

Strategic Risk Management

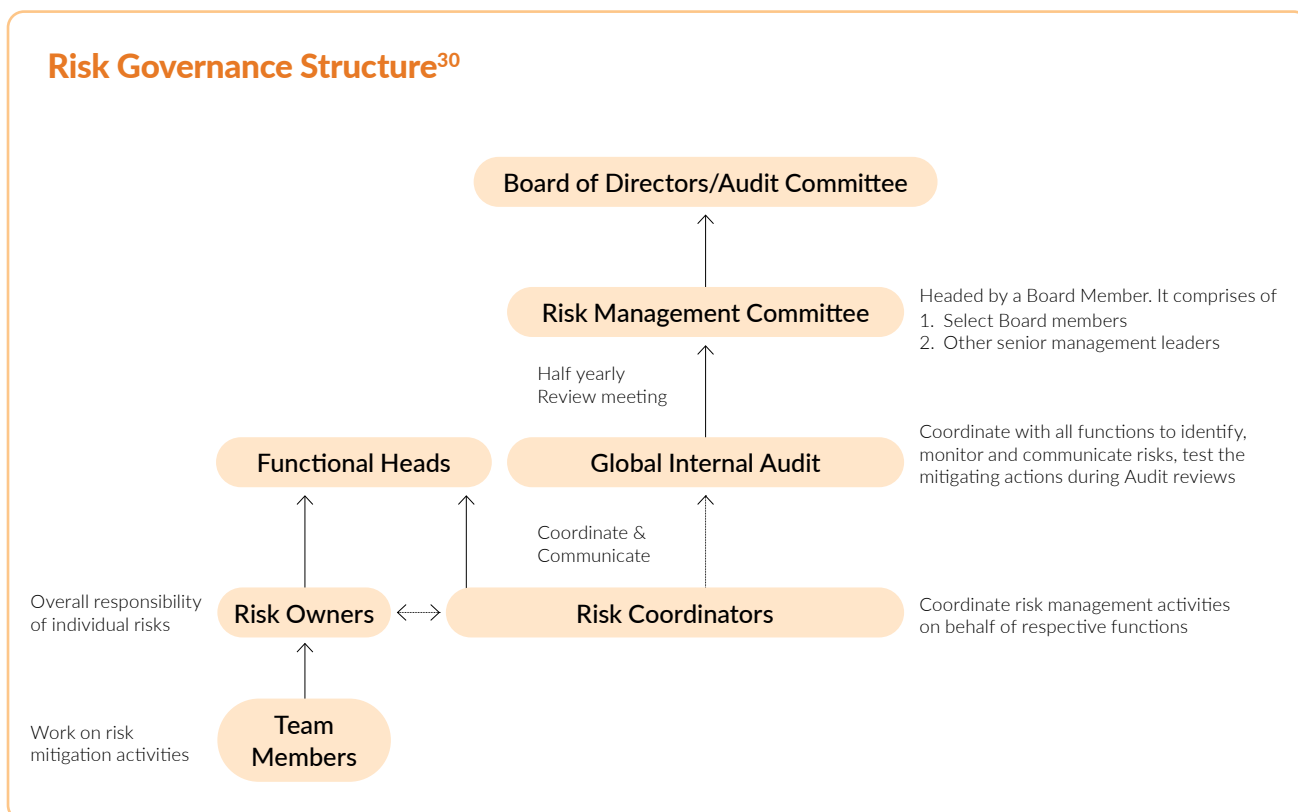
Focus on Risk Mitigation

At Sun Pharma, risk management is entrenched within our corporate strategy. The focus is on risk assessment, mitigation and de-risking while simultaneously enhancing risk management capabilities.

From strategic and regulatory risks to financial, operational and market risks, we remain exposed to many uncertainties owing to the nature, expanse, and location of operations worldwide. Through our Enterprise Risk Management (ERM) framework, we closely monitor, analyse, and mitigate these risks. Guided by a comprehensive risk governance mechanism, our integrated risk management approach enables us to successfully navigate current and emerging risks while pursuing our business objectives with resilience and fortitude.

Our Enterprise Risk Management Framework

Our Enterprise Risk Management (ERM) framework lays the foundation for our risk monitoring and response mechanism, designed with the interests of internal and external stakeholders. Moreover, we have integrated various pertinent and insightful practices recommended by the ISO 31000:2018 and Treadway Commission's Committee of Sponsoring Organizations (COSO) to strengthen our commitment to excellence in risk management processes and frameworks. The ERM framework (depicted below) is applicable across all our business units, subsidiaries, regions, and support functions.



³⁰For detailed information about the roles and responsibilities of each stakeholder, please refer to the Company's synopsis of Enterprise Risk Management Policy available at <https://sunpharma.com/wp-content/uploads/2022/08/Sun-Pharma-Risk-Management-Policy-Synopsis-May-2022.pdf>

At Sun Pharma, risk management is undertaken through a cross-functional approach to facilitate cohesion in the response and management of risk incidents. The Board of Directors have constituted a Risk Management Committee (RMC) with the overall risk management responsibility. The RMC also assesses the adequacy of mitigation plans to address the risks identified in the Company's risk register. Furthermore, the Global Internal Audit team coordinates with all business teams to identify, monitor and communicate risks and test the effectiveness of mitigation strategies during audit reviews.

Our materiality assessment process also enables us to capture stakeholder views on their perception of the pertinent topics for our business. This approach also allows our management to consider external views while reviewing the risk register. It enables us to prepare risk responses to the material topics that can impact our

ability to preserve, create or erode the value-creation potential of our business. We review our material topics annually with the senior management to assess any changes in the global macroeconomic trends, business landscape or strategy, which might necessitate the addition, relegation, or re-prioritisation of specific topics.

We also ensure that responsible personnel have the necessary knowledge and skills for effective risk management. In compliance with the requirements of Regulation 25(7) of the Listing Regulations, the Company has put in place a Familiarisation Programme for the Independent Directors to acclimatise them with our Company, their roles, their rights, responsibilities towards the Company, the nature of the industry in which our Company operates, and our business model. Currently, five Non-executive/Independent Directors have experience in risk management.

Risk Management Approach

We promptly escalate new risks and review the existing ones at least twice a year or more if necessary. If an adverse incident materialises, the Company management promptly communicates with all relevant stakeholders. Updates are shared with the Board depending on the event's criticality. Additionally, every six months, the Risk Management Committee is briefed on newly identified key emerging risks, ensuring a dynamic risk management approach and transparency in risk outlook.



Risk Identification

Our functional heads identify internal and external events that may impact our Company's operations. These risks are logged in a risk register, capturing key details such as risk descriptions, root causes, and existing mitigation plans.



Risk Assessment

The identified risks are carefully evaluated and prioritised based on their estimated likelihood of occurrence and magnitude of impact. The assessment follows our risk prioritisation criteria and aligns with our defined risk appetite. This process helps us prioritise the most critical risks.



Risk Treatment and Mitigation

With ownership assigned, the risk owners develop clear mitigation plans with specific action steps and timelines. These plans are presented to senior management for their approval and support.

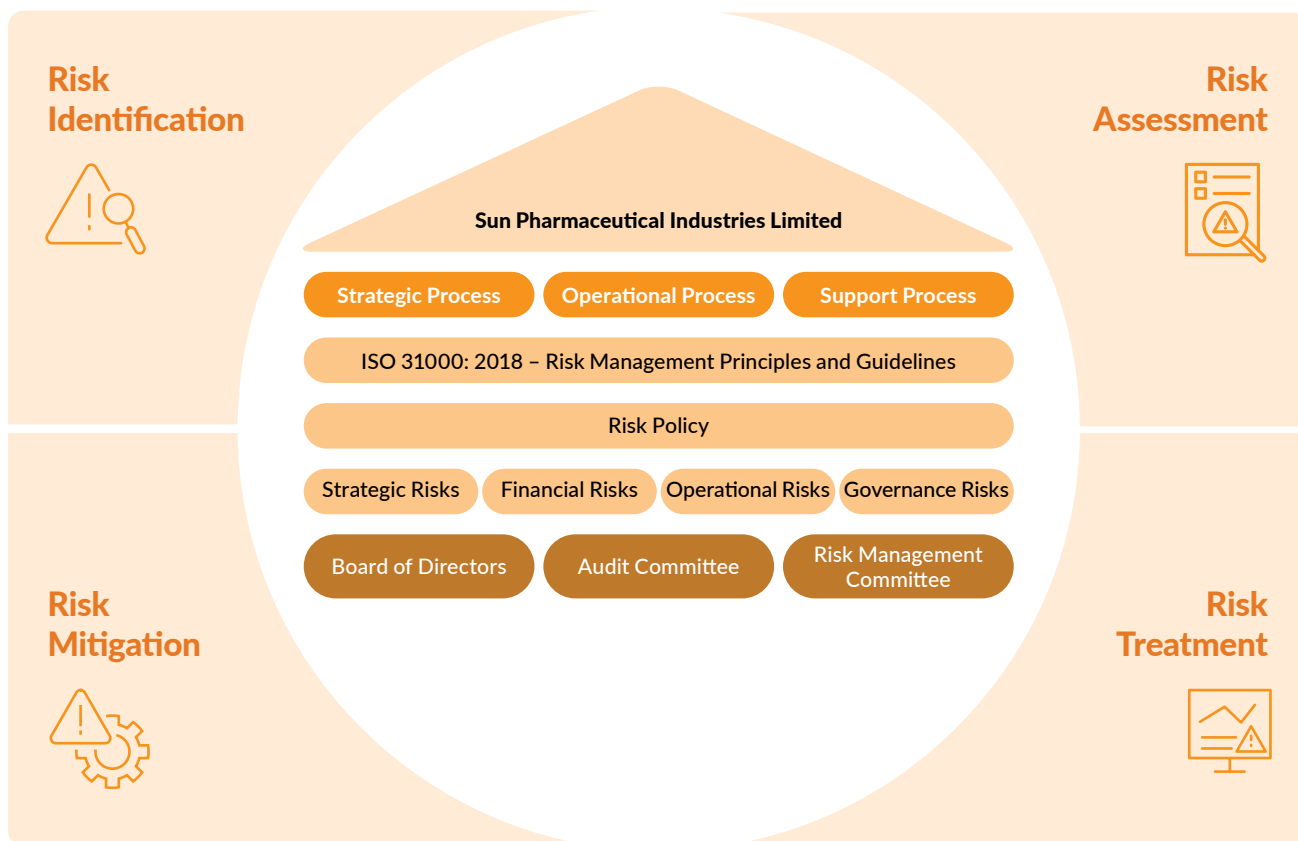


Risk Monitoring

Our management establishes a well-defined and periodic risk review process to monitor the risks and their mitigation plans. For the key risks, the Risk Management Committee reviews the status of action plans agreed upon. Regular updates on risk-related matters are provided to the Risk Management Committee, enabling informed decision-making and promoting effective risk governance.

Strategic Risk Management (continued)

ERM Framework



Key Risks

Following the management’s extensive assessment, we have identified significant risks that may impact our business operations, financial performance, and overall success. Below is a summarised account of the key risks and the impact(s) that merit careful consideration of the organisation’s exposure to these risks. The list of mitigation actions is not exhaustive. It only indicates the comprehensive approach we take to manage the risks.

Corporate Governance and Business Ethics

Description

Addresses the requirements of maintaining a high standard of compliance across diverse markets, staying updated with evolving regulations, and upholding and enforcing ethical business practices.

Potential Impact

Failure to maintain the highest corporate governance and business ethics standards may lead to regulatory repercussions and financial and reputational loss.



Mitigation

We reduce non-compliance risk, ensure regulatory compliance across our operations/markets through proactive interaction with regulatory organisations.

We ensure all employees strictly adhere to the Company’s policies through regular training on business ethics and code of conduct. We also strongly emphasise our quality control

measures in operating locations to ensure cGMP compliance.

We maintain accurate books and records and sufficient internal controls to abide by all applicable anti-bribery laws, including the U.S. Foreign Corrupt Practices Act (FCPA) and the local laws in every country in which we undertake business.

Product Quality, Safety and Recall Management

Description

Ensuring the safety of our products throughout their lifecycle. It includes issues such as adverse event reporting, compliance with Good Manufacturing Practices (GMP) regulations, and communication of safety-related information.

Potential Impact

Any major issues identified in product quality and safety may result in recalls and warnings from regulatory agencies, leading to temporary disruption of operations and brand/reputation loss. It may also expose us to litigation risks, fines, and penalties.



Mitigation

We ensure strict adherence to global quality standards and procedures.

We employ robust and centralised pharmacovigilance processes encompassing detailed SOPs that ensure efficient surveillance and reporting of adverse events in compliance with regulations, including the Narcotic Drugs and Psychotropic Substances (NDPS) Act.

We consistently invest in technological interventions, training on cGMP standards, automation and digitalisation, and employee capacity-building.

We undertake periodic quality reviews of third-party suppliers.

We implement brand protection (IP and trademark) and anti-counterfeit measures to ensure the authenticity of our products in the market.

Cybersecurity and Data Privacy

Description

Vulnerabilities arise from legacy systems, lack of regular technology updates, and potential cyber threats from hackers and data breaches that compromise sensitive information and digital assets.

Potential Impact

The lack of a robust data integrity and security mechanism could increase the rate of data breaches and result in the loss of valuable data that may harm the business. Customer/stakeholder data breaches may expose us to litigations, fines, and penalties.



Mitigation

To avoid breaches related to the Company and stakeholders' data, the vulnerability of our technology and IT systems is evaluated regularly.

We have processes and guidelines that ensure compliance with data security and privacy laws, such as the General Data Protection Regulation (GDPR).

We implement perimeter security, IT monitoring systems, antivirus, and patch management to mitigate the risks associated with cybersecurity and data breaches. We have also conducted cybersecurity training for our employees. We also enhance awareness of our employees via periodic internal e-mails related to safe practices surrounding data security, protection against potential phishing emails, and prevention of hacker attacks.

Strategic Risk Management (continued)

Human Capital Development

Description

Attention and investment towards talent management initiatives, including talent acquisition, retention, development, employee well-being and satisfaction, is imperative.

Potential Impact

As our business depends on our people's well-being, failure to meet/exceed employee expectations may harm the Company's employee retention rate, productivity, and business continuity, impacting the Company's growth.



Mitigation

We have multiple initiatives to attract and retain talent through development programmes encompassing global talent management, competitive remuneration, inclusive work culture, and other employee benefits programmes.

We have a formal succession planning programme for all leadership positions.

We ensure employee skill enhancement through continuous training and development.

Product Access and Affordability

Description

Addressing impediments related to product portfolio, product accessibility, and pricing is paramount.

Potential Impact

In the long run, the inaccessibility of products and the inability to expand geographically might negatively impact the Company's brand value and long-term growth.



Mitigation

We focus on establishing a robust and diversified product portfolio by enhancing cross-functional synergies, organisational capabilities, project management, and governance focused on product identification, development, planning, and launch.

We are strengthening the in-licensing and out-licensing of products.

We prioritise developing and commercialising complex generics and specialty products, among others.

We focus on operational excellence programmes to enhance yields, ensure supply chain continuity, and maintain adequate inventories.

Climate Change

Description

Ineffective management of greenhouse gas (GHG) emissions may expose the Company to climate-related physical and transition risks, which might disrupt operations and affect business continuity.

Potential Impact

Potential immediate physical risks to our operations may damage our assets, leading to business interruptions and increased expenses for repairing and restoring damaged sites.

The transition risks associated with climate change could also result in more stringent regulations in the countries of our operations and exports, leading to higher compliance costs or investment costs in newer technologies.

Failure to adapt to the adverse impacts of climate can also lead to a loss of reputation and stakeholder trust.



Mitigation

We have taken a target to reduce 35% of GHG emissions (covering Scope 1 and Scope 2) by 2030 compared to the baseline year of 2020.

We also conduct climate risk assessments across our operations to evaluate physical and transition risks.

We are continuously exploring avenues to reduce our reliance on fossil fuels by increasing the share

of biomass, procuring renewable energy, and implementing energy efficiency initiatives to optimise our energy consumption, by increasing energy efficiency at our operation, initiating energy reduction projects, procuring renewable fuels including biomass, shifting power from non-renewable to renewable source.

Environmental Impact Management

Description

Focused efforts for efficient water usage, reduced waste generation, and proper disposal demonstrate the Company's commitment to a sustainable future and a healthy planet.

Potential Impact

Failure to manage environmental impacts can lead to adverse legal, regulatory, and financial consequences, loss of reputation and stakeholder trust, ultimately leading to a loss of operating license.



Mitigation

We continuously identify opportunities to manage its environmental impact. We have established targets for water conservation and waste management. We aim to reduce water consumption by 10% by 2025 and co-process 30% of hazardous waste by 2025 compared to the baseline year of 2020.

We are continuously monitoring our performance on water and waste parameters. We focus on efficient water consumption, reducing water withdrawal, and increasing water recovery.

For waste management, we focus on improving the share of recycling and reuse within our operations and co-processing hazardous waste.

We have established a robust Environment, Health, and Safety (EHS) policy and requisite procedures that ensure compliance with Central Pollution Control Board guidelines and local regulatory mandates stipulated by the relevant State Pollution Control Boards.

Strategic Risk Management (continued)

Sustainable Supply Chain and Responsible Procurement

Description

Any supply chain disruption may impact business continuity or product quality, and the risk of non-substitutable suppliers can affect the availability of critical raw materials.

Potential Impact

Long-term commercial partnerships with suppliers may be impacted if suppliers do not comply with various social, environmental and safety standards, leading to a loss of business value.

Non-substitutable and critical raw material suppliers may impact the business in case of any unforeseen disruptions.



Mitigation

We continuously explore opportunities to de-risk the supply chain by evaluating alternate suppliers for critical or non-substitutable raw materials.

As part of the Company's Supplier Code of Conduct, the suppliers are expected to adhere to the Company's ESG standards mentioned in the code.

We emphasise developing quality products to enhance the safety of consumers. We ensure the quality of raw materials for our production process by conducting periodic supplier audits.

Occupational Health and Safety (OHS)

Description

OHS is a vital component of the Company's commitment towards providing a safe and secure working environment. The ineffectiveness of the current health and safety management programmes may lead to many health and safety incidents.

Potential Impact

Frequent health and safety incidents will negatively influence the Company's safety and workforce well-being performance, consequently impacting the brand image, reputation and the Company's ability to attract and retain talent.



Mitigation

We have a robust EHS management system, including regular internal and external audits of its EHS practices.

We have based our risk assessment methodology and safety practices on guiding principles of our Process Safety Management System, which adds cohesiveness to our health and safety approach from the

aspects of risk assessment and working conditions.

We adopt a detailed corrective action plan post-identifying hazards and assessing safety incidents to help prevent such instances.

Ethical Clinical Trials and Animal Testing

Description

Risks and safety-related concerns are associated with the ethical trials on human subjects and animal testing.

Potential Impact

Failure to comply with guidelines and regulations of clinical trials and animal testing can undermine the efficacy and safety of the Company's clinical trials. It may also have an adverse regulatory/legal impact, lead to financial damages and reputation loss, and harm participants' health and safety. Delays at any stage can also prolong the overall timeline for drug development, leading to increased costs.



Mitigation

We comply with all relevant regulatory requirements governing clinical trials and animal testing. We have dedicated teams responsible for ensuring adherence to these regulations, which involve obtaining necessary approvals and permits and maintaining thorough documentation.

We also implement robust quality control and safety measures throughout the research process. This strategy involves monitoring and auditing clinical trials, data collection, and analysis to ensure accuracy, reliability, and compliance with relevant standards.

Long-term safety studies are undertaken for some of our innovative specialty products, post-commercialisation, to evaluate and measure safety parameters over a longer time horizon.

We collaborate with academic institutions, research organisations, and regulatory agencies to share knowledge, expertise, and resources on certain projects. Such collaborations enable the deployment of collective checks and balances to enhance the quality and ethical standards of clinical trials and animal testing.

Business Interruption/Operational Inefficiencies

Description

Potential disruptions or inefficiencies caused by natural disasters, regulatory delays, cybersecurity threats, or labour shortages may affect manufacturing and supply chain efficiency.

Potential Impact

This risk might lead to revenue loss, increased operational expenses, and, in the worst-case scenario, damage to the Company's reputation.

Market entry delays may affect competitiveness.

Incidents of data breaches could increase legal and financial liabilities.



Mitigation

We undertake three-month planning exercises to ensure the availability of critical raw materials to avoid stockouts.

We keep a safety stock for approximately three months for most of our key products. In case of a supply delay, we reduce lead time by using air shipments and ensure product availability.

Senior management periodic overview and department-wise responsibility is assigned to ensure compliance with regulatory requirements and product launch timelines.

We maintain an inventory of critical spares at multiple sites for uninterrupted availability.

Install backup solutions like DG sets and tanker supplies to mitigate power and raw material shortages.

We proactively manage labour shortages by timely recruitment and conduct regular operational and business reviews which ensures business continuity.

Strategic Risk Management (continued)

Intellectual Property (IP), Trademark, Technology, and other Confidential Information

Description

Potential threats to our valuable intellectual assets include unauthorised use, theft, or infringement of patents, trademarks, and confidential data.

Potential Impact

Infringement of valuable assets can result in costly legal battles and damage the Company's reputation.

Loss of stakeholder trust if confidential data is compromised, affecting partnerships and customer confidence.



Mitigation

We engage with drug authorities to enforce compliance and for cancellation of the manufacturing licenses of counterfeiters.

We train our field force to identify and locate potential violations in the market.

We have established a dedicated team at the head office to manage field inputs and execute necessary actions.

We regularly check new trademark filings to identify conflicts and avoid infringements.

We have established a framework and standard operating procedures to protect our IP for branded products in key markets.

Price, Cost and Margin Pressures

Description

Market competition, healthcare reforms, government-led price controls, and fluctuations in raw material and manufacturing expenses impact business profitability.

Potential Impact

Negative impact on financial performance and business sustainability.



Mitigation

We strengthen the product portfolio with new and innovative offerings to differentiate from competitors and withstand pricing pressures.

We focus on cost-effective solutions such as:

- We assess the feasibility of developing alternative vendors/sites for products to optimise production costs and reduce dependencies.

- We enhance the sea-air ratio in favour of more cost-effective sea shipments to reduce transportation expenses.

- We explore alternative economic options, such as using alternate fuels and automation to improve cost efficiency in manufacturing processes.



Emerging Risks

At Sun Pharma, our risk management process accounts for the likelihood and impact of risks and the period a risk could occur. In addition to current risks, we evaluate emerging risks at least once every three years for timely remediation and prevention of any adverse consequences. In line with our risk management framework, emerging risks are also identified based on how likely they are to occur and the potential impact on the business.

Identification and classification of risks as emerging involves a thorough analysis of internal and external data, industry trends, market study, regulatory requirements, and expert insights. This holistic and systematic approach allows us to correctly gauge potential risks that could evolve to harm the business and allow for the implementation of mitigation strategies on time.

We have identified carbon tax and the weaponisation of artificial intelligence by cyber criminals as two important long-term emerging risks. We are making focused efforts to develop and implement mitigation measures to safeguard our business from these risks.

Risk Culture

In addition to a robust risk management framework for timely identification and mitigation of risks, we recognise the importance of inculcating an appetite for risk management across the organisation. Providing an all-encompassing and robust risk culture is integral to effective risk management.

We provide focused risk training to employees across the organisation. We also focus on ensuring that our employees are aligned with compliance and regulatory requirements, including environmental parameters, such as reducing water usage and waste generation, managing GHG emissions, and implementing renewable energy programmes.

Our employees are also encouraged to report any potential risks. The Global Internal Audit team is responsible for coordination across departments for various types of risks. The Company provides employees suitable platforms to raise concerns and highlight potential risks. Insights gained from such sessions further enhance mitigation strategies and enable a more robust risk culture.

As a pharmaceutical Company, we also recognise the importance of incorporating risk criteria within product development and approval. We have developed a reliable global quality standard to provide all users with critical information on managing risk throughout a product's lifecycle, from product development to disposal.