Patients

As a pharmaceutical company, and aligned to our purpose of improving the health and quality of life of patients, we have a responsibility, and the opportunity, to make a meaningful contribution to the global challenge of making healthcare available to all.

Strategic objectives

Stakeholders

Capitals

Our commitment

We are committed to promoting access to medicines by providing a reliable supply of high quality, affordable products across the geographies of our operations.

Our impact

- Improved health and quality of life for the patients who use our medicines
- Maintained a reliable supply of quality and affordable treatment options and medicines for HCPs and healthcare systems
- Increased capacity and technical know-how to respond to emerging healthcare crises in Africa, and the world
- Concluded a collaboration agreement to manufacture and make available four Aspen-branded vaccines for Africa

225 million
doses of COVID-19 vaccines manufactured

180 medicines
on the WHO Essential Medicines List

Patients in
more than 60 low- and middle-income countries
treated with our medicines

162 SED initiatives
aimed at strengthening healthcare, including emergency product donations

Our material sustainability topics

- Access to medicines
- Health security
- Patient safety
- Responsible advocacy and lobbying
- Responsible marketing
- Reliable supply of quality products
- Responsible product portfolio

Our contribution to the SDGs

We contribute to the following SDG and targets through our actions aligned to our material sustainability topics:

SDG 3 Ensure healthy lives and promote well-being for all at all ages

3.4 By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being

3.8 Achieve universal health coverage, including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all

Additional information available online:

Aspen Sustainability and ESG Data Supplement

Aspen Code of Conduct

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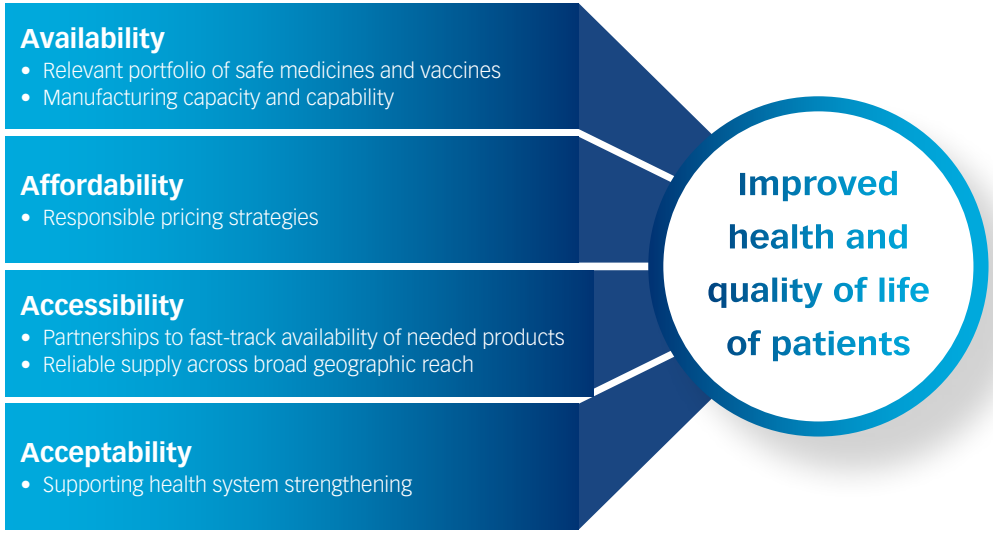
Access to high quality, affordable medicines

Access to affordable healthcare is a global priority. We support the WHO's promotion of Universal Health Coverage and are committed to advancing the goals and outcomes of the UN SDG3 of "ensuring healthy lives and promoting well-being for all at all ages". We believe that our market position as a global pharmaceutical company with a relevant portfolio of medicines and vaccines is the most fundamental way in which we contribute to increasing access to medicines and furthering the global goal of universal access to healthcare. The medicines we manufacture and distribute improve health, enhance the quality of life of patients globally and contribute to creating economic benefit through healthier, more productive populations. We continue to focus on developing a product portfolio that leverages our intellectual and manufacturing advantage, including investment in effective older specialty medicines that provide viable treatment options compared to expensive new innovative drugs. Effective treatments contribute to lower healthcare costs and prevent more costly treatment requirements. Through our extensive global presence, and a strong presence in developing regions, we extend the availability of our medicines and products to new patient populations.

We are intently committed to making our increased sterile manufacturing capacity available to ensure equitable access to vaccines for less developed countries, with a particular emphasis on African countries. We have demonstrated our ability to produce vaccines and are well positioned to make a meaningful contribution to strengthening health security and achieving enhanced access to high quality, affordable medicines. We look forward to our partnership with the Bill & Melinda Gates Foundation and CEPI through which we will receive grant funding to support African regional manufacturing capacity for an affordable supply of vaccines to, among others, African countries and Gavi/UNICEF, as well as contributing to pandemic preparedness through a share of our manufacturing capacity over a period of 10 years.

We share the responsibility to build resilient and sustainable healthcare systems with governments and private stakeholders, such as healthcare professionals, NGOs and other private sector participants.

During this year, we have worked on developing an access to medicines position paper to galvanise our efforts to contribute toward the achievement of this goal which is at the forefront of our sustainability strategy. Under the direction of the Executive Sustainability Forum, and oversight of the Social & Ethics Committee, we are crafting our access to medicines strategy focusing on the following key elements:



Essential medicines

Our diverse product portfolio in targeted therapeutic areas and unique trusted brands provides effective treatment options for patients. 180 of our products are included in the WHO Essential Medicines List (issued 2021).

Product reach

Our medicines are accessible to patients in over 115 countries and regions, including patients in emerging economies. In the 2022 financial year, we supplied medicines to more than 60 low- and middle-income countries (and 48 of the 106 countries identified in the Access to Medicines Index as countries where better access to medicines is most needed).

Affordability and pricing

Our product portfolio mainly comprises established, post-patent medicines and generics. Our product portfolio is not protected by patent exclusivity and is therefore subject to market and regulatory mechanisms aimed at achieving affordable access to medicines. Pricing decisions are overseen by the Group's Pricing Committee, established to ensure an appropriate balance of responsible pricing and business sustainability.

Our response to COVID-19

The reliable supply of life-saving medicines used to treat COVID-19 in patients, many of whom receive this treatment in intensive care units, has been of paramount importance during the period of this pandemic. Certain of our anaesthetic products are used in the tracheal intubation of

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patients, while anticoagulants are used to counter the increased risk of thrombotic complications in patients who have suffered from COVID-19. Aspen's dexamethasone, in particular, has also been widely used as a treatment option for hospitalised COVID-19 patients. In response to the global demand for these and other essential medicines, we established a supply chain task force to coordinate our efforts in ensuring the continued supply of products where they were needed most.

We are proud to have been selected by Johnson & Johnson to manufacture its COVID-19 vaccine at our Gqeberha manufacturing site and to have successfully delivered more than 225 million doses of the vaccine. We further concluded the agreement with Johnson & Johnson for the manufacture and sale of an Aspen-branded COVID-19 vaccine, Aspenovax, to public sector markets in Africa through transactions with designated multilateral organisations and with national governments of member states of the African Union. We are ready to supply COVID-19 vaccines to Africa under a regional procurement pronouncement and as committed by the African Union, COVAX and AVATT.

Collaboration to manufacture, market and distribute four Aspen-branded vaccines in Africa

Our collaboration agreement with Serum Institute to manufacture, market and distribute four vaccines – the pneumococcal vaccine, the rotavirus vaccine, the polyvalent meningococcal vaccine and the hexavalent vaccine – provides the opportunity for Aspen to support African nations with their Expanded Programs on Immunisation.

Product portfolio

Our medicines fall into the following business segments:

Regional Brands
(page 68)

Our diverse regional portfolios provide patients and consumers with a broad range of treatments across a number of therapeutic categories in the hospital, prescription and OTC areas. This segment includes our high potency and cytotoxic medicines, which are often used in life-saving medical interventions, and due to their potency and toxicity are manufactured under specialist conditions. Included in the high potency and cytotoxics range are products designed to treat underactive thyroid conditions, immunosuppressants, oncological products, female hormonal replacement therapies, anabolic steroids, glucocorticoids and oestrogens.

Sterile Focus Brands
(page 67)

Our Sterile Focus Brands segment comprises our specialty brands in two therapeutic-focused portfolios, Anaesthetics and Thrombosis.

Anaesthetics portfolio

Patients require anaesthesia during major surgery, local surgical procedures, and for more minor pain control situations. Our portfolio offers the most comprehensive range of anaesthetic treatments available from any one company. It includes products indicated for the induction and maintenance of general anaesthesia; opioids used during induction, maintenance and recovery; as well as neuro-muscular blocking agents used to facilitate intubation and to relax the muscles for surgical procedures. Our regional and local anaesthetic products include both injectables and topical agents such as ointments, gels, sprays, creams and patches.

Thrombosis portfolio

Thrombosis occurs as a result of the body's haemostatic pathway being activated inappropriately, leading to the formation of blood clots. This condition is life-threatening and, if not appropriately treated, may lead to a stroke, myocardial infarction, ischemia and other complications. Our basket of Thrombosis products fits into the injectable anticoagulant category, aimed at the prevention and treatment of thrombotic diseases including deep vein thrombosis, pulmonary embolism and acute coronary syndrome. Our focus in this portfolio is on the low molecular weight heparin, Xa inhibitors and heparin derivatives.

Product pipeline

Intellectual property, in the form of developed, licensed and acquired product molecule dossiers, is the key driver for organic growth in the pharmaceutical industry. Our product pipeline largely represents opportunities related to acquired and internally developed product dossiers, planned product line extensions to leverage existing brands within and across territories and targeted branded product acquisitions. Our internal product development takes place under the direction of our highly skilled scientists, both in our own laboratories as well as in collaboration with other global pharmaceutical companies and research facilities.

Products in the pipeline are aimed at therapeutic categories relevant to disease profiles in each territory. The pipeline continually undergoes technical and commercial feasibility testing for the territories where they are aimed to be launched. Acquisitive growth, in the form of corporate acquisitions and product distribution arrangements, largely entered into with leading multinational pharmaceutical companies, supplements our organic growth strategy and strengthens our ability to respond to identified healthcare needs.

During the year, we continued to launch new products and grow our pipeline, with 56 products launched in 26 countries and territories.

Number of launches per region (56 in total)

Africa Middle East	25
Americas	20
Australasia	8
Asia	3

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Responsible marketing and promotion of products

We are committed to providing accurate and balanced information about our products by ensuring that we promote them responsibly across our commercial operations. The Group's position on responsible marketing and promotion of our products is described in our Group Policy on Product Promotion and Scientific Engagement, which is aligned with the International Federation of Pharmaceutical Manufacturers & Associations' Code of Practice. Compliance with this policy will form part of the Group's overall ethics and compliance processes, and certification training on this new Group policy is currently underway. An amended version of the existing Group Code of Marketing Practice is now an annexure to the policy and is aimed at ensuring that any promotional activities and interactions with HCPs, other healthcare staff, government officials, regulatory officials, patient groups, media and the general public are carried out in a responsible, ethical, professional and legal manner. We are also committed to complying with other relevant regulations and legislation in respect of matters relating to consumer relationships, including advertising standards and consumer engagement protection laws. Compliance by Aspen's businesses is monitored through the Group quality audit schedule, This is a new initiative that started in Q4 2022. There were no instances of non-compliance with regulations related to marketing and promotion identified during the year.

Our Aspen Learning Academy provides training to our qualified medical representatives across the Group, ensuring that they have specialist product knowledge to support and guide HCPs whom they interact with. This includes competency training for all trainers within the organisation responsible for disease and product knowledge training. We have further initiated continuous improvement projects for the standardisation of learning materials for brands shared across our learning management systems to support certification.

We also conduct product awareness training for employees and for customers, as appropriate. Since we do not deliver products directly to the end-customer or consumer, we ensure that only accredited third-party distributors are used to provide logistics services and, in certain countries, wholesaling services. Our suppliers and service providers are bound by the Aspen Supplier and Service Provider Code of Conduct and are required to uphold prescribed ethical and human rights standards across the supply chain.

Patient safety

The Group Pharmacovigilance team, supported by the local business units, is responsible for monitoring and managing the safety of all our products globally. Pharmacovigilance covers the activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems, and is core to our patient responsibility.

As part of our product lifecycle management process, we continuously assess the risk/benefit relationship of our products. In collaboration with health regulatory authorities, we endeavour to provide all HCPs and patients with comprehensive up-to-date safety information, which allows for the safe use of our products. In line with best practice, we have continued to invest in digital tools to enhance our surveillance of product safety information from multiple global sources and ensure the effective consolidation and review of this data. We use this information to enhance our product safety information, which is made available through the required channels. The Social & Ethics Committee provides oversight of consumer relationships as this relates to product quality and adverse drug reaction incidents reported globally.

Our sustainability commitments in action

Applying the brakes to slow down myopia in children

Myopia, also known as near-sightedness, is a condition in which someone can see objects nearby clearly, but objects farther away are blurry. Myopia is a growing public health concern worldwide and increasingly it is an issue for children. Childhood myopia is critically important to address as it can progress to the more severe version called high myopia, which can lead to an increased risk of sight-threatening eye disease in the years to come.

With the combination of younger children spending more time on devices than ever before, less time spent outdoors, COVID-19-related lockdowns, remote learning and isolation, there are increasing numbers of children being diagnosed with myopia in Australia and other parts of the world, and this is being called a 'crisis of myopia'.

In response to a patient unmet need that was identified by a local paediatric ophthalmologist and opinion leader, four years ago Aspen Australia initiated the development process that has subsequently led to the launch of Eikance (0,01% atropine sulfate) eye drops in 2022. Eikance is a prescription medicine used to treat children with myopia who are aged 4 to 14 years old by slowing down the progression of myopia.

As part of the launch activities, a consumer media project was developed to inform and educate families about myopia and raise awareness of the availability of Eikance, reaching over 4,3 million Australians.

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Clinical trials

We have limited involvement in clinical trials. Clinical studies are conducted to fulfil regulatory authority obligations or are limited to post-marketing studies. Clinical activities are therefore limited to well-known and established medicines, involve a small number of patients and do not pose a risk to patient safety. Market research studies that are conducted involve gathering marketing-related information by means of a patient or HCP questionnaire, or they involve a retrospective data review, which means these are non-interventional studies with no risk to the patient. In order to obtain registration of our products in certain markets, like China, it is a requirement to submit clinical data relevant to the local population. Therefore, we are planning to conduct two studies in China to fulfil the regulatory requirements for two of our well-established products.

Before and while conducting a clinical trial (be it a clinical study, a post-marketing study or a bioequivalence study), it is mandatory to secure the required regulatory and ethics approvals. We have several policies that govern the standards and processes utilised during the process of conducting a clinical trial. These policies describe the role of the sponsor and mandate that the sponsor oversight should always be evident. Detailed project plans with milestones are in place for each trial, with performance measures to ensure completion of studies.

Animal testing

To date, we have not undertaken pre-clinical research, but on very rare occasions, we have been required by regulatory authorities to conduct animal testing as part of new drug development or to determine the safety of manufactured APIs. Where animal testing has been required by regulatory authorities, we have outsourced only to partners who adhere to our high ethical standards. Considering that, in future we may need to undertake pre-clinical research in respect of vaccine development, regulatory validation and quality release testing using animals, we have adopted a formal policy on animal research. This policy espouses our commitment to the three Rs: reducing the number of laboratory animals required by improving existing methods of testing; refining existing methods; and finding alternative methods (replacement).

Product safety and quality

Since patient safety is of primary importance, we have a zero-defect approach to managing product quality. We recognise that we are accountable for the responsible manufacture and supply of products in accordance with applicable pharmaceutical regulations, legislation and guidelines. This underpins the trust in the Aspen brand. Stringent compliance procedures are in place across the supply chain to maintain and grow customer confidence. Regulated in-process and supply chain quality management controls are in place and adhered to. Raw materials and packaging materials are purchased from accredited and authorised suppliers who meet the necessary quality, regulatory and Aspen-specified requirements.

Products are manufactured at our own manufacturing sites or sourced from reputable third-party suppliers. Manufacturing sites are required to comply with GMP, which governs the manufacture of products in the pharmaceutical industry, and to uphold the status of pharmaceutical regulatory approvals applicable to the supplied territories. The Aspen Quality Assurance Department as well as various regulatory agencies conduct audits of potential and existing suppliers to support the high quality objectives and compliance with GMP across the supply chain. All inspection findings are closely managed through to close-out, with critical findings receiving executive management oversight. Only products that meet the prescribed quality and regulatory standards are released for sale and regulated quality compliance controls are in place. The quality and efficacy of supplied products are monitored throughout the product lifecycle using systems approved and monitored by regulatory authorities. As the owner and/or holder of the marketing authorisation, we are responsible for the quality of our own products across all territories.

During the year, our sites were subject to various regulatory inspections. No warnings or notices were issued pursuant to these inspections.

Seven product recalls were initiated during the year, marginally increasing from six in the prior year. These product recalls were mostly because of incorrect packaging, labelling and health authority requests for affected batches only. All product recalls are thoroughly investigated and appropriate corrective action taken to minimise the risk of reoccurrence.

Measures to combat counterfeit medicines

In line with global trends to combat counterfeit medicinal products, we are committed to compliance with all medicine serialisation requirements implemented globally. These measures require a comprehensive system to track-and-trace medicines through the entire supply chain to the end user, the patient. This allows us to identify every product by a unique serial number in addition to the origin, shelf life and batch number for that product. We have implemented serialisation in European, Asian and Middle Eastern markets where required.

Markets in scope for implementation going forward are Indonesia (October 2022), United Arab Emirates (aggregation – December 2022), Argentina (serialisation at site – January 2023) and USA (aggregation – November 2023). Currently Brazil, Canada and Australia are not in scope.

Reliable supply of quality products

We have commenced a strategic transformation project, referred to as IBP, to create a modern, agile and integrated end-to-end supply chain. The improvement in the links between commercial forecasting and manufacturing, coupled with improved visibility and shared accountability for end-to-end supply chain performance, will result in the overall improvement of delivery of quality medicines to patients who need them. This robust process, which will be underpinned by new technology and data tools, improves delivery to patients, reduces service costs, and reduces the risk of stock-outs and inventory write-offs.