STRATEGIC RISK MANAGEMENT

At Sun Pharma, we have seamlessly incorporated Enterprise Risk Management framework into our corporate strategy.

Our emphasis lies in assessing, mitigating, and minimising risks while continuously improving our risk management competencies.

Strategic Risk Management

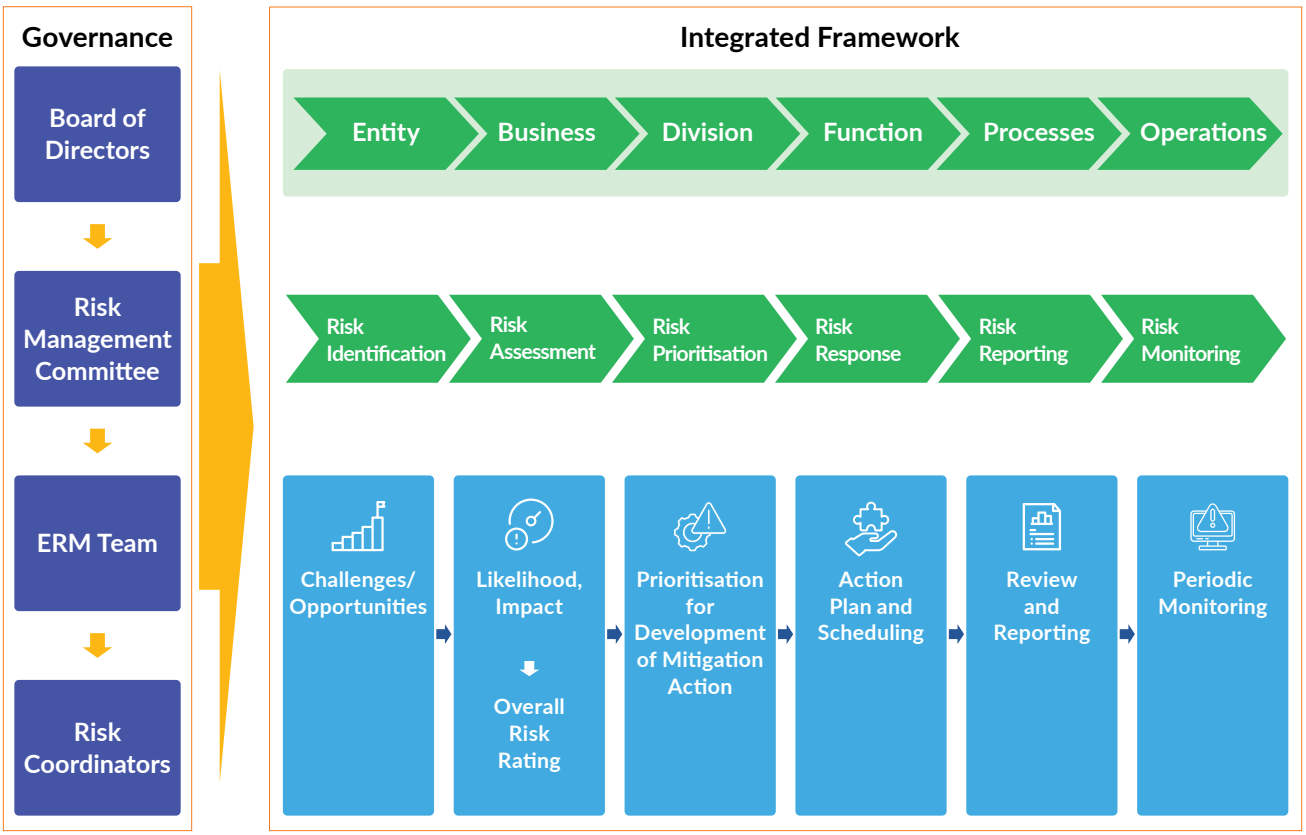
Managing and Mitigating Risks for Resilience

Due to the global nature and scope of our operations, we face various uncertainties, including strategic, regulatory, financial, operational, market, econimic, political and sustainability risks. Our Enterprise Risk Management (ERM) framework allows us to closely monitor, analyse, and manage these risks effectively. Our robust risk governance strategy, supported by a strong governance framework, effectively tackles current and emerging challenges, enabling us to pursue our business objectives with resilience and determination.

Our Enterprise Risk Management Framework

Our Enterprise Risk Management (ERM) framework incorporates risk monitoring and response systems tailored for internal and external stakeholders. To enhance our risk management processes, we have incorporated globally benchmarked practices from ISO 31000:2018 and the Treadway Commission's Committee of Sponsoring Organisations (COSO) framework. The ERM framework applies to all business units, subsidiaries, regions, and support functions.

ERM Framework



Risk Governance Structure

The independent Risk Management Committee (RMC), constituted by the Board of Directors guides the Enterprise Risk Management (ERM) function and assess the occurrence and impact of risks. The ERM is tasked with ensuring that appropriate systems and processes are in place to monitor and evaluate risks associated with our business, monitoring the implementation of our Risk Management Policy and evaluating effectiveness of our systems. The RMC also conducts quarterly reviews of the Enterprise Risk Management framework and updates the Board on the evolving risk landscape and actions to be taken[30]. At the operational level, we have dedicated frontline risk coordinators whose primary responsibility is to manage and coordinate all risk management activities. The risk coordinators undertake regular reviews of the risk register to ensure adequate coverage of all respective business and support functions. They also facilitate and provide support to respective functions to identify, assess, prioritise, document, monitor, and report on potential and actual risks. Further, they maintain direct oversight of the current status of all risks, track the progress of the implemented mitigation plan, and submit periodic findings and updates to our Enterprise Risk Management (ERM) team.

The risk coordinators are supported by function heads, constituting the second line of operational risk management. Function heads are primarily responsible for identifying, assessing, and managing risks pertaining to their function. They undertake periodic meetings to monitor trends and factors under their respective functional areas that impact our risk profile, communicate internally on findings, and ensure the same is updated in risk register. Regular reviews of function-specific risk registers are also undertaken to assess the need to include any new risks. Function heads also evaluate the effectiveness of existing mitigation measures and implement additional actions for reduced risk exposure. Our ERM team maintains and monitors the risk register for all business and support functions.

They are responsible for ensuring the adequacy of our risk management processes and its implementation. They also track the progress of mitigation measures for significant risks. Risk reports are regularly prepared by the team and submitted to the RMC.

Our Internal Audit team led by the Head of Global Internal Audit acts as the third line of defense by assessing the operational effectiveness of our policies, and recommending improvements through periodic internal audits.

Through our materiality assessment process, we capture stakeholder feedback on important sustainability topics for our business, enabling management to integrate external perspectives while evaluating the risk register and developing risk responses. We also review and evaluate our material topics annually with senior management to monitor and evaluate changes in global macroeconomic trends, business landscape, or strategic priorities, ensuring appropriate adjustments to our risk priorities.

Risk Management Approach

We promptly address new risks and review existing ones at least biannually or more often if needed. In case of an adverse incident, management quickly informs relevant stakeholders. Depending on the severity of the event, updates are shared with the Board. Every six months, the Risk Management Committee is briefed on critical and high risks, ensuring a proactive and transparent risk management approach.

Risk Identification
Functional heads identify internal and external events that may impact the Company's operations. These risks are documented in a risk register, detailing their descriptions, causes, and mitigation strategies.

Risk Assessment and Prioritisation
Identified risks are assessed/rated for their likelihood and impact based on Company's risk appetite by senior management, using both quantitative and qualitative methods. The organisation then prioritises significant risks to develop an effective mitigation strategy.

Risk Response
Respective function heads develop mitigation strategies, along with clear action plans with timelines, and present them to senior management for approval. The activity or situation posing a risk may be reduced, accepted, shared, transferred, or avoided depending on the facts and circumstances.

Risk Reporting
The ERM team and respective risk coordinators/ functional heads review all risks. Key risks are periodically reported to the senior management.

Risk Monitoring
Management has defined a periodic process for reviewing risks and their mitigation plans. The RMC periodically evaluates the status of action plans for key risks, as agreed upon with risk coordinators/ function heads.

[30]For 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/2024/07/2024-05-21-Risk-Management-Policy-Synopsis.pdf

Strategic Risk Management

Key Risks

We have identified significant risks that may impact our business operations, financial performance, and overall success. Below is a summary 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 an overview of our comprehensive approach to managing the risks.

Risk Area – Corporate Governance and Business Ethics

Risk Description – Addresses the requirements of sustaining a high standard of compliance across various markets, staying up to date with changing regulations, and enforcing ethical business practices.

Impact

Failure to maintain and uphold the highest standards of corporate governance and business ethics could result in regulatory consequences as well as financial and reputational damage and business continuity.

Mitigating Actions

1. Consistent and regular engagement with regulatory agencies in all our markets, to ensure compliance and reduce any possibility of non-compliance.
2. Focused and regular training is provided to all staff members to ensure strict compliance with the Company's business ethics and Global Code of Conduct. Strong focus is also given to quality control at all operational locations to maintain cGMP compliance.

Risk Area – Product Quality, Safety, and Recall Management

Risk Description – These risks are associated with an identification of the difficulties in monitoring and making sure of the safety of our products throughout their lifecycle. It includes the following issues such as adverse event reporting, compliance with GxP regulations, and communication of safety-related information.

Impact

Significant concerns about product safety and quality could lead to recalls and regulatory alerts, temporarily impair business operations, and harm our reputation and brand. It could also result in legal repercussions, fines and penalties.

Mitigating Actions

1. Ensure continued and strict compliance with global quality standards and protocols and the applicable local regulatory requirements.
2. Provide robust and centralised pharmacovigilance systems with thorough Standard Operating Procedures (SOPs) to ensure effective monitoring and reporting of adverse events.
3. Regular investment in technological advancement, training programmes on current Good Manufacturing Practices (cGMP), automation, digitalisation, and employee skill development.
4. Undertake detailed and regular quality assessments of third-party suppliers.
5. Implement measures to protect our brand (intellectual property and trademarks) and combat counterfeiting, to ensure the authenticity of our products in the market.

Risk Area – Cyber Security and Data Privacy

Risk Description – Vulnerabilities of IT systems, absence of regular technology updates, and potential cyber threats from hackers and data breaches that compromise sensitive information and digital assets.

Impact

The absence of a strong data integrity and security mechanism significantly increases the risk of data breaches, potentially leading to the loss of valuable data with potential adverse effects on the business. Breaches of customer/ stakeholder data may expose us to litigation, fines, and penalties.

Mitigating Actions

1. Regular vulnerability assessments and simulated hacker attacks on our IT systems are undertaken to prevent breaches of Company or stakeholders' data.
2. We have implemented patch management, antivirus software, IT monitoring systems, and perimeter protection to reduce the risks associated with cyber security and data breaches. Furthermore, we regularly provide training to our staff members on cybersecurity and reaffirm this knowledge through recurring internal emails that address secure data practices, safeguarding against phishing emails, and averting hacker attacks.

Risk Area – Human Capital Development

Risk Description – Focused investment in talent management initiatives, such as talent acquisition, retention, development, employee well-being, and satisfaction.

Impact

Neglecting to meet employee expectations could lead to adverse long-term effects on productivity and hinder the Company's growth trajectory.

Mitigating Actions

1. We implement various initiatives to attract and retain talent, including global talent management programs, competitive compensation, fostering an inclusive work culture, and offering employee benefits programs.
2. We have established a formal succession planning programme for all leadership positions.
3. We prioritise employee skill enhancement through continuous training and development opportunities.

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Risk Area – Access and Affordability

Risk Description – Addresses hindrances in product portfolio, product accessibility, and pricing.

Impact

Long-term brand value and growth prospects may suffer if the Company's products become inaccessible or if expansion into new geographic markets is hindered.

Mitigating Actions

1. We prioritise building a robust and diversified product portfolio through improved cross-functional synergies, organisational capabilities, project management, and governance throughout the product lifecycle.
2. We enhance our capabilities in both licencing and out-licencing of products.
3. Our focus lies on the development and commercialisation of complex generics and specialty products, among other priorities.
4. We emphasise operational excellence programmes aimed at improving yields, ensuring supply chain continuity, and maintaining sufficient inventory levels.

Risk Area – Environmental Impact Management

Risk Description – Increased efforts for efficient water usage and reduced waste generation, and proper disposal are necessary to demonstrate the Company's commitment to a sustainable future and a healthy planet.

Impact

Neglecting environmental effects can result in unfavorable legal, regulatory, and financial repercussions, a decline in shareholder trust and reputation, and finally could lead to potential loss of an operating license.

Mitigating Actions

1. We continue to identify opportunities to minimise any adverse environmental effects from our operations. We have adopted targets for waste management and water conservation. Our goals include reducing water consumption by 10% till FY25 considering baseline of FY20 and co-processing 30% of hazardous waste by 2025.
2. We closely monitor and track our waste management and water consumption. Our priorities are to enhance water efficiency, reduce water withdrawal, and increase water recovery. For waste management, we focus on co-processing hazardous waste and promoting recycling and reuse within our operations.

Risk Area – Climate Change

Risk Description – Inefficacious management of greenhouse gas (GHG) emissions could lead to climate-related physical and transition risks for the Company, causing disruption of operations and affecting business continuity.

Impact

Our assets could be harmed by possible direct physical threats to our activities, which consequently can result in a temporary suspension of some of our operations and a rise in the cost of repairing and rebuilding affected locations. Transition risk associated with climate change may result in the introduction of more stringent regulations, which would increase the cost of compliance or new technology investments. Losing reputation and the trust of stakeholders can also result from a failure to respond to the negative effects of climate change.

Mitigating Actions

1. The Company has set a 35% reduction target for absolute carbon emissions (Scope 1 and Scope 2) by 2030 compared to the baseline of 2020.
2. To identify and assess the physical and transitional risks associated with our operations, we have also undertaken climate risk assessments.
3. By expanding energy sourcing from renewable sources such as solar and wind, increasing use of biomass and implementing energy efficiency programmes, we are continually seeking ways to reduce our reliance on fossil fuels in our operations.

Risk Area – Sustainable Supply Chain and Responsible Procurement

Risk Description – Consists of supply chain disruptions that could affect the business continuity or product quality and the risk of non-substitutable suppliers that can affect the continued availability of critical raw materials.

Impact

Long-term commercial partnerships with suppliers may be impacted if standards related to various social, environmental, and safety aspects are not complied with by suppliers, leading to loss of business value. Non-substitutable and critical raw material suppliers may impact on the business in case of any unforeseen disruptions.

Mitigating Actions

1. We are constantly looking for ways to reduce supply chain risk, such as by assessing potential substitute sources for essential or non-replaceable raw materials.
2. The suppliers are required to abide by the Company's ESG requirements as part of the Supplier Code of Conduct.
3. The Company has high focus on developing quality products and the safety of consumers. The quality of raw materials for our production process is ensured by conducting periodic supplier audits.

Strategic Risk Management

Risk Area – Occupational Health and Safety (OHS)

Risk Description – OHS is an integral part of our commitment to providing a safe and secure work environment for employees. Having an ineffective Health and Safety management system and programmes may cause many health and safety incidents.

Impact

A regular occurrence of health and safety issues will negatively impact the performance of the Company concerning worker well-being and safety. This will influence the Company's reputation, brand image, and capacity to draw in and retain talent.

Mitigating Actions

1. The business maintains a robust Environmental Health and Safety (EHS) management system, comprising regular audits of its EHS procedures, both internal and external.
2. Our Process Safety Management system's guiding principles serve as the foundation for both our safety procedures and risk assessment methodology, which unifies our approach to health and safety from the perspectives of working conditions and risk assessment.
3. After potential risks are identified and safety incidents are evaluated, a thorough corrective action plan is established to prevent the occurrence of similar incidents in the future.

Risk Area – Ethical Clinical Trials and Animal Testing

Risk Description – Addressing risks associated with clinical trials and animal testing is critical to demonstrate our commitment to responsible research practices, especially around the ethical and safety-related concerns of trials on human subjects and animal testing. Adverse events related to research practices can cause delays in product development and could lead to financial losses and negative public perception.

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 participant's health and safety. Delays at any stage can also prolong the overall timeline for drug development, leading to increased costs.

Mitigating Actions

1. The Company complies with all relevant regulatory requirements governing clinical trials and animal testing. We have dedicated teams responsible for ensuring compliance with these regulations, which involve obtaining necessary approvals, and permits, and maintaining thorough documentation.
2. We also implement robust quality control and safety measures throughout the research process. This involves monitoring and auditing the conduct of clinical trials, data collection, and analysis to ensure accuracy, reliability, and compliance with relevant standards.
3. 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.
4. On certain projects we collaborate with academic institutions, research organisations, and regulatory agencies to share knowledge, expertise, and resources. Such collaborations also enable collective efforts, and checks and balances to enhance the quality and ethical standards of clinical trials and animal testing.

Risk Area – Business Interruption/Operational Inefficiencies

Risk Description – Possible disruptions or inefficiencies by natural disasters, regulatory hindrance, cyber security threats, or workmen shortages could have an impact on the manufacturing and supply chains.

Impact

Business interruptions/operational inefficiencies can result in the loss of revenue, surge in operational expenses, and, in extreme cases, damage to the Company's reputation.

Additionally delays in the entering the market could have an impact on our competitiveness. Data breach cases could escalate legal and financial liabilities.

Mitigating Actions

1. We have robust planning process in place to avoid stock-outs of finished products.
2. We have norms for safety stocks that ensure availability of finished products and thereby ensure continuity of our operations. When there is a supply delay, decrease lead time by transporting shipments through air and ensuring availability of the product.
3. Regular review by senior management and department-wise responsibility given to ensure adherence with relevant regulatory requirements and product launch timeframes.
4. We keep a stock of essential spares at many sites to ensure uninterrupted availability.
5. Install backup solutions like DG sets and tanker supplies to decrease the chances of power and raw material shortages.
6. Timely recruitment and availability of human resources are ensured to manage shortage in manpower. We also evaluate loss of production at the site, if any, due to non-availability of manpower.

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

Risk Description – Possible threats to our intellectual assets include theft, unauthorised usage, or violation of patents, trademarks, and confidential data.

Impact

Breach of valuable assets could lead to costly legal battles and erode the Company's reputation. Further, stakeholder trust could be impacted if confidential data is compromised, impacting partnerships and customer confidence.

Mitigating Actions

1. Work with Drug Controllers to execute compliance and revoke manufacturing licences of counterfeiters.
2. Provide training for identifying potential market violation to the field force.
3. We have set a dedicated team at the head office to manage field inputs and carry out actions deemed necessary.
4. Inspecting new trademark filings periodically to recognise conflicts and avoid infringements.
5. Setting up a standard operating procedure and framework and standard to safeguard our IP for branded products in important markets.

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Risk Area – Price, Cost, and Margin Pressures

Risk Description – Market competition, revisions in the prices controlled by the government and changes in the costs or prices of raw materials and manufacturing expenses affect the business profitability.

Impact

Adverse effects on the overall financial performance and long-term business viability.

Mitigating Actions

1. Reinforce product portfolio with new and innovative products to be distinct from competitors and withstand pricing pressures. Cost-effective solutions such as:
   - Identify the feasibility of creating alternative vendors/ sites for products to optimise production costs and reduce dependencies.
   - Optimise the dependencies on air transport in favour of cost-effective sea shipments to decrease transportation expenses.
   - Explore other options such as usage of alternate fuels and automation to increase cost efficiency in manufacturing processes.

Emerging Risks

At Sun Pharma, we assess risks by evaluating their likelihood, potential impact, and timeframe for occurrence. We review emerging risks at least every three years to ensure timely resolution and prevent serious consequences, focusing on their probability and potential effects on the business in line with our risk management framework.

The management conducts a thorough analysis of internal and external data, including industry trends, market study, regulatory requirements, and expert insights, to identify and classify emerging risks. This systematic approach enables timely implementation of mitigation strategies to address potential threats to the business. We present below two of the emerging risks identified by the management.

Geopolitical Fragmentation

High risk to manufacturing facilities and customers situated in regions experiencing heightened geopolitical tensions in the Middle East, and Eastern Europe. Sun Pharma has operations in Israel, Russia, Bangladesh, and Ukraine which are experiencing extended regional conflict.

Impact

Sun Pharma has global presence with manufacturing locations and customers located in several countries. Some of our manufacturing facilities are located in Israel, Russia and Bangladesh. These regions are experiencing heightened regional tensions over the past few years.

For us, supply chain disruptions are a significant concern, as conflicts can hinder the transportation of raw materials and finished products, leading to production delays or stoppages. The safety of our workforce becomes critical, with potential reductions in staff availability due to security threats. Facilities may also suffer physical damage, further interrupting manufacturing and research activities. Extended conflict causes disruptions in local healthcare infrastructure and can impede patient access to medications. Governments in conflict regions can impose trade restrictions or sanctions that hinder international transactions. Also, economic instability can lead to currency volatility, affecting operational costs and profitability.

Mitigation Action

Comprehensive risk management and contingency planning is implemented to prepare for potential geopolitical disruptions. The Company has implemented steps to mitigate the impacts of geopolitical fragmentation through strategic planning, resource allocation and by building stronger international relationships. Additionally, our corporate social responsibility initiatives and engagement with local communities helps us to build goodwill to mitigate political risks. Investments in healthcare infrastructure and community programmes strengthens relationships with local stakeholders.

Spread of Inaccurate Information and Declining Trust

Increasing use of technology has a potential to be misused and may knowingly or unknowingly lead to spread of wrong or incorrect information about our medicines and organisation through social media. There is a possibility of misuse of the same by individuals/organisations to propagate incorrect information, knowingly or unknowingly against the Company, industry, product, molecules and may have a potentially negative impact on reputation. Sustained inaccurate information and resulting campaigns can potentially lead to long term erosion of trust for the concerned organisation. This risk is increasingly becoming important as pharmaceutical organisations are under constant attacks from alternative medicine practitioners, specifically in India.

Impact

Dissemination of incomplete and/or incorrect information regarding the dangers or inefficacy of medications can result in mistrust on part of the patient and non-adherence to recommended treatment regimen resulting in non-compliance and a negative impact on the patient's health outcome. Continuous spread of incomplete or misinformation can prompt unwarranted scrutiny from regulatory bodies, potentially leading to investigations and inspections. A decline in public confidence can have a negative impact on product sales, directly impacting the Company's financial performance. Continued spread of incomplete and or incorrect information may lead to a decrease in stock prices and investor confidence. Erosion of trust can cause research institutions to be hesitant to collaborate on research projects, affecting innovation and development of novel products.

Mitigation Action

Sun Pharma has undertaken initiatives aimed at promoting scientific medical and pharmaceutical research outcomes for public health improvement. It involves sharing medical and pharmaceutical research with the public after conducting scientific research on ways to improve public health. This initiative has helped young scientists and scholars in the medical and pharmaceutical fields to work towards improving public health. We also implement a programme on Mobile Healthcare Unit that emphasises Health Promotion and Preventive Healthcare Education in underserved and marginalised areas and also provides Curative Treatment to those in dire need. Sun Pharma also supports various patient education initiatives through doctors to improve awareness of disease and its management. With regards to our products we have taken significant measures in our product packaging to address product counterfeit issues and continue to educate the health care practitioners on the same on a regular basis. Sun Pharma is also working very closely with the policy making authorities and industry associations to address the issues related to counterfeit medicines.

Risk Culture

We recognise the importance of instilling a risk management culture across the Company, backed by a robust framework for timely risk assessment and mitigations. We believe that having a holistic and robust risk culture is necessary for effective risk management. We provide focused risk training to our employees to help them learn and increase their awareness of potential risks and understand the importance of timely identification and reporting of risks for effective mitigation. Our Information Technology Security Team and Company Secretary regularly share information on various risks. We make consistent efforts to ensure that employees follow regulatory requirements.

As part of the familiarisation programme for the Board Members as envisaged under Regulation 25(7), of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, the functional heads/senior executives make presentations to the Board Members on various topics covering operations, functional overviews, business performance and opportunities, risk management framework, and the regulatory environment in which the Company operates.

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.