

Our risks and opportunities

Risks are inherent to our business. Our operating environment is complex, highly regulated and uncertain. Identifying, analysing and responding appropriately to these business risks is vital to us attaining our strategic objectives, protecting the interests of stakeholders and meeting legal requirements. Our success depends not only on our ability to minimise downside impacts, but also on our ability to capitalise on the potential opportunities for value creation presented in an uncertain future.

An integrated approach to risk management

The identification and management of risks are processes central to achieving our strategic objectives. These processes protect us against potential negative impacts, enables us to take risk for strategic reward and improve our resilience against emerging risks. To this end, we have an integrated approach to risk management, giving due consideration to economic, environmental and social factors which impact Aspen and our stakeholders. Both the opportunities and threats underlying each identified risk are considered to ensure a balanced outcome between risk and reward for the sustainability of the Group as a whole.

Risk management activities occur at all levels in the organisation. We strive to embed sound risk management in our strategy, planning, budgeting and performance management processes. Senior executives are accountable for performing effective risk management within their areas of responsibility and for promoting a culture of risk awareness throughout the organisation. The Group Risk Management Policy and the Risk Management Framework provide structure for these activities to be embedded into our key decision-making processes and day-to-day activities which achieves alignment with the Group's risk appetite and tolerance levels. On a quarterly basis, the Group Risk function coordinates the completion and consolidation of risk assessments across the Group and undertakes activities to identify new emerging risks and opportunities. We consider opportunities identified which demonstrate the value that our initiatives and strategies could yield to the growth and sustainability of the Group. Our value creation process (page 25), business model (page 26) and business strategy (page 30) elaborate on how we leverage opportunities to ultimately create value. The Group's different risk profiles are discussed and reviewed regularly by the Executive Risk Forum (comprising senior Group Executives) and are assimilated into a Group Risk Report for consideration by the Audit & Risk Committee and the Board.

Risk governance

The Board is ultimately responsible for the Group's approach to risk management and internal controls. It defines the Group's risk appetite, enabling the Group to determine the level of risk it is prepared to take in achieving the Group's strategic objectives. It has delegated oversight of the implementation of risk management to the Audit & Risk Committee. The Audit & Risk Committee reviews the material risks facing the Group and obtains assurance of the effectiveness of the risk management process and risk responses through the implementation of a combined assurance approach.

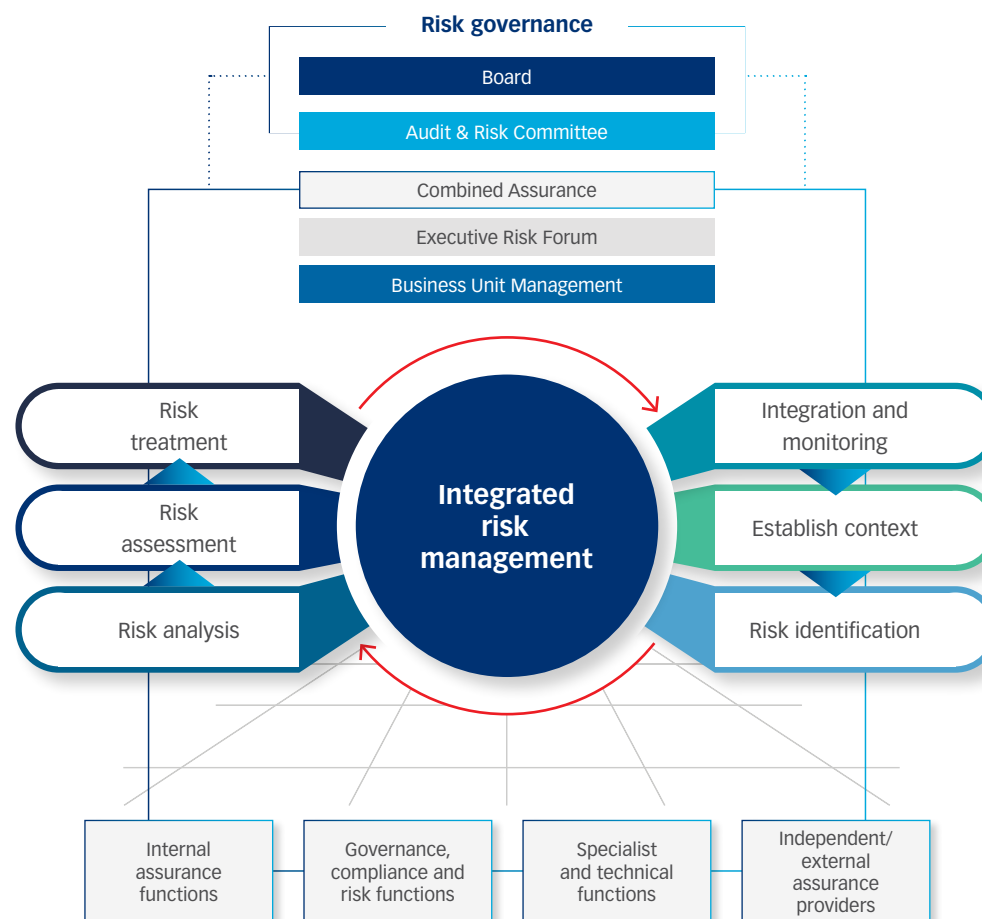
Risk landscape

Two years since the onset of the COVID-19 pandemic creating uncertainty and challenges for people and companies across the globe, our business model has proven to be resilient and enabled us to contribute towards the global management of this and other diseases by supplying vaccines and critical medicines used in the treatment of patients.

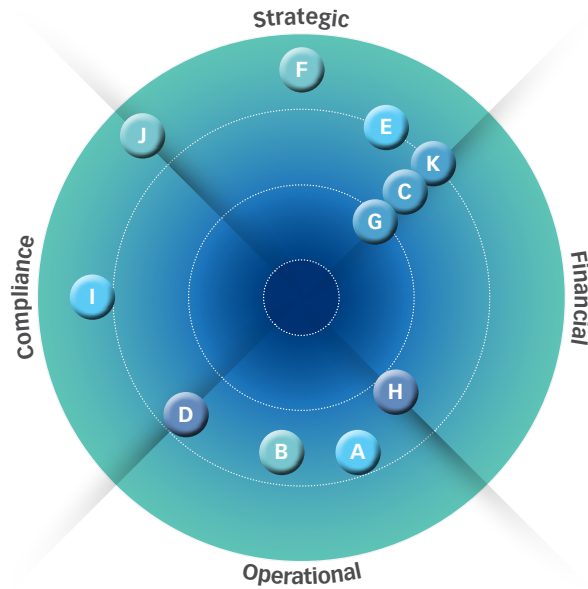
During this financial year, our resilience continued to be tested as we faced disruption associated with the Russia/Ukraine conflict and the contagion effect on energy and inflation. During this challenging time, our priority has been to minimise impacts on patients who rely on our products and safeguard our impacted employees. While we continue to be exposed to significant uncertainty, including COVID-19 related impacts, macro-economic volatility and logistical constraints, we have embedded the management of these impacts

into our risk management approach and have appropriately adapted our responses. Emerging risks are monitored by executives, under the direction of the Board (also refer to "Our external operating context" on page 38).

The key risks and opportunities that could have a material impact on our ability to achieve our strategic objectives and create value are outlined in the table overleaf.



Our risks and opportunities continued



Summary of key risks and opportunities

(presented in alphabetical order)

Risk

- A** Attraction, development, well-being and retention of skills
- B** Continuity of supply
- C** Delivery of pipeline and new products
- D** Digital transformation and information security
- E** Environmental sustainability, including climate action
- F** Ethical conduct and stakeholder relationships
- G** Execution of our business strategies
- H** External macro factors
- I** Legislation, regulation and compliance
- J** Patient safety and product quality
- K** Realising expected benefits from acquisitions and divestments

Attraction, development, well-being and retention of skills

Risk context

We need a diverse, skilled and committed pool of talented employees to execute the Group's strategy in an increasingly complex environment. There is strong competition for the best talent, especially in certain technical and/or specialist fields within the regions in which we operate. Increased flexibility and new ways of working are key value drivers in attracting top talent. Employee engagement and retention can be impacted by organisational change and the resultant uncertainty. Health and safety of our personnel is a key priority, which is supported by compliance with health and safety laws, as well as the alignment of our systems, processes and procedures with in-territory regulations.

Opportunity for value creation

Through the development of a compelling employee value proposition, the Group seeks to position itself as an employer of choice in the competitive landscape. Maintaining a safe and healthy working environment further enables a motivated and productive workforce with a high-performance culture, innovation and alignment to strategic goals.

Our response

Talent management is a key focus area in our human capital strategy and initiatives are being introduced to enhance the definition and understanding of our talent supply and demand requirements. Targeted programmes have been implemented to increase diversity and gender representation, strategically accelerate development of high potential employees and increase employee succession pool through focused skills development and enhanced behavioural awareness programmes. Various support programmes and initiatives are available within the business to nurture employee well-being. Change management initiatives are implemented in business units impacted by organisational changes. Our health and safety management systems are aligned to global standards and performance is monitored through the Social & Ethics Committee.

Strategic objectives



Capital



Risk trend



Our risks and opportunities continued

Continuity of supply

Risk context

Our end-to-end value chains may be impacted by unplanned external interruptions, including unavailability of essential raw materials, utilities, manufacturing components and services, or closure of our manufacturing sites as a result of natural disasters, civil unrest, regulatory interventions, fire and pandemics. The technical and regulated nature of the manufacturing and supply of pharmaceuticals has an inherent heightened risk of quality failures, which may result in batch rejection or product recalls (refer to Patient safety and product quality risk [page 52](#)). We have a key reliance on certain specialised raw material suppliers and third-party manufacturers to provide products within specification and required time frames. We continue to be engaged in multiple projects to transfer certain products to new manufacturing lines. These technical transfers achieve more cost-effective and/or reliable manufacturing, but can pose execution risk. Also refer to Our external operating context on [page 38](#).

Opportunity for value creation

We strive to maintain a reliable supply of medicines to our customers and to the patients who depend on them. Our ability to effectively manage the risks within our complex supply chain and to effectively respond when disruptions do occur, is a key value driver which supports our reputation as a responsible and reliable pharmaceutical company. Consistent availability of supply also allows us to take advantage of supply disruptions which may be experienced in respect of other products. More cost-effective manufacturing will also allow for greater affordability, increasing access to medicines.

Our response

We build strong long-term relationships with API suppliers and third-party manufacturers to ensure continuity and security of supply. Where appropriate, we manufacture our own API. Our strategy to invest in our sterile manufacturing capability to in-source the manufacturing of Anaesthetics further increases our ability to manage our supply chain. Skilled and experienced teams are involved in technical transfer projects and there is oversight by the Group operations division to ensure progress is monitored and required milestones are achieved. Safety stock of raw materials and finished product is generally held to provide a buffer in the event of supply disruption. We are continually strengthening our systems and processes, as well as our business continuity plans, to allow for a coordinated response to supply disruptions. Appropriate insurance coverage is held for high-impact events.

Strategic objectives



Capital



Risk trend



Delivery of pipeline and new products

Risk context

The identification, development and commercialisation of new products is both time-consuming and costly, involving a high degree of business risk. A project may fail or be delayed at any stage of the process due to several factors. As a result of the lengthy time frames associated with new product development projects, the assumptions made at the initiation of these projects could change, impacting the planned return on investment. New products may not be accepted by the health regulator, may not perform as expected or may face greater-than-anticipated competition. Timing of new product launches is dependent on the speed of processing the necessary registrations by the regulatory authorities in each country.

Opportunity for value creation

Successfully launched products from the pipeline represent opportunities to expand access to treatment options for healthcare providers and patients. A healthy pipeline is a key driver in our sustainable growth strategy, representing opportunities to leverage our investment in IP and manufacturing capability.

Our response

Our product portfolio management strategy focuses on the identification of opportunities that align with our business strategy. This leverages our intellectual and manufacturing advantage and aligns with the local market conditions in a broad geographic footprint. Through the implementation of product development lifecycle management, our regional business and Group product portfolio development teams continuously review and refine our pipeline, increasing the focus on molecules with confirmed commercial feasibility and enhanced value creation potential.

Strategic objectives



Capitals



Risk trend



Our risks and opportunities continued

Digital transformation and information security

Risk context

Digital technologies continue to revolutionise the way companies conduct business and operate. Keeping pace with the speed of digital transformation is imperative to remaining competitive and relevant, while keeping employees abreast of digital developments (refer to Attraction, development, well-being and retention of skills risk [page 47](#)). Patients and HCPs are increasingly becoming accustomed to the convenience of digital and remote healthcare. This requires pharmaceutical companies to adopt innovative technologies to engage with their stakeholders (also refer to Our external operating context on [page 38](#)). This also requires the adoption of an agile digital strategy, enabled by an investment in IT infrastructure, systems and capabilities. Large-scale IT projects are exposed to implementation risk. With the growing incidents of cyberattacks, there is an increasing need to ensure secure and reliable IT systems and infrastructure as well as the careful management of the information that is in our possession to ensure data privacy. Failure to adequately protect critical and sensitive systems and information may affect our ongoing business operations, resulting in the loss of commercial or strategic advantage or in breach of data privacy regulations.

Opportunity for value creation

Digital technologies are an enabler in driving our strategic objectives forward and supporting sustainable operations. Increased digitalisation provides opportunities for efficiency gains, development of employees' digital skills, improved collaboration internally and with our key partners, as well as for information-driven decision-making.

Our response

Our digital transformation has received increased focus, with an emphasis being placed on foundational areas that will position us for growth and optimisation, including governance, cybersecurity and risk management. We have continued to make a considerable investment in modernising our ERP, regulatory and compliance systems and manufacturing execution systems, while digital platforms are being increasingly used to enhance communication and collaboration with our various stakeholders. Our data privacy policies ensure that we collect, transfer and store electronic and hard copy personal data appropriately. The Audit & Risk Committee provides oversight of I&T.

Strategic objectives



Capital



Risk trend



Environmental sustainability, including climate action

Risk context

Our operations are reliant on the consumption of scarce natural resources and result in negative impacts on the environment such as carbon emissions and waste. Inherent to our industry is an elevated risk of environmental contamination. There is an increasing global focus from regulators, investors, HCPs, customers and the broader society for companies to implement measures needed to transition to a low-carbon economy. These transitional risks could include changes in regulations in countries or territories in which we operate, including mechanisms implemented by governments to accelerate climate action, such as carbon taxes. Our customers and business partners may place an increasing weight on our environmental sustainability performance, and that of our value chain, in their purchasing decisions. Physical impacts from climate change could pose business continuity threats to our own operations and across the entire value chain.

Opportunity for value creation

Addressing the risks relating to environmental sustainability and our environmental impact creates opportunities to reduce our carbon footprint while achieving increased efficiencies in using scarce natural resources. It also builds resilience against physical impacts. Contributing to the broader issue of environmental stewardship creates the opportunity to further support our commitment to being a responsible corporate citizen and contributing towards healthier communities.

Our response

We have implemented the Group's safety, health and environment ("SHE") programme and embarked on a process to better understand the potential impact of climate change on our business. We are committed to developing a climate action plan with related targets. We are equally committed to reducing our waste generation and water consumption. This will build on the environmental and resource efficiency initiatives that we have already implemented to reduce our reliance on scarce resources and our impact on the environment. We support the Taskforce on Climate-related Financial Disclosures and aim to develop our disclosures in line with its recommendations (refer to [page 101](#)).

Strategic objective



Capitals



Risk trend



Our risks and opportunities continued

Ethical conduct and stakeholder relationships

Risk context

We understand that to be successful, we must conduct our operations ethically and in a manner which meets the expectations of our stakeholders. Poor ethical behaviour or a failure to subscribe to our values and our Code of Conduct could result in the loss of confidence by stakeholders and reputational damage.

Opportunity for value creation

Maintaining a corporate culture which is underpinned by ethical conduct is fundamental to building trust with our various stakeholders and enhancing our corporate reputation.

Our response

We have a zero-tolerance approach to unethical behaviour. Our Code of Conduct is a values-based code aimed at governing the conduct of our employees. Employee understanding of our Code of Conduct is reviewed on an annual basis. A formalised ethics management programme has been implemented and the effectiveness of this programme is overseen by the Social & Ethics Committee. Our approach to stakeholder relationship management entails identifying and engaging transparently on issues that may impact our commitment to practising good corporate citizenship.

Strategic objectives



Capital



Risk trend



Execution of our business strategies

Risk context

There are several risks that could impact the development and execution of our business strategies. Increased competition, the global challenge of affordable healthcare, fluctuations in demand due to pandemics, changes in healthcare policies, the introduction of new pricing policies and programmes, legislated pricing cuts, volatile market environments, commercial team performance and availability of supply are just some of the factors that could impact the achievement of expected performance. If the execution of our business strategies does not succeed as anticipated, increased pressure is placed on financial sustainability. Sustained deterioration in the commercial performance of specific products may result in an impairment in IP, while underutilised manufacturing capacity could negatively impact returns on invested capital. Also refer to Our external operating context on [page 38](#).

Opportunity for value creation

The ability to achieve our business performance expectations underpins the strategy of the Group to create sustainable long-term value for all our stakeholders. Through implementing responsible pricing strategies, we aim to achieve the appropriate balance between making our products affordable, while achieving reasonable returns on investments made. We have proven manufacturing capability and continue to expand our capacities, creating access and sustainability collaboration opportunities for multinationals.

Our response

We continue to reshape our product portfolio to achieve an appropriately balanced and diversified basket of Sterile Focus and Regional Brands, with a focus on niche specialty brands where we perceive opportunities to be better. We continually invest in our commercial team structures, manufacturing capabilities, processes and skills as well as seek mutually beneficial collaboration arrangements to source sustainable third-party volumes. Through actively engaging with regulatory authorities and other key stakeholders, each country or territory can monitor and adjust their approach to manage pricing pressures. Our strategy to transfer the production of certain products into our own facilities is expected to deliver margin benefit, increased competitiveness and improved security of supply. We focus on achieving efficiencies, cost reductions and synergies in this challenging and regulated pricing environment. We are actively engaged with a number of potential business partners regarding opportunities to productively utilise the additional manufacturing capacity we have and are building.

Strategic objectives



Capitals



Risk trend



Our risks and opportunities continued

External macro factors		
Risk context	Opportunity for value creation	
We are a multinational Group and therefore exposed to various geopolitical, social and economic risks that may potentially impact our operations. These risks are complex and constantly evolving, creating an uncertain environment in which to do business. While many territories present opportunities, these macro factors can hinder growth and include but are not limited to policy uncertainty, restrictions on access to funds, currency volatility, rising interest rates, social unrest and increased inflationary effects. Also refer to Our external operating context on page 38.	The ability to effectively navigate the dynamic and uncertain market environments creates opportunity to achieve growth, enhanced returns and further diversification.	
Our response		
Our diverse geographical footprint provides partial mitigation to localised macro factors. We continuously monitor socio-economic trends and geopolitical events in countries where we operate. Strategic responses are implemented where required, including strict management of our operating expenses.		
Strategic objectives	Capitals	Risk trend
		

Legislation, regulation and compliance		
Risk context	Opportunity for value creation	
The pharmaceutical industry is subject to intricate, costly and evolving regulations governing the approval, manufacturing, labelling, marketing and sale of pharmaceutical products. These regulations vary by region and country or territory and are rigorously monitored and enforced. All other aspects of our business are subject to extensive legislation and regulation, which increases in complexity due to the multinational nature of our business operations. Changes in these laws and regulations can significantly impact our operations or increase the risk of non-compliance.	Maintaining compliance and being well-informed with relevant laws, regulations and standards forms an essential part of our licence to operate and is fundamental to our commitment to being a responsible corporate citizen.	
Our response		
Our business behaviour is strengthened by our ethical drive and a commitment to comply with our legislative compliance management processes. A robust regulatory and compliance management framework is in place across the Group's operations. Legislative and regulatory developments are monitored on an ongoing basis. Internal communication and training on the ethics standards expected from each employee is performed while the key regulatory and compliance requirements are assessed on a regular basis. Legal and regulatory compliance is monitored by Group executives and the Board.		
Strategic objectives	Capitals	Risk trend

Our risks and opportunities continued

Patient safety and product quality		
Risk context	Opportunity for value creation	
Our products, most of which are prescription medicines, are used by a multitude of patients in a vast number of countries. We have the responsibility to implement appropriate pharmacovigilance procedures and systems to identify, investigate and resolve any potential safety concern relating to these products. The quality requirements for pharmaceuticals are rigorous across the entire supply chain and include standards that are applicable to suppliers, manufacturing and distribution. The intricate technical manufacturing processes associated with our products increase the inherent risk of quality deviations and batch rejection.	Our overriding responsibility is to the patients who use our products, the HCPs who prescribe them and the regulators who protect public health. Our ability to provide a reliable supply of high quality, affordable medicines, and effectively respond to safety or quality incidents as and when they occur, underpins the trust these stakeholders have in the Aspen brand.	
Our response		
Our Group Pharmacovigilance function, supported by local business units globally, is responsible for monitoring and managing the safety of all our products throughout the product lifecycle using robust systems and processes to monitor manufacturing quality standards, compliance with current GMP and other regulatory requirements. Our Quality Assurance department conducts audits to support the achievement of our high quality standards. Our responsibility to our patients and consumers is monitored by the Social & Ethics Committee. The Group holds the appropriate product liability insurance.		
Strategic objectives	Capitals	Risk trend
		

Realising expected benefits from acquisitions and divestments		
Risk context	Opportunity for value creation	
An integral component of our strategy is achieved through acquisition, licensing, collaboration and divestment transactions. The risk in respect of acquisitions is that the Group may fail to identify suitable acquisition opportunities or realise the expected benefits of the acquisitions, or may incur unexpected risks and obligations because of the transaction. The success of the Group's acquisition strategy is dependent, among other things, on the successful incorporation of the technologies, products and businesses it acquires, and their subsequent successful incorporation and growth. The Group may decide to dispose of assets that are no longer deemed core. When disposing of assets, the Group may not be able to complete the disposal on acceptable terms and may be required to give guarantees and warranties, or may expose itself to claims from purchasers, as well as creditors of the transferred business.	Through successful portfolio management, we are able to meet the medical needs of patients, build focused therapeutic portfolios, achieve a desired geographical footprint and leverage our manufacturing and supply chain capabilities. Acquisition and disposal transactions are key to our Portfolio Management Model to provide the opportunity to accelerate strategy and to achieve accretive growth in the overall economic value of the Group as well as to reshape and renew our product offering in response to changes in our operating environment.	
Our response		
We perform extensive due diligence to strategically identify, value and execute transactions. External specialists are involved where required. Transactions are negotiated by experienced and highly skilled professionals. We have an established approvals framework and proposed transactions are critically reviewed by executive management, and where required, approved by the Board. We have dedicated integration teams to execute defined transition agreements to ensure a successful transfer of processes and product distribution. Post-acquisition performance is monitored closely to ensure integration and delivery on business plans.		
Strategic objective	Capitals	Risk trend
		