to read the chart:**

The inner circle reflects the impact topic clusters. The top four material clusters are highlighted in dark grey. The outer circle represents the 30 individual impact topics. The relative importance of a topic is indicated by the height of the column, not its width. The cluster ranking (inner circle) is based on a separate topic cluster ranking question; it is not derived from a calculation of the individual impact rankings of topic-specific questions.

#### Access to healthcare

- 1 Affordability & pricing
- 2 Availability of medicines
- 3 Intellectual property
- 4 Health system strengthening
- 5 Patient assistance programs

#### Sustainable financial performance

- 6 Business model innovation
- 7 Sustainable allocation of capital
- 8 Impact-based operational decisions
- 9 Profit margins and dividends

#### **Environmental sustainability**

- 10 Pharmaceuticals in the environment
- 11 Emission, waste & effluents
- 12 Resource consumption

#### **Ethical business practices**

- 13 Ethical & compliant behavior
- 14 Responsible use of data & artificial intelligence
- 15 Corporate citizenship
- 16 Responsible use of new bio-technologies

#### **Good governance**

- 17 Corporate governance
- 18 Data privacy and security
- 19 Supply chain management

#### Innovation

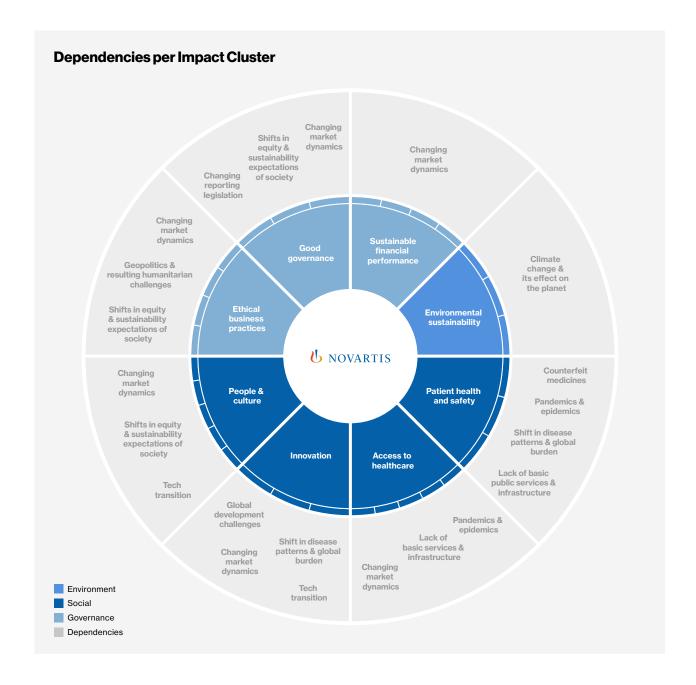
- 20 Advanced technologies for improved health outcomes
- 21 Transformative treatments for unmet medical needs
- 22 Patient-centric innovation "beyond the pill"

#### People & culture

- 23 Health & safety of employees
- 24 Fair working conditions
- 25 Diversity, inclusion & corporate culture
- 26 Employee training & upskilling for digital workplace
- 27 Employee attraction & retention

### Patient health & safety

- 28 Pharmacovigilance, safety profile and quality of drugs
- 29 Prevention of counterfeits & drug use stewardship
- 30 Health education & prevention



As previously outlined, the purpose of the Novartis Materiality Assessment is to determine what the environmental and societal impact of the company is while also identifying the external forces and trends which could potentially affect its operations, known as dependencies. To achieve a truly inclusive picture of an organization's impacts and dependencies, incorporating the social and environmental value the company creates into its decision-making is essential.

This is the ultimate purpose of conducting materiality assessments, which also enables the company to identify potentially significant risks as well as discovering opportunities for adaptation, resilience, and efficiency. The chart above regroups the eight key impact clusters of Novartis, while also indicating what external factors are impacting the company's activities in this sector the most.

### **Priority Impact Topics**

The following sections feature 15 impact topics identified as priorities from a managerial perspective. This analysis helps us to deep dive into the findings and identify a subset of topics that need to be

managed with priority moving forward. Topics were identified as priority if they fulfil one or several of the following criteria:



# High impact and low performance

All topics which were rated high on impact but relatively low on performance. Five of the priority topics were seen to be fulfilling this criterion



# Comparatively low performance:

All topics where Novartis' performance was relatively low, indicating where the company should focus on improving its performance. Six of the priority topics were seen to be fulfilling this criterion



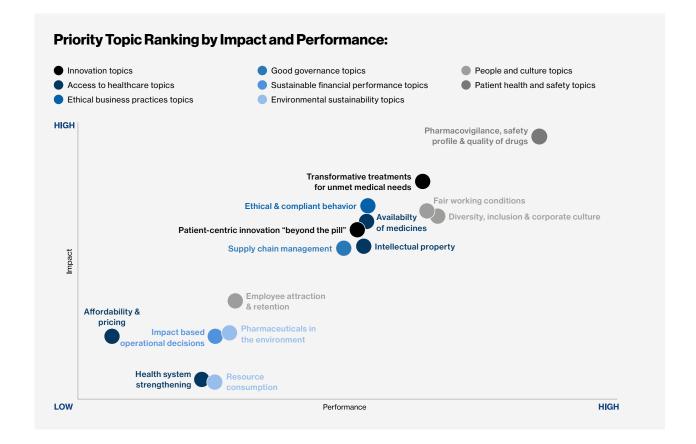
# Identified during interviews:

Topics which were frequently mentioned by interviewees, and which were identified as priorities as a result of our qualitative analysis. Four topics were identified as priorities as a result from interviews



# Human rights exposure:

Topics that pertain to upholding human rights. Nine of the priority topics were seen to be fulfilling this criterion



Internal and external stakeholders were given the opportunity to comment on the topics via open text fields in the surveys and through interviews. For each priority topic discussed below, we explain how it may impact Novartis and outline specific stakeholder observations in terms of what Novartis

does well and where there are opportunities to improve its performance. While the stakeholder opinions discussed do not always reflect Novartis' own views, we believe disclosing them is important for our assessment to be both transparent and comprehensive.

### **Patient Health & Safety**

## Pharmacovigilance, Safety Profile & Quality of Drugs

**Definition:** Ensuring healthcare products are manufactured at the highest quality level and the efficacy and safety features of a medicine outweigh its risks (e.g. side effects), as well as to collect and record adverse event reports. This may

include compliance with relevant regulations and standards (e.g. Good Manufacturing Practice), as well as transparent and timely communication in the case of product safety or quality issues (e.g. prompt product recalls).

### **How does it impact Novartis?**

Pharmacovigilance, safety profile & quality of drugs is a topic that is essential for any pharmaceutical company to operate, as the safety and quality of our products have a direct impact on patient health. In addition, a medicine being withdrawn from the market over safety concerns has a disruptive impact on patient treatment and can have a detrimental impact on trust in a company. While pharmacovigilance is widely seen as a "hygiene" (must have) factor for pharmaceutical companies, a truly robust performance in this space can make a company stand out in making patient safety the core of its business activities. A strong performance in this space also goes a long way towards establishing medicineproducing companies as trusted, which in turn makes their products more trustworthy for patients. Securing and maintaining patient trust is therefore key for companies like Novartis, and this can be achieved through transparency and immediate action in the event of product quality or safety issues.

#### Stakeholder observations

Stakeholders familiar with pharmacovigilance and product quality and safety view Novartis as performing very strongly on these topics, including in comparison to competitors; some believe this gives the company a competitive advantage. At the same time, this strong performance also raises stakeholder expectations for Novartis, putting pressure on the company to maintain its "first class standards". Overall, stakeholders felt that Novartis has strong pharmacovigilance reporting standards, particularly those in developed markets. Stakeholders in developing markets also noted there is trust in the quality of medicines included within Novartis' portfolio.

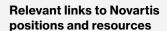
This is a topic being prioritized by the pharmaceutical industry as it gains prominence in several markets including the United States. In addition, there is an observed gap in Novartis pharmacovigilance between developed countries and developing countries, where it is considered by some stakeholders as being

somewhat less established. Pharmacovigilance in clinical trials, particularly in developing countries, was cited as an area where Novartis should be more rigorous, and concerns were raised that outsourcing could potentially impact the quality of safety reporting. Stakeholders also called for Real-World Evidence studies to be conducted in more countries, beyond the US and the EU. There were suggestions among stakeholders that Novartis could work towards ensuring more diversity in clinical trials. Some suggested that building quality of life into drug development and strengthening collaboration with patient groups should also be a focus for Novartis. Finally, leveraging the potential of anonymized big data analytics on collected data in R&D was seen by stakeholders as holding a lot of potential for pharmaceutical companies like Novartis, while respecting privacy standards.

BB

I'm very familiar with safety and pharmacovigilance, and I think that I've had a very positive experience with Novartis in this area, I think the company is strong."

**Patricia Gonzalez Garcia,** CEO, The Max Foundation



**Ensuring Patient Health and Safety** 

**Quality Assurance** 

**Quality Management System** 



### **Affordability & Pricing**

**Definition:** Responsible pricing for innovative and generic medicines that takes into consideration regional affordability, a favorable cost-benefit ratio, and overall healthcare costs. Examples may include models such as tiered pricing, managed

entry agreements, outcome-based pricing, price considerations throughout the supply chain to manage mark-ups, and non-exclusive voluntary licensing.

### **How does it impact Novartis?**

Ensuring affordability and setting responsible pricing levels can lead to elevated shareholder confidence and reduced reputational risk. However, the company's innovative pipeline, which includes highly innovative gene therapies such as Zolgensma, has faced significant societal pressures over pricing. Indeed, the pharmaceutical industry as a whole faces reputational challenges stemming from an ongoing public debate on pricing. The COVID-19 pandemic has also resulted in a reset of society's expectations about a new 'social contract' between pharmaceutical companies and healthcare systems. As a result of these shifting societal expectations, stakeholders look to Novartis to be a genuine partner to healthcare systems, co-creating sustainable solutions.

### Stakeholder observations

External stakeholders generally agreed that Novartis had a competitive edge in affordability and pricing due to strong patient assistance programs (such as the US Novartis Patient Assistance Foundation) and its emerging market brand strategy which expands access to innovative medicines to people in Lowto-Middle-Income Countries. The Novartis Access Principles were also recognized as being an important step in the right direction in terms of expanding patient access for critical medicines. In addition, issuing a sustainability-linked bond in 2020 helped reinforce stakeholders' views about how seriously the company takes this subject.

Stakeholders suggested that Novartis could do more in the area of affordability and pricing, particularly for gene therapies. They noted the emergence of crowdfunding campaigns, seen as a last resort for patients to access high-price treatments, and therefore encouraged Novartis to do more when it comes to patient assistance. While there was understanding from stakeholders about value-based pricing, many mentioned that such strategies were not affordable for all health systems, notably in the field of cell and gene therapies, and also mentioned that

their rationale needed to be communicated better to the public. Overall, there was agreement that prices needed to better align with the particular disease burden as well as local purchasing power, while markups by third parties should be prevented. Finally, internal respondents mentioned that incorporating access strategies within country Profit & Loss reports remained challenging, particularly for Sandoz.



Overall, I believe Novartis is doing well [in terms of affordability] – at the end of the day you need to make a profit. However, the higher-priced therapies for instance in oncology are an issue particularly in developing countries which you will have to continue managing in the future."

External interviewee from NGO community



Relevant links to Novartis positions and resources

**Access Principles** 

Value-Based Pricing

Affordability and Novartis Access Strategies

### **Availability of Medicine**

**Definition:** Efforts to manage barriers that may prevent, restrict, or delay treatment availability for patients in need in both well-connected and remote areas. Effective management of such

barriers may include more efficient distribution, and improved supply chain strategies and registration process requirements.

### **How does it impact Novartis?**

While ensuring medicines are available to patients has always been important, the COVID-19 pandemic has shone an even brighter spotlight on the topic – both at a societal and political level. As the disruption caused by the pandemic has impacted supply chains, reduced healthcare budgets and delayed treatment availability, there are growing expectations that large pharmaceutical companies such as Novartis should do more to improve the availability of their medicines for patients.

Stakeholder observations

Several external stakeholders said Novartis was a leader in the pharmaceutical sector when it came to ensuring the availability of its medicines. In particular, they praised the commitment of Novartis to provide innovative medicines to more patients in Sub-Saharan Africa through both a dedicated governance structure and a new strategy. The wide country reach of the company's Patient Access Programs was also hailed as an asset. Finally, recent efforts to extend product registration to more countries, as well as the company's strong Global Health Programs for flagship and legacy compounds, were cited by external stakeholders as being strong tools for improving medicine availability.

Stakeholders felt that the generics capabilities of Novartis could be further leveraged as a competitive advantage. Sandoz in particular was often seen as an underused strategic asset from a global health perspective by both internal and external stakeholders, who argued that Novartis could expand access to medicines through the increasing its generic medicine activities. Some stakeholders also noted Novartis could provide increased access to innovative medicines for a larger number of patients. Despite Novartis' position as a leader when it comes to Access to Medicines, external stakeholders encouraged Novartis to continue and intensify efforts to make available and register its innovative products in LMICs. In addition, it was mentioned that commercially driven decisions to withdraw products

without first considering whether viable alternatives were available should be avoided wherever possible. Some external stakeholders also called for smoother reimbursement transitions for patients in clinical trials. Respondents also highlighted the need to inform healthcare professionals about the company's different Patient Access Programs; many also noted their preference for a simplified qualification process for such programs. Finally, prioritizing the product delivery of less strategic brands to countries with lower volumes of pharmaceutical consumption and high amounts of stock-outs was mentioned as a way to build trust with stakeholders.



Most companies are struggling to even make complex treatments available across Europe, let alone in Sub-Saharan Africa, Southeast Asia or Latin America. So even though there are few companies that move further than Novartis does, there is still much more that needs to be done to reach all eligible patients."

#### **Marijn Verhoef**,

Company Engagement Manager at the Access to Medicine Foundation



# Relevant links to Novartis positions and resources

**Access Principles** 

<u>Commitment to Patients and Caregivers – Expanding Access to our Medicines</u>

**Novartis Oncology Access** 

## **Health System Strengthening**

**Definition:** Efforts to improve healthcare infrastructure and deliver healthcare-related services "beyond the pill". Examples may include capacity building, training and education, improved health data collection, provision of physical

infrastructure, partnerships involving the public and private sectors to improve healthcare access in underserved areas, and contributions to reducing healthcare costs for payers, insurance companies and consumers.

### **How does it impact Novartis?**

While Novartis is not primarily accountable for ensuring that health systems function well, such systems are essential for ensuring medicines reach the patients who need them. As such, Novartis has a direct interest in partnering to support well-functioning health systems. Robust health systems can help control costs and reduce price pressure and coupled with skilled healthcare workers, they can help ensure proper diagnoses and administration of the company's medicines. In addition, reliable regulatory systems are key in supporting pharmacovigilance, good manufacturing and clinical practices, which in turn help improve patient outcomes.

### Stakeholder observations

External stakeholders were often aware of the company's activities in health system strengthening, particularly in R&D, and viewed the company as being ahead of its peers. Some internal stakeholders noted that while gaps persisted, Novartis was in the process of developing a harmonized approach to such initiatives.

There was agreement among both internal and external stakeholders that the lack of basic public services and infrastructure was a key dependency when it came to ensuring access to healthcare. There were, however, diverging views both internally and externally on whether Novartis should do more to support the strengthening of healthcare systems. Several external stakeholders argued that, in the wake of the COVID-19 pandemic that has put a strain on healthcare budgets, particularly in LMICs, there will be increasing expectations placed on the company to do more, and partner with governments to strengthen systems. Novartis was encouraged to establish long-term partnerships and increase accessibility to information on health system strengthening efforts and patient support. Notably, there were calls for the company's approach to health system strengthening to be more inclusive, by better tailoring it to local needs, particularly when it came to capacity building,

training and education, improved health data collection, provision of physical infrastructure and when advocating for Health Technology Assessment & Universal Health Coverage. Continued transparency on the long-term access benefits of health system strengthening activities was encouraged.

GG

You are not a healthcare provider: your responsibility is to innovate and create products that the health sector can use in order to prevent and treat diseases. The access issue is really more of an issue for governments."

**Andreas Seiter,**Global Lead for Private Sector,
World Bank



Relevant links to Novartis positions and resources

**Framework** 

**Access Principles** 

Strengthening Healthcare Systems

## **Intellectual Property**

**Definition:** Responsible patent exclusivity management that balances Intellectual Property (IP) protection with the provision of affordable drugs, and stimulates third party R&D for IP assets that have not been selected for in-house

development. Examples may include transparent patent management, participation in patent sharing arrangements, voluntary licensing and avoidance of compulsory licensing.

### **How does it impact Novartis?**

A solid IP framework encourages and protects innovation and provides the incentives required to drive R&D investments for areas of unmet medical need. At the same time, IP rights are perceived by some as presenting a barrier to access. The recent debate over IP waivers for COVID-19 vaccines and products has brought renewed attention to this topic, which could potentially result in a loss of shareholder confidence across the pharmaceutical sector if unaddressed. As healthcare budgets become stretched in the wake of the pandemic, there is growing pressure from regulators, patients, politicians and payers to lower or limit the price of pharmaceutical products, which in turn brings IP rights further into the spotlight.

Patents should be used to fully recover its investment but not as a main source of income, as Novartis's role is to provide access to its drugs."

**Peter van der Werf,** Senior Manager Engagement, Robeco

### Stakeholder observations

Novartis received positive feedback regarding the registration of products in LMICs without IP protection.

According to a number of stakeholders, the rationale driving the patenting strategy of Novartis could be better articulated. Increased attention should be given to transparency, especially for products included on WHO Model Lists of Essential Medicines. Similarly, Novartis was encouraged to more actively consider voluntary licenses, collaborate in early discovery through IP sharing programs. Stakeholders called for Novartis and the wider pharmaceutical industry to support more systemic access to medicines and health. Concerns also remain around the high prices of gene therapies, with stakeholders calling for pharmaceutical companies including Novartis to use IP protection sparingly.



# Relevant links to Novartis positions and resources

Patents and Licensing

**Novartis Position on Intellectual Property** 

Access to Healthcare - Needs-based R&D and Intellectual Property

### **Innovation**

# Patient-centric Innovation "Beyond the Pill"

**Definition:** Embedding patients' perspectives in the development and delivery of holistic treatments and healthcare services to tailor interventions accurately to their needs. Holistic treatments "beyond the pill" may include flexible

companion diagnostic tests, mobile applications supporting treatment regimes, adaptable treatment administration, technology-enabled health data collection and analytics.

### **How does it impact Novartis?**

Patient-centered innovation "beyond the pill" is an important tool for ensuring patients are able to benefit as much as possible from Novartis treatments. While some may consider such innovations as outside of the core responsibilities of Novartis, "beyond-the-pill" solutions remain essential in ensuring patients have access to both accurate diagnostics and adequate treatment administration. The company's support and investment in such innovation helps improve patient outcomes while also building trust in the company among stakeholders, particularly patient organizations.

### Stakeholder observations

While some stakeholders felt that the patient community expected Novartis simply to develop innovative medicines rather than provide care, others viewed patient-centric innovation as an additional positive and mentioned projects underway that support patient adherence and health. Examples of these include smart injectors and an innovative drug delivery service.

Some stakeholders felt Novartis was outpaced by peers in patient-centric innovation "beyond the pill". Stakeholders considered holistic treatment approaches as an area where Novartis could lead mentioned the importance of focusing on LMICs, especially through digital interventions, ultimately making transformative treatments more accessible, affordable and effective. They also said the use of digital technology could support health outcomes and bring additional value in a cost-constrained landscape. Several internal stakeholders discussed that while privacy concerns surrounding patient data remained an important topic, the company should be mindful of inflexible bureaucratic processes that could risk slowing the development of "beyond-the-pill" solutions.



I know that Novartis has quite a number of smart people who are looking into patient-centric innovation. It's a company that is on the leading edge of these issues."

**Andreas Seiter,**Global Lead for Private Sector,
World Bank



Relevant links to Novartis positions and resources

**Digital Health Solutions** 

Addressing Global Health Problems

Research & Development - Novartis Pipeline

### **Innovation**

### **Transformative Treatments for Unmet Medical Needs**

**Definition:** Maintaining a high level of investment in creating innovative treatments that address unmet medical needs, with a focus on optimizing health outcomes before considering market potential. This includes both research into new compounds as well as the modification of existing medicines,

and improving access or efficacy for diverse and especially-vulnerable patient groups. This may include R&D for diseases which disproportionately affect people in low-income settings, for which little or no treatment options are available, and where market failure limits research activities.

### **How does it impact Novartis?**

Developing innovative and transformative treatments for patients is at the very core of the mission of Novartis. It continually assesses its product portfolio to see where it can deliver new solutions for vulnerable populations, including developing new formulations, and conducting research to expand the clinical use of existing medicines into new indications and new populations. Ensuring stakeholders understand that Novartis is investing to address disease areas where unmet global need is greatest is therefore critical for building trust in the company.

Stakeholder observations

Innovation was lauded as a main strength of Novartis by interviewees, with the company's successful track record in developing new treatments, especially cutting-edge gene therapies, contributing to the perception. Novartis is viewed especially positively for embedding multiple new technologies and approaches within its portfolio, and its high standards of quality in genomics and biotherapeutics.

Many stakeholders believed Novartis should further invest in innovation by conducting research into those disease areas where the global unmet need is greatest. External stakeholders in particular shared views that gene therapies such as Zolgensma, while highly innovative, help a smaller number of patients. Similarly, it was often discussed that Novartis could define its pipeline based on forecasted social impact. In addition, the company was encouraged to view transformative treatments from the point of view of patients, not solely technology. For example, it was felt R&D should also focus on prevention and early detection to maximize its impact. Many also said Novartis could expand its innovation by making transformative treatments more accessible and/ or affordable, particularly in LMICs. The academic and scientific communities called for closer cooperation from the company when it comes to working with peers and across sectors to reduce the fragmentation of private sector contributions. Other stakeholders saw increasing focus on digitalization as an opportunity for Novartis to address unmet needs. Internal stakeholders meanwhile cautioned against the divestment of certain products, noting this was perceived as contrary to the company's objective of delivering transformative therapies for patients. Internal and external interviewees mentioned the benefits of a more holistic approach to R&D, for example improving the understanding of how patient lifestyles and education may impact health and disease management In addition, a more equitable balance in R&D activity was encouraged between common and rare diseases.

BB

There is nobody out there with a treatment that prevents sickling\* that is as good as the Novartis biologic."

Kawaldip Sehmi,

CEO, International Alliance of Patients' Organizations (IAPO)

\*Sickling is when the hemoglobin inside red blood cells sticks or clumps together, causing the cell to become fragile, rigid, and crescent – or sickle – shaped.



# Relevant links to Novartis positions and resources

Putting Patients at the Center of our Clinical Trials

**Innovative Medicines** 

**Core Therapeutic Areas** 

### **Ethical Business Practices**

## **Ethical & Compliant Behavior**

**Definition:** Processes and systems to ensure Novartis operates in line with high principle-based ethical standards especially in regards to interactions with HCPs. Examples may include adherence to laws, regulations and international conventions (such as on Human Rights), and antibribery, anti-corruption and anti-trust legislation.

Other examples include supporting whistleblowing channels, fostering open discussions on ethical dilemmas, responsible lobbying and political contributions, being sensitive over promotional activities, drug prescription stewardship and responsible incentive structures and compensation.

### **How does it impact Novartis?**

While stakeholders generally agreed that the reputation of Novartis had recovered from legacy integrity issues, trust remains easy to lose. Ensuring we behave in an ethical and transparent manner is at the very core of our license to operate as a company. In addition, operating ethically and in compliance with laws and regulations is essential for attracting investment and ensuring Novartis is perceived as a leader in the pharmaceutical industry. Finally, scrutiny from governments alongside increased societal expectations mean this will only increase in prominence as a topic.

### Stakeholder observations

There was general agreement among stakeholders that Novartis has made significant progress in recent years, and has created positive momentum due to initiatives such as its code of ethics and the conclusion of the 2020 settlements for investigations into legacy behaviors. Many internal Novartis respondents, felt that the company's investment in online trainings has further supported compliance awareness and had an impact on the company's reputation. While some stakeholders noted prior issues impacted their perceptions of Novartis, internal and external stakeholders (particularly investors and advisors) also often noted that the company had significantly improved. They mentioned that under new leadership, they felt Novartis had improved in ensuring ethical and compliant behavior was embedded in its processes.

As Novartis is a global company, stakeholders felt it must keep in mind that what constitutes ethical behavior, whether from a regulatory, political or cultural standpoint, may vary from country to country. Therefore, employees may benefit from further information on companywide ethics/compliance trainings, their complementary country-specific programs and how these are customized to meet

local regulations. While Novartis has global systems in place to report ethics or compliance concerns, some internal stakeholders were unaware while others felt company action in this area could be expedited. In addition, stakeholders flagged moral concerns related to the high price of cell and gene therapies as well as with innovative biotechnologies in general. Stakeholders also underlined ethical concerns in the work environment, not specific to Novartis but for the company's continued vigilance; for example, operations in low salary countries, trust around personal data and how R&D success was measured.



We view Novartis as having a good reputation, free of negative publicity, acting with integrity and being worthy of our trust. The lack of negative events always popping up solidifies our ability to trust the company."

### William Butterly,

General Counsel and Director of Sustainability and Engagement, Boston Partners Global Investors



# Relevant links to Novartis positions and resources

Ethics, Risk and Compliance

Code of Ethics

SpeakUp Office

## **Diversity, Inclusion & Corporate Culture**

**Definition:** Creating a corporate culture in which each associate can contribute and be recognized, ensuring equal opportunities and fostering a diverse and inclusive workplace. Examples may include empowering employees to achieve their

personal and professional goals, unconscious bias training, equal pay, and strategies aimed at attracting talent regardless of age, ethnicity, gender, nationality, language, sexual orientation, physical ability, or religious and personal belief.

### **How does it impact Novartis?**

Diversity and inclusion are at the very center of the cultural journey of Novartis. While there is work to be done to improve representation, the company's efforts to become more inclusive were recognized by stakeholders. As society's expectations in the area grow, diversity, inclusion and a strong corporate culture are essential as they affect a wide range of the company's activities and stakeholders (patients, clinical investigators, vendors/ suppliers and others). Stakeholders believe Novartis can outpace its competitors by pressing for even more diverse workplaces, beyond gender diversity targets, and in return gain deeper trust and more commitment from employees, patients and shareholders.

### Stakeholder observations

There was general agreement that Novartis is making significant efforts to ensure diversity and inclusion in its workforce. In particular, there was positive feedback from the LGBTIQ+ community at the company. Other internal stakeholders mentioned parental leave, pensions and investment options as being in line with ESG standards.

Stakeholders felt that Novartis could show how its statement and policies have a tangible impact on culture and the wellbeing of its associates. There were also some concerns raised about equitable treatment across genders, as some stakeholders felt that, in line with a broader predominant trend across society, men were often assessed more favorably than women, regardless of actual work output. Some stakeholders also suggested that the efforts of Novartis to ensure greater diversity were largely focused on gender, with less emphasis on race and ethnicity.

Internal stakeholders pointed out that corporate culture would improve with more proactive responses from managers when diversity and inclusion issues were flagged to them. Some also noted that the shift of certain roles to other countries contributed to concerns of job security.



We do have the impression of a company that is really forward-looking and trying to do the best it can in relation to culture, to inclusion, to respect for its people – which at the end enhances retention."

#### Esperanza Martinez,

Head of Health, the International Committee of the Red Cross (ICRC)



# Relevant links to Novartis positions and resources

**Diversity & Inclusion** 

People and Culture

<u>Unleash the Power of our People –</u> <u>Diversity & Inclusion Performance</u>

### **Employee Attraction & Retention**

**Definition:** Human capital management that aligns recruitment efforts with the company's purpose and strategy, and provides talent management programs to engage and retain associates with relevant skillsets. This may include mentoring and learning programs for personal and career

development skills, adopting new approaches such as agile management styles, and offering more flexible working models tailored to augmented workforce schedules and workplace transformations.

### **How does it impact Novartis?**

Attracting and retaining talent is crucial to maintaining a high level of productivity and ensuring an influx of expertise. Yet increasing competition for talent continues to challenge recruitment and retention efforts. Remaining reputational biases toward the pharmaceutical sector also further impedes talent attraction. Keeping a highly talented workforce motivated, while being an employer of choice for new candidates, is critical for Novartis to remain competitive.

### Stakeholder observations

The ongoing evolution in company culture was perceived positively by both internal and external stakeholders, although many noted there was work still to be done, particularly in the prioritization of diversity and inclusion throughout all aspects of the business. Novartis was seen as being an employer who makes safe working conditions one of its top priorities. This was notably showcased by the company's prioritization of the wellbeing of its employees during the COVID-19 pandemic. Additionally, the multiple career paths offered within the organization, and general levels of work flexibility, were mentioned positively.

Talent retention, particularly across high-performing staff, was flagged as a challenge by internal stakeholders, with organizational restructuring noted as a retention hurdle. Reducing high workloads was raised as a potential solution for attracting and retaining talent. In addition, streamlining internal communications and channels was another frequently cited point for improvement. Internal stakeholders also supported salary increases and promotions for better employee retention. Some external stakeholders specialized in workforce and staffing solutions felt that open positions are at times not sufficiently promoted by Novartis, and that the benefits of contract workers did not always align with those for Novartis employees.

BB

I have just seen it too often, that we let knowledge go and believe we can easily hire someone else."

**Novartis employee** 



Relevant links to Novartis positions and resources

Associates' Well-Being

Supporting and Protecting our Employees

**Awards and Recognitions** 

## **Fair Working Conditions**

**Definition:** Ensuring fair employment processes, including upholding labor rights, freedom of association and collective bargaining, good

labor relations and union practices, and fair compensation and benefits. This may also include work-life balance considerations.

### **How does it impact Novartis?**

Fair working conditions are important to attract, motivate and retain talent, helping the company stay competitive. But they are also about treating people with the respect that everyone deserves. Fair conditions can help reduce turnover, protect productivity levels and protect the corporate culture that Novartis has worked hard to build.

### Stakeholder observations

The company's internal stakeholders praised its corporate culture of encouraging employees to give upward feedback and for providing ongoing opportunities for acquiring new skills. In addition, the commitment of Novartis to pay a living wage to all its employees – usually above the minimum wage requirements in each country – was hailed as an asset. Respondents also agreed that Novartis put its employees' health and safety at work first, viewed as a highly positive commitment from the company.

Internal respondents often remarked that heavy workloads were a concern among employees, impacting both personal health and the organization's productivity. They suggested a greater focus on improved change management, more proactive balancing of workloads, addressing high turnover and better hiring practices. Some external stakeholders noted difficulty in being hired directly by Novartis as a contractor.



We see Novartis building global programs that support and respect the diversity in your workplace. For example, by providing a minimum level of 14 weeks parental leave for all associates across the world, or to better support associates experiencing gender dysphoria. Global Diversity and Inclusion initiatives like these are really being embedded within the corporate culture."

**Cathy Course,** Enterprise Client Leader, Aon



Relevant links to Novartis positions and resources

**Living Wages** 

Safe Workplace

Supporting and Protecting our Employees

### **Good Governance**

## **Supply Chain Management**

**Definition:** Processes to ensure responsible supply chain practices, and that suppliers uphold the appropriate social, human rights and environmental standards. Examples may include supplier risk assessments and audits, the

sanctioning of non-compliance and transparent reporting practices. They may also include upholding company standards in outsourcing decisions and third-party manufacturing, and collaborating with clinical research organizations.

### **How does it impact Novartis?**

Supply chain management and mitigating third-party risk more broadly is an essential step in fulfilling society's expectations of a pharmaceutical company. With an effective supply chain management strategy, organizations can diagnose problems and disruptions quickly and effectively. As a result of the pandemic, supply chain management has attracted increasing attention: in the EU for example, the forthcoming Sustainable Corporate Governance initiative has brought the topic under a greater spotlight. As part of the proposed legislation, supply chain due diligence will be more thoroughly regulated for any producer operating in the EU market. Whether in the EU or elsewhere. Novartis will have to adhere to future standards in order to retain the trust of financial stakeholders and society alike.

### Stakeholder observations

Internal and external stakeholders broadly agreed that Novartis was doing a good job in protecting its supply chain. The company's risk management system was considered to be thorough, and constituted best practice for the sector. The company was also lauded for its efforts to build even more efficient supply chains.

Stakeholders noted that although the company's thirdparty risk management system was indeed thorough, it was not without issues. Internally, the reporting burden was perceived as being onerous for example, affecting the productivity of business owners due to the responsibility they needed to take over the whole process. Stakeholders shared concerns about transparency and the impacts of outsourcing on product quality. To mitigate this, stakeholders felt that the cost-saving assessments used in procurement could be reviewed. Respondents also suggested there were too many stockouts for medicines in the pharmaceutical sector broadly, and the single sourcing of critical supplies should not become standard practice.



We look into questions like 'How do you protect that supply chain? How do you protect those really expensive drugs? How do you protect and make sure that anything that needs to get delivered at a certain temperature is done, and you don't have too many losses?' And we saw Novartis [...] is doing this quite well."

**Cathy Course,** Enterprise Client Leader, Aon



Relevant links to Novartis positions and resources

**Third-Party Risk Management** 

Quality - Third-Party Suppliers

**ESG Management Targets** 

### **Sustainable Financial Performance**

### **Impact-based Operational Decisions**

**Definition:** Holistic operational decision-making that factors in financial, economic, social and environmental impacts and their long-term costs, even if currently externalized. Examples may

include commitments to retaining talent for as long as possible and to avoid outsourcing to low-cost locations, selecting low carbon energy suppliers, and local procurement.

### **How does it impact Novartis?**

A company's impact on ESG topics and issues needs to be accurately factored into its operational decision making because it is fundamental in ensuring the company impacts society positively. Stakeholders agree that companies' societal and environmental impacts are becoming increasingly important, in the eyes of the public, investors and policymakers. A long-term approach and perspective is needed to meet stakeholder expectations, generate positive societal outcomes and maintain the financial sustainability of Novartis.

### Stakeholder observations

External interviewees were positive about the company's targeted stakeholder engagement activities, noting they felt Novartis listens to the views of others about its impact on society as a whole. In addition, one external stakeholder pointed to the engagement of Novartis in the Value Balancing Alliance – which aims to create a way of measuring and comparing the value of contributions made by businesses to society – as a demonstration that Novartis was working to ensure its operational decisions had a positive impact.

Those stakeholders familiar with the topic argued that although Novartis conducted thorough impact valuation efforts, the results should more consistently feed into concrete business decisions (such as in procurement or portfolio choices). External and internal stakeholders also noted that the immediate social outcomes of the company's activities should be more actively measured beyond the social impact of products to the social impact of its supply chain. An example of this was the need to consider not just how transferring manufacturing can reduce costs, but can also have broader, non-financial consequences.

Finally, some internal and external stakeholders suggested that low scores for impact-based operational decisions could be related to a lack of awareness about the steps Novartis was taking (such as in ensuring that suppliers meet sustainability criteria), rather than a lack of attention or action from the company.

GG

You're moving your manufacturing [...] to Slovenia, Romania or some other place to cut costs and it has a huge impact. I don't think the impact this has on operations is ever understood by those who make the decision"

Patricia Gonzalez Garcia, CEO, The Max Foundation



Relevant links to Novartis positions and resources

**Group Performance** 

**ESG Management Targets** 

**Our Strategy** 

### **Environmental Sustainability**

### **Pharmaceuticals in the Environment**

**Definition:** Efforts undertaken to minimize the negative environmental impact of the company's activities and products over their life cycle, and to ensure the proper and legal disposal of waste that contains active pharmaceutical ingredients. Examples may include product evaluation through

environmental risk or wastewater assessments, raising awareness about responsible use of medicines and drug disposal stewardship, fostering environmentally friendly behavior among patients and engaging with third parties to improve manufacturing and discharge standards.

### **How does it impact Novartis?**

Pharmaceuticals in the environment can have a significant, negative long-term impact on natural resources and society, and the public expects companies to mitigate it. The topic that most frequently surfaced was that of pharmaceutical contaminates in water supplies fostering antimicrobial resistance (AMR). It was noted that the issue mainly exists downstream, in the final stages of production. Nevertheless, many stakeholders perceive there is still some action to be taken on the topic not only by Novartis but by the pharmaceutical sector as a whole.

#### Stakeholder observations

Overall, internal stakeholders believed that the company was already acting with the required sensitivity in terms of managing its impact on pharmaceuticals in the environment. In addition, it was generally perceived that the methodology currently used by Novartis assessed the company's impact to the appropriate standard that was needed.

Still, many believed Novartis should continue to innovate its approach to mitigate impact, even in the face of challenges in assessing the effects of this along the whole value chain. Some stakeholders suggested that Novartis could take more action to ensure pharmaceutical take-back programs were available globally. Finally, several external stakeholders suggested there was a lack of awareness about the focus of Novartis when it came to the wider topic of pharmaceuticals in the environment, and urged the company to do more to raise its profile.



It isn't just a Novartis problem. It's a societal problem about the sheer amount of drugs and drug by-products that are out there in the environment because of the way that we manage our waste, which isn't as effective as it needs to be."

#### William Heisel.

Director of Global Services for IHME Client Services, Institute for Health Metrics and Evaluation



# Relevant links to Novartis positions and resources

Pharmaceuticals in the Environment

Novartis Environmental Sustainability and Occupational Health and Safety Data Supplement 2020

**Enhancing Environmental Sustainability** 

### **Environmental Sustainability**

### **Resource Consumption**

**Definition:** Measures and incentives to ensure the efficient consumption of energy, water and other natural resources. The objectives of such measures may range from managing a company's impact on the planet and animal life to preserving biodiversity as a whole. Examples include responsible sourcing, recycling and re-use of natural resources.

### **How does it impact Novartis?**

Medicine production ultimately relies on the long-term protection and sustainable management of natural resources. The unsustainable use of energy, water or other resources can have substantial, negative long-term impacts on the environment and society, and carries with it regulatory and reputational risk. Increasingly, companies are also being held accountable for the performance of their supply chains, which can be complex. By using resources more efficiently, Novartis can therefore not only reduce costs, but also assume a leading role in sustainability and help preserve biodiversity.

### Stakeholder observations

External stakeholders generally agreed that Novartis was ahead of its peers in terms of ensuring sustainable resource consumption. Ongoing efforts such as reducing the use of packaging contributed to this perception. There was a widespread view, especially among NGOs, that the pharmaceutical sector was not among the primary contributors to climate change. Nevertheless, a number of NGO stakeholders said that there was an opportunity for Novartis to take the initiative and become a leader among its peers. Some stakeholders also noted the science-based targets Novartis has set to reduce its consumption have had a positive impact.

Stakeholders generally agreed digitalization could help the company increase efficiency while reducing its use of packaging. Ensuring stewardship over the entire life cycle of products was highlighted as another area in which Novartis could improve. Finally, external stakeholders who specialized in biodiversity called for a clearer link to be made between the company's resource use and the impact of its consumption on biodiversity loss.



I believe that in the long term, the design process for pharmaceutical manufacturing needs to be reviewed for resource and costs flows through production."

#### Nicolai Schaaf,

Senior Manager Swedish Waterhouse, Stockholm International Water Institute



**Enhancing Environmental Sustainability** 

**Environmental Sustainability** 

Novartis - Climate Change 2021



### **Comparison to Previous Years**

When comparing the results of the Novartis Materiality Assessment 2021 with the 2017 edition, several prominent trends can be noticed. First, when looking at the impact topics selected for this year's edition, we see that there was a marked increase of topics related to digital, the use of data and Artificial Intelligence. Other new impact topics included the sustainable allocation of capital and patient-centric innovation "beyond the pill", highlighting the ongoing debate around how the industry can further add value for patients.

On the topic of **Patient Health & Safety** and **Pharmacovigilance** in particular, since 2017 the perception of Novartis' performance remains strong. Notably, the topic of diversity in clinical trials is something that has emerged since 2017. In the 2021 edition of the Novartis Materiality Assessment, stakeholders also called for more Real-World Evidence studies.

In terms of the findings themselves, a clear trend was that stakeholders' concerns around **Access to Healthcare** topics were exacerbated since 2017. Topics such as pricing and intellectual property were always high on stakeholders' agenda when speaking with the industry. However, stakeholders cited the combined impact of strained healthcare budgets in the wake of the COVID-19 pandemic and the perceived lack of accessibility of highly innovative Novartis therapies as reasons for Novartis to innovate its approach to access.

When it comes to **Innovation**, drug resistance was newly classified as a dependency rather than an impact topic. The 2021 materiality assessment explored the role Novartis can play in preventing antimicrobial resistance by reinforcing drug use stewardship. Overall, there was more focus around Novartis activities for delivering transformative therapies to patients, with concerns expressed around accessibility and on the need to focus on addressing disease areas where the burden is greatest. However, the highly innovative character of Novartis therapies was more commonly praised.

On **Ethical Business Practices**, there was an overall perception that litigation and controversies resulting in negative media coverage have largely receded. This was in large part due to a recent perceived cultural change in relation to integrity and ethics within the company as part of a wider cultural transformation seen to be driving a positive change on ethical behavior.

Stakeholders' views on Novartis' performance on **People & Culture** topics changed considerably since 2017. Employee attraction and retention continues to be a complex topic for Novartis to manage. Findings showed that concerns around work flexibility and a more diverse workforce have largely been addressed. However, more concerns around workload and organizational restructuring were raised.

On **Good Governance** and **Corporate Governance** specifically, stakeholders felt that the performance of Novartis has improved. Specifically, they pointed out that they consider the rationale in decision-making at Novartis to be both clear and transparent, a remarkable change compared to 2017.

Regarding the **Sustainable Financial Performance** topic, in 2017 like in 2021 investors considered Novartis to be a financially healthy company. However, in both editions of the materiality assessment different stakeholder groups also mentioned a focus on short-term profits at the expense of longer-term financial sustainability as a challenge. In the 2021 edition of the materiality assessment there were particular concerns around profit margins and dividends having an adverse impact in Low- and Middle-Income Countries, with stakeholders arguing that profit margins often stand in the way of volume pricing.

On **Environmental Sustainability** topics, while performance scores remain relatively low, one notable finding was that the ambitious goals set by Novartis, including for the company to become fully carbon neutral by 2030 and to achieve net zero by 2040, went a long way toward building trust in the company's efforts to reduce its environmental footprint. Furthermore, stakeholders tended to trust more in Novartis' efforts in areas such as Pharmaceuticals in the Environment compared to the 2017 edition of the Novartis Materiality Assessment.



### **Strategic Implications**



Our 2021 materiality assessment delivered comprehensive insights on Novartis' impact on society at large, how Novartis activities are being impacted by external forces or trends as well as how our internal and external stakeholders view our performance in managing them. Rapidly changing societal expectations and technological progress mean that increasingly innovation must go beyond Research & Development. Accordingly, it is essential for the way Novartis evaluates its impact to adapt to the company's changing role in an ever-changing world. As Novartis works to evolve its new ESG strategic framework and roadmap, the materiality assessment findings will be used as a foundation on which the strategy will be built.

The results presented in this report will also be used to help us **identify key quantitative performance indicators** for the different topics surveyed, which in turn will help us track our progress and performance. The results of the materiality assessment have been

shared internally with the functions in charge of managing the respective topics, providing concrete objectives for our topic/issue owners to work toward.

As part of our 2021 materiality assessment cycle, Novartis also conducted a **boundaries analysis of the materiality topics for our business**. This analysis is how we bring Novartis' four key value creation areas together, including financial, economic, environmental, social governance. Doing so also enables us to assess where we have the most impact: whether it is upstream, through our direct operations or downstream.

Finally, the results of the materiality assessment were also integrated into our 2021 Enterprise Risk Management (ERM) process. The ERM process identified potential risk areas from the 15 priority topics and key dependencies. These key company risks have been mapped to identify potential blind spots and were then presented and discussed at the Enterprise Risk Workshop which took place in mid-September 2021.

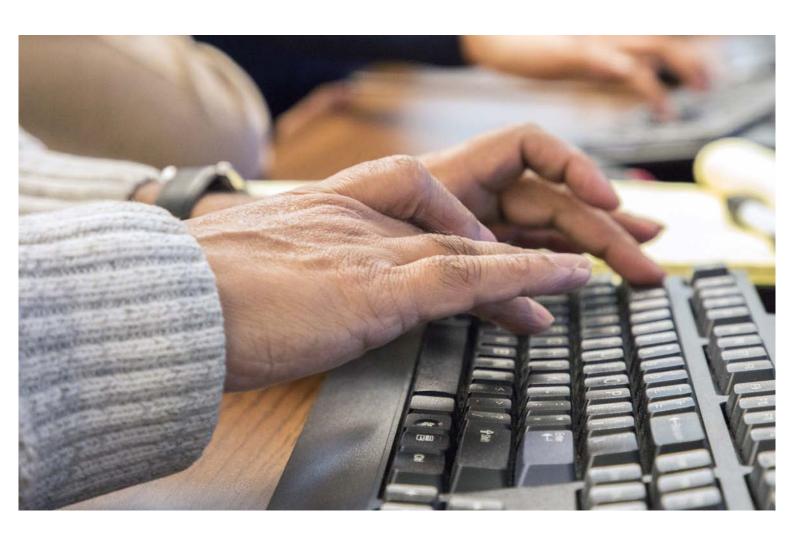
### **Next Steps**

### **Stakeholder Dialogue**

The results of our materiality assessment have been shared with all relevant internal stakeholders. Doing so will help the results gain traction and provide us with a clearer view of our employees' expectations. First, we will review the findings; based on the input received, we assess if new activities are needed to address any potential performance gaps or needs in how we engage with this stakeholder group. Following this important step, the focus of our activity will then shift toward how to keep the dialogue going with our internal and external stakeholders.

Internally, the goal of our consultation efforts is to enable our stakeholders to provide us with their views on our progress of addressing gaps and opportunities. Doing so enables us to also build important and mutually beneficial relationships with our internal stakeholders, which is essential to further increase the interest in the materiality assessment process and strengthen the validity of our findings over time.

Building and maintaining strong relationships with our external stakeholders is at the very core of the materiality assessment's objectives. The first step in doing so is to share the materiality assessment results with our external participants. We are also currently exploring additional ways we can stay engaged with our stakeholders on ESG topics outside of the materiality assessment cycles. Should you have any thoughts and/or feedback you would like to share with us or if you wish to share your views on the scope of the next materiality assessment as one of our valued stakeholders, please reach out to cr.materiality@novartis.com.





# **External Support**

### R.A.T.E. GmbH

R.A.T.E. GmbH is a measurement-based communications firm supporting clients with improving their results in corporate benchmarks such as rankings, awards, indices and ratings in areas including corporate sustainability. R.A.T.E. supported the Novartis Materiality Assessment 2021 with the conduction and statistical analysis of the materiality assessment survey.

### **Edelman**

Edelman is a global communications and public relations firm that partners with businesses and organizations to evolve, promote and protect their brands and reputations. Edelman supported with the qualitative component of the Novartis Materiality Assessment 2021 as well as with the qualitative analysis of the results and the elaboration of the key conclusions.

### **Appendix**

### **Impact Topic list**

Following a thorough review of our last materiality assessment, and after conducting initial research, a total of 30 impact topics have been selected for examination. In turn, these have been divided between eight impact clusters that are of particular relevance to the company's activities. These eight clusters are:

### **Access to Healthcare**

A group of topics which focus on improving access to medicines and healthcare services for all patients with needs, a key priority for Novartis. The topics in this cluster, and a summary of the perceptions stakeholders have about the company for each of them, are:

- Affordability & pricing: This looks at the need to set responsible pricing levels for innovative and generic medicines that takes into consideration regional affordability, a favorable cost-benefit ratio and overall healthcare costs. Stakeholders tended to have a negative perception of the performance of Novartis in this area, largely due to the high cost of innovative cell and gene therapies
- Availability of medicines: This topic includes efforts
  to manage barriers that may prevent, restrict or
  delay treatment availability for patients in both wellconnected and remote areas. The company's Sandoz
  division is widely seen as an asset in this area, and
  stakeholders called for expanding access to therapies
  in Low-to-Middle Income Countries (LMICs)
- Health system strengthening: This assesses attempts to improve healthcare infrastructure and deliver healthcare-related services that go "beyond the pill". Despite a relatively low performance, some internal and external stakeholders questioned whether strengthening healthcare systems should actually be part of the company's role at all. Others argued that activities that strengthened healthcare systems benefited Novartis in the long term, and should be viewed as an investment, not a cost
- Intellectual property: A topic which considers how to balance responsible patent exclusivity management with Intellectual Property (IP) protection. Many stakeholders viewed the performance of Novartis in this space poorly, and called for more transparency and for the company to protect its IP more sparingly
- Patient assistance programs: This looks at supporting access to Novartis products for designated patients in need of financial support, or patients in need of access prior to approval outside of a clinical trial or where a product is not commercially available post-approval. Overall, external stakeholders agreed there were signs Novartis was moving in the right direction in this field, with patient assistance programs in oncology having been noted in particular as being an example of best practice

### **Sustainable Financial Performance**

This Cluster includes topics which relate to the company's long-term financial performance, and includes:

- Business-model innovation: This topic looks at efforts to respond to emerging health needs and trends by changing existing strategies for sustainably conducting business and/or developing new business models. Both internal and external stakeholders argued there was room for Novartis to develop more innovative business models in this field
- Impact-based operational decisions: An examination of holistic operational decision-making, factoring in financial, economic, social and environmental impacts and their long-term costs, even if currently externalized. Overall, stakeholders argued there was still room for Novartis to better take account of the social and environmental impact of its activities in the future
- Profit margin & dividends: This topic involves examining how to ensure the company's continued viability, financial health and performance through supporting the long-term profitability of its business model and operations. Overall, Novartis was seen both internally and externally as a financially healthy company, creating trust among financial stakeholders. Concerns remained however among external stakeholders that high profit margins hinder patient access to the products of Novartis
- Sustainable allocation of capital: This topic assesses how Novartis applies sustainable solutions to its corporate financing decisions related to debt and financial asset management, including its corporate pension funds. External stakeholders suggested that one way for Novartis to improve its performance in this area would be to allocate more capital to innovation, and less to patent protection



### **Environmental Sustainability**

The topics which have been gathered together in this cluster, and a summary of perceptions about how Novartis is performing, are:

- Emission, waste & effluents: An examination of the ways in which a substantial reduction and better management of emissions, waste, and effluents can be achieved through the company's operations and products, as well as in its supply chain. Both internal and external stakeholders felt that while Novartis could improve its performance, as a pharmaceutical company its impact on the topic was limited
- Pharmaceuticals in the environment: A topic
  which assesses efforts to minimize the negative
  environmental impact of the company's activities
  and products over their life cycle, and to ensure the
  proper, legal disposal of waste containing active
  pharmaceutical ingredients. While the work Novartis
  is doing to measure and address its impact there
  was recognized, external stakeholders suggested
  that more could be done to mitigate the company's
  footprint
- Resource consumption: This topic explores measures and incentives to ensure the efficient consumption of energy, water and other natural resources. The science-based targets that Novartis has set to reduce its consumption have gone a long way toward building trust in the company's environmental commitments, however external stakeholders argued there was still room for improvement in terms of cutting back on unnecessary resource usage

### **Ethical Business Practices**

This cluster involves topics about the wider ways in which Novartis ensures that it goes about its business in an ethical manner. It includes:

- Corporate citizenship: This looks at how Novartis ensures its conduct is responsible and makes a fair contribution to society. This is an area where Novartis is perceived as performing strongly, although some external stakeholders argued that the company should make more effort to communicate the impact on society of it programs and policies which support its corporate citizenship goals
- Ethical & compliant behavior: This topic considers the processes and systems required to ensure Novartis operates in line with the highest principles-based ethical standards, such as its interactions with Health Care Professionals (HCPs). There was a distinct impression among external stakeholders that Novartis had put past controversies behind it, and as a result was improving its performance in this area
- Responsible use of data & artificial intelligence
   (AI): This embraces the standards and governance systems needed to ensure data and AI are utilized in accordance with the highest ethical standards. While most internal and external stakeholders viewed the performance of Novartis in this topic as relatively robust, there was a notable exception among government representatives, who believed that more could be done to improve the company's performance in this area
- Responsible use of new biotechnologies: This analyzes how Novartis ensures the appropriate handling of controversial ethical questions relating to biotechnological advancements. Novartis is seen by many to have rigorous standards in this area, although several external stakeholders argued that the lack of accessibility to some of the company's most expensive treatments raised ethical issues that needed to be addressed

### **Good Governance**

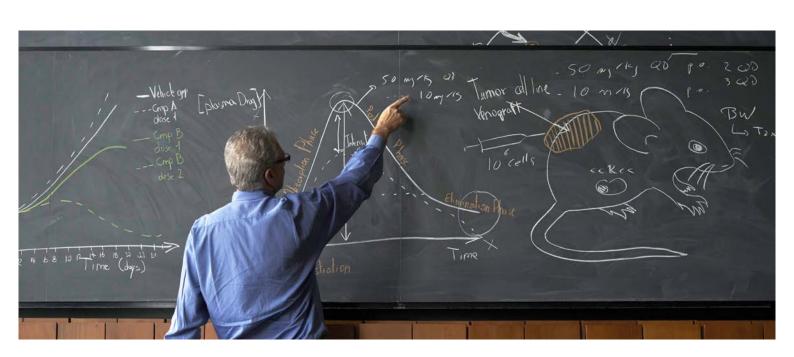
Topics is this area include how Novartis ensures that it has the most robust internal systems and processes in place. They are:

- Corporate governance: This topic assesses how the company's management structure balances the interests of its different stakeholders and allows for appropriate target-setting and performance monitoring. It also examines how transparent it is, and the extent to which it discloses critical information to stakeholders, including the outcomes and impacts of its corporate activities. Internal stakeholders rated the performance of Novartis lower than external stakeholders in this area and said transparency around the company's approach to corporate governance was an area for improvement, while external stakeholders generally felt Novartis' transparency in terms of governance was sufficient
- Data privacy & security: This examines the systems and processes in place to ensure information about patients, employees, business partners, suppliers and others is responsibly and securely collected, transferred and stored. While Novartis has progressed in improving its data privacy and security standards, both internal and external stakeholders argued they would like to see further progress in the field
- Supply chain management: This looks at the processes in place to ensure responsible supply chain practices are in place, and the way Novartis ensures that its suppliers uphold the appropriate social and environmental standards, including in the area of human rights. Internal stakeholders were often more likely to perceive a gap between the impact and performance of the company in this topic, arguing that while it was thorough, the company's third-party risk management system was relatively complex and resulted in a loss of productivity

#### **Innovation**

This cluster of topics examines how Novartis performs when it comes to innovating and adopting new technologies. The topics, and the response to them, are:

- Advanced technologies for improved health outcomes: This topic examines how Novartis leverages advanced health technology platforms to revolutionize treatments and optimize outcomes for patients. Quantitative scores for this topic were high, reflecting the fact that Novartis is generally viewed as a leader in innovation both by internal and external stakeholders
- Patient-centric innovation "beyond the pill":
   This analyses how Novartis embeds patients' perspectives in the development and delivery of holistic treatments and healthcare services so as to more accurately tailor interventions to their needs. While opinions were divided on the role and responsibility of Novartis for this topic, external stakeholders and government representatives in particular held the view that Novartis could further improve its performance in this area
- Transformative treatments for unmet medical needs: This looks at how the company performs in terms of maintaining significant investment in creating innovative treatments that address unmet medical needs, with a focus on optimizing health outcomes before considering market potential. While external stakeholders praised the company's capacity to innovate, many stated that the company could do more to focus its efforts in areas where global unmet needs are greatest



How does Novartis harness its employees to ensure the company makes the maximum use of their skills, while also ensuring it remains an attractive place to work? This cluster takes into account the topics which involve the company's people, and includes:

- Diversity, inclusion & corporate culture: This topic assesses how Novartis creates a corporate culture where everyone who works there can contribute and be recognized, ensures equal opportunities for all, and fosters a diverse and inclusive workplace. While Novartis has made significant progress in ensuring it has a diverse and inclusive workforce, internal and external stakeholders alike held the view that further progress could be achieved in translating its rhetoric to tangible impacts on culture and the wellbeing of associates
- Employee attraction & retention: An examination of how human capital management aligns recruiting efforts with company purpose and strategy, and the extent to which the company provides talent management programs to engage and retain associates with relevant skillsets. Much like in 2017, internal stakeholders tended to rate the company's performance in this space toward the lower end of the scale, although the company's ongoing cultural journey was accepted as having had a positive impact on the company
- Employee training & upskilling for the digital workplace. This topic looks at how Novartis ensures employees are equipped with the skills required to adapt to the changing demands of the workplace, and to succeed as digitalization transforms businesses around the world. Overall, internal stakeholders agreed the company currently invested significantly in training and in digital upskilling, however some felt this could result in an excessive workload being placed on employees
- Fair working conditions: This topic examines the company's fair employment practices, including upholding labor rights, freedom of association and collective bargaining, labor relations, union practices, and fair compensation and benefits. External stakeholders rated the performance of Novartis higher than internal stakeholders, some of whom argued the company could improve its record in terms of better balancing employees' workloads
- Health & safety of employees: This topic analyses the physical and mental health and safety of associates. Novartis' performance in this area was seen as very robust by both internal and external stakeholders

### **Patient Health & Safety**

The three topics in this cluster assess the ways in which Novartis ensures the safe treatment of those who use its medicines. They are:

- Health education & disease prevention: This topic looks at efforts to increase disease prevention awareness and health literacy, and ensure a more effective use of medicines. External stakeholders were divided as to whether this topic should be part of the responsibilities of Novartis. Patient groups however argued that more could be achieved through intensified engagement with patient communities and associations
- Pharmacovigilance, safety profile & quality of drugs: This involves examining how Novartis ensures that healthcare products are manufactured to the highest quality levels. It also looks at how the company decides that the efficacy and safety features of a medicine outweigh its risks, as well as the way it collects and records adverse event reports. Pharmacovigilance was widely seen by both sides as an area in which Novartis is a global leader: indeed, several external stakeholders argued it gave the company a competitive edge over its rivals
- Prevention against counterfeits & drug use stewardship: This looks at the way the company uses its influence to fight substandard and falsified medicines around the world, and contributes to the global response to drug resistance. While the performance of Novartis in the area was generally seen as being reasonably strong, both internal and external stakeholders agreed it could focus more on combatting the disruptive impact of counterfeit products, particularly in developing countries

### **Glossary**

#### **Clusters:**

The materiality assessment makes use of clusters to regroup together similar or closely linked impacts/dependencies. This also enables the materiality assessment to examine a wider range of topics, while keeping the information digestible.

### **Dependencies:**

Dependencies are forces and trends originating from the external environment that have the potential to affect Novartis operations and, ultimately, the company's value to stakeholders.

#### ESG:

Environmental, Social and Governance factors/topics, which companies like Novartis use as a basis to evaluate their performance on sustainability. The ESG concept is widely used by investors to describe the three types of non-financial factors that may affect the financial performance of a company.

#### Impacts:

Also known as "externalities", impacts are effects that an organization has on society, the environment, and/or the economy. Such effects can be intended or unintended by the organization, and positive or negative in nature.

#### **Impact Valuation:**

Efforts aimed at measuring the company's actual performance and not how it is perceived by Novartis stakeholders. This is notably achieved using impact valuation metrics, which consider benefits and costs to society in monetary terms and reflect how value is created, sustained or reduced.

### Interdependencies:

Material topics do not exist independently: they are linked to one another and their position on the matrix should be understood accordingly. Exploring the interdependencies of these topics helps us identify the necessary system-wide approaches to put in place in order to drive progress on ESG topics.

### **Material topics:**

Topics that have a substantial likelihood of influencing the judgment and decisions of key stakeholder groups and significantly impact the overall business performance of Novartis.

### **Topics:**

While they are sometimes grouped into clusters, the Novartis Materiality Assessment also examines impacts and dependencies as individual topics. The basis for including individual topics within the scope of the Novartis Materiality Assessment is if they are deemed to have a substantial likelihood to influence the judgment and decisions of key stakeholder groups and/or have a significant impact on Novartis performance and business overall.

