



Best Practices in **SUSTAINABILITY IN PHARMACEUTICAL INDUSTRY**



Focus on Environmental,
Social Responsibility and Governance (ESG)



PREFACE

The Indian Pharmaceutical Alliance (IPA) has consistently championed the advancement of quality standards within the Indian pharmaceutical industry. In alignment with this mission, the IPA launched the Quality Forum (QF) in April 2015 to support Indian manufacturers in achieving parity with global benchmarks and strengthening their quality systems. Since its inception, the QF has undertaken a multi-year journey to address critical industry challenges and develop best-practice guidance documents that enable sustainable quality excellence.

Over the past years, the QF has focused on key priority areas such as Data Reliability, Best Practices & Metrics, Culture & Capability, and Investigations. As part of this sustained effort, the Forum has developed a series of comprehensive best practices documents designed to guide the industry in meeting evolving regulatory expectations and adopting a science- and risk-based approach to quality.

This guidance document, Sustainability has been developed as a practical, sector-relevant guide to help pharmaceutical companies translate sustainability aspirations into structured action. It frames sustainability through an Environmental, Social and Governance (ESG) lens and consolidates leading practices, tools, and examples that can inform strategy and execution across operations and value chains. The content is designed to be pragmatic: it identifies the key sustainability and ESG themes most material to pharmaceutical manufacturing and business conduct, outlines emerging trends shaping stakeholder expectations, and provides a clear view of how sustainability performance links to business outcomes such as operational efficiency, risk mitigation, regulatory readiness, access to capital, and reputation

The development of this document was undertaken by a dedicated working group constituted during the IPA meeting held in September 2024, under the guidance of Shirish Belapure and Rajiv Desai. The working committee comprised the following experts: Archit Soni (Abbott), Pankaj Barbind (Ajanta Pharma), Ruhana Zariwala (Cipla), Suresh Raju (Mankind Pharma), Geena Malhotra (Signet Excipients), Parag Joshi (Torrent), Niraj Sheth (Torrent), and Jayant Dwivedy (USV)

Over a period of seven months, the committee collaborated intensively sharing current practices, benchmarking them against applicable regulatory guidance, drafting a detailed framework, and incorporating feedback from subject matter experts and regulatory stakeholders. Their collective expertise, dedication, and commitment to quality have been instrumental in shaping this guidance.

The IPA expresses its sincere appreciation to the working group and acknowledges the continued support of the CEOs of the six member companies who contributed time, resources, and funding to this important initiative.

This document is intended to serve as a practical reference for manufacturers across India and globally. It will be made publicly available on the IPA website (www.ipa-india.org) to ensure broad accessibility and industry-wide benefit.

Mumbai
February 2026

- INTRODUCTION
- PURPOSE AND OBJECTIVE
- SCOPE OF THE REPORT
- UNDERSTANDING ESG IN THE PHARMACEUTICAL INDUSTRY
- IMPORTANCE OF ESG
- HISTORICAL PERSPECTIVE OF ESG IN THE PHARMACEUTICAL SECTOR
- MEGATRENDS AND FUTURE OUTLOOK
- ENVIRONMENTAL SUSTAINABILITY
- ENVIRONMENTAL IMPACT OF PHARMACEUTICAL MANUFACTURING
- SUSTAINABLE SOURCING OF RAW MATERIALS
- ENERGY EFFICIENCY AND GHG REDUCTION
- WASTE MANAGEMENT AND RECYCLING
- WATER WITHDRAWAL AND CONSERVATION
- CASE STUDIES
- SOCIAL RESPONSIBILITY
- EMPLOYEE WELL-BEING AND LABOUR PRACTICES
- DIVERSITY, EQUITY, AND INCLUSION (DEI)
- ETHICAL MARKETING AND SALES PRACTICES
- CASE STUDIES
- GOVERNANCE
- ESG GOVERNANCE STRUCTURES
- STAKEHOLDER ENGAGEMENT
- CASE STUDIES
- REGULATORY FRAMEWORK AND STANDARDS
- GLOBAL ESG STANDARDS AND GUIDELINES
- ENVIRONMENTAL STANDARDS
- SOCIAL STANDARDS
- GOVERNANCE STANDARDS
- REPORTING FRAMEWORKS
- INDUSTRY-SPECIFIC REGULATIONS
- ENVIRONMENTAL REGULATIONS
- SOCIAL REGULATIONS
- GOVERNANCE REGULATIONS
- ADDITIONAL CONSIDERATIONS
- ESG MEASUREMENT AND REPORTING
- KEY PERFORMANCE INDICATORS (KPIs) FOR ESG
- DATA COLLECTION AND MANAGEMENT
- REPORTING TOOLS AND TECHNOLOGIES
- RISK MANAGEMENT AND MITIGATION
- ESG RISKS IN THE PHARMACEUTICAL INDUSTRY
- IMPORTANCE OF RISK MANAGEMENT AND MITIGATION
- A CASE STUDY ON JOHNSON & JOHNSON - TALCUM POWDER LITIGATION
- A CASE STUDY ON ASTELLA PHARMA'S RISK MANAGEMENT
- INNOVATION AND TECHNOLOGY

TECHNOLOGICAL INNOVATIONS FOR ENVIRONMENTAL SUSTAINABILITY
TRANSITION TO LOW ECOLOGICAL FOOTPRINT PRODUCTS AND PACKAGING
FUTURE TRENDS AND EMERGING TECHNOLOGIES
CASE STUDY: NOVARTIS – HARNESSING INNOVATION AND SUSTAINABILITY IN
THE PHARMACEUTICAL INDUSTRY
PARTNERSHIPS AND COLLABORATIONS
INDUSTRY COLLABORATIONS AND ALLIANCES
PUBLIC-PRIVATE PARTNERSHIPS
CASE STUDIES ON SUCCESSFUL PARTNERSHIPS
FINANCIAL PERFORMANCE AND ESG
IMPACT OF ESG ON FINANCIAL PERFORMANCE
ESG INVESTING AND FINANCING
CASE STUDY ON FINANCIAL PERFORMANCE LINKED TO ESG

CHAPTER 2

VALUE CREATION MODEL

57

VALUE TO BUSINESS
VALUE TO STAKEHOLDERS
VALUE TO EMPLOYEES
VALUE TO VENDOR ESG COMPLIANCE
ADDITIONAL SUGGESTED VALUES
CONCLUSION

CHAPTER 3

STAKEHOLDER ENGAGEMENT IN THE PHARMACEUTICAL SECTOR

70

UNDERSTANDING STAKEHOLDER REQUIREMENTS
INTRODUCTION TO STAKEHOLDER ENGAGEMENT
KEY ASPECTS OF STAKEHOLDER REQUIREMENTS
DIFFERENT COMPONENTS IN STAKEHOLDERS
INTERNAL STAKEHOLDERS
EXTERNAL STAKEHOLDERS
IMPORTANCE OF STAKEHOLDER ENGAGEMENT
MODES OF STAKEHOLDER ENGAGEMENT
ONE-WAY ENGAGEMENT
TWO-WAY ENGAGEMENT
ACHIEVING BUSINESS EXCELLENCE THROUGH EFFECTIVE STAKEHOLDER
ENGAGEMENT
CONCLUSION

CHAPTER 4	
SUSTAINABILITY IN PHARMA OPERATIONS - SENSITIZATION AND CAPABILITY BUILDING	80
ANNEXURE 1	84
ANNEXURE 2	85
ANNEXURE 3	86
ANNEXURE 4	87
ANNEXURE 5	89
ANNEXURE 6	91
ANNEXURE 7	92

Introduction

Purpose and Objective

The purpose of this report is to analyse and address, in a comprehensive manner, the multifaceted aspects of sustainability within the pharmaceutical industry, focusing on the value creation potential and unmet needs of various stakeholders. The report outlines a vision for sustainable operations, emphasizing environmental stewardship, social responsibility, and economic viability. It identifies both the challenges and opportunities inherent in achieving these aspirations. Additionally, the report examines current capability gaps within the industry, offering a compilation of best practices from leading organizations that exemplify sustainable operations. Finally, it provides actionable recommendations, and a roadmap designed to guide the industry towards a more sustainable future, ensuring that all efforts are aligned with long-term goals and stakeholder expectations.

Scope of the report

The report covers an overview of the sustainability best practices and policies relevant to the pharmaceutical sector.

Understanding ESG in the Pharmaceutical Industry

Importance of ESG

The importance of Environmental, Social, and Governance (ESG) criteria in the pharmaceutical industry has grown significantly. This framework helps assess companies' sustainability and ethical impact and plays a crucial role in shaping the industry's future. The concept of sustainability has evolved and is no longer solely focused on harmful emissions into the atmosphere. The reason the spotlight is on the pharma sector is that it is a major contributor to global greenhouse gas (GHG) emissions, but its impact on the environment is multi-faceted. This impact derives from R&D activity, supply chains, transport and logistics, the disposal of pharmaceutical products, and chemistry.

Social sustainability necessitates corporate accountability for the impact of a business on local communities. However, this is a complex issue that requires a delicate balance between the drive to create and deliver drugs that improve and extend life, and the need to maintain profitability. Achieving this balance involves a careful analysis of various factors, including pricing, market access, quality of supply chains, R&D practices, and drug development.

The third pillar of ESG, governance, relies not only on regulatory frameworks and external initiatives but also on the willingness of pharmaceutical companies to commit to meaningful action. This includes regulatory compliance, transparency in sharing data about their activities, adherence to quality standards, and upholding ethical business practices.

The prioritization of ESG by leading industry names, such as GlaxoSmithKline (GSK) and AstraZeneca in the environmental domain, and Johnson & Johnson (J&J) with its social initiatives, underscores its significance to the pharmaceutical sector.

As pressure mounts on the industry to become more sustainable, there is a growing responsibility to substantiate commitments with real actions. This involves engaging in collaborative initiatives and adopting a proactive stance toward sustainability.

Historical Perspective of ESG in the Pharmaceutical Sector

The pharmaceutical sector has a long history of grappling with Environmental, Social, and Governance (ESG) issues, reflecting its vital role in public health and safety. Initially, the sector's focus was largely on ensuring product efficacy and regulatory compliance, with a primary emphasis on governance and ethical practices in drug development and distribution.

In the 1990s and early 2000s, environmental concerns around waste disposal, emissions, and resource management led to an increased commitment to sustainability practices. Pharmaceutical companies began to prioritize reducing their ecological footprint, often setting benchmarks around waste management and sustainable sourcing of raw materials. To address climate change, companies like Fisher & Paykel Healthcare and AstraZeneca have dedicated resources to ensure carbon-negative emissions for the near future.

The social pillar has been a key focus, as the core goal of the industry is to improve and extend life, but more attention must be given to the environmental and governance components of ESG. The social dimension of ESG also gained traction, emphasizing ethical interactions with healthcare professionals, transparent marketing practices, and access to affordable medicines. Recent years have seen a more holistic approach, with companies integrating comprehensive ESG strategies that include community welfare, fair labour practices, and contributions toward global health challenges, such as access to essential medicines and pandemic response.

Megatrends and Future Outlook

The pharmaceutical industry faces significant ESG challenges that impact its sustainability. To meet sustainability goals and improve its reputation, the industry must take proactive, collaborative actions.

Key Macroeconomic Trends Impacting ESG in the Pharmaceutical Sector

- 1. Climate Change:** Significant reductions are possible through sustainable supply chains and operational redesigns that maintain health outcomes. For example, Fisher & Paykel Healthcare committed to reducing GHG emissions by 67% by 2034 through the Science Based Targets initiative (SBTi). AstraZeneca also aims to make its supply chain carbon-negative by 2030, with specific goals of cutting Scope 1 emissions by 20%, Scope 2 by 95%, and Scope 3 by 25% per \$1 million in sales by 2025.
- 2. Access to Medication in Developing Countries:** The World Health Organization (WHO) reports that two billion people lack access to essential medicines, with the potential to save ten million lives annually through improved access—especially in Africa and Southeast Asia. Leading pharmaceutical companies have significantly expanded efforts to address this issue. In 2010, only eight major firms had an access strategy for low- and middle-income countries; now, 17 of the top 20 do. For instance, GSK has tailored its business model and pipeline to address Africa's healthcare needs.
- 3. Drug Pricing and Affordability:** The high cost of pharmaceutical innovation, driven by rigorous clinical trials and patent protections, is intended to encourage R&D investment and promote competition post-patent. However, excessive pricing practices aimed at maximizing profits have led to widespread criticism and scrutiny. In 2020, pushback on unjustifiable drug pricing sparked demands for transparency, as stakeholders questioned whether prices truly reflect R&D investments and deliver fair value for consumers.

The pharmaceutical industry faces mounting pressure to address both environmental inefficiencies and social disparities within its operations. Currently, pharmaceutical supply chains and procurement processes are highly energy-intensive and produce 55% more greenhouse gas emissions than even the automotive sector, besides

Using over 23% of the world's water supplies. For every kilogram of drug produced, approximately 100 kilograms of waste is generated, underscoring the environmental and cost inefficiencies inherent in drug development. To meet sustainability targets, the industry will need to overhaul its supply chains, adopt low-emission technologies, and implement circular practices to reduce waste.

Socially, the sector also has room for growth, with women occupying less than 10% of all CEO and leadership roles, highlighting a critical need for diversity and inclusion initiatives. Moving forward, the industry's focus on cleaner operations and equitable leadership structures will be key to meeting stakeholder expectations.

Environmental Impact of Pharmaceutical Manufacturing

Over the past 30 years, international organizations and the pharmaceutical industry have increasingly recognized the environmental impact of pharmaceutical products on a global scale. Pharmaceutical products enter the environment at various life cycle stages, particularly during production. One of the greatest threats is that releasing antibiotics into the environment can accelerate the natural development of antibiotic-resistant pathogens, making infections more difficult to treat.

Pharmaceuticals permeate the environment through an intricate web of pathways, underscoring the multifaceted nature of this escalating issue. These pathways are primarily classified into three categories:

Direct industrial release: Pharmaceutical pollution largely originates from the industry itself, where drugs are produced on a massive scale. Despite strict regulations, manufacturing plants often discharge waste directly into water sources. This waste, containing active pharmaceutical ingredients (APIs), enters rivers and streams when treatment protocols are either ineffective or not followed, leading to serious local pollution. In areas with many pharmaceutical factories, the problem is even worse, with direct and severe impacts on nearby communities whose water and food sources are contaminated. This pollution also harms aquatic ecosystems, further endangering wildlife and human health.

Indirect release through biological excretion: The second prominent source of pharmaceutical pollution is much more diffused and extends to virtually every household: the excretion of pharmaceutical residues by humans and animals. Not all APIs consumed are fully metabolized by the body; significant quantities are expelled via urine and faeces, which eventually enter sewage systems. This issue is magnified with the use of veterinary pharmaceuticals, where residues can be directly introduced into the environment through the application of manure on agricultural land. Such contributions make human and animal excretion a widespread and challenging source of pharmaceutical pollution to tackle.

Inappropriate disposal of unused medications: Improper disposal of unused or expired medicines is a serious threat to the environment. People often throw unused drugs in the trash or flush them down toilets and sinks. This allows these chemicals to go straight into landfills or household wastewater, where they have no chance of being removed or broken down before they reach the environment. Though this might seem small, when repeated on a global scale, it becomes a major source of pharmaceutical pollution.

Sustainable Sourcing of Raw Materials

Sustainable sourcing in pharma involves selecting materials and suppliers that minimize environmental impact and uphold ethical standards. This includes using renewable resources, reducing carbon emissions, and ensuring transparency across the supply chain. By adopting sustainable procurement, pharmaceutical companies can benefit from cost savings, improved brand reputation, and greater customer satisfaction, while also meeting regulatory and industry standards. As the industry faces rising costs and margin pressures, these sustainable practices are becoming increasingly essential.

The Pharmaceutical Supply Chain Initiative (PSCI) serves as the leading membership organization dedicated to promoting excellence in safety, environmental stewardship, and social responsibility within the global pharma and healthcare supply chain. PSCI focuses on ensuring fair and safe working conditions, fostering responsible business practices, and promoting environmental sustainability through the efficient use of resources. By sharing knowledge and expertise, the PSCI aims to drive complex, global change more effectively than any single organization can achieve alone. The initiative is committed to advancing responsible supply chain management and enhancing business conditions across the industry. The three main goals include driving leadership practices at member companies, enabling suppliers to continually improve, and enhancing engagement across the industry and with key stakeholders.

Energy Efficiency and GHG Reduction

There are numerous opportunities to reduce energy consumption in pharmaceutical laboratories, manufacturing facilities, and other buildings without compromising productivity. Although upgrading equipment often comes to mind as a primary strategy for energy-efficient investments, shifts in staff behaviour and attitudes can also significantly influence energy savings. Energy efficiency improvements should be approached from multiple angles, starting with a comprehensive corporate-wide energy management program that addresses facilities, operations, environmental concerns, and employee health and safety. Key opportunities for energy savings include upgrading to energy-efficient motors, optimizing compressed air systems, and refining system designs, such as reducing laboratory ventilation.

Implementing an organization-wide energy management program is one of the most effective and cost-efficient methods for achieving energy efficiency improvements. Such a program lays the groundwork for positive change and guides the management of conservation protocols throughout the organization. It ensures that energy efficiency is not a one-time effort but a continuous process of identifying and implementing improvements.

The pharmaceutical industry is estimated to generate approximately 52 megatons of CO₂e annually, making it significantly more emissions-intensive than the automotive sector. To align with the goals of the Paris Agreement, the industry must reduce its emissions intensity by around 59% from 2015 levels by 2025. This highlights the importance of establishing clear targets to decrease emissions and ultimately achieve net-zero status.

The pharma industry is following global recommendations to reduce GHG emissions by 45% by 2030 and become net zero by 2050. Many companies are trying to accomplish this by 2040 (Novartis, Pfizer, and Sanofi, to name a few) and have explicitly committed to becoming net zero across all scopes by 2045. Additionally, each of these companies has committed to becoming carbon neutral by 2030 across all scopes.

Waste Management and Recycling

Pharmaceutical manufacturing plants are significant sources of pharmaceutical waste and must properly dispose of chemical residues from their processes. This waste includes unused products, spent chemical containers, and cleaning materials like rags and mop heads. Sending this refuse to landfills is not an option, as chemicals could leach into soil and groundwater, contaminating local water supplies. Similarly, flushing unused pharmaceuticals and chemicals down the drain can harm wildlife and interfere with water treatment processes. Therefore, plants must follow strict regulations for waste disposal to protect human health and the environment while avoiding regulatory penalties.

In the pharma sector, three main types of waste are generated: liquid/effluent waste, packaging waste, and drug waste (hazardous/biomedical waste). The latter category may consist of leftover material, off-specification material or product batches that do not meet quality assurance criteria. All of these are generated at the manufacturing unit; apart from this, there are also expired medicines or products damaged after distribution, during storage.

The liquid waste needs to be treated at effluent treatment plants; the sludge generated from this process is hazardous and needs to be sent to Common Hazardous Waste Treatment, Storage, and Disposal Facilities (TSDFs), whereas the solid waste, which is the basic bulk drug waste and formulation waste, must be incinerated. Pharma production facilities are mandated to have a zero liquid discharge (ZLD) system, 100% of the liquid waste has either to be recycled or evaporated. First, all effluents need to be treated as per norms, after which it is sent through a reverse osmosis system that can recover 85-90% of water for reuse. The remaining 10% has very high total dissolved solids; the water part is evaporated, and the solid component is sent to the TSDF.

Extended Producer Responsibility (EPR) is mandatory for the pharmaceutical industry, requiring manufacturers to register with the state pollution control board if they operate in two states, and with the central pollution control board if they operate in more than two states. In the pharma sector, 100% of collected plastic is recyclable, as high-quality, pure plastic is typically used, which offers a significant recyclability value. Items such as saline bottles, syringes, and tubes are primarily made from HDPE. At biomedical waste facilities, these materials undergo a process of disinfection through autoclaving, followed by segregation, shredding, and another round of autoclaving before being sent to registered plastic recyclers.

Water Withdrawal and Conservation

The pharmaceutical industry demands consistent, high-quality water for both production and wastewater treatment to comply with increasingly stringent regulatory discharge limits. To address these challenges, companies need to rethink conventional practices and explore innovative technologies and solutions to maintain their competitive edge. Reducing water consumption and emphasizing wastewater treatment is a growing trend in the pharmaceutical industry. Motivated by various factors, wastewater management has become increasingly vital to pharmaceutical manufacturing operations over the past decade. Fortunately, companies can adopt various strategies to not only meet compliance requirements but also enhance global water quality.

Pharmaceutical wastewater treatment is typically more intensive than in other industries, but there are various in-house processing options available. These options utilize modular equipment solutions designed for specific treatment types

Pharma manufacturers are using three common solutions to take control of their wastewater treatment.

Ultrafiltration (UF): This pressure-driven process utilizes a membrane to remove emulsified oils, metal hydroxides, dispersed materials, suspended solids, and other large molecules from wastewater. UF is particularly effective for clarifying solutions with suspended solids, bacteria, and high concentrations of macromolecules, such as oil and water. It can reduce oily water volumes by up to 98% without chemical additives. Companies have reported reductions in wash water and detergent costs by up to 75% and waste disposal costs by up to 90%. As a result, UF membrane technology is rapidly becoming the preferred choice over conventional filtration methods.

Vacuum evaporation and distillation: Evaporation is a natural phenomenon, and a clean separation technology recognized as a Best Available Technique (BAT) in several wastewater treatment processes. Because it removes the water from the contaminants, rather than filtering the contaminants from the water, it is distinct from other separation processes. No other technology can attain such high water-recovery and concentration rates as vacuum evaporators, which accelerate the natural evaporation process to treat and distil pharma wastewater amounts from 1-120 tons per day.

Reverse Osmosis Systems: Reverse osmosis (RO) technology removes dissolved solids and impurities from water using a semi-permeable membrane that allows water to pass while retaining most dissolved salts and contaminants. RO requires higher-than-osmotic pressure and high-pressure water to operate effectively. A well-designed RO system can eliminate up to 99.5% of incoming dissolved salts and impurities, along with nearly all colloidal and suspended matter, even in challenging waste and feed water applications. In some cases, RO serves as the final treatment step following ultrafiltration or chemical treatment.

Case Studies

Novartis reported a 49% reduction in its GHG emissions (Scope 1 and 2) in 2022, compared to its 2016 baseline. Novartis is aiming for carbon neutrality for Scope 1 and 2 by 2025, and is looking to become fully carbon neutral by 2030, along with achieving net zero by 2040.

Roche is targeting its achievement of net zero for Scope 1 and 2 by 2050, without relying on offsetting. In 2019, the company set an ambitious 18% Scope 3 reduction target by 2025. To help accomplish this, in 2020 Roche developed a method for measuring Scope 3 emissions and identified about 100 strategic suppliers who are responsible for almost 32% of the company's total carbon footprint. In 2021, Roche launched a pilot in Germany that accompanies 100 suppliers in the measurement, management, and improvement of their environmental performance. This initiative has been expanded with the launch of a global supplier improvement program, which will reach about 100 suppliers that produce 43% of Roche's Scope 3 emissions.

Pfizer is looking to decrease its GHG emissions by 95%. The company is also seeking to cut emissions from its value chain by 90% from 2019 baselines by 2040. While in the interim, it is looking to reduce GHG emissions within Scope 1 and 2 by 46% by 2030. Residual emissions will be offset with carbon credits. As Pfizer relies on supplier engagement, the company has announced that 100% of its key suppliers will manage their environmental impacts, including GHG emissions, while 90% of its key suppliers will set targets to reduce GHG emissions.

AstraZeneca's Raw Materials Responsible Sourcing Framework commits to sustainable sourcing practices, aiming for 95% sustainable paper in secondary and tertiary product packaging by 2022. By 2025, the company plans to implement action plans for all materials covered under this framework, AstraZeneca supports organizations that work to improve responsible sourcing standards, such as membership in the Roundtable on Sustainable Palm Oil, thus highlighting its dedication to environmental sustainability and responsible sourcing in its supply chain.

GSK, in 2023, reduced operational waste by 1% compared to 2022, achieving a total reduction of 21% since 2020. The company increased material recovery through circular routes to 53% while maintaining zero operational waste sent to landfills. Notably, GSK is working to decrease waste incineration at its wastewater treatment facility in Jurong, Singapore, and its site in Marburg, Germany. Additionally, GSK is conducting a waste footprint assessment in its supply chain to enhance supplier engagement on waste reduction strategies, demonstrating its commitment to sustainability and responsible waste management practices.

Pfizer is dedicated to conserving water, especially in water-stressed areas, by minimizing water withdrawal, mitigating potential impacts on water quality from its operations and supply chain, and responsibly managing discharges into water bodies. Pfizer focuses on water stewardship through three priorities: assessing water stress at its sites and key suppliers, developing Water Stewardship Plans in water-stressed areas, and promoting community involvement. These plans include quantifying water use, setting conservation targets, and protecting water quality and are committed to responsibly managing wastewater discharges from its internal and supplier sites by ensuring that antibiotic production meets published Predicted No-Effect Concentrations (PNECs) by 2025. The company also aims to safeguard human health and the environment throughout the lifecycle of its medicines. Additionally, Pfizer is spearheading the development of an industry standard with AMRIA to establish a certification scheme for responsible antibiotic manufacturing, to certify its antibiotics to this standard.

Social Responsibility

Employee Well-being and Labour Practices

Pharmaceutical companies prioritize employee well-being by fostering a holistic work environment that emphasizes growth, inclusivity, and support. They invest in talent acquisition and onboarding processes, ensuring that new hires are equipped with the necessary skills through continuous learning initiatives. This includes online and offline training, leadership workshops, and skill development sessions, all aimed at keeping the workforce future-ready and innovative. Performance reviews further enhance career development, while a robust rewards and recognition program acknowledges individual contributions.

To support physical and mental well-being, companies implement sports initiatives, provide healthcare facilities, and offer access to professional counselling. Flexible working hours and family benefits, including childcare and paid parental leave, create a balanced work-life dynamic. Employee support programs focusing on stress management and health initiatives further enrich the employee experience, ensuring that staff feel valued, respected, and empowered to thrive in their roles.

Pharmaceutical companies are also increasingly prioritizing fair labour practices through a comprehensive approach that integrates internationally recognized human rights standards into their operations. They align their policies with the UN Guiding Principles on Business and Human Rights, supported by Human Rights Steering Groups that report to senior leadership, ensuring accountability and oversight. Training initiatives for employees and suppliers are pivotal in fostering a deep understanding of human rights and labour principles, with programs designed to equip procurement and engagement teams to identify and address issues during supplier interactions. Regular audits and site visits monitor compliance with labour rights and environmental standards, with action plans implemented for any identified concerns.

Moreover, companies are committed to fair and equitable pay, guaranteeing competitive wages that sustain a living standard. Certifications from organizations like the Fair Wage Network validate their commitment to living wages. A zero-tolerance policy for discrimination and harassment, combined with established reporting processes, underscores their dedication to inclusive workplaces. By setting public targets for gender representation and conducting gender pay gap analyses, these companies strive for equity.

Compliance with all applicable labour laws in their operating regions is a cornerstone of their practices, with no significant risk for child or forced labour, or violations of freedom of association. Respect for workers' rights to collective bargaining is paramount, with regular engagement with unions to address labour-related matters. This proactive stance reinforces their commitment to upholding human rights and fostering a fair work environment for all stakeholders.

Diversity, Equity, and Inclusion (DEI)

Pharmaceutical companies are increasingly committed to fostering Diversity, Equity, and Inclusion (DEI) in multiple facets of their operations. They aim to create an inclusive workplace where all employees feel valued and can thrive, recognizing that diverse perspectives enhance innovation and performance. To build a diverse workforce, companies are focusing on improving access to STEM education for under-represented communities, engaging in community programs, and collaborating with universities to mentor young professionals entering the field.

In clinical trials, recognizing the importance of representation, pharma companies are utilizing epidemiologic data to ensure that trial participants reflect the diverse demographics of real-world patient populations affected by the diseases under study. This approach aims to enhance the relevance of clinical research and its outcomes for various ethnic, racial, and age groups.

Moreover, these companies are committed to supporting diversity within their supply chains by mentoring and engaging small, diverse-owned businesses, identifying growth opportunities for them. Their inclusive culture is reinforced through mandatory training that emphasizes the importance of inclusivity and the impact of individual behaviours on others.

Pharmaceutical companies are also setting leadership aspirations for race, ethnicity, and gender, ensuring their senior management reflects the diversity of their workforce and the communities they serve. Additionally, they strive to create workplaces that are accessible and empathetic, where differences are embraced. Employee Resource Groups (ERGs) play a vital role in this mission, providing platforms for collaboration and input on strategic initiatives. The establishment of forums like the Intersectionality and Inclusion Council further allows for a comprehensive approach to DEI, addressing the interconnectedness of various diversity dimensions. Overall, these efforts illustrate a dedicated commitment to building a more equitable and inclusive pharmaceutical industry.

4.3 Community Engagement and Social Impact

Pharmaceutical companies are increasingly recognizing the importance of community engagement and social impact as integral components of their business strategies. These companies are actively working to build trust and strengthen relationships with communities by addressing public health needs and contributing to local welfare. One key initiative is the establishment of partnerships with local organizations and nonprofits to promote health education, disease prevention, and access to healthcare services. For example, many pharma companies are investing in awareness campaigns about chronic diseases, offering free screenings, and supporting vaccination drives, particularly in underserved populations.

Additionally, companies are focusing on improving health literacy by providing resources and training that empower communities to make informed health decisions. They are also exploring innovative approaches to ensure equitable access to medications, including patient assistance programs that help low-income individuals afford necessary treatments. Some firms have adopted sustainable practices that not only benefit the environment but also enhance the well-being of local communities.

Furthermore, pharmaceutical companies are increasingly engaging with stakeholders through open dialogues, feedback mechanisms, and community forums, ensuring that the voices of local residents are heard in decision-making processes. This proactive approach not only fosters goodwill but also aligns with the broader corporate social responsibility goals, helping to create healthier communities while enhancing the company's reputation. Overall, the shift towards a more engaged and socially responsible model reflects a growing recognition that the health of the community is intrinsically linked to the long-term success of the industry.

4.4 Patient Access and Affordability of Medicines

Pharmaceutical companies are taking significant steps to ensure patient access and affordability of medicines and vaccines, particularly for underserved communities. By adopting value-based pricing strategies, they aim to balance sustainability with the need for equitable access to essential treatments. This includes implementing tiered pricing models based on the socio-economic status of countries, which allows for more affordable options in low- and middle-income regions. Collaborating with global health partners, these companies systematically evaluate their vaccine pipelines to identify which immunizations can effectively address public health challenges in these populations.

In addition to making vaccines accessible, many pharmaceutical firms are actively engaging with local communities and health systems to strengthen infrastructure and tackle systemic barriers that hinder health care delivery. This collaboration ensures that the voices of underserved populations are heard, empowering them to lead initiatives that directly affect their health outcomes. In least developed and low-income countries, companies often choose not to enforce patents, allowing for the production of generic alternatives, which increases the availability of vital vaccines.

Furthermore, by leveraging cutting-edge technologies such as artificial intelligence and data analytics, pharmaceutical companies can accelerate the development of innovative vaccines tailored to specific disease burdens. This focus on unmet health needs and patient involvement in the development process ensures that vaccines not only reach those who need them most but also provide meaningful benefits to individuals and health systems. Ultimately, this comprehensive approach aims to reduce health disparities and improve overall public health by making essential medicines and vaccines accessible to underserved communities.

Ethical Marketing and Sales Practices

Ethical marketing and sales practices in the pharmaceutical industry are essential for promoting patient safety, building trust, and ensuring public health. The significance of these practices lies in their ability to prevent misinformation and inappropriate use of medications, which can have serious consequences for patient care. By adhering to ethical standards, pharmaceutical companies can maintain the integrity of their products and foster a responsible healthcare environment.

To implement ethical marketing and sales practices, the pharmaceutical industry focuses on several core principles. First, companies must provide accurate and scientifically substantiated information in their promotional materials, ensuring that claims about drug efficacy and safety are not misleading. This commitment allows healthcare professionals to make informed decisions based on balanced information about benefits and risks.

Additionally, compliance with regulatory guidelines, such as those established by the FDA, is critical. These regulations dictate the proper channels for marketing drugs, requiring transparency and honesty in communications. The industry also emphasizes the importance of continuing medical education, offering healthcare providers unbiased information to support their prescribing practices without exerting undue influence.

Sales representatives are trained to uphold ethical standards, prioritizing respect for healthcare professionals and patients alike. Furthermore, transparency regarding financial relationships, such as disclosing payments made to healthcare providers, enhances accountability and trust. By prioritizing these practices, the pharmaceutical industry can ensure that its marketing and sales efforts align with the ethical principles that underpin effective and safe healthcare delivery.

Case Studies

GSK exemplifies social responsibility through initiatives focused on employee well-being, diversity, community engagement, patient access, and ethical practices. The company prioritizes employee health and safety with its 12 Life Saving Rules and tailored training, while also ensuring fair pay as a certified Living Wage employer.

In promoting diversity, equity, and inclusion (DEI), GSK has enhanced accommodations for employees with disabilities and invested in STEM education for underrepresented groups through initiatives like the GSK Science in the Summer™ program, reaching over 380,000 children. The company is recognized as a Gold employer in Stonewall's Top Global Employers Index for its LGBTQ+ inclusion efforts.

GSK engages with communities by investing £1 billion over ten years to accelerate global health research, focusing on diseases affecting lower-income populations. It collaborates with organizations to improve healthcare systems and ensure access to essential medicines.

With a commitment to making medicines affordable, GSK aims to positively impact 2.5 billion people by 2030, using tiered pricing strategies for lower-income countries. Upholding high ethical standards, GSK's comprehensive Code of Conduct and mandatory anti-bribery training help foster trust and integrity in its operations and stakeholder relationships.

AstraZeneca, another leader in the pharma industry, has implemented several unique initiatives to promote social responsibility. One of the standout programs is Healthy Heart Africa, which addresses cardiovascular diseases in the continent by improving access to diagnosis, treatment, and education about hypertension. Additionally, the company is committed to enhancing access to its medicines in low- and middle-income countries through tiered pricing and partnerships with governments and NGOs. AstraZeneca also emphasizes environmental sustainability, setting ambitious targets to reduce its carbon footprint, waste, and water usage in alignment with global climate goals.

Moreover, AstraZeneca engages patients in the development of new therapies and strives to improve healthcare experiences through initiatives that prioritize patient voices. The company invests in STEM education programs aimed at inspiring the next generation of scientists, particularly among underrepresented groups. Lastly, AstraZeneca actively promotes diversity and inclusion within its workforce and supply chain, fostering an inclusive environment that values diverse perspectives. Together, these initiatives reflect AstraZeneca's commitment to advancing healthcare while addressing broader social and environmental challenges.

Governance

ESG Governance Structures

ESG governance encompasses the decision-making processes, board oversight, rules, policies, and procedures that guide an organization's approach to ESG matters. Companies with robust ESG governance practices are marked by accountable owners and leadership, well-defined ESG accountability frameworks, and effective process controls.

ESG Governance broad overview:

Board Oversight: The board of directors or a designated ESG committee oversees ESG strategy, ensuring alignment with corporate goals and stakeholder expectations.

- ❖ **Example:** A company's board establishes a dedicated ESG or sustainability committee that meets quarterly to review ESG performance, assess risks, and approve new ESG initiatives, such as carbon reduction goals or diversity targets.

Leadership Accountability: Senior management is responsible for executing ESG initiatives, with defined roles and responsibilities to drive accountability at every level.

- ❖ **Example:** The Chief Sustainability Officer (CSO) reports directly to the CEO and leads an ESG task force, with leaders across departments (e.g., operations, HR, supply chain) accountable for meeting specific ESG targets, like reducing water usage or improving employee engagement scores.

Policies and Standards: Policies outline the company's ESG commitments, covering areas like environmental stewardship, social impact, ethical conduct, and transparency.

- ❖ **Example:** The company enacts a policy committing to net-zero carbon emissions by 2030, a code of conduct prohibiting human rights abuses across its supply chain, and a policy on data privacy that ensures customer information is protected in compliance with regulatory standards.

Metrics and Reporting: Systems are in place to track, measure, and report ESG performance, enabling ongoing assessment and disclosure to stakeholders.

- ❖ **Example:** The company tracks key ESG metrics, such as greenhouse gas emissions, gender diversity, employee turnover, and community investment.

Stakeholder Engagement: A process to engage with stakeholders — including investors, employees, and communities — to gather feedback and adapt strategies based on stakeholder priorities.

- ❖ **Example:** The company holds annual stakeholder forums and conducts regular surveys to gather input from investors, employees, customers, and local communities. Feedback from these sessions informs the company's ESG strategy.

Stakeholder Engagement

The first step involves identifying those groups or individuals who have the greatest impact on or are most affected by, the organization's activities and strategic goals. This process typically starts with a thorough analysis of all stakeholder groups, such as customers, employees, investors, suppliers, communities, and regulatory bodies.

Organizations often prioritize stakeholders based on criteria like influence, dependency, and risk, determining which groups are essential to the success of key initiatives or the achievement of long-term objectives. High-influence stakeholders, such as major investors, key customers, or regulatory authorities, are typically prioritized due to their direct impact on financial and operational outcomes. Stakeholders who are highly dependent on the organization, such as local communities or employees, are also considered material, as their well-being is closely tied to corporate actions. Regular reviews and updates of this prioritization ensure that the company stays attuned to shifts in stakeholder importance or emerging issues, ultimately enabling better alignment with evolving stakeholder expectations and sustainability objectives.

Stakeholder Engagement plays a crucial role in fostering trust and transparency, as open communication demonstrates a commitment to addressing stakeholder concerns and priorities. By incorporating diverse perspectives, organizations improve their decision-making, aligning strategies with stakeholder expectations and societal trends, which ultimately enhances their reputation and resilience. Engaging stakeholders also allows companies to proactively identify risks, adapt to environmental or regulatory changes, and create shared value that benefits both the business and its community, contributing to long-term sustainable growth.

Case Studies

Roche

The company's stakeholder engagement strategy is centred on maintaining consistent and structured communication with a diverse array of stakeholders, including patients and caregivers, patient organizations, employees, healthcare professionals, payers, policymakers, regulatory bodies, industry associations, NGOs, local communities, investors, and suppliers. Through various channels websites, publications, social media, and direct consultations.

Roche not only shares sustainability-related information but also gathers valuable feedback to align its initiatives with stakeholder needs and expectations. Roche hosted a OneRoche Patient Think Tank where patient groups assessed the company's sustainability framework, emphasizing the importance of transparency to build trust and calling for greater patient involvement in clinical trial design. Following this, Roche facilitated additional sessions with diverse stakeholders to further refine its sustainability strategy, reinforcing the value of accessible and clear communication.

Roche's commitment to transparency is further reflected in its updated policies on clinical trial data, its open disclosure of relationships with patient groups and physicians, and its publication of position papers addressing stakeholder-specific concerns, underscoring a comprehensive approach to responsible, trust-building engagement.

Sun Pharma

The company's stakeholder engagement process is designed to continuously refine its understanding of stakeholder priorities and integrate these insights into its business strategy. The approach begins by identifying key internal and external stakeholders and gathering topics of interest from past engagement cycles. Through structured, need-based conversations, Sun Pharma captures valuable feedback and aligns stakeholder expectations with its strategic objectives. Insights from these discussions are then embedded into business strategy reviews, enabling the development of programs that address stakeholder needs. Sun Pharma ensures ongoing transparency by periodically sharing progress updates and maintaining a responsive and collaborative relationship with stakeholders.

AstraZeneca

Its sustainability strategy and ESG governance is led by the Senior Executive Team (SET), with oversight from the Board of Directors and specific Board Committees. While all Board Committees consider sustainability as very important, three committees – Sustainability, Audit, and Remuneration – hold delegated authority for decision-making on key ESG matters.

The Board of Directors at AstraZeneca holds collective responsibility for the Group's success, retaining authority over key decisions and delegating other matters to the CEO or five Board Committees. The Board oversees sustainability strategy, risk, and corporate governance, monitors progress on objectives and is accountable to shareholders while representing all stakeholder interests.

- ❖ The Sustainability Committee monitors progress on the sustainability strategy, oversees stakeholder communication, and advises the Board on sustainability issues. In 2023, the Committee held two formal meetings, covering topics such as sustainability reporting, product sustainability, health equity strategy, double materiality assessments, and updates on the "Ambition Zero Carbon" initiative.
- ❖ The Audit Committee oversees sustainability disclosures in financial statements, including the TCFD and EU Taxonomy in the Annual Report. In 2023, the Committee reviewed updates on US, EU, and UK sustainability regulations and potential new audit requirements, staying informed of regulatory changes impacting financial and sustainability reporting.
- ❖ The Remuneration Committee ensures executive, and workforce pay aligns with business performance and strategic goals, incorporating ESG achievements as evaluation criteria. Since 2021, "Ambition Zero Carbon" has been a key metric in the Performance Share Plan (PSP), with targets set in collaboration with the Sustainability Committee, which also validates performance outcomes for the Remuneration Committee's review.

- ❖ The Sustainability Steering Committee (SteerCo), led by finance and sustainability leaders, oversees sustainability impacts, risks, and compliance. SteerCo ensures effective mitigation measures, data quality, and coordination across functions to manage ESG risks and regulatory compliance, supporting the company's sustainability objectives.

Regulatory Framework and Standards

Global ESG Standards and Guidelines

In recent years, the pharmaceutical industry has increasingly recognized the importance of ESG standards and guidelines as integral to sustainable and responsible business practices. In India, pharmaceutical companies are adopting a variety of ESG frameworks to enhance their operational sustainability, bolster stakeholder trust, and contribute positively to society.

Environmental Standards

ISO 14001: Environmental Management Systems

ISO 14001 is an international standard that outlines the requirements for an effective Environmental Management System (EMS). This framework assists organizations in systematically managing their environmental responsibilities. For pharmaceutical companies, compliance with ISO 14001 facilitates the identification, management, and reduction of their environmental impact. By establishing policies and objectives that align with legal requirements and stakeholder expectations, companies can improve their environmental performance, demonstrating a commitment to sustainability.

Green Chemistry Principles

The principles of green chemistry emphasize the design of chemical products and processes that minimize the generation and use of hazardous substances. In the pharmaceutical sector, this approach encourages companies to incorporate sustainable practices throughout drug development. This includes reducing the use of harmful solvents, utilizing renewable feedstocks, and enhancing energy efficiency. By adopting green chemistry principles, pharmaceutical companies can significantly lower their environmental footprint while contributing to the development of safer and more sustainable products.

Waste Management Regulations

The management of hazardous waste is critical in the pharmaceutical industry, given the nature of the products involved. In India, the Hazardous Waste (Management, Handling and Transboundary Movement) Rules, 2008, govern the disposal and management of hazardous waste. Pharmaceutical companies must ensure compliance with these regulations to responsibly manage waste generated from production processes, including pharmaceutical formulations, solvents, and packaging materials. Effective waste management not only mitigates environmental harm but also enhances a company's reputation and stakeholder confidence.

Social Standards

Corporate Social Responsibility (CSR) Guidelines

The Companies Act, 2013, mandates that Indian companies meeting certain criteria allocate a minimum of 2% of their average net profits from the last three financial years toward CSR activities. These activities can encompass various initiatives, including healthcare, education, and community welfare programs. By engaging in CSR, pharmaceutical companies can demonstrate their commitment to societal well-being, thereby fostering goodwill and enhancing their public image.

Patient Safety and Rights

Patient safety is a paramount concern in the pharmaceutical industry, necessitating strict adherence to regulations established by the Drugs Controller General of India (DCGI). These regulations ensure the safety and efficacy of pharmaceutical products through ethical clinical trials and comprehensive post-marketing surveillance. Companies are required to conduct clinical trials ethically, ensuring informed consent from participants and actively monitoring adverse effects. Upholding patient safety not only fulfills regulatory obligations but also reinforces trust with consumers and healthcare professionals.

Diversity and Inclusion Policies

Creating a diverse and inclusive workplace is essential for fostering innovation and improving employee satisfaction. Pharmaceutical companies are increasingly implementing policies that promote diversity and inclusion, ensuring equitable hiring practices and opportunities for career advancement. By cultivating a culture that values diverse perspectives, companies can enhance their organizational effectiveness and better meet the needs of a varied customer base.

Governance Standards

Companies Act, 2013

The Companies Act, 2013, provides a comprehensive framework for corporate governance in India, mandating various norms that companies must follow. Key requirements include board composition, which mandates the inclusion of independent directors, and stringent financial disclosure obligations. Compliance with these governance norms is crucial for maintaining transparency and accountability, which are fundamental to building stakeholder trust.

Securities and Exchange Board of India (SEBI) Regulations

For publicly listed pharmaceutical companies, compliance with SEBI regulations is vital. These regulations require timely and accurate disclosures of financial and non-financial information, thereby promoting accountability and protecting investor interests. Adhering to SEBI's corporate governance codes helps companies maintain investor confidence and aligns their operations with best practices.

Code of Conduct

Establishing an internal code of conduct is a critical step for pharmaceutical companies in promoting ethical behaviour among employees. A well-defined code sets forth the company's values, guiding employee behaviour in compliance with legal and ethical standards. This includes addressing conflicts of interest, ensuring compliance with laws, and upholding ethical marketing practices. A strong code of conduct fosters a culture of integrity, further enhancing the company's reputation.

Reporting Frameworks

Global Reporting Initiative (GRI)

GRI provides a comprehensive framework for sustainability reporting, enabling organizations to disclose their economic, environmental, and social performance. Many pharmaceutical companies leverage GRI standards to transparently communicate their sustainability efforts to stakeholders. Adopting GRI guidelines not only enhances transparency but also aids in identifying areas for improvement.

Sustainability Accounting Standards Board (SASB)

SASB offers industry-specific standards that guide companies in disclosing material sustainability information to investors. Pharmaceutical companies can utilize these standards to report on key ESG metrics pertinent to their sector. By aligning disclosures with SASB guidelines, companies can enhance their credibility with investors and demonstrate their commitment to sustainable practices.

In essence, the adoption of ESG standards and guidelines is essential for pharmaceutical companies in India as they strive to operate sustainably and ethically. By embracing environmental management practices, social responsibility initiatives, robust governance frameworks, and transparent reporting mechanisms, these companies can not only mitigate risks but also enhance their overall value. The journey toward sustainability is not just a regulatory obligation; it is a strategic imperative that can lead to long-term success and a positive impact on society.

6.2 Regional Regulatory Requirements

Pharmaceutical regulation is a critical aspect of ensuring the safety and efficacy of medical products worldwide. Each region has developed its own regulatory framework, tailored to address specific public health needs and operational challenges. Below, we explore the regulatory landscapes in three key regions: the United States, the European Union, and the United Kingdom, focusing on health authority interactions, the submission and review process, and post-market surveillance.

United States

In the United States, the regulatory framework for pharmaceuticals is overseen by the Food and Drug Administration (FDA). The FDA encourages proactive engagement with companies throughout the drug development process at no charge. Opportunities for interaction include pre-Investigational New Drug (pre-IND) meetings, End-of-Phase meetings, and pre-submission meetings. These interactions provide invaluable guidance and clarity, enabling companies to align their development strategies with regulatory expectations. However, it is important to note that meeting requests are not guaranteed; the FDA may refuse a request based on various criteria.

The submission and review process in the U.S. is streamlined through a single regulatory body — the FDA — allowing for efficient processing of marketing applications. Once a submission is made, the FDA conducts a thorough review to ensure that the product meets the requisite safety and efficacy standards.

In terms of post-market surveillance, the U.S. employs a robust pharmacovigilance system known as the FDA Adverse Event Reporting System (FAERS). This system collects information on adverse reactions and includes specific regulations regarding the cadence of reporting, the data required, and any additional studies that may be mandated.

European Union

In the European Union, the regulatory landscape is managed by the European Medicines Agency (EMA), in collaboration with the health authorities of the 27 EU member states and additional countries. Unlike the U.S., interactions with the EMA are not strictly tied to development milestones. While companies can seek Scientific Advice from the EMA, which incurs fees, there is essentially no limit on the frequency of these consultations. This flexibility allows companies to engage with the EMA throughout the development process, seeking guidance tailored to their specific needs.

The EU offers a centralized submission process, wherein applications are submitted to the EMA for a single authorization that is valid across all member states. Additionally, the decentralized procedure allows companies to submit applications simultaneously to multiple member states, providing alternative pathways for market access.

Post-market surveillance in the EU is facilitated by the EudraVigilance system, which collects and analyses data on adverse drug reactions. The EU has established specific reporting regulations, including detailed requirements on what data must be submitted and the timelines for reporting. Public involvement initiatives, such as the EU's pharmacovigilance framework, promote transparency and patient safety.

United Kingdom

Following Brexit, the United Kingdom established its own regulatory body, the Medicines and Healthcare products Regulatory Agency (MHRA). This independent agency is responsible for regulating all medicines and medical devices within the UK. Like the U.S., the MHRA allows companies to engage with them during the drug development process, although the specifics of these interactions can differ.

In the UK, marketing applications are submitted to the MHRA, resulting in a streamlined review process similar to that of the U.S. and EU. However, companies must adapt to the unique regulatory landscape post-Brexit, which may involve navigating different requirements and expectations.

The UK has implemented its own pharmacovigilance system, notably through the Yellow Card scheme, which enables the public and healthcare professionals to report adverse reactions. This initiative, alongside the MHRA's monitoring activities, ensures that safety remains a top priority in the post-marketing phase.

Navigating the regulatory frameworks of the United States, European Union, and United Kingdom presents both challenges and opportunities for pharmaceutical companies. A deep understanding of the distinct requirements in each region is essential for successful market entry and compliance. As the global pharmaceutical landscape continues to evolve, staying informed about regulatory developments and fostering collaboration with regulatory authorities will be crucial for ensuring that innovative therapies reach patients safely and effectively.

Industry-Specific Regulations

The pharmaceutical industry is subject to a multitude of regulations that address ESG factors. These regulations are crucial for ensuring that companies operate responsibly while minimizing their impact on the environment and society.

Environmental Regulations

Pollution Control

Pharmaceutical companies are required to comply with a range of local, national, and international regulations aimed at controlling air and water pollution. These regulations often set strict limits on emissions of volatile organic compounds (VOCs) and particulate matter. Compliance not only helps protect the environment but also ensures that companies can operate without facing significant legal or financial penalties.

Effluent Discharge

The discharge of wastewater from pharmaceutical manufacturing processes is regulated by strict guidelines. For instance, the Clean Water Act in the United States establishes standards that prevent harmful effluents from entering water bodies. Adhering to these guidelines is essential for safeguarding aquatic ecosystems and maintaining the quality of local water supplies.

Hazardous Waste Management

Regulations such as the Resource Conservation and Recovery Act (RCRA) govern the management of hazardous waste generated by pharmaceutical companies. These regulations mandate proper storage, treatment, and disposal methods to minimize risks to public health and the environment. Companies must develop comprehensive waste management plans to comply with these requirements.

Groundwater Protection

Groundwater is a vital resource that must be protected from contamination. Laws like the Safe Drinking Water Act in the U.S. aim to ensure that pharmaceutical activities do not compromise groundwater quality. Companies must implement practices that safeguard water sources, particularly in regions where they operate facilities that could impact local ecosystems.

Chemical Safety

The management of chemical substances used in pharmaceutical manufacturing is regulated under laws such as the Toxic Substances Control Act (TSCA). These regulations require companies to report and manage risks associated with chemicals, ensuring that safety protocols are followed throughout the production process. This not only protects employees and consumers but also supports environmental sustainability.

Sustainable Sourcing

Sustainable sourcing practices are becoming increasingly important in the pharmaceutical sector. Regulations often require companies to report on the sustainability of their supply chains, particularly concerning raw materials that may be sourced unsustainably. This shift toward sustainability is driven by stakeholder demand for ethical business practices and environmental responsibility.

Social Regulations

Labour Acts

Pharmaceutical companies must adhere to labour laws set by ILO and UNGP standards that promote fair wages, safe working conditions, and the prohibition of discrimination and child labour. Compliance with these regulations is not only a legal obligation but also a crucial aspect of corporate social responsibility. Companies that prioritize ethical labour practices are better positioned to attract and retain talent.

Health and Safety Regulations

Ensuring employee safety is paramount in the pharmaceutical industry. The Occupational Safety and Health Administration (OSHA) sets standards that govern workplace safety, particularly in manufacturing and research settings. Companies must implement rigorous health and safety protocols to protect their workforce and comply with these regulations.

Clinical Trial Regulations

The conduct of clinical trials is subject to strict ethical standards and regulations, including Good Clinical Practice guidelines. These regulations are designed to protect the rights and welfare of trial participants, ensuring that informed consent is obtained and that safety measures are in place. Compliance with these standards is critical for the integrity of the research process.

Access to Medicines

Pharmaceutical companies are increasingly held accountable for their pricing practices and their commitment to ensuring access to essential medications, particularly in low-income regions. Regulatory scrutiny in this area emphasizes the need for equitable access to healthcare and medicines, reinforcing the social responsibilities of pharmaceutical firms.

Governance Regulations

Corporate Governance Standards

Corporate governance regulations ensure transparency and accountability within pharmaceutical companies. These standards encompass board composition, shareholder rights, and executive compensation. Adhering to these regulations is essential for maintaining stakeholder trust and fostering a culture of ethical business practices.

Anti-Corruption and Bribery Laws

Compliance with anti-corruption laws, such as the Foreign Corrupt Practices Act (FCPA), is critical for pharmaceutical companies, especially those operating internationally. These laws help prevent unethical practices and promote fair competition, safeguarding the integrity of the industry.

Data Privacy Regulations

As pharmaceutical companies handle sensitive patient data, compliance with data privacy regulations like the General Data Protection Regulation (GDPR) is essential. These laws govern the collection, storage, and use of personal information, ensuring that patient confidentiality is maintained throughout the clinical research process.

Disclosure Requirements

Many jurisdictions require pharmaceutical companies to disclose ESG-related risks and impacts. This includes transparency in environmental management practices and social responsibility initiatives. By adhering to disclosure requirements, companies can demonstrate their commitment to responsible business practices and build trust with stakeholders.

Additional Considerations

Biodiversity

Regulations aimed at protecting biodiversity can significantly affect pharmaceutical companies that rely on natural resources for drug development. Compliance with these regulations is essential for minimizing adverse impacts on ecosystems and ensuring the sustainability of the resources used.

Product Safety and Efficacy

Regulatory bodies such as the FDA and EMA enforce strict guidelines to ensure the safety and efficacy of pharmaceutical products. These regulations intersect with governance practices, emphasizing the importance of transparency and accountability in product development.

Supply Chain Transparency

Pharmaceutical companies may be required to disclose supply chain practices, particularly regarding conflict minerals or ethically sourced materials. Increased scrutiny in this area underscores the importance of responsible sourcing and transparency throughout the supply chain.

In summary, the pharmaceutical industry is subject to a diverse array of regulations that govern environmental sustainability, social responsibility, and corporate governance. By understanding and adhering to these regulations, pharmaceutical companies can mitigate risks, enhance their reputations, and respond to the growing demand for responsible corporate behaviour in the ESG space. The evolving regulatory landscape necessitates proactive engagement and a commitment to sustainable and ethical practices in all aspects of operations.

ESG Measurement and Reporting

Key Performance Indicators (KPIs) for ESG

In the pharmaceutical industry, ESG (Environmental, Social, and Governance) Key Performance Indicators (KPIs) are essential for measuring a company's sustainability, ethical practices, and impact on society.

ESG Category	Key Performance Indicators (KPIs)
<p style="text-align: center;">Environment</p>	<ul style="list-style-type: none"> ❖ Carbon Emissions (Scope 1, 2, and 3) ❖ Energy Consumption ❖ Water Usage ❖ Waste Management ❖ Sustainable Packaging ❖ Environmental Impact of R&D ❖ Supply Chain Sustainability
<p style="text-align: center;">Social</p>	<ul style="list-style-type: none"> ❖ Patient Access & Affordability ❖ Employee Health and Safety ❖ Diversity, Equity, and Inclusion (DEI) ❖ Clinical Trials and Patient Safety ❖ Community Impact & Engagement ❖ Employee Satisfaction and Retention
<p style="text-align: center;">Governance</p>	<ul style="list-style-type: none"> ❖ Board Diversity and Independence ❖ Ethics and Compliance ❖ Data Privacy and Security ❖ Executive Compensation and ESG Alignment ❖ Supply Chain Transparency ❖ Anti-Corruption Policies ❖ Product Safety and Quality

Environmental KPIs

These focus on reducing the company's ecological footprint, including carbon emissions (across Scope 1, 2, and 3), total energy consumption, and the use of renewable energy sources. Companies also track water usage, waste management practices, and the proportion of waste that is recycled or diverted from landfills. Sustainable packaging initiatives, such as the percentage of products with recyclable or biodegradable packaging, are also key metrics. Additionally, environmental impact in R&D activities, like reducing chemical waste or improving energy efficiency, and supply chain sustainability, where companies monitor the environmental practices of their suppliers, are important to measure.

Social KPIs

These KPIs typically focus on improving patient access and affordability. These include metrics like the availability of products in low-income markets and the effectiveness of patient assistance programs. Employee health and safety is another critical social KPI, with companies tracking lost time injury rates and ensuring that a significant percentage of employees are trained in safety protocols. Diversity, equity, and inclusion (DEI) is also a key area, with companies measuring gender and ethnic diversity within the workforce, as well as in leadership roles. Social KPIs also look at ethical clinical trial practices, ensuring that clinical trials are inclusive of diverse patient populations and that patient safety is prioritized. Community engagement is another important aspect, with companies tracking investments in public health, charitable donations, and employee volunteer hours. Employee satisfaction and retention are also crucial, measured through engagement scores, turnover rates, and the availability of training opportunities.

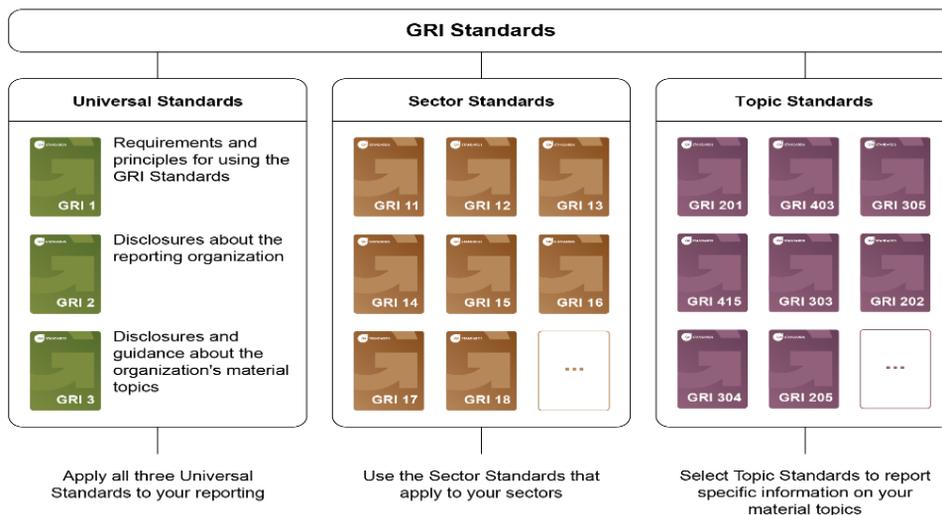
Governance

From this perspective, pharmaceutical companies typically track the diversity and independence of their boards, ensuring a majority of independent board members and promoting gender and ethnic diversity at the leadership level. Ethical governance is closely monitored, including compliance with regulations and the number of legal violations, as well as the implementation of ethical guidelines, particularly related to marketing and anti-bribery efforts. Data privacy and security are also important, with KPIs related to data breaches, compliance with privacy regulations like GDPR and HIPAA, and the adoption of cybersecurity measures. Executive compensation is another governance metric, particularly whether a significant portion of compensation is linked to achieving ESG targets. Additionally, transparency in executive pay is monitored to ensure alignment with performance and long-term company values. Supply chain transparency is increasingly scrutinized, with companies measuring how many of their suppliers are audited for compliance with ESG standards. Lastly, anti-corruption policies and the number of reported corruption cases are key governance KPIs, along with product safety and quality metrics, such as the number of product recalls and adherence to Good Manufacturing Practices (GMP).

7.2 ESG Reporting Frameworks (e.g., GRI, SASB, TCFD)

In the pharmaceutical industry, companies use a variety of reporting frameworks to communicate their ESG performance to stakeholders, including investors, regulators, and consumers. These frameworks provide standardized metrics, transparency, and accountability. Some of the most widely used frameworks are:

1. Global Reporting Initiative (GRI)



The GRI is a widely adopted framework for sustainability reporting that helps organizations disclose their ESG impacts. It provides a standardized structure for companies to report their performance across various sustainability topics, including climate change, human rights, and economic performance.

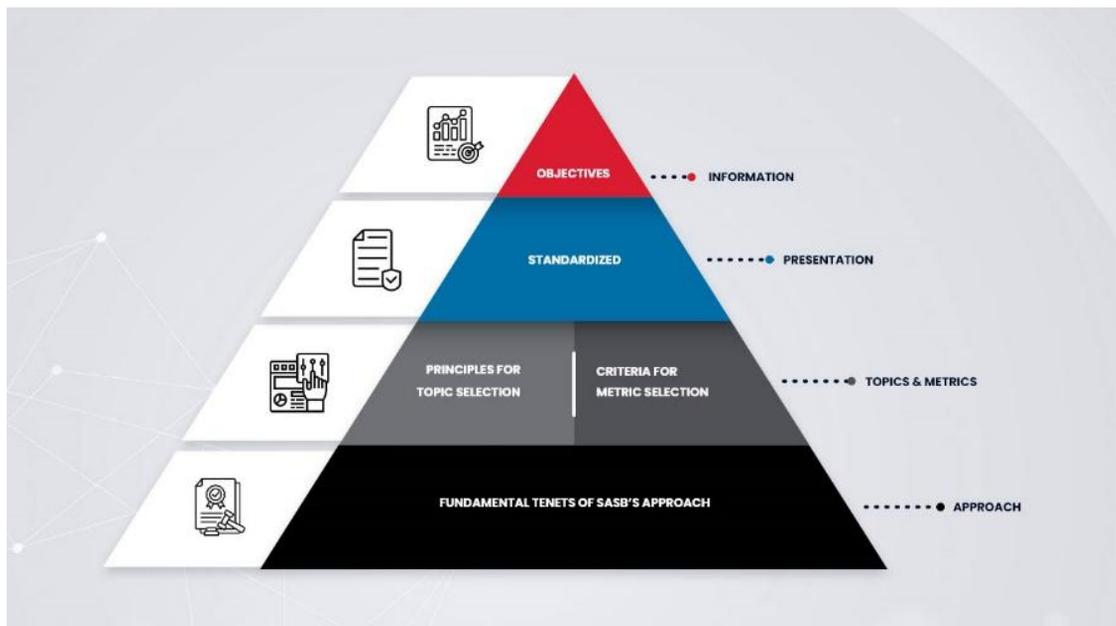
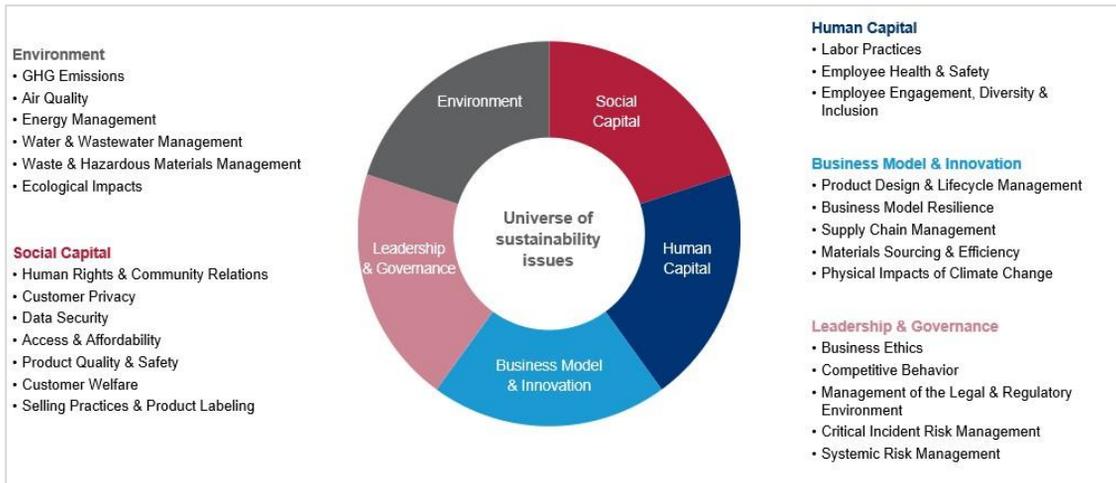
Key Components:

- ❖ **Universal Standards:** These cover the basics of reporting, such as the organization's governance, strategy, ethics, and stakeholder engagement.
- ❖ **Topic-specific Standards:** These are divided into three areas — Economic, Environmental, and Social. Each area is further broken down into specific indicators, such as emissions, energy use, water consumption, labour practices, human rights, supply chain sustainability, and community impact.
- ❖ **Reporting Principles:** GRI emphasizes principles like materiality (focusing on the most important issues), stakeholder inclusiveness, sustainability context, and completeness in reporting.

Relevance to Pharma:

For the pharmaceutical industry, GRI standards are particularly useful for reporting on social and environmental issues, such as access to medicines, labour practices, and environmental footprint. Transparent reporting helps build trust with stakeholders and aligns the industry with global sustainability goals.

2. SASB (Sustainability Accounting Standards Board)



SASB develops industry-specific standards for disclosing material sustainability information to investors. The standards focus on financial materiality, addressing ESG factors that are likely to have a significant impact on financial performance within different sectors, including the pharmaceutical industry.

Key Components:

- ❖ **Industry Standards:** SASB has developed 77 industry-specific standards, covering sectors like healthcare, energy, financials, and consumer goods. For pharmaceuticals, SASB has a specific standard that addresses issues like product quality and safety, drug pricing, regulatory compliance, R&D investments, and supply chain management.
- ❖ **Material Topics:** SASB focuses on ESG factors that directly impact the financial performance of a company, such as regulatory and legal risks, litigation risks, and product recalls.
- ❖ **Metrics and Disclosures:** SASB provides specific metrics for companies to report, ensuring consistency in ESG disclosures across sectors. Metrics include factors like R&D spending, number of product recalls, clinical trial diversity, and supply chain transparency.

Relevance to Pharma:

SASB is particularly relevant to investors in the pharmaceutical sector, as it focuses on issues that can have a direct financial impact. For example, product safety and regulatory compliance can have significant costs related to recalls or lawsuits. Additionally, SASB encourages reporting on innovation in drug development, which is a key differentiator for pharmaceutical companies. Investors can use SASB disclosures to evaluate the sustainability of a company's business model and its resilience to ESG-related risks.

1. TCFD (Task Force on Climate-related Financial Disclosures)

The TCFD is a set of recommendations that guide companies in disclosing climate-related risks and opportunities, focusing on governance, strategy, risk management, and metrics related to climate change. It is designed to promote transparent and consistent reporting of climate-related financial information.



Key Components:

The TCFD recommends disclosures across four key areas:

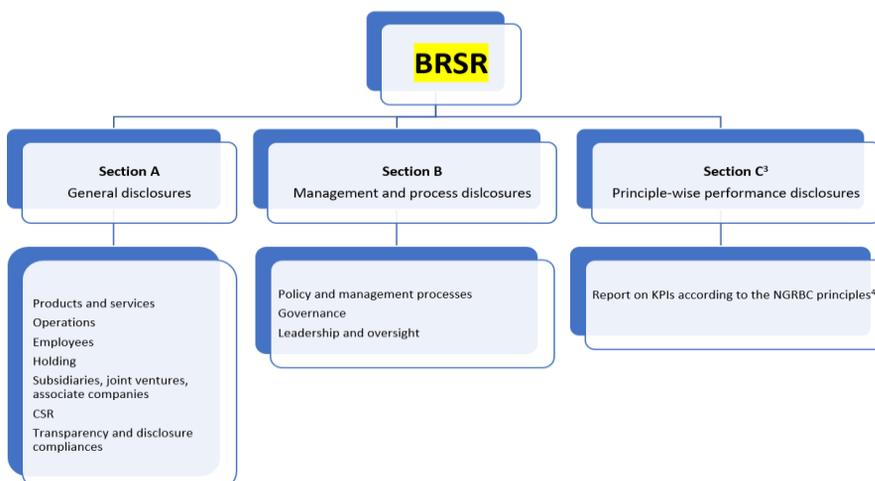
- ❖ **Governance:** Disclosures should include how the company’s governance structure and board oversee climate-related risks and opportunities.
- ❖ **Strategy:** Companies should describe how climate-related risks and opportunities could impact their business strategy, financial planning, and long-term goals.
- ❖ **Risk Management:** This involves disclosing how companies identify, assess, and manage climate-related risks, including physical risks (e.g., extreme weather events) and transition risks (e.g., regulatory changes).
- ❖ **Metrics and Targets:** TCFD recommends the disclosure of specific climate-related metrics (e.g., greenhouse gas emissions and energy consumption) and how companies measure progress toward climate-related goals, such as net-zero emissions.

Relevance to Pharma:

The pharmaceutical industry’s impact on climate change is growing, particularly in terms of energy consumption for manufacturing processes and emissions from transportation and supply chains. TCFD disclosures help pharmaceutical companies better understand and report their exposure to climate risks and opportunities. These may include risks from regulations (e.g., carbon taxes), physical risks (e.g., supply chain disruptions from extreme weather), and opportunities from innovations in green chemistry or sustainable packaging. Transparent climate risk reporting helps pharma companies address investor concerns about long-term viability in a changing climate.

1. BRSR (Business Responsibility and Sustainability Report)

The BRSR is a framework developed by the Securities and Exchange Board of India (SEBI) for companies listed in India. It mandates disclosures on the principles of responsible business conduct, including governance, ethical behaviour, environmental responsibility, and social impacts.



Key Components:

The BRSR is structured around nine principles:

1. Ethical Business Conduct: Ensuring transparency, integrity, and fairness in business practices.
2. Product Life Cycle Responsibility: Ensuring that products are safe, sustainable, and benefit society.
3. Employees' Well-being: Promoting fair labour practices, occupational health, and diversity.
4. Stakeholder Engagement: Reporting on stakeholder relationships and how the company integrates their expectations into business decisions.
5. Environment Responsibility: Managing resources efficiently and reducing environmental impacts.
6. Governance, Transparency & Accountability: Providing a governance structure that ensures ethical business practices.
7. Human Rights: Addressing human rights issues across the supply chain.
8. Community Welfare: Reporting on social impacts and corporate social responsibility (CSR) activities.
9. Disclosures and Reporting: Providing clear and accurate disclosures on business operations and impacts.

Relevance to Pharma:

For pharmaceutical companies, especially those listed in India, the BRSR framework is essential for reporting on sustainability, governance, and ethical issues. Pharma companies can use BRSR to address access to medicines, product safety, and ethical clinical trials, while also focusing on community welfare through CSR initiatives. It is also an important tool for tracking the company's environmental impact in manufacturing processes and supply chain management, ensuring compliance with local regulations and stakeholder expectations.

Data Collection and Management

In today's rapidly changing business landscape, organizations are increasingly recognizing the importance of ESG initiatives. It is not only crucial for organizations to have clear ESG goals but also to measure and report on their progress. This is where data quality plays a critical role. High-quality data is essential for accurate ESG reporting, informed decision-making, and maintaining compliance with evolving standards.

Every organization is unique and has its own set of ESG goals and priorities. To effectively measure and track progress, these goals need to be specific, measurable, achievable, relevant, and time-bound (SMART). Data plays a crucial role in setting clear ESG goals by providing organizations with the necessary insights and metrics to define their objectives. For example, organizations can leverage data to measure their carbon footprint, assess energy efficiency, track waste management, and evaluate their social impact.

Accurate and reliable data is essential for measuring ESG performance and reporting on it. ESG metrics help organizations assess their impact in various areas such as environmental sustainability, social responsibility, and governance practices. These metrics enable organizations to make informed decisions, identify areas for improvement, and demonstrate their commitment to sustainable practices. However, to ensure the integrity of ESG reporting, it is crucial to maintain data quality throughout the data collection, aggregation, and analysis processes.

Data collection for ESG KPIs can be done both manually and through automated systems. Manual data collection typically involves tracking metrics through spreadsheets or other data entry tools like Excel, where employees input information on energy consumption, emissions, diversity metrics, or other relevant factors. While this method is simple, it can be time-consuming, error-prone, and difficult to scale as data volume increases. On the other hand, automated systems leverage technology such as software platforms or integrated data solutions to capture, analyse, and report ESG data in real-time, offering greater efficiency and accuracy. As organizations increasingly recognize the importance of robust ESG reporting, many are moving towards automation to ensure more reliable, scalable, and timely data management.

Reporting Tools and Technologies

ESG tools are used by organizations to measure, manage, and report on their sustainability and social responsibility efforts. Updapt, Credible, Microsoft, and SAP are among the key players providing software solutions to help businesses track their ESG performance. Here is how each platform is used:

1. Updapt

Updapt is a platform designed to streamline ESG reporting, compliance, and transparency for businesses. It focuses on providing real-time data and insights to help organizations manage their ESG strategies more effectively.

Key Uses:

- ❖ **ESG Reporting:** Updapt helps companies prepare accurate, comprehensive, and real-time ESG reports, which align with international standards like the GRI or SASB.
- ❖ **Data Aggregation:** The platform collects ESG data from multiple sources across an organization, making it easier to assess performance and track progress toward sustainability goals.

- ❖ **Compliance:** Updapt supports organizations in meeting regulatory requirements by ensuring their ESG practices align with local and global regulations.
- ❖ **Stakeholder Engagement:** Companies use Updapt to communicate ESG initiatives to investors, customers, and other stakeholders, building trust and accountability.

2. Credible

Credible is an ESG tool primarily focused on enabling businesses to provide transparent, verifiable data to investors and other stakeholders regarding their sustainability efforts. It emphasizes data accuracy and reliability, which is essential for companies that want to strengthen their ESG credibility.

Key Uses:

- ❖ **ESG Data Validation:** Credible ensures that the ESG data a company reports are accurate, complete, and verifiable. This can involve third-party audits or certifications, adding credibility to the organization's ESG claims.
- ❖ **Third-Party Verification:** Credible provides third-party validation of ESG metrics, offering independent assessment to enhance transparency and trust.
- ❖ **Investor Engagement:** With growing interest from investors in sustainable and responsible investing, Credible helps businesses provide accurate and well-validated ESG data to attract and retain investors.
- ❖ **ESG Disclosures:** Credible enables businesses to comply with evolving ESG disclosure frameworks, such as those set by the EU Non-Financial Reporting Directive (NFRD) or TCFD.

3. Microsoft

Microsoft offers various tools and services to help businesses manage and optimize their ESG performance, particularly around the environment (sustainability), social impact, and governance (data security, ethics, etc.). Microsoft's offerings include cloud-based solutions, AI, and analytics to facilitate ESG efforts.

Key Uses:

- ❖ **Cloud Sustainability:** Through Microsoft Azure, companies can track and reduce their carbon footprint by optimizing energy use and employing sustainable practices. Azure provides tools to help businesses measure energy consumption, carbon emissions, and sustainability metrics.

- ❖ **AI and Data Analytics:** Microsoft uses artificial intelligence to provide actionable insights into ESG data, helping organizations identify opportunities to reduce environmental impact and improve social outcomes.
- ❖ **Sustainable Business Solutions:** Tools like Microsoft Cloud for Sustainability help businesses set and track sustainability goals, manage carbon emissions, and report progress. The platform integrates with other Microsoft software like Power BI to help visualize and share ESG data.
- ❖ **Supply Chain Management:** Microsoft offers solutions to optimize supply chains and ensure that suppliers meet ESG criteria, such as ethical labour practices and environmental standards.

4. SAP

SAP is a global leader in enterprise software, and it offers various tools and applications to support ESG initiatives, especially in terms of data management, supply chain optimization, and reporting.

Key Uses:

- ❖ **SAP Responsible Design and Production:** This tool helps companies manage their product lifecycle, ensuring sustainability and compliance with regulations regarding product design, manufacturing, and disposal. It helps companies make decisions based on ESG factors, such as resource usage and environmental impact.
- ❖ **SAP S/4HANA for ESG:** SAP's enterprise resource planning (ERP) platform, S/4HANA, includes features for managing sustainability and ESG efforts across the business. It integrates with financial systems and provides data-driven insights for decision-making regarding environmental impact, social responsibility, and governance practices.
- ❖ **Sustainable Supply Chain Management:** SAP's Ariba Network allows companies to collaborate with suppliers and ensure that supply chains adhere to ESG standards. This includes assessing supplier risk, tracking sustainability metrics, and ensuring ethical sourcing practices.
- ❖ **SAP Sustainability Control Tower:** This is a platform for real-time monitoring of a company's sustainability and ESG performance. It provides visibility across various sustainability data points, such as carbon emissions, energy consumption, and waste generation, and helps businesses track their progress toward ESG goals.
- ❖ **ESG Reporting and Compliance:** SAP provides tools that align with global ESG reporting standards, such as the GRI and the United Nations Sustainable Development Goals (SDGs). These tools help businesses generate reports, track metrics, and ensure regulatory compliance.

Risk Management and Mitigation

The pharmaceutical industry faces significant ESG risks that can impact its operations, reputation, and financial performance. These risks arise from various factors, including regulatory compliance, product safety, environmental impact, ethical practices, and supply chain vulnerabilities. Effective risk management and mitigation strategies are essential for pharmaceutical companies to navigate these challenges, maintain stakeholder trust, and ensure sustainable business practices.

ESG Risks in the Pharmaceutical Industry

The pharmaceutical industry faces a wide array of ESG risks that can impact its operations, reputation, and financial performance. Effective risk management and mitigation strategies are crucial for addressing these risks and maintaining stakeholder trust. Key ESG risks in the pharmaceutical industry include:

Regulatory Compliance:

- ❖ **Stringent Regulations:** Pharmaceutical companies must comply with stringent regulations set by bodies such as the U.S. FDA, EMA, and other national regulatory authorities. These regulations govern various aspects of drug development, manufacturing, marketing, and post-market surveillance. Compliance is crucial to ensure the safety and efficacy of pharmaceutical products.
- ❖ **Penalties for Non-compliance:** Non-compliance with regulatory requirements can lead to severe penalties, including fines, product recalls, and suspension of operations. For example, the FDA issued 121 warning letters to pharmaceutical companies in 2020 alone, highlighting the importance of adhering to regulatory standards.

Product Safety:

- ❖ **Adverse Events:** Ensuring the safety and efficacy of pharmaceutical products is paramount. Adverse drug reactions or product defects can lead to widespread harm, litigation, and loss of consumer trust. In 2020, there were over 2 million adverse drug event reports submitted to the FDA's MedWatch program, underscoring the need for rigorous safety monitoring.
- ❖ **Recalls:** Product recalls can be costly and damaging to a company's reputation. For instance, in 2019, there were 126 drug recalls in the U.S., affecting millions of units. Recalls often result from manufacturing defects, contamination, or labelling errors, and they highlight the critical need for robust quality control measures.

Environmental Impact:

- ❖ **Emissions and Waste:** The production and disposal of pharmaceuticals can have significant environmental impacts. Pharmaceutical manufacturing processes can generate hazardous waste, emissions, and effluents. Companies must manage these impacts to comply with environmental regulations and minimize their ecological footprint. Effective waste management and emission control measures are essential to reduce the environmental impact of pharmaceutical operations.
- ❖ **Sustainable Practices:** Many pharmaceutical companies are adopting green chemistry and sustainable manufacturing practices to reduce their environmental impact. For example, the Pharmaceutical Supply Chain Initiative (PSCI) promotes sustainable practices across the industry, encouraging companies to implement environmentally friendly processes and reduce resource consumption.

Ethical Practices:

- ❖ **Bribery and Corruption:** Ethical issues such as bribery and corruption can lead to severe legal and reputational consequences. High-profile cases, such as the GSK bribery scandal in China, highlight the risks associated with unethical practices. Pharmaceutical companies must implement robust anti-bribery and anti-corruption policies to ensure ethical conduct across their operations.
- ❖ **Marketing Practices:** Ethical marketing practices are essential to maintaining trust. Companies must avoid misleading advertising and ensure that marketing practices comply with regulatory standards. Ethical marketing involves providing accurate information about drug efficacy and safety, avoiding off-label promotion, and ensuring that marketing activities do not compromise patient welfare.

Supply Chain Risks:

- ❖ **Disruptions:** The pharmaceutical supply chain is complex and global, making it vulnerable to disruptions. Natural disasters, geopolitical issues, and quality control failures can affect the availability of critical medications. The COVID-19 pandemic highlighted the vulnerabilities in the pharmaceutical supply chain, leading to shortages of essential drugs and medical supplies. Companies must develop strategies to enhance supply chain resilience and ensure the continuous availability of medications.
- ❖ **Quality Control:** Ensuring the quality of raw materials and finished products is crucial. Pharmaceutical companies must implement stringent quality control measures to prevent contamination, ensure product consistency, and comply with regulatory standards. Effective quality management systems are essential to maintain product safety and efficacy.

Importance of Risk Management and Mitigation

Effective risk management and mitigation strategies are essential for pharmaceutical companies to navigate the complex regulatory environment, ensure product safety, and maintain stakeholder trust. Key strategies include:

- ❖ **Robust Compliance Programs:** Implementing comprehensive compliance programs to ensure adherence to regulatory requirements and ethical standards. These programs involve regular audits, employee training, and the establishment of compliance committees to oversee regulatory adherence.
- ❖ **Continuous Monitoring:** Establishing systems for continuous monitoring of product safety and efficacy, including post-market surveillance. This involves collecting and analysing data on adverse drug reactions, conducting periodic safety reviews, and implementing corrective actions when necessary.
- ❖ **Sustainable Practices:** Adopting sustainable manufacturing and environmental practices to minimize the ecological footprint. Companies can implement green chemistry principles, reduce waste and emissions, and invest in renewable energy sources to enhance environmental sustainability.
- ❖ **Ethical Governance:** Promoting ethical governance and transparency to build trust with stakeholders. This includes implementing anti-bribery and anti-corruption policies, ensuring ethical marketing practices, and fostering a culture of integrity within the organization.
- ❖ **Resilient Supply Chains:** Developing resilient supply chains to mitigate risks associated with disruptions and ensure the continuous availability of medications. Companies can enhance supply chain resilience by diversifying suppliers, implementing advanced logistics solutions, and establishing contingency plans for emergencies.

A Case Study on Johnson & Johnson - Talcum Powder Litigation

Identifying ESG Risks

Johnson & Johnson, a global leader in pharmaceuticals and consumer health products, encountered severe ESG risks associated with its talcum powder products. For decades, Johnson & Johnson's Baby Powder was a flagship product, trusted by millions of consumers. However, allegations emerged that the talcum powder contained asbestos, a known carcinogen. This led to thousands of lawsuits claiming that the use of the product caused ovarian cancer and mesothelioma.

- ❖ **Reputational Risks:** The widespread media coverage and the nature of the allegations severely damaged Johnson & Johnson's reputation. Consumers began to question the safety and transparency of the company's products, leading to a decline in brand trust and loyalty.
- ❖ **Legal Risks:** The company faced over 19,000 lawsuits related to its talcum powder products. The legal battles not only drained resources but also posed the threat of substantial financial liabilities in the form of settlements and judgments.
- ❖ **Financial Risks:** The litigation and associated negative publicity impacted Johnson & Johnson's financial performance. The company had to allocate significant funds for legal defence and potential settlements, affecting its profitability and stock performance.

Mitigation Strategies and Best Practices

Faced with these significant risks, Johnson & Johnson undertook several measures to mitigate the impact and restore stakeholder trust:

- ❖ **Enhanced Product Testing:** Johnson & Johnson intensified its product testing procedures. The company implemented more rigorous and transparent testing protocols to ensure that its talcum powder was free from contaminants like asbestos. These measures were aimed at addressing safety concerns and demonstrating the company's commitment to product integrity.
- ❖ **Improved Disclosure:** Transparency became a key focus. Johnson & Johnson increased efforts to disclose detailed information about the ingredients and safety testing of its talcum powder products. This included publishing test results and safety data to provide stakeholders with clear and accurate information, thereby rebuilding consumer confidence.
- ❖ **Corporate Governance:** Johnson & Johnson strengthened its corporate governance structures. The company enhanced board oversight of product safety and risk management processes. Specialized committees were formed to regularly review and monitor product safety issues, ensuring that potential risks were identified and addressed promptly.

Crisis Management and Response

Johnson & Johnson's response to the crisis involved several strategic actions:

- ❖ **Public Communication:** The company engaged in proactive public relations campaigns. This included issuing press releases, holding press conferences, and appearing in media interviews to directly address public concerns. Johnson & Johnson aimed to communicate its commitment to safety and responsibility, attempting to reassure consumers and stakeholders.

- ❖ **Legal Strategy:** Johnson & Johnson adopted a multifaceted legal strategy. While defending itself robustly in court, the company also explored settlement options to resolve pending lawsuits. This approach aimed to manage financial liabilities and prevent prolonged litigation from further damaging the company's reputation.
- ❖ **Product Withdrawal:** In a decisive move, Johnson & Johnson announced in May 2020 that it would discontinue the sale of its talc-based baby powder in North America. This decision was made to focus on other product lines and reduce litigation risks. The company continued to sell the product in other regions where demand remained strong and regulatory environments were different.

A Case study on Astellas Pharma's Risk Management

Astellas Pharma Inc. is committed to robust risk management as a fundamental aspect of its corporate governance. The company's risk management framework is designed to systematically identify, assess, and mitigate risks that could potentially impact its business operations, ensuring long-term sustainability and stakeholder confidence.

Key Components of Astellas' Risk Management Framework:

Risk Management Policy:

- ❖ Astellas has established a comprehensive Risk Management Policy that provides a framework for identifying, assessing, and mitigating various risks. This policy underscores the company's commitment to proactive risk management and sets the foundation for all risk-related activities.

Risk Management Structure:

Astellas has implemented a multi-layered risk management structure that integrates risk management into all levels of the organization:

- ❖ **Board of Directors:** The Board is responsible for providing overall oversight of risk management activities. The Board ensures that risk management is embedded within the company's strategic decision-making processes.
- ❖ **Risk Management Committee:** The Risk Management Committee, which operates under the Board of Directors, oversees the implementation and effectiveness of risk management policies and procedures. The committee regularly reviews and updates risk management practices to align with corporate objectives and regulatory requirements.
- ❖ **Risk Management Department:** This department is tasked with the day-to-day execution of risk management activities. It collaborates with various business units to identify, assess, and mitigate risks. The department also provides support and guidance to ensure consistent application of risk management practices across the organization.

Risk Assessment and Identification:

- ❖ **Regular Risk Assessments:** Astellas conducts regular risk assessments to identify potential risks that could affect its operations. These assessments consider both internal and external factors, including market trends, regulatory changes, technological advancements, and operational challenges.
- ❖ **Tools and Methodologies:** The company employs a variety of tools and methodologies to systematically assess risks. This includes scenario analysis, which helps anticipate the impact of different risk scenarios, and stress testing, which evaluates the company's resilience to adverse conditions.

Risk Mitigation and Control:

- ❖ **Mitigation Measures:** Astellas implements a range of mitigation measures to address identified risks. These measures include developing contingency plans, establishing robust internal controls, and conducting regular audits to ensure compliance and effectiveness.
- ❖ **Continuous Improvement:** The company is committed to continuously improving its risk management practices. This involves regularly updating risk management policies, procedures, and controls to adapt to the evolving business environment and emerging risks.

Monitoring and Reporting:

- ❖ **Ongoing Monitoring:** Astellas has established robust processes for monitoring the effectiveness of its risk management activities. This includes the use of key risk indicators (KRIs) to track risk levels and ensure timely responses to emerging risks.
- ❖ **Regular Reporting:** The Risk Management Department provides regular reports to the Risk Management Committee and the Board of Directors. These reports include updates on risk assessments, mitigation measures, and any significant changes in the risk landscape.

Training and Awareness:

- ❖ **Employee Training:** Astellas emphasizes the importance of risk management training and awareness among its employees. The company provides regular training programs to ensure that employees understand their roles and responsibilities in the risk management process.
- ❖ **Awareness Programs:** The company also conducts awareness programs to keep employees informed about the latest risk management practices and

Astellas Pharma's comprehensive risk management framework ensures that the company can effectively identify, assess, and mitigate risks. By integrating risk management into its overall strategy and corporate governance, Astellas maintains sustainable operations and safeguards stakeholder trust.

Innovation and Technology

Pharmaceutical companies are harnessing innovation and technology to tackle ESG challenges, boost sustainability, and enhance health outcomes. This heightened focus on ESG is motivated by regulatory mandates, stakeholder expectations, and the industry's dedication to ethical and sustainable practices.

Technological Innovations for Environmental Sustainability

Pharmaceutical companies are adopting technological innovations to enhance environmental sustainability. These innovations focus on reducing the environmental impact of manufacturing processes, minimizing waste, and promoting the use of renewable resources.

Green Chemistry:

- ❖ **Principles of Green Chemistry:** Green chemistry involves designing chemical products and processes that reduce or eliminate the use and generation of hazardous substances. Pharmaceutical companies are incorporating green chemistry principles to develop safer and more sustainable manufacturing methods.

Examples: Companies like Merck & Co. are implementing green chemistry techniques to optimize synthetic pathways, reduce solvent use, and minimize waste. These practices not only improve environmental outcomes but also enhance process efficiency and cost-effectiveness.

Energy Efficiency:

- ❖ **Energy-efficient Technologies:** Pharmaceutical companies are investing in energy-efficient technologies to reduce their carbon footprint. This includes upgrading equipment, optimizing heating, ventilation, and air conditioning (HVAC) systems, and implementing energy management systems.

Examples: Pfizer has implemented energy-efficient technologies across its manufacturing facilities, resulting in significant reductions in energy consumption and greenhouse gas emissions. The company has also committed to sourcing 100% renewable energy for its operations by 2030.

Water Conservation:

- ❖ **Advanced Water Technologies:** Water conservation is a critical aspect of environmental sustainability. Pharmaceutical companies are adopting advanced water recycling and reclamation systems to minimize water usage and improve water efficiency in manufacturing processes.

Examples: Companies like Johnson & Johnson are implementing water conservation measures, such as closed-loop water systems and advanced filtration technologies, to reduce freshwater consumption and enhance sustainability.

Transition to Low Ecological Footprint Products and Packaging

Pharmaceutical companies are also focusing on reducing the ecological footprint of their products and packaging. This involves developing eco-friendly packaging solutions, minimizing packaging waste, and adopting sustainable sourcing practices.

Sustainable Packaging:

- ❖ **Eco-friendly Materials:** Companies are exploring the use of recyclable, biodegradable, and plant-based materials for packaging. These materials reduce environmental impact and promote a circular economy.

Examples: Unilever has introduced sustainable packaging initiatives, such as using recyclable plastics and biodegradable materials. The company aims to make all its packaging recyclable, reusable, or compostable by 2025.

Packaging Optimization:

- ❖ **Reducing Packaging Volume:** Optimizing packaging design to reduce size and weight helps minimize material usage and lower transportation emissions. This approach also reduces the overall environmental footprint of packaging.

Examples: AstraZeneca has implemented packaging optimization strategies, such as reducing the size and weight of packaging materials, to decrease waste and improve sustainability.

Sustainable Sourcing:

- ❖ **Ethical and Sustainable Materials:** Pharmaceutical companies are sourcing raw materials from certified sustainable and ethical sources. This ensures that packaging materials are produced responsibly and have a lower environmental impact.

Examples: GSK is committed to using sustainably sourced materials for its packaging. The company collaborates with suppliers to ensure that materials meet environmental and ethical standards.

Future Trends and Emerging Technologies

The pharmaceutical industry is continuously exploring future trends and emerging technologies to enhance sustainability and address ESG challenges. These innovations have the potential to transform the industry and drive significant environmental and social benefits.

Continuous Manufacturing:

- ❖ **Advantages of Continuous Manufacturing:** Continuous manufacturing offers significant environmental benefits compared to traditional batch manufacturing. It reduces energy consumption, lowers raw material usage, and enhances process efficiency.

Examples: Companies like Novartis are investing in continuous manufacturing technologies to improve sustainability and reduce the environmental impact of drug production.

Digitalization and Automation:

- ❖ **Industry 4.0:** The adoption of digital technologies and automation is transforming pharmaceutical manufacturing. Advanced data analytics, machine learning, and automation enhance process control, reduce resource consumption, and minimize waste.

Examples: Pfizer is leveraging digitalization and automation to optimize manufacturing processes, improve efficiency, and reduce environmental impact. The company's digital initiatives include predictive maintenance, process optimization, and real-time monitoring.

Biotechnology and Synthetic Biology:

- ❖ **Sustainable Production Methods:** Biotechnology and synthetic biology offer innovative solutions for sustainable pharmaceutical production. These technologies enable the production of complex molecules using environmentally friendly methods, reducing reliance on traditional chemical synthesis.

Examples: Amgen is exploring the potential of biotechnology and synthetic biology to develop more sustainable manufacturing processes. The company is focused on using microbial fermentation and cell culture technologies to produce biologics with lower environmental impact.

Circular Economy Initiatives:

- ❖ **Promoting Circularity:** Pharmaceutical companies are embracing circular economy principles to keep materials in use for as long as possible. This includes designing products for recyclability, promoting take-back programs, and developing strategies to extend product life and reduce waste.

Example: Johnson & Johnson is implementing circular economy initiatives, such as recycling programs for medical devices and take-back schemes for expired medications, to enhance sustainability and reduce environmental impact.

Advanced Recycling Technologies:

- ❖ **Chemical Recycling:** Advanced recycling technologies, such as chemical recycling, can convert plastic waste back into its original components. This technology has the potential to recycle types of plastic that are currently not recyclable through traditional methods.

Example: Unilever is investing in advanced recycling technologies to improve the recyclability of plastic packaging and reduce plastic pollution. The company's initiatives aim to create a closed-loop system for plastic waste.

Case Study: Novartis – Harnessing Innovation and Sustainability in the Pharmaceutical Industry

Novartis, headquartered in Switzerland, is a global healthcare leader known for its commitment to innovation and sustainable practices. The company leverages advanced technologies and sustainable strategies to address ESG challenges, enhance sustainability, and improve health outcomes.

Cutting-Edge Technologies Advancing Environmental Sustainability

Novartis has been a pioneer in adopting continuous manufacturing technologies, which allow for uninterrupted production processes. This approach significantly reduces energy consumption, minimizes

waste, and enhances overall process efficiency. For example, the implementation of continuous manufacturing for Entresto, a heart failure medication, has streamlined production and lowered the environmental footprint of the drug's manufacturing process.

In addition to continuous manufacturing, Novartis incorporates green chemistry principles into its drug development processes. Green chemistry involves designing chemical products and processes that reduce or eliminate the use and generation of hazardous substances. By developing more efficient synthetic pathways, Novartis has reduced the use of harmful solvents and minimized waste, thus improving both environmental sustainability and process efficiency.

Minimizing Environmental Impact with Eco-Friendly Packaging

To minimize the environmental impact of its products, Novartis employs eco-friendly packaging solutions. The company uses recyclable and biodegradable materials, which significantly reduce plastic waste. For instance, Novartis has introduced sustainable packaging for its over-the-counter products, using materials that are either recyclable or biodegradable. This initiative supports a circular economy and minimizes the environmental footprint of the company's packaging operations.

Novartis also optimizes its packaging design to reduce size and weight, which helps minimize material usage and lower transportation emissions. By redesigning the packaging for oncology products, Novartis has decreased the volume and weight of packaging materials, leading to reduced waste and improved sustainability throughout the supply chain.

Investigating Upcoming Trends and Breakthrough Technologies

Novartis is at the forefront of digital transformation in the pharmaceutical industry. The company leverages advanced data analytics, machine learning, and automation to optimize manufacturing processes, improve efficiency, and reduce environmental impact. One notable example is the use of digital twins—virtual replicas of physical processes—that enable Novartis to simulate and optimize manufacturing operations in real-time. This technology has enhanced operational efficiency and reduced the environmental footprint of production activities.

In addition to digital transformation, Novartis is exploring biotechnology and synthetic biology to develop more sustainable pharmaceutical products. These technologies enable the production of complex molecules using environmentally friendly methods, reducing reliance on traditional chemical synthesis. Novartis invests in microbial fermentation and cell culture technologies, which offer sustainable alternatives to chemical synthesis and lower environmental impact.

The company is also embracing circular economy principles to keep materials in use for as long as possible. This includes designing products for recyclability, promoting take-back programs, and developing strategies to extend product life and reduce waste. Novartis has launched a take-back program for unused or expired medications, ensuring responsible disposal and preventing environmental pollution.

Partnerships and Collaborations

Industry Collaborations and Alliances

The pharmaceutical industry is increasingly recognizing the importance of ESG factors in its operations. To address ESG challenges and opportunities, many pharmaceutical companies are forming industry collaborations and alliances. These collaborations aim to leverage collective expertise, share resources, and drive innovation in sustainable practices.

Key Collaborations and Alliances

1. Pharmaceutical Supply Chain Initiative (PSCI)

- ❖ **Overview:** PSCI is a group of pharmaceutical and healthcare companies that collaborate to promote sustainable supply chain practices.
- ❖ **Objectives:** The initiative focuses on improving labour, health, and safety, environmental, and ethical practices across the supply chain.
- ❖ **Achievements:** PSCI provides a platform for member companies to share best practices, conduct joint audits, and engage suppliers in sustainability training programs.

2. Innovative Medicines Initiative (IMI)

- ❖ **Overview:** IMI is a public-private partnership between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA). It is the world's largest public-private partnership in the life sciences sector.
- ❖ **Objectives:**
 - a) Accelerate drug development.
 - b) Improve health outcomes.
 - c) Promote sustainable practices.
 - d) Foster collaboration between stakeholders.

3. Achievements:

- ❖ **IMI Projects:** Numerous projects addressing health areas like antimicrobial resistance, cancer, and rare diseases.

- ❖ EHDEN Project: Harmonized health data across Europe, supporting better healthcare decisions and faster drug development.
- ❖ Sustainable Chemistry: Projects like CHEM21 developed greener manufacturing methods.
- ❖ Knowledge Sharing: Facilitated best practice sharing through workshops and publications.

Public-Private Partnerships

Public-private partnerships (PPPs) are essential in addressing complex ESG challenges that require the combined efforts of the public sector, private sector, and civil society. In the pharmaceutical sector, PPPs play a crucial role in driving innovation, improving access to medicines, and addressing public health issues.

Key Public-Private Partnerships

1. Medicines for Malaria Venture (MMV)

- ❖ **Overview:** MMV is an initiative focused on discovering, developing, and delivering new antimalarial drugs.
- ❖ **Objectives:** The partnership aims to reduce the burden of malaria by ensuring the availability of affordable and effective treatments.
- ❖ **Achievements:** MMV has developed several new antimalarial drugs that have saved millions of lives, particularly in low-income countries.

2. Global Health Innovative Technology Fund (GHIT Fund)

- ❖ **Overview:** The GHIT Fund is a PPP that brings together the Japanese government, pharmaceutical companies, and international organizations to accelerate the development of new health technologies for infectious diseases.
- ❖ **Objectives:** The fund aims to address neglected diseases by supporting research and development of new drugs, vaccines, and diagnostics.
- ❖ **Achievements:** The GHIT Fund has supported numerous projects, leading to the development of new treatments for diseases such as tuberculosis and malaria.

Case Studies on Successful Partnerships

1. GSK and Save the Children

- ❖ **Overview:** GSK and Save the Children formed a strategic partnership to improve child health and survival.
- ❖ **Objectives:** The partnership focuses on developing child-friendly medicines, strengthening health systems, and responding to humanitarian emergencies.
- ❖ **Achievements:** The collaboration has led to the development of innovative treatments for neonatal sepsis and pneumonia. Additionally, the partnership has improved healthcare access for millions of children in underserved communities.*

2. Pfizer and the International Trachoma Initiative (ITI)

- ❖ **Overview:** Pfizer partnered with the International Trachoma Initiative to eliminate trachoma, a leading cause of blindness.
- ❖ **Objectives:** The initiative aims to distribute antibiotics, conduct surgeries, and improve sanitation to eliminate trachoma.
- ❖ **Achievements:** Pfizer has donated over 850 million doses of antibiotics, contributing to significant reductions in trachoma prevalence in several countries.**

Conclusion

Partnerships and collaborations are critical for advancing ESG goals within the pharmaceutical sector. Industry collaborations, public-private partnerships, and successful case studies demonstrate the significant impact that collective efforts can have on promoting sustainability, improving public health, and addressing global challenges. By continuing to grow these partnerships, the pharmaceutical industry can drive meaningful progress towards a more sustainable and equitable future.

Financial Performance and ESG

Impact of ESG on Financial Performance

The integration of ESG principles is increasingly seen as a driver of long-term financial performance and sustainability in the pharmaceutical sector. ESG considerations help companies manage risks, improve operational efficiency, enhance reputation, and attract investment.

*<https://www.savethechildren.org/us/about-us/be-inspired/partner-spotlight/glaxosmithkline>

**<https://www.pfizer.com/news/announcements/pfizer-and-international-trachoma-initiative-deliver-one-billionth-zithromaxr>

Key Impacts

1. Risk Management:

- ❖ **Environmental Risks:** Companies with proactive environmental management practices are better equipped to handle regulatory changes and climate-related risks. For example, Pfizer's Climate Action Plan aims to reduce greenhouse gas emissions by 60% by 2030 from a 2019 baseline.
 - ❖ **Social Risks:** Addressing social issues such as equitable access to healthcare can mitigate reputational risks and legal liabilities. For instance, Merck's Access to Health programs have reached over 100 million people since 2010.
 - ❖ **Governance Risks:** Strong governance practices, including transparent reporting and ethical conduct, reduce risks of corruption and non-compliance. Johnson & Johnson's governance framework emphasizes board diversity and independence, with 45% of board members being women or from underrepresented groups.
2. **Operational Efficiency:** Implementing sustainable practices can lead to cost savings. For example, Novartis reported saving \$10 million annually through energy efficiency initiatives, resulting in a 14% reduction in energy use since 2016.
 3. **Reputation and Brand Loyalty:** Companies with strong ESG performance build trust and loyalty among stakeholders. GSK ranks among the top in the Access to Medicine Index, enhancing its reputation for social responsibility.
 4. **Financial Performance:** Studies show a positive correlation between high ESG ratings and financial performance. A 2020 MSCI study found that companies with high ESG scores had lower cost of capital and higher profitability (Source: MSCI Research Insights).

ESG Investing and Financing

ESG investing has gained significant traction, with investors seeking to align their portfolios with their values while achieving financial returns. In the pharmaceutical sector, ESG investing focuses on companies committed to sustainability, ethical practices, and social impact.

Key Trends

- 1. Growth in ESG Funds:** ESG funds have seen substantial inflows, with global sustainable fund assets reaching \$3.9 trillion by the end of Q1 2021, up from \$2.7 trillion in 2020.
- 2. Green Bonds and Sustainability-Linked Loans:** Pharmaceutical companies are increasingly issuing green bonds and sustainability-linked loans. For instance, Roche issued a €750 million sustainability bond in 2021 to finance projects that improve environmental and social outcomes.
- 3. Impact Investing:** Impact investors target pharmaceutical companies with measurable social and environmental goals. The Bill & Melinda Gates Foundation's investment in CureVac, a biotech company developing mRNA vaccines, exemplifies impact investing in healthcare.
- 4. ESG Ratings and Indices:** ESG ratings guide investment decisions. Companies like AstraZeneca, which ranks highly in the Dow Jones Sustainability Index, attract ESG-focused investors.

Case Study on Financial Performance Linked to ESG

Johnson & Johnson

- ❖ **Overview:** Johnson & Johnson (J&J) is a global healthcare company with a strong commitment to ESG principles.
- ❖ **Financial Performance:**
 - a) Sustainability Goals:** J&J aims to achieve carbon neutrality by 2030. In 2020, the company reduced its carbon footprint by 34% compared to 2016 levels, saving approximately \$50 million in energy costs (Source: Johnson & Johnson 2020 ESG Report).
 - b) Social Responsibility:** J&J's community health programs have improved access to healthcare for over 30 million people since 2015 (Source: Johnson & Johnson 2020 ESG Report).
 - c) Governance Practices:** J&J's governance practices have led to high investor confidence, reflected in its consistent stock performance. The company's stock price increased by 15% over the past five years, outperforming the S&P 500 Pharmaceuticals Index.***

***https://healthforhumanityreport.jnj.com/2023/_assets/downloads/2020-esg-summary.pdf?h=AFbmtf3p

Conclusion

The integration of ESG factors into the pharmaceutical sector has significant implications for financial performance. Companies that prioritize sustainable practices, ethical governance, and social responsibility can achieve better risk management, operational efficiency, and investor confidence. The growing trend of ESG investing and financing underscores the importance of ESG considerations in driving long-term financial success. Through case studies of companies like Johnson & Johnson, Novartis, and AstraZeneca, it is evident that a strong ESG focus can lead to positive financial outcomes and a sustainable future for the pharmaceutical industry.

Chapter 2 Value Creation Model

ESG stands for “Environmental, Social and Governance.” ESG describes a set of practices (policies, procedures, metrics, etc.) that organisations implement to enhance positive impact on the environment, society, and governance bodies.

In recent years, investors have become more aware of the importance of ESG criteria in their investment decisions. As a result, many businesses have begun to integrate ESG into their operations and business strategies.

ESG considered a subset of sustainability, which is defined by the UN World Commission on Environment and Development as ‘meeting the needs of present generations without compromising the ability of future generations to meet their own needs.’

- ❖ The E in ESG, environmental criteria, includes the energy the company takes in and the waste it discharges, the resources it needs, and the consequences for living beings as a result. Not least, E encompasses carbon emissions and climate change. company uses energy and resources; every company affects, and is affected by, the environment.
- ❖ S, social criteria, addresses the relationships the company has and the reputation it fosters with people and institutions in the communities where you do business. S includes labour relations and diversity and inclusion. Every company operates within a broader, diverse society.
- ❖ G, governance, is the internal system of practices, controls, and procedures the company adopts to govern itself, make effective decisions, comply with the law and meet the needs of external stakeholders. Every company, which is itself a legal creation, requires governance.

Sustainability has become a vital part of any organisation, as it has a bearing on customer choices, employee support, and investment decisions. Business leaders integrating sustainability and ESG considerations across value chains and business models are setting up their companies for long-term success and resilience.

Sustainability helps businesses innovate and grow while also addressing environmental and societal challenges that pose significant risks to the future existence of businesses. Every business is deeply intertwined with ESG risk and opportunities to improve. It makes sense, therefore, that a strong ESG proposition can create value.

When stakeholders examine a business to assess its likelihood of long-term success, they typically evaluate areas like growth, cash flow, and market share. These factors remain essential, but alone they do not present the entire picture. Stakeholders also examine material risk factors which relate to the financial performance of a company in areas often termed ESG.

Embarking on a sustainable journey requires reconsideration of a business or organisation’s vision, goals and objectives for the future. It calls for transforming short-term profit-oriented strategies to an economically, environmentally and socially sustainable strategy that aligns with the financial and non-financial goals.

A strong ESG proposition links to value creation in five essential ways.

	Strong ESG proposition (examples)	Weak ESG proposition (examples)
Top-line growth	<p>Attract B2B and B2C customers with more sustainable products.</p> <p>Achieve better access to resources through stronger community and government relations.</p>	<p>Lose customers through poor sustainability practices (e.g., human rights, supply chain) or a perception of unsustainable/unsafe products.</p> <p>Lose access to resources (including from operational shutdowns) as a result of poor community and labour relations.</p>
Cost reductions	<p>Lower energy consumption. Reduce water intake.</p>	<p>Generate unnecessary waste and pay correspondingly higher waste disposal costs.</p> <p>Expend more in packaging costs.</p>
Regulatory and legal interventions	<p>Achieve greater strategic freedom through deregulation.</p> <p>Earn subsidies and government support.</p>	<p>Suffer restrictions on advertising and point of sale</p> <p>Incur fines, penalties, and enforcement actions.</p>
Productivity uplift	<p>Boost employee motivation.</p> <p>Attract talent through greater social credibility</p>	<p>Deal with “social stigma,” which restricts talent pool.</p> <p>Lose talent as a result of weak purpose.</p>
Investment and asset optimization	<p>Enhance investment returns by better allocating capital for the long term (e.g., more sustainable plant and equipment).</p> <p>Avoid investments that may not pay off because of longer term environmental issues.</p>	<p>Suffer stranded assets as a result of premature write-downs.</p> <p>Fall behind competitors that have invested to be less “energy hungry”.</p>

Value to Business

- ❖ ESG functions as a valuation technique that takes into account environmental, social and governance issues. ESG in the private sector is a set of criteria used to evaluate a company's risks and practices.
- ❖ ESG frameworks are important to sustainable investing because they can help individuals or other corporations determine whether the company is in alignment with their values, as well as analyse the ultimate worth of a company for their purposes.
- ❖ Top-line growth: a strong ESG proposition helps companies tap new markets and expand into existing ones. When governing authorities trust corporate actions, they are more likely to award them the access, approvals, and licenses that afford fresh opportunities for growth.

Risk Mitigation and Regulatory Compliance:

- ❖ A thorough understanding of carbon footprint allows the company to anticipate and comply with environmental regulations, such as carbon taxes, emissions trading schemes, or mandatory ESG reporting requirements.
- ❖ Conducting LCAs identifies environmental hotspots, reducing the risk of regulatory penalties and ensuring alignment with national and global climate policies.

	Enviromental	Social	Governance
Potential Issues	<ul style="list-style-type: none"> ❖ Climate change ❖ Greenhouse gas (GHG) emissions ❖ Natural resource depletion ❖ Waste and pollution ❖ Deforestation ❖ Hazardous materials ❖ Biodiversity 	<ul style="list-style-type: none"> ❖ Working conditions, including slavery and child labour ❖ Impact on local communities ❖ Conflict regions ❖ Health and safety ❖ Employee relations and diversity ❖ Product misselling ❖ Data protection 	<ul style="list-style-type: none"> ❖ Executive pay ❖ Bribery and corruption ❖ Political lobbying and donations ❖ Board diversity and structure ❖ Tax strategy ❖ Data breaches
How to address these issues?	<ul style="list-style-type: none"> ❖ Reduce GHG emissions by switching to renewable energy sources. ❖ Increase use of energy-efficient assets. ❖ Properly dispose of waste and reduce pollution. 	<ul style="list-style-type: none"> ❖ Implement policies for child labour and human rights. ❖ Innovate on safe, high-quality products. ❖ Launch employee safety programs. 	<ul style="list-style-type: none"> ❖ Link ESG metrics to incentive plans. ❖ Increase women and underrepresented groups on board committees. ❖ Increase transparency on tax.
Impact on business and operation	<ul style="list-style-type: none"> ❖ Positive natural capital news: positive impact on stock price. ❖ Negative natural capital news: negative impact on stock price. 	<ul style="list-style-type: none"> ❖ Positive social or human capital news: positive impact on stock price. ❖ Negative social or human capital news: negative impact on stock price. 	<ul style="list-style-type: none"> ❖ Positive or negative governance and leadership news: limited impact on stock price.
Value	<ul style="list-style-type: none"> ❖ Significant direct financial value at stake. 	<ul style="list-style-type: none"> ❖ Reputational and indirect value at stake. 	<ul style="list-style-type: none"> ❖ Limited opportunity to create value.

Most direct link to financial value is through environmental efforts, particularly decarbonization and waste reduction. Investing in renewable energy requires upfront capital costs, but these can be offset through tax incentives and favourable financing terms. Decarbonization efforts can improve energy efficiency, which has a direct impact on operating costs and margins. Progress on decarbonization also can reduce the risk of negative repercussions on a company's share price or penalties from regulators.

Operational Efficiency and Cost Savings:

- ❖ Identifying inefficiencies in resource use through LCA helps optimize energy consumption, reduce waste, and lower operating costs.
- ❖ Carbon foot printing highlights opportunities to transition to renewable energy, optimize logistics, and implement energy-efficient technologies, delivering financial and environmental benefits.
- ❖ Cost reductions ESG also reduce costs substantially. Among other advantages, executing ESG effectively can help combat rising operating expenses (such as raw-material costs and the true cost of water or carbon).
- ❖ Reduced regulatory and legal interventions provides a stronger external-value proposition that can enable companies to achieve greater strategic freedom, and easing regulatory pressure. In fact, in case after case across sectors and geographies, it has been observed that strength in ESG helps reduce companies' risk of adverse government action. It can also engender government support. The value at stake may be higher than seems apparent. Typically, one-third of corporate profits are at risk from state intervention.
- ❖ Investment and asset optimization is helped by a strong ESG proposition. This can enhance investment returns by allocating capital to more promising and more sustainable opportunities for example, renewables, waste reduction, and scrubbers). It can also help companies avoid stranded investments that may not pay off because of longer-term environmental issues (such as massive write-downs in the value of oil tankers). Taking proper account of investment returns requires that the company starts from the proper baseline.

Market Differentiation and Competitive Advantage:

- ❖ Adopting a robust net-zero strategy distinguishes an organization as an industry leader in sustainability, making it more attractive to customers, partners, and investors.
- ❖ Sustainability credentials enhance the company's ability to win new business, particularly as clients increasingly prioritize ESG compliance in their procurement processes.

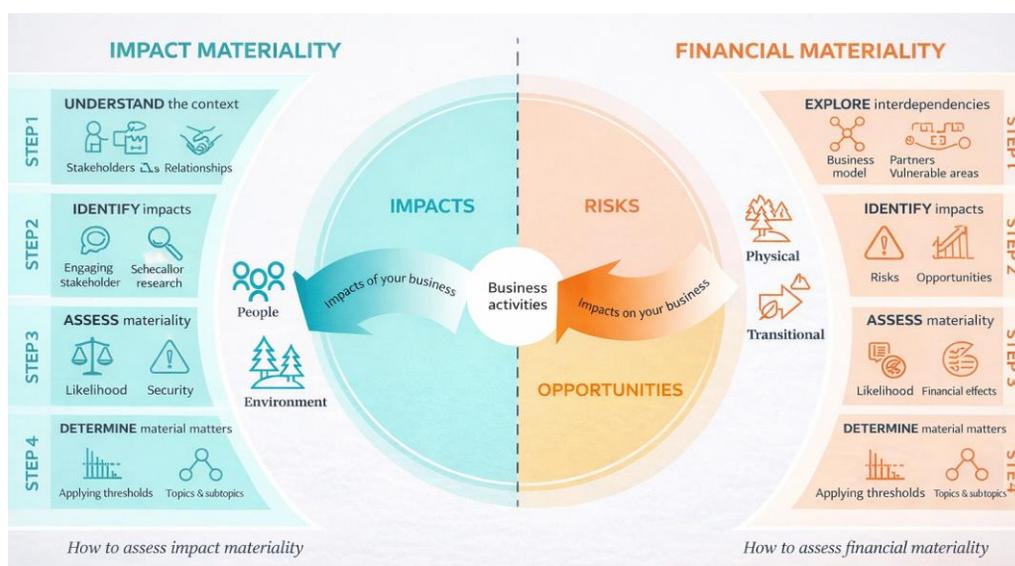
Value to Stakeholders

Transparency and Accountability:

- ❖ Materiality assessments ensure that the company focuses on and reports the most critical ESG issues, enhancing transparency and fostering trust among investors, customers, and regulators.
- ❖ Stakeholders gain confidence in the company's ability to manage environmental and social risks effectively, ensuring long-term alignment with their priorities.
- ❖ The International Sustainability Standards Board (ISSB) was established in November 2021 at COP26, aiming to create a global baseline of high-quality sustainability disclosure standards tailored to investors' needs.
- ❖ Overseen by the IFRS Foundation, the ISSB adopts a signal materiality approach, focusing on financial material "outside-in" impacts on enterprise value from environmental, social, and governance (ESG) issues.

Investor Confidence and Financial Benefits:

- ❖ Transparency in materiality assessments and net-zero commitments reassures ESG focused investors, improving the company's access to green bonds, sustainability-linked loans, and other funding opportunities.
- ❖ A strong ESG strategy mitigates risks associated with stranded assets or resource dependencies, protecting the company's financial stability in the long term.



Strengthened Relationships:

- ❖ ESG initiatives build stronger connections with local communities, regulators, and partners by demonstrating a genuine commitment to sustainability and ethical practices.
- ❖ Proactively addressing stakeholder concerns reduces the likelihood of disputes, reputational risks, and operational delays.

Resilience Through Collaboration:

- ❖ Aligning stakeholder expectations with ambitious sustainability goals creates a unified approach, ensuring a shared vision for long-term success.

Value to Employees

Engagement and Retention:

- ❖ Employees increasingly seek purpose-driven workplaces. ESG commitments inspire pride and loyalty, enhancing morale and reducing turnover rates.
- ❖ Demonstrating leadership in sustainability strengthens internal culture, making employees feel they contribute to a greater societal cause.
- ❖ Employee productivity uplift is a result of a strong ESG proposition since this can help companies attract and retain quality employees, enhance employee motivation by instilling a sense of purpose, and increase productivity overall. Employee satisfaction is positively correlated with shareholder returns.
- ❖ High ESG goals and commitments inspire employees to perform better; a weaker ESG proposition can drag productivity down. The most glaring examples are strikes, worker slowdowns, and other labour actions within an organization. But it is worth remembering that productivity constraints can also manifest outside of a company's four walls, across the supply chain. Primary suppliers often subcontract portions of large orders to other firms or rely on purchasing agents, and subcontractors are typically managed loosely, sometimes with little oversight of workers' health and safety.
- ❖ Talent attraction is another significant benefit arising from having strong ESG values. Younger generations prioritize working for organizations with such values. A visible commitment to net-zero and sustainable practices positions us as an employer of choice.

- ❖ Skill development and growth is another significant benefit, since good ESG initiatives offer employees opportunities to work on innovative projects, such as carbon reduction strategies and sustainability reporting, thereby developing new skills and expertise.
- ❖ Training in ESG-related fields creates a workforce adept at managing future challenges and capitalizing on emerging opportunities.

Value of Innovation

Driving Operational Innovation:

- ❖ Carbon footprinting and LCA identify inefficiencies, prompting innovations in manufacturing, logistics, and waste management.
- ❖ ESG strategies encourage exploration of circular economy models, such as product reuse, recycling, and sustainable materials.
- ❖ Reducing carbon footprint helps companies to enhance their commitment in reducing carbon footprint in environmental initiatives. Also, this helps to navigate the company to achieve this through the strategic implementation of energy-efficient technologies, emission reduction strategies, and the optimization of energy consumption.
- ❖ To ensure the efficient utilisation of energy, companies invest in cutting-edge equipment and automation at its manufacturing facilities, effectively managing energy consumption.
- ❖ Decarbonization initiatives such as installation of LEDs, the utilisation of variable frequency drives for conveyor belt systems in select plants, the adoption of briquettes/biofuel as an alternative energy source, and the centralization of air compressor, water chiller, and vacuum pump systems, all contributing to a substantial reduction in energy usage.
- ❖ Ongoing efforts are directed towards the decarbonization process and the reduction of Scope 1, 2, and 3 emissions.

Product and Service Innovation:

- ❖ Sustainability initiatives inspire the development of eco-friendly products and services that cater to growing consumer demand for green solutions.
- ❖ Using LCA insights, a company can market products with lower environmental footprints, providing a competitive edge.

- ❖ **Minimizing Emissions:** Environmental extensive measures to control emissions, such as installation of wet scrubbers on all industrial exhausts to effectively eliminate harmful particles and gases before they are released into the atmosphere . This helps to reduce emission levels, and to consistently adhere to permissible limits, with no instances of non-compliance. Thus, the company can diligently report their emissions to the central and state pollution control boards.
- ❖ A carbon sink is a natural or artificial carbon sequestration process that removes a greenhouse gas, an aerosol or a precursor of a greenhouse gas from the atmosphere. This commitment to environmental preservation extends to maintaining maximum possible acreage of a green belt, with the maximum number of trees that can be supported. This extensive green belt serves as a valuable carbon sink, helping to absorb carbon dioxide from the atmosphere.

R&D Collaboration:

- ❖ ESG goals foster partnerships with academic institutions, startups, and industry peers to research and implement cutting-edge solutions for emissions reduction and energy efficiency.
- ❖ Efficient water usage is another important area of focus. ESG strategies consistently work on freshwater consumption optimization across all operations. The strategic approach includes the installation of online auto cut-off meters at various plants to monitor water usage, promoting responsible water uses across facilities, rainwater harvesting, and zero liquid discharge plants to recycle, reuse and reduce the water requirements.
- ❖ Waste recycling means adopting modern approaches to achieve a circular economy for plastics. Collaborations with partners are important to introduce innovative, 100% reusable, recyclable, or compostable packaging. In order to achieve 'Zero Plastic' waste requires a commitment that entails collecting and responsibly disposing of an equivalent or greater quantity of plastic waste compared to the total plastic generation of the company. Best-in-class waste management practices and partnerships with certified waste co-processing partners drive this initiative. Companies should make efforts to make plastic packaging more recyclable, reusable, or compostable. Such efforts have resulted in significant progress.

Value to Vendor ESG Compliance

Aligned Supply Chain Standards:

- ❖ Engaging with vendors on ESG compliance ensures alignment across the supply chain, thereby reducing risks of non-compliance, poor practices, or reputational harm.
- ❖ ESG-aligned procurement policies prioritize partnerships with suppliers who meet sustainability criteria, strengthening our value chain.
- ❖ Supply chain carbon footprint reduction is an important objective in the pursuit of sustainability. To achieve this, it is important to leverage advanced technologies to optimise supply chain management and reduce travel-related emissions. Collaborative knowledge-sharing sessions with supply chain vendors and channel partners further empower them to minimise power consumption, contributing to the collective goal of reducing the company's supply chain's carbon footprint.
- ❖ Sustainable sourcing requires that the company to establish a comprehensive sustainable procurement policy that delineates sustainable sourcing strategy, dedicated R&D teams that continuously explore eco-friendly alternatives, formulations, and processes which reduce water and resource consumption. This commitment can result in the development of products featuring environmentally friendly raw materials.

Encouraging Vendor Improvement:

- ❖ Setting clear sustainability expectations encourages vendors to adopt best practices, fostering collaborative improvement and shared environmental benefits.

Cost-Effective and Sustainable Sourcing:

- ❖ Sustainable sourcing practices identified through LCA reduce long-term procurement risks and ensure the availability of critical materials.

Additional Suggested Values

Regulatory Readiness:

- ❖ ESG strategies prepare the company for upcoming regulations by embedding compliance into its operations and reporting frameworks, reducing the risk of non-compliance.
- ❖ Early adoption of sustainability practices ensures smoother transitions to future regulatory requirements, such as carbon neutrality or ESG disclosures.
- ❖ Reduced regulatory and legal interventions is a significant benefit. A stronger external-value proposition can enable companies to achieve greater strategic freedom, easing regulatory pressure. In fact, in case after case across sectors and geographies, it is observed that strength in ESG helps reduce companies' risk of adverse government action. It can also engender government support.

Optimize Value Creation: By understanding the specific benefits of ESG initiatives, companies can prioritize those that deliver the greatest value to the business, society, and the environment.

Identify Synergies and Alignment: ESG value propositions can help businesses uncover opportunities to align their sustainability efforts with their core business objectives. This can lead to more efficient and effective use of resources.

Demonstrate Impact: Clear ESG value propositions enable businesses to effectively communicate their sustainability achievements to stakeholders, including investors, customers, and employees. This can enhance the company's reputation and attract support.

Global Competitiveness:

- ❖ Aligning with international ESG frameworks (e.g., TCFD, GRI, CDP) enhances a company's reputation and competitiveness in global markets where sustainability is a key criterion for partnerships and investments.

Customer Loyalty and Retention:

- ❖ Transparency in carbon foot printing and progress toward net-zero builds trust with eco-conscious customers, improving retention and loyalty.
- ❖ Demonstrating leadership in ESG differentiates a firm in competitive markets, attracting customers who value sustainability.

- ❖ Lower cost of customer acquisition is a direct benefit.
- ❖ Increase in favourable media exposure is also a major benefit.

Climate Resilience and Long-Term Viability:

- ❖ ESG initiatives prepare us for climate-related risks, such as supply chain disruptions, resource scarcity, and extreme weather events, ensuring operational continuity and business resilience.

Sustainability Leadership:

- ❖ Demonstrating leadership in ESG establishes a company as a trusted, forward-thinking organization, enhancing our reputation among all stakeholders.
- ❖ Sharing the company’s ESG journey inspires others in the industry, fostering collective progress toward a sustainable future.

Summary of How ESG activities affect drivers of value

	Positive ESG Benefits	Negative ESG Costs
1 Sales growth rate	<ul style="list-style-type: none"> ❖ Increase consumer satisfaction and willingness to pay, reduce churn. 	<ul style="list-style-type: none"> ❖ Loss of customers to competitors who provide sustainable products and services.
2 Operating margin	<ul style="list-style-type: none"> ❖ Increase worker productivity (through more purpose-driven culture). ❖ Increase cost efficiency by reducing waste. 	<ul style="list-style-type: none"> ❖ Higher employee turnover due to poor workplace culture and dissatisfaction. ❖ Raise disposal costs for excess waste.
3 Incremental investment rate	<ul style="list-style-type: none"> ❖ Increase return on investment by allocating capital to more sustainable assets and fuel types. 	<ul style="list-style-type: none"> ❖ Loss of competitiveness due to stranded assets or lagging in the transition to a low-carbon economy.
4 Cash tax rate	<ul style="list-style-type: none"> ❖ Tax credits, incentives, and tax advantaged financing help offset ESG investments. 	<ul style="list-style-type: none"> ❖ Higher effective tax rate.
5 Cost of capital	<ul style="list-style-type: none"> ❖ Access new sources of capital (e.g., sustainable financing instruments). ❖ Lower cost of capital through improved credit ratings. 	<ul style="list-style-type: none"> ❖ Loss or limitation of capital sources. ❖ Increased cost of capital due to poor sustainability credit ratings.
6 Debt/write-offs	<ul style="list-style-type: none"> ❖ Increase resilience in assets by incorporating climate risk in investment decisions. ❖ Avoid destroying value by reducing waste and carbon footprint. 	<ul style="list-style-type: none"> ❖ Write-offs of physical assets due to adverse climate events. ❖ Fines for pollution/fees for carbon emissions.

Conclusion

By embedding corporate carbon foot printing, LCA, net-zero strategies, and materiality assessments into its operations, a company can unlock value across financial performance, stakeholder trust, employee engagement, and innovation. These initiatives position it as a leader in sustainability, driving long-term growth, resilience, and impact.

Understanding Stakeholder Requirements

Stakeholder requirements refer to the interests, needs, and concerns of various groups affected by the operations and decisions of a pharmaceutical company. These requirements are typically diverse, ranging from regulatory compliance to ethical considerations and financial returns. Understanding these is critical for fostering collaboration and ensuring that projects, policies, and products align with stakeholder expectations.

Introduction to Stakeholder Engagement

In the dynamic and highly regulated pharmaceutical industry, stakeholder engagement is essential for aligning business strategies with the needs of all parties involved. Effective engagement contributes to smoother project execution, regulatory approval, market access, and the overall sustainability of the business.

Key Aspects of Stakeholder Requirements:

Stakeholder engagement is a critical aspect of the pharmaceutical sector for several reasons:

- ❖ **Regulatory Compliance:** The pharmaceutical industry is one of the most heavily regulated industries globally. Engaging with regulatory stakeholders such as the FDA in the US, EMA in Europe, and other national regulatory bodies is essential for compliance with legal requirements for drug development, approval, and post-marketing surveillance.
- ❖ **Research and Development:** Stakeholders such as patients, healthcare professionals, and academic institutions provide valuable insights into unmet medical needs and the effectiveness of treatments. This information is crucial for guiding R&D efforts towards therapies that are both needed and viable.
- ❖ **Market Access and Reimbursement:** Pharmaceutical companies must work with payers, insurance companies, and government health agencies to ensure that their products are covered and reimbursed. This requires demonstrating the value and cost-effectiveness of their drugs.
- ❖ **Patient Safety and Pharmacovigilance:** Engaging with patients and healthcare providers is vital for monitoring the safety of medications post-launch. This helps in identifying adverse drug reactions and ensuring that the benefits of a drug continue to outweigh its risks.
- ❖ **Corporate Reputation:** The pharmaceutical industry often faces scrutiny regarding drug pricing, ethical practices, and transparency. Engaging with stakeholders such as patient advocacy groups, NGOs, and the media can help companies build trust and a positive reputation.

- ❖ **Innovation and Collaboration:** Collaborations with biotech firms, universities, and other companies can lead to innovative treatments and business growth. Stakeholder engagement facilitates partnerships and joint ventures.
- ❖ **Supply Chain Management:** Engaging with suppliers and distributors is essential for ensuring the quality and availability of medications. This includes managing risks related to raw materials, manufacturing, and logistics.
- ❖ **Investor Relations:** Pharmaceutical companies require significant capital for R&D and operations. Engaging with investors and financial stakeholders is necessary to secure funding and support long-term financial health.
- ❖ **Policy Influence:** Engaging with policymakers and industry groups can help shape the regulatory and policy environment in which pharmaceutical companies operate. This can lead to more favourable conditions for business operations and patient access to medications.
- ❖ **Sustainability and Social Responsibility:** Engaging with stakeholders on issues such as environmental impact, ethical sourcing, and social contributions is increasingly important for maintaining a license to operate and for meeting the expectations of society at large.

Thus, stakeholder engagement in the pharma sector is necessary for navigating the complex landscape of drug development and commercialization, ensuring compliance with regulations, fostering innovation, managing risks, and maintaining a positive corporate image.

Different components in Stakeholders



Figure 1 Stakeholders of a Company

Internal Stakeholders:

Internal stakeholders of a pharmaceutical company are groups or individuals who are directly involved in the organization's operations and have a vested interest in its success. Following are the key internal stakeholders within a pharmaceutical company:

1. Employees:

- ❖ Employees are the backbone of any pharmaceutical company, performing a wide range of functions from manufacturing and quality control to sales and marketing.
- ❖ They are directly affected by the company's policies, culture, and success, and their engagement and satisfaction can significantly impact productivity and retention.
- ❖ Employees are often the first to interact with external stakeholders, representing the company's values and mission.
- ❖ Their well-being and development are crucial, and companies often invest in training, benefits, and a positive work environment to keep employees motivated and skilled.

2. Management and Executives:

- ❖ This group includes the leadership team responsible for setting the strategic direction of the company and making high-level decisions.
- ❖ Executives such as the CEO, CFO, CMO, and department heads play a critical role in steering the company towards its goals, managing resources, and navigating challenges.
- ❖ They are responsible for fostering a corporate culture that aligns with the company's values and objectives.
- ❖ Management also serves as a bridge between the company's workforce and its board of directors, ensuring that both operational and strategic perspectives are considered in decision-making.

3. Research and Development Teams:

- ❖ R&D teams are at the heart of the pharmaceutical industry, tasked with discovering and developing new drugs and therapies.
- ❖ They work on the front lines of innovation, translating scientific research into marketable products that can improve patient health.

- ❖ Collaboration within R&D teams and with external researchers is essential for sharing knowledge and accelerating the development process.
- ❖ These teams must also work closely with regulatory affairs to ensure that new products meet stringent safety and efficacy standards.
- ❖ R&D's success is critical for the company's growth and sustainability, as the pipeline of new products determines the long-term viability of the firm.

External Stakeholders:

External stakeholders of a pharmaceutical company are individuals or organizations outside the company that can affect or be affected by the company's activities, products, and policies. Some of the key external stakeholders are mentioned below:

1. Regulatory Bodies (FDA, EMA, etc.):

- ❖ Regulatory agencies such as the FDA in the United States, the EMA in Europe, and other institutions in other countries are responsible for evaluating and approving new drugs and monitoring their safety post-approval.
- ❖ These bodies set the standards for clinical trials, manufacturing practices, labelling, and advertising.
- ❖ Pharmaceutical companies must engage with these agencies throughout the drug development process to ensure compliance and to facilitate the approval of new therapies.

2. Patients and Patient Advocacy Groups:

- ❖ Patients are the end-users of pharmaceutical products, and their well-being is the goal of the company's efforts.
- ❖ Patient advocacy groups represent the interests of patients and often campaign for access to new treatments, affordability, and disease awareness.
- ❖ Engaging with these groups helps companies understand patient needs, gain insights into the real-world impact of their drugs, and build trust within the patient community.

3. Healthcare Providers and Medical Institutions:

- ❖ Doctors, nurses, pharmacists, and healthcare institutions are the intermediaries between pharmaceutical companies and patients.

- ❖ They prescribe medications, provide feedback on drug efficacy and safety, and are influential in treatment decisions.
- ❖ Building strong relationships with healthcare providers is essential for educating them about new drugs and gathering valuable feedback.

4. Investors and Shareholders:

- ❖ Investors and shareholders provide the capital necessary for the company's R&D and operations.
- ❖ They are interested in the company's financial performance, growth prospects, and strategic direction.
- ❖ Regular communication and transparency with this group are vital for maintaining their confidence and support.

5. Governments and Policy Makers:

- ❖ Governments and policy makers shape the healthcare landscape through legislation, pricing policies, and healthcare programs.
- ❖ Pharmaceutical companies often engage in policy discussions and advocacy to influence decisions that affect the industry.
- ❖ Collaboration with governments can also lead to public-private partnerships and funding for research.

6. NGOs and Advocacy Groups:

- ❖ NGOs and advocacy groups can be focused on health issues, ethical practices, access to medicines, and more.
- ❖ These organizations can be both collaborators and critics, and they often have a significant influence on public opinion.
- ❖ Engaging with NGOs can help companies address societal concerns and improve their corporate social responsibility efforts.

7. Suppliers and Distributors:

- ❖ Suppliers provide raw materials, components, and services necessary for drug production.
- ❖ Distributors are responsible for ensuring that medications reach pharmacies, hospitals, and other healthcare providers.
- ❖ A reliable supply chain is critical for maintaining product quality and availability, and strong relationships with these stakeholders are essential for effective operations.

8. Media and Public Opinion:

- ❖ The media plays a crucial role in shaping public opinion about pharmaceutical companies and their products.
- ❖ Positive media coverage can enhance a company's reputation, while negative coverage can lead to public relations challenges.
- ❖ Engaging with the media through transparent communication and public relations strategies is important for managing the company's public image.

Importance of Stakeholder Engagement

Engaging with stakeholders is not just a regulatory requirement; it is a strategic necessity that provides numerous benefits to pharmaceutical companies. Successful stakeholder engagement helps build trust, enhance innovation, mitigate risks, and create long-term value. Successful stakeholder engagement has the following merits:

- i. **Informed Decision-Making:** Engaging with stakeholders allows pharmaceutical companies to gather diverse perspectives and insights, which can lead to better-informed decision-making. For example, patient feedback can inform drug development, leading to more effective and user-friendly medications.
- ii. **Regulatory Compliance:** Regulatory bodies are key stakeholders in the pharmaceutical industry. Engagement with these entities is crucial to ensure compliance with legal and regulatory requirements, which can vary significantly across different markets.
- iii. **Market Access and Adoption:** By engaging with healthcare professionals and payers, pharmaceutical companies can better understand the factors that influence the adoption and reimbursement of new therapies, thus facilitating market access.
- iv. **Reputation Management:** Active stakeholder engagement helps build trust and credibility, which are essential for maintaining a positive reputation. This is particularly important in an industry that is often under public scrutiny.
- v. **Risk Management:** Engaging with stakeholders can help identify potential risks early on, allowing companies to address issues before they escalate. This proactive approach can prevent costly setbacks and protect the company's interests.
- vi. **Innovation and Research:** Collaboration with academic institutions, researchers, and other industry players can drive innovation and lead to the development of new treatments and technologies.
- vii. **Corporate Responsibility:** Pharmaceutical companies have a responsibility to ensure that their products are safe and effective. Stakeholder engagement is a way to demonstrate commitment to ethical practices and social responsibility.

The benefits to stakeholders from successful stakeholder engagement include:

- ❖ **Patients:** Patients benefit from having their needs and experiences considered in the drug development process, leading to treatments that are more aligned with their preferences and requirements.

- ❖ **Healthcare Professionals:** Engagement provides healthcare professionals with up-to-date information on new drugs and treatments, enabling them to make better-informed recommendations to their patients.
- ❖ **Regulators:** Regular interaction with pharmaceutical companies helps regulators ensure that industry practices meet the required standards, ultimately protecting public health.
- ❖ **Investors:** Investors gain a clearer understanding of the company's strategy, risks, and opportunities, which can lead to more informed investment decisions.
- ❖ **Suppliers:** Suppliers can align their services and products more closely with the needs of the pharmaceutical companies, leading to stronger partnerships and business opportunities.
- ❖ **Advocacy Groups:** Advocacy groups can influence the pharmaceutical industry's focus on certain diseases or patient populations, ensuring that underrepresented groups receive attention.
- ❖ **Community:** The broader community benefits from the pharmaceutical industry's contributions to public health, economic growth, and employment.

Stakeholder engagement in the pharmaceutical sector is essential for aligning the interests of the company with those of its stakeholders. It leads to better health outcomes, more sustainable business practices, and a more robust and responsive healthcare ecosystem. By fostering open communication and collaboration, pharmaceutical companies can navigate the complex landscape of drug development and commercialization more effectively, while also contributing to the well-being of society.

Modes of Stakeholder Engagement

Stakeholder engagement can take many forms, depending on the nature of the stakeholders and the objectives of the engagement. These modes can be categorized into one-way and two-way communication, each serving different purposes in stakeholder relations.

One-Way Engagement:

- ❖ **Press Releases and Public Announcements:** These are used to inform stakeholders about major company developments, including product launches, regulatory approvals, and corporate changes.
- ❖ **Annual Reports and Sustainability Reports:** These are aimed at investors, shareholders, and regulatory bodies to provide transparency on the company's financial health, sustainability efforts, and overall performance.

- ❖ **Social Media and Online Platforms:** These allow companies to disseminate information quickly and reach a broad audience, including the public and patients.

Two-Way Engagement:

- ❖ **Surveys and Questionnaires:** These are used to gather feedback from patients, healthcare providers, and other external stakeholders regarding product efficacy, side effects, and overall satisfaction.
- ❖ **Stakeholder Meetings and Advisory Boards:** These provide a platform for in-depth discussions, often involving regulators, healthcare professionals, and patient advocacy groups to ensure that products and strategies align with market needs.
- ❖ **Focus Groups:** These are small, interactive sessions that allow companies to gain detailed insights from specific stakeholder groups, such as patients or healthcare providers.
- ❖ **Partnerships and Collaborations:** These are collaborative initiatives with healthcare institutions, research organizations, or patient advocacy groups that can drive innovation, ensure product relevance, and improve health outcomes.
- ❖ **Digital Engagement and Tools:** With the rise of digital transformation in the pharmaceutical industry, new tools have emerged to facilitate stakeholder engagement, such as:
 - ❖ **Online Patient Portals and Apps:** These allow patients to provide feedback on treatments, engage in discussions, and access medical information.
 - ❖ **Webinars and Virtual Conferences:** These platforms enable real-time interaction between pharmaceutical companies, regulators, healthcare providers, and researchers.
- ❖ **Data Analytics and Artificial Intelligence (AI):** These technologies are increasingly being used to analyse stakeholder feedback and predict future trends in healthcare needs.

Achieving Business Excellence Through Effective Stakeholder Engagement

When stakeholder engagement is done right, it not only enhances corporate reputation but also contributes to long-term business success and operational excellence. Effective engagement aligns business goals with stakeholder expectations, improves operational efficiency, and fosters sustainable growth.

- ❖ **Boosts Innovation and R&D Efficiency:** Engaging with regulators, healthcare providers, and patient groups early in the R&D process leads to faster, more efficient development cycles. Companies can create treatments that are more likely to succeed in clinical trials and meet regulatory requirements, reducing time to market.
- ❖ **Strengthens Regulatory Relationships:** Proactive and transparent engagement with regulatory bodies minimizes the risk of compliance issues, accelerates approvals, and builds trust in the company's processes and products.
- ❖ **Enhances Reputation and Brand Loyalty:** Companies that prioritize stakeholder concerns and engage with transparency are more likely to build brand loyalty and maintain a positive reputation, which is critical in the pharmaceutical industry where public trust is essential.
- ❖ **Sustainable Business Growth:** Stakeholder engagement leads to a deeper understanding of market trends, customer needs, and potential risks. This insight enables companies to make informed decisions that drive long-term growth while minimizing risks associated with regulatory challenges or public perception.
- ❖ **Improved Crisis Management:** When companies maintain strong stakeholder relationships, they can more effectively manage crises, whether they arise from product recalls, safety concerns, or regulatory scrutiny. Stakeholders who feel engaged and valued are more likely to support the company during challenging times.

Conclusion

In the pharmaceutical industry, successful stakeholder engagement is not just a best practice; it is a cornerstone of business excellence. By understanding stakeholder requirements, employing a range of engagement strategies, and leveraging these relationships to foster innovation and trust, pharmaceutical companies can drive sustainable growth, ensure compliance, and achieve long-term success. Effective stakeholder engagement ultimately creates value for both the company and society, helping to bring life-saving medicines to patients around the world.

As per the United Nations, Sustainability is defined as “meeting the needs of the present without compromising the ability of future generations to meet their own needs.” Today, countries are seeking ways of meeting their development needs, but with the increasing threat of climate change, concrete efforts must be made to ensure development today does not negatively affect future generations.

The Sustainable Development Goals (SDGs) or Global Goals are a collection of seventeen interlinked objectives designed to serve as a "shared blueprint for peace and prosperity for people and the planet, now and into the future."



ESG

ESG has three important pillars on which the companies are expected to report, i.e. Environment, Social and Governance.

It is a process for setting, managing, and reporting on an organization’s sustainability goals, governance mechanisms, environmental, and social impacts and related policies, that allows the board and company leadership to consider perspectives from relevant stakeholders and provide stakeholders with appropriate information.

A company’s ability to demonstrate how ESG and other trends impact its strategy, operations, and long-term prospects is important to meeting the needs of its shareholders and other stakeholders, as below.

- ❖ **Investors and lenders** use ESG data to inform investment and voting decisions. They also encourage companies to disclose ESG data on topics that are financially relevant to their business.
- ❖ **Leading asset owners and managers** are requesting that their portfolio companies establish ESG governance and oversight and disclose such efforts.

- ❖ **Ratings organizations and proxy advisors** use ESG data to inform ratings and voting recommendations.
- ❖ **Governments** are establishing laws/regulations requiring businesses to disclose ESG data.
- ❖ **NGOs, local communities, and the public** use ESG information to hold businesses accountable and use such data inform their decision making.
- ❖ **Customers** are increasingly interested in sustainable products and companies.
- ❖ **Employees** want to work for companies that are aligned with their purpose.
- ❖ **Value chain partners** are keen to partner and associate with companies who have clear ESG/Sustainability agenda and demonstrated compliance.

Sensitization and capability building for ESG (Sustainability) is necessary because:

- ❖ Business leaders globally are now planning more stringent ESG practices in their organization.
- ❖ Consumers say that ESG practices of the firm would impact their buying choices.
- ❖ Workers want to work for companies that have the same values as them.
- ❖ Investors are interested in investing in organizations that take ESG factors into account.
- ❖ The number of existing laws requiring due diligence in the supply chain is increasing.

To conclude, it can be said that there is a shift from shareholders to stakeholders and from purely financial parameters to include non-financial parameters as well.

The pharmaceutical industry needs to strengthen its resilience in terms of sustainable operations so that it can continue to shape the future of healthcare and help more people, in more places, lead fuller, healthier lives. Sustainability is about human wellbeing and that is exactly the goal of the pharma industry.

That commitment begins with the healthcare products and technologies created by the industry and carries through everything the industry does as a key member of the healthcare sector.

Personal

There is a need to have a vision for the future that is focused on building and sustaining people's health by creating a true healthcare system, rather than the traditional, treatment-focused "sick care" system.

Hence, it is important to develop technologies that can provide people greater knowledge and power in the management of their health, enabling them to better understand the unique language of their bodies and to respond optimally. In this way, a company will be able to better see emerging trends and connections, allowing it to provide more of the answers people are seeking to their expanding health needs.

Societal

Along with making healthcare more personal, it is necessary to simultaneously work towards bringing those benefits to more people than ever before. For this, it is necessary to design products that may be used remotely, helping to reduce the need for care in higher-cost institutional settings. It can mean using materials that reduce product cost. Or, it can mean delivering operational efficiency for health system customers, allowing them to care for people at lower cost, achieving greater impact at the societal level.

It means helping communities build greater understanding of health and how to sustain it. The industry can educate children about health and inspire them to make healthy choices for their futures, while Future Well Communities help to address social drivers of health, such as access to nutritious food.

This also means helping to build needed healthcare infrastructure, including creating physical infrastructure, e.g., the network of laboratory, hospital etc. across the country, and human infrastructure, e.g. emergency medicine training program, first aid trainings, etc. The company should prioritize projects that are sustainable over the long term, and commit resources to maximizing their impact through the years.

Environmental

Environmental sustainability is the foundation of human sustainability. That is why it is important to work across the company's operations to minimize the impact of the business on the environment, reducing waste production, water usage, packaging materials, and emissions.

Here are ways it is possible to create sensitization and capability building for sustainable pharma operations.

Innovate for access and affordability

- ❖ Make access and affordability core to new product innovation. Integrate access and affordability and data insights as design principles into R&D work and portfolio.
- ❖ Partner with other organizations, including academic institutions and NGOs, to leverage expertise and resources.
- ❖ Support global efforts to address diseases and malnutrition.
- ❖ Deliver scalable, integrated solutions to help reduce preventable deaths and infectious diseases (malaria, hepatitis B/C, HIV, COVID-19, and others) with diagnostics, treatment, and education programs, especially in high-prevalence areas.
- ❖ Advance health equity through partnerships.
- ❖ Expand affordable access to healthcare for underserved, diverse, and at-risk communities, including women and children, by delivering innovative, decentralized models of care that advance prevention and early diagnosis, improve nutrition, provide quality treatment and care, and lower total costs.
- ❖ Partner with stakeholders to improve health outcomes by advancing standards and building access to affordable, integrated solutions.

Annexure 1

Guiding Checklist for Innovation for Access and Affordability

Build the diverse, innovative workforce of tomorrow

- ❖ Provide development and job opportunities for current and future employees.
- ❖ Create opportunities in science, technology, engineering, and math programs and internships for young people.
- ❖ Drive diversity and inclusion strategies that create a meaningful employee experience and advance culture in order to:
 - Achieve gender balance across the pharma operations including employees, trainees, interns, leadership roles, etc.
 - Anticipate future workforce needs and achieve talent readiness. Maintain or improve rates of internal succession for leadership roles.
 - Fill new jobs with internal talent by upskilling, cross-skilling, and creating learning opportunities.
 - Provide industry-leading programs that help people achieve their personal health and well-being.
 - Support financial security of employees
- ❖ Implement training sessions and workshops to educate stakeholders about the importance of sustainability and ways to achieve it.

Annexure 2

Guiding Checklist for Building Workforce for Tomorrow

Responsibly connect data, technology, and care

- ❖ It is necessary to have secure and responsible data collection, use, management, and privacy in order to protect patients and customers, empower them to make better, more complete decisions about their health, and drive innovation through insights and analytics.

Create a resilient, diverse, and responsible supply chain

- ❖ Ensure that the ESG requirements are incorporated in all contracts/agreements.
- ❖ Ensure ethical sourcing from all suppliers with high-risk sustainability factors through 100% auditing.
- ❖ Ensure an inclusive environment by increasing spending with diverse and small businesses. Encourage procurement from local suppliers.
- ❖ Regularly share information on sustainability goals, achievements, and best practices with relevant stakeholders.
- ❖ Involve all stakeholders, including suppliers and customers, in sustainability initiatives to ensure a collective effort.

Annexure 3

Guiding Checklist for Responsible Data Management and Use, and Creating Responsible Supply Chain

Protect a healthy environment

- ❖ Reduce GHG emissions with definite timelines, consistent with the objectives of the Science Based Targets initiative (SBTi).
- ❖ These SBTi goals shall include suppliers of purchased goods and services and transportation and distribution networks.
- ❖ Achieve water stewardship of manufacturing sites. Work towards zero liquid discharge for manufacturing sites. Work with key suppliers and local community to reduce water quality and quantity risks.
- ❖ Develop and implement strategies to minimize waste and promote recycling.
- ❖ Work for sustainable packaging through innovation and development by:
 - Employing circularity principles through smart design and material selection.
 - Eliminating and reducing materials.
 - Improving energy efficiency.
 - Optimizing packaging, pallet, and truckload efficiency.
 - Reducing waste impacts by using a circular economy approach to achieve maximum diversion rate.
 - Engage with key suppliers to reduce the environmental impact of materials.
 - Develop and track supplier waste diversion initiatives.

Annexure 4

Guiding Checklist for Protecting Healthy Environment

1. Integrate Access and Affordability into Product Innovation and R&D

- ❖ Embed access and affordability considerations in product design stage gates.
- ❖ Use real-world data and epidemiological insights to guide pipeline decisions.
- ❖ Develop cost-effective formulations and dose-optimized therapies for LMICs.
- ❖ Prioritize heat-stable, easy-to-administer, low-cost delivery formats.
- ❖ Include equity-focused KPIs in innovation and product portfolio governance.

2. Partner with Academia, NGOs, and Public Health Institutions

- ❖ Establish R&D collaborations with universities and global health foundations.
- ❖ License under non-exclusive, access-friendly terms for neglected diseases.
- ❖ Participate in shared IP platforms or pre-competitive consortia.
- ❖ Contribute to open-access databases and collaborative disease registries.

3. Support Global Efforts on Diseases and Malnutrition

- ❖ Align R&D or CSR priorities with WHO/UN targets (e.g., SDG 3).
- ❖ Invest in nutraceutical or therapeutic R&D addressing child malnutrition.
- ❖ Support integrated public health campaigns (e.g., immunization + nutrition).
- ❖ Contribute funding, product donations, or technical support for NTD programs.

4. Deliver Scalable, Integrated Solutions to Prevent Infectious Diseases

- ❖ Develop or adapt affordable diagnostics for diseases like HIV, TB, Hepatitis.
- ❖ Partner with governments and NGOs for treatment distribution in high-burden areas.
- ❖ Support community health workers with educational tools and mobile health kits.
- ❖ Deploy telehealth and mobile clinics to enhance rural diagnostic outreach.

5. Advance Health Equity through Partnerships

- ❖ Collaborate with local health systems to reduce access gaps.
- ❖ Co-create culturally relevant education and behaviour-change campaigns.
- ❖ Invest in gender- and age-inclusive clinical research.
- ❖ Partner with public health insurers to pilot affordable therapy bundles.

6. Expand Access to Underserved and At-Risk Communities

- ❖ Pilot decentralized models like mobile health vans, last-mile delivery, or point-of-care diagnostics.
- ❖ Innovate around prevention tools (e.g., self-tests, micronutrient packs).
- ❖ Provide affordable therapy options through tiered pricing or pooled procurement.
- ❖ Develop health tech tools (apps, AI triage, SMS education) in local languages.

7. Collaborate to Improve Outcomes and Build Affordable Solutions

- ❖ Work with government bodies to scale successful care delivery models.
- ❖ Engage with insurers and health financing institutions to reduce out-of-pocket burden.
- ❖ Build training programs for health workers in remote or high-need areas.
- ❖ Track impact metrics: DALYs averted, access numbers, cost per patient, etc.

Annexure 5

Checklist: Build the Diverse, Innovative Workforce of Tomorrow

1. Provide Development and Job Opportunities for Current and Future Employees

- ❖ Establish Individual Development Plans (IDPs) for all employees.
- ❖ Define career growth tracks and promote lateral and vertical mobility.
- ❖ Launch mentorship and sponsorship programs for career advancement.
- ❖ Publicize internal job openings with structured pathways to apply.

2. Create STEM Opportunities for Youth and Early-Career Talent

- ❖ Partner with schools/universities to run STEM awareness sessions.
- ❖ Offer structured internships and apprenticeships in pharma labs, QA/QC, manufacturing, etc.
- ❖ Provide summer research programs and exposure visits for students.
- ❖ Set aside seats in internship programs for underrepresented communities.

3. Implement Diversity, Equity & Inclusion (DEI) Strategies for a Meaningful Culture

Achieve Gender Balance Across All Levels

- ❖ Set gender diversity goals across employee categories (staff, leadership, interns).
- ❖ Promote flexible work, parental leave, and returnship programs.
- ❖ Ensure unbiased hiring panels and use gender-neutral job descriptions.

Future Workforce Planning and Leadership Succession

- ❖ Map critical roles and build internal succession pipelines.
- ❖ Run leadership development programs tailored to mid- and senior-level talent.
- ❖ Include DEI metrics in succession planning dashboards.

Upskilling and Cross-Skilling the Workforce

- ❖ Launch internal learning academies with micro-certifications.
- ❖ Promote job rotations and stretch assignments across functions.
- ❖ Use digital platforms (LMS, AI-based learning tools) for continuous learning.

4. Invest in Employee Health, Well-being and Financial Security

Health and Well-being

- ❖ Offer holistic wellness programs (mental, physical, emotional).
- ❖ Provide on-site or virtual counselling, yoga, and health checkups.
- ❖ Encourage work-life balance via hybrid models and reasonable workload norms.

Financial Security

- ❖ Provide transparent compensation benchmarking and fair wage policies.
- ❖ Offer long-term savings plans, medical insurance, and emergency support.
- ❖ Educate employees on financial literacy and retirement planning.

5. Educate Stakeholders on Sustainability

- ❖ Conduct sustainability induction for all new hires.
- ❖ Organize workshops on ESG, green manufacturing, circular economy, etc.
- ❖ Include sustainability KPIs in role objectives for relevant functions (R&D, supply chain, HR).
- ❖ Recognize and reward employees contributing to ESG or CSR projects.

Annexure 6

Checklist: Create a Resilient, Diverse, and Responsible Supply Chain

1. Embed ESG Requirements into Contracts and Agreements

- ❖ Incorporate ESG clauses in all supplier and third-party contracts.
- ❖ Include mandatory compliance with environmental, labour, and ethical standards.
- ❖ Set clear KPIs for GHG emissions, waste management, water use, and social responsibility.
- ❖ Require regular disclosures and certifications (e.g., EcoVadis, SA8000, ISO 14001).

2. Ensure Ethical Sourcing Through 100% Auditing of High-Risk Suppliers

- ❖ Identify high-risk suppliers based on location, category, and historical performance.
- ❖ Conduct prequalification audits focusing on sustainability, labour rights, and environmental impact.
- ❖ Engage third-party auditors or use digital ESG assessment platforms.
- ❖ Develop remediation plans for non-compliant suppliers and monitor improvements.

3. Promote Inclusive and Local Procurement

- ❖ Increase sourcing from MSMEs, women-owned, and minority-led enterprises.
- ❖ Set annual diversity spend targets for procurement teams.
- ❖ Offer capacity-building and training support to small or local suppliers.
- ❖ Prioritize local sourcing to reduce logistics emissions and strengthen regional supply chains.

4. Share Sustainability Goals and Best Practices Transparently

- ❖ Publish an annual supplier ESG bulletin or newsletter.
- ❖ Conduct supplier briefings/webinars on your sustainability roadmap.
- ❖ Create a supplier portal for sharing tools, templates, and success stories.
- ❖ Provide regular feedback on supplier ESG performance.

5. Collaborate with Suppliers and Customers on ESG Initiatives

- ❖ Co-develop emissions reduction or waste minimization programs with key suppliers.
- ❖ Invite suppliers to participate in joint sustainability innovation challenges.
- ❖ Share your sustainability expectations with customers and align on joint impact goals.
- ❖ Celebrate collaborative ESG achievements across the value chain.

6. Implement Anticorruption and Antibribery Measures

- ❖ Embed anti-corruption clauses in all procurement contracts.
- ❖ Train procurement and vendor management teams on ethical sourcing and reporting.
- ❖ Set up anonymous reporting channels for whistleblowing.
- ❖ Conduct regular due diligence and background checks on vendors.

Annexure 7

Checklist: Protect a Healthy Environment in Pharma Operations

1. GHG Emissions Reduction (Aligned with SBTi)

- ❖ Conduct a baseline GHG emissions assessment (Scope 1, 2, and 3).
- ❖ Set time-bound, science-based GHG reduction targets (SBTi aligned).
- ❖ Transition to renewable energy (solar, PPA, REC, etc.).
- ❖ Electrify boilers, chillers, and fleet vehicles where feasible.
- ❖ Upgrade to energy-efficient HVAC, lighting, and process equipment.

2. Scope 3 Engagement: Suppliers and Logistics

- ❖ Map major Scope 3 emissions (suppliers, logistics, packaging).
- ❖ Integrate sustainability KPIs into supplier contracts and procurement.
- ❖ Engage transport/logistics providers using fuel-efficient or EV fleets.
- ❖ Host supplier training on GHG tracking and mitigation.

3. Water Stewardship and Zero Liquid Discharge (ZLD)

- ❖ Conduct a comprehensive water audit across manufacturing sites.
- ❖ Implement or upgrade Effluent Treatment Plants (ETPs) for ZLD.
- ❖ Install rainwater harvesting systems and reuse treated water.
- ❖ Monitor water quality indicators (BOD, COD, TDS) at discharge points.

4. Collaborate on Water Risk Reduction

- ❖ Identify and engage suppliers in water-stressed geographies.
- ❖ Set supplier water conservation benchmarks.
- ❖ Support watershed development and community water projects.

5. Waste Minimization and Recycling

- ❖ Segregate hazardous and non-hazardous waste at source.
- ❖ Set and monitor site-level waste diversion targets (>90%).
- ❖ Partner with certified recyclers for plastic, metal, e-waste, and drums.
- ❖ Implement take-back or reverse logistics programs where viable.

6. Sustainable Packaging Initiatives

Circular Design and Material Optimization

- ❖ Use recyclable mono-materials or easy-to-disassemble formats.
- ❖ Incorporate Post-Consumer Recycled (PCR) content where regulations allow.
- ❖ Replace PVC and multi-layer plastics with sustainable alternatives.

Material Reduction & Efficiency

- ❖ Eliminate unnecessary components (e.g., leaflets, outer boxes).
- ❖ Use lightweight materials to reduce carbon intensity.

Energy and Transport Efficiency

- ❖ Optimize packaging for lower energy consumption in production.
- ❖ Redesign cartons and pallets for improved truckload efficiency.
- ❖ Use software to simulate space optimization for logistics.

Circular Economy and Waste Impact

- ❖ Set up refillable, reusable, or returnable packaging pilots.
- ❖ Recover and recycle used packaging from institutional customers.

7. Supplier Engagement on Packaging and Waste

- ❖ Share LCA tools to evaluate environmental impact of packaging.
- ❖ Encourage supplier use of certified sustainable materials.
- ❖ Track supplier waste diversion rates quarterly.
- ❖ Support suppliers in achieving ISO 14001 or TRUE Zero Waste certifications.



Published by:

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February 2026