

The Road to Success: A Story of Strategic Planning

2017-2022

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Planning**



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ACKNOWLEDGEMENT



I write these words with immense gratitude to all my colleagues at the Saudi Food and Drug Authority (SFDA). This gratitude is for the remarkable success we have achieved together during recent years.

You are the cornerstone of this success, which would not have been possible – after Allah’s grace – without the tremendous efforts and continuous hard work of everyone at the SFDA. Through your dedication, diligence and unwavering perseverance, you have become the foundation of our success, the human capital of the SFDA and the pillar of these accomplishments.

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We all have seen the significant impact of this impressive success on the Saudi community, as well as at the regional and international levels. Our achievements reflect the strength of our national cohesion and the efforts we’ve exerted to fulfil the critical task of ensuring food and drug safety in the Kingdom of Saudi Arabia.

By promoting the safety of food and drugs, we help keep our community safe, in accordance with the directions of the wise leadership – may Allah bless them – and the goals of Saudi Vision 2030, aiming at creating a healthy and vibrant society.

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May Allah perpetuate our dedication and diligence and bless the sustainable impact of the SFDA – which you at the SFDA always provide through your work. May He reward you for your heroic efforts, leading to successive achievements and permanent progress. I also ask His Almighty to guide and empower us to benefit and serve this country and its leadership – may Allah bless them.

May peace, mercy and blessings from Allah be upon you all.


H.E. Prof.
Hisham bin Saad Aljadhey,
CEO, SFDA

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FOREWORD

This is the story of the
SFDA's journey during
2017-22.

The year 2022 marked the culmination of the SFDA's third strategic plan 2018-22, and I believe we have much to be proud of in terms of successes and lessons learnt. Since my appointment as CEO of the SFDA in October 2016 we have worked together as an organisation to become a more efficient and dynamic regulator that can serve the public with confidence and operational excellence.

The SFDA is one of the primary organisations responsible for ensuring the safety of various products, including food, drugs and medical devices, in Saudi Arabia. Product safety is internationally recognised as one of the primary pillars in consumer protection. Thus, the authority has a wide-reaching mandate spanning food, drugs, medical devices, cosmetics, pesticides and feed. Everything we do supports our vision to be a leading international and science-based regulator that protects and promotes public health. We are guided by our mission to safeguard the community through regulations and effective controls to ensure the safety of products under our purview, while also protecting the market and facilitating and supporting business in the Kingdom.

During
2017-22 we took steps
to align more closely with
this vision and mission.

These included a series of goals to strengthen our capabilities, improve communication and enhance regulatory compliance – which we believe have helped to advance public health. We defined and set key performance indicators, many of which we have since exceeded. The authority faced several obstacles over this period, the most notable of which was the Covid-19 pandemic and its associated unprecedented disruption. In the years since, the SFDA has helped to guide the Kingdom on the road to recovery.



This booklet details this journey, including the challenges, successes and lessons learnt over the five-year period. This journey serves as an important backdrop for our aim: we aspire to become one of the leading food and drug regulators worldwide, and we feel we are now well on the way to achieving this goal.

These pages also offer an insight into how we have more closely aligned with the objectives of the Kingdom's Vision 2030 in recent years. This national vision is helping to transform Saudi Arabia into a more vibrant society, with a thriving economy. As we continue working to realise these long-term ambitions, the SFDA is helping Saudi Arabia to become a healthier, safer and more prosperous place to live.

H.E. Prof.
Hisham bin Saad Aljadhey,
CEO, SFDA

Our LEADERSHIP



H.E. Prof. Hisham bin Saad Aljadhey has been the CEO of the SFDA since October 2016. Prior to his appointment, he served as dean at the College of Pharmacy, King Saud University.

He began his career at King Saud University in 2008 as director of the medication safety research chair. He has worked in various positions at the university – including vice dean for academic affairs, as well as vice dean for graduate study and research, and supervisor of pharmacy services in Medical City.

He received his doctorate in pharmacy from Purdue University in Indiana, US, and a PhD in pharmacoepidemiology and drug safety from the University of North Carolina, also in the US.

Our STORY

TIMELINE

The SFDA commences work on its third strategic development plan, covering 2018-22 – learning from the achievements and challenges of previous iterations. The third instalment centres on measurable outcomes and value creation for stakeholders; efficient operations; reliance on scientific evidence and risk assessment; and collaboration with partners to monitor and control different components of the value chain.

2017

The authority begins to implement changes, laying the foundation for its new development plan. Key 2018 goals include restructuring the organisation, developing its leadership expertise and centralising SFDA offices in a new purpose-built building. These measures also support the Kingdom's Vision 2030 objectives, such as improving the business environment, increasing the efficiency of government spending and creating agile organisations.

2018

In the second year of implementing its third plan, the SFDA starts to witness notable results across multiple domains related to this development roadmap and organisational restructuring – progress aligned with the objectives of Saudi Arabia's Vision 2030. Throughout the organisation, various departments and experts embrace the plan and are tasked with ensuring comprehensive engagement with internal and external stakeholders.

2019

Covid-19 presents significant and widespread challenges for individuals and organisations across the globe. The trust of the Kingdom's leadership in the SFDA's expertise, alongside cooperation with local and international experts and proactive communication with industry and the public, help to empower the organisation to respond effectively. The SFDA plays a key role in securing safe and effective vaccines for Saudi Arabia's population.

2020 -21

The SFDA focuses on guiding the Kingdom towards post-pandemic recovery, while also initiating the development of its fourth strategic plan, for 2023-27. Owing to gradual improvements in internal capacity, the organisation formulates the next instalment without the need for external consultants. The authority relies instead on the expertise of SFDA specialists, reflecting once again on the achievements and challenges of its previous iteration, and aligning its aims with national objectives.

2022

2017

Identifying Challenges and Developing a New Strategic Plan

Since its establishment in 2003, the SFDA has undertaken a series of developmental phases – each marked by achievements and challenges. It is these challenges that form the basis for subsequent objectives. The first strategic plan was in effect from 2007-11, followed by a second initiative in 2012-16. A third one for 2018-22 (“the Plan”) was developed in 2017.

The first plan focused on building a regulatory framework and the capabilities required to assume regulatory responsibilities. The second plan sought to build up operational capabilities further, address gaps in the SFDA’s mandate, and develop organisational capabilities, policies and procedures. Next, the Plan was designed to focus on measurable outcomes and value creation for a wide range of stakeholders; promote efficient and effective operations that leverage existing capabilities; rely on scientific evidence and risk assessment; and work with partners to effectively monitor and control different components of the value chain.

Implementing the Plan involved addressing challenges related to ports, laboratory efficiency and regulatory enforcement.

among other areas. Exploring the Plan's five strategic themes, this chapter details some of the key challenges faced and how they influenced the authority's central priorities for the 2018-22 instalment – underpinned by the Kingdom's long-term development objectives, as outlined in its Vision 2030 roadmap.

Supporting the Private Sector

Private sector organisations, such as food and pharmaceutical product manufacturers and retailers, regularly interact with the SFDA for services ranging from product registration to the resolution of regulatory issues. This involves a large number of SFDA transactions, so steps have been taken to adopt effective communication practices and streamline procedures to ensure that the authority's operations and regulatory requirements do not interrupt the work of the private sector. A lack of such measures could increase exposure to supply-chain-related delays and limited product availability, which could adversely affect the public's health.

Prior to the development of the Plan, companies seeking a specific SFDA service were required to visit multiple offices and locate individual employees from specific departments.





The Plan highlighted customer satisfaction as one of its five strategic themes, with a focus on the public and private sectors.

There was no central team to receive visitors from the private sector and coordinate requests. SFDA systems for companies to complete product clearance and registration requirements were also limited. Some SFDA team members viewed the demands of the private sector as unreasonable or unwarranted, deterring the authority from looking into or studying some of these incumbent, systemic issues.

In order to address this, the Plan highlighted customer satisfaction as one of its five strategic themes. This included a focus on working effectively with both the public and private sectors, in addition to international partners. The strategy outlined the SFDA's intentions to streamline communication with the private sector and position the sector as a partner rather than an obstacle. This aligns with the Vision 2030 objectives of promoting the private sector as a key pillar of economic growth and diversification, strengthening relationships between the public and private sectors, and improving the Kingdom's business environment.

Clearing Shipments at Speed

Another priority is facilitating timely clearance at ports, enabling goods to enter the market without the kinds of delays that could disrupt trade and lead to the spoiling or damaging of perishable goods and heat-sensitive products. Shortages resulting from such issues could lead to elevated prices for consumers. Prior to this, it was not uncommon for Saudi Arabia's ports to witness a backlog of shipments amid clearance delays. Multiple authorities were involved in clearance procedures, and it was unclear who was responsible for resolving such problems. To address this, the SFDA sought to clearly define responsibilities to avoid overlapping duties and define a process timeline, thereby supporting the second of the Plan's five strategic themes: helping customers access safe, effective products in a timely manner.

Streamlining Laboratory Operations

Operating laboratories is costly and requires skilled individuals. A high degree of operational efficiency, as well as close coordination between laboratories, is therefore important for the long-term success of the SFDA. Indeed, improving the efficiency of government resources is aligned with the Kingdom's Vision 2030 objectives. As the regulator, the SFDA serves as a source of guidance for laboratory analysis across Saudi Arabia's increasingly diverse economy.

Previously, the SFDA had a large number of laboratories, coordination between which was limited. The majority of these laboratories conducted the routine analysis of food and drugs, which could alternatively have been undertaken at private facilities. Furthermore, each laboratory was equipped with the same devices, equating to a duplication of resources and high operating costs. Communication regarding the stockpiling and management of chemicals stored in each laboratory was limited.

In order to address these challenges, the Plan sought to improve the operational efficiency of the Kingdom's laboratories. The proposed measures included improving the competencies of staff and the utilisation of equipment, which is in line with the Plan's strategic theme of organisational excellence – and, more specifically, supports its objective of basing decisions on scientific evidence. Key performance indicators (KPIs) for improved internal competencies by the end of the Plan included 100%-accurate laboratory results and the on-time completion of 100% of sample testing requests. Meanwhile, the SFDA sought to increase the utilisation of laboratory capabilities and transfer a greater proportion of food samples to private laboratories for analysis – supporting Vision 2030 aims to grow the role of Saudi Arabia's private sector while enhancing public sector efficiency.

Improving Internal Communications

Effective and swift communication among various departments is crucial for operational efficiency. The SFDA's previous communications structure was fragmented and overly centralised, with the authority's offices dispersed across four buildings. This constrained organisational effectiveness, while some managers had a closed-door policy that limited communication and transparency with SFDA experts. All communication between the SFDA's three sectors – food, drugs and medical devices – and 16 port offices previously passed through headquarters in Riyadh, which slowed operations. For example, inspectors were required to send post-inspection reports to the capital and wait for a regulatory decision before taking action.

The centralised structure disrupted workflows and resulted in inspectors not being empowered to perform their duties, triggering a backlog of unresolved reports. Failure to respond to inquiries led to an increased volume of calls from clients seeking to follow up on the status of their cases. The Plan sought to empower the SFDA to be more innovative and effective by promoting digital transformation – a Vision 2030 objective – and a culture of collaboration.



When I look back at the situation and challenges of the SFDA in 2017, it could be summarised as a gap in communication with our regulated business partners as well as among our own branches. This translated into a passive organisational culture that was resistant to change, without efficient utilisation of resources. This resulted in delays in the clearance of goods, inconsistent regulatory decisions and a vague relationship with consumers. This led us to focus our new strategic plan towards operational and execution excellence.

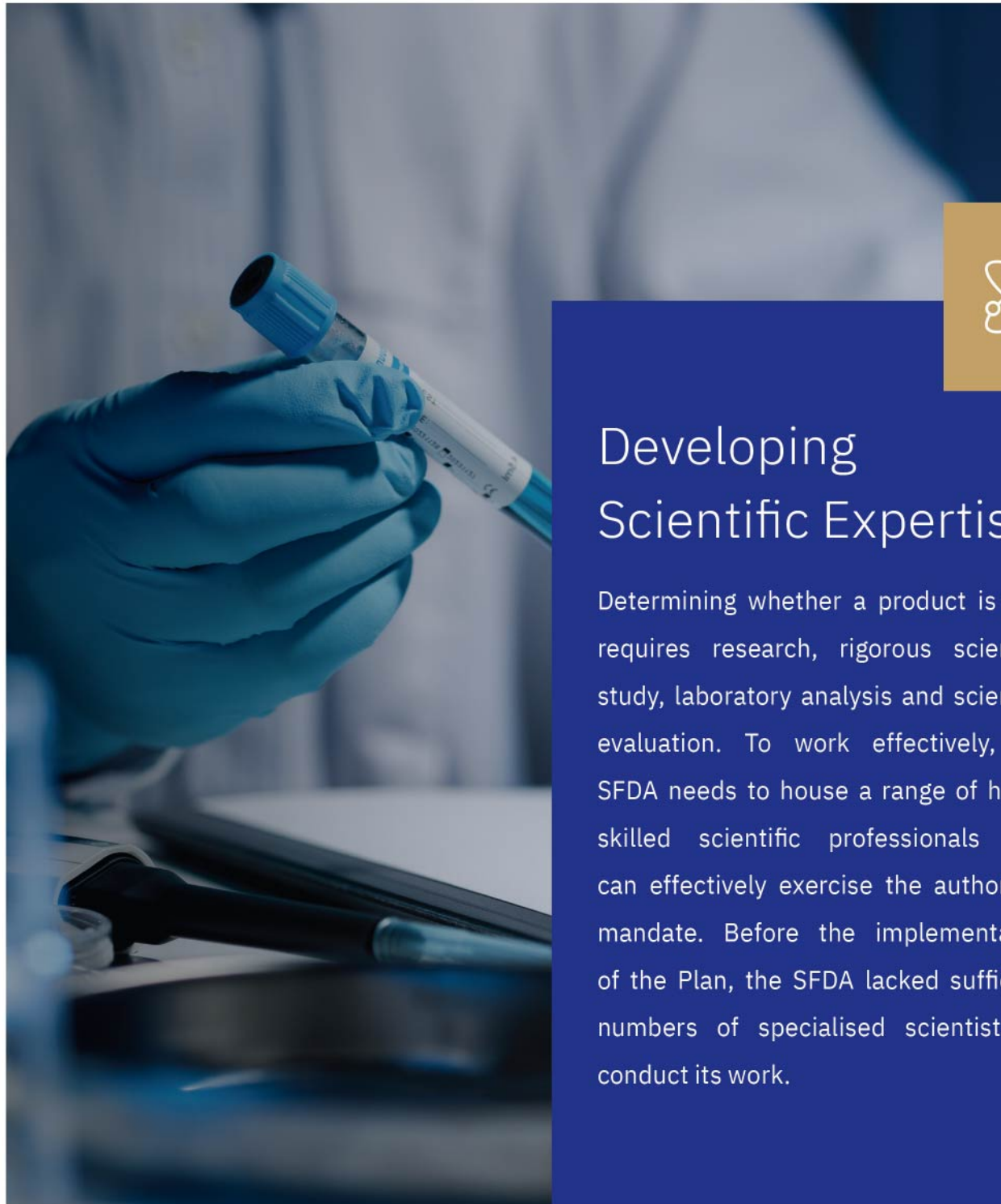
H.E. Prof. Hisham bin Saad Aljadhey,
CEO, SFDA

Enforcing Regulations

Ensuring that market operators comply with food, drug and medical device regulations is an integral part of the SFDA's mandate and value proposition.

The SFDA needs to house a range of highly skilled scientific professionals who can exercise the authority's mandate.

While SFDA inspection procedures have long been in place, there were shortcomings in enforcing compliance. Fines and decisions to shut down non-compliant establishments were not effectively and consistently implemented, as inspectors were not seen as wielding sufficient authority to cause concern among repeat offenders. As a consequence, some actors wilfully violated regulations and failed to remedy their non-compliance. In order to address these issues, the SFDA aimed to raise compliance rates through stricter enforcement, improving inspection processes and enforcing regulations for all products under the authority's remit. KPIs included a 100% rate of compliance with the SFDA's regulatory requirements for establishments, and a 99% rate of compliance with product specifications.



Developing Scientific Expertise

Determining whether a product is safe requires research, rigorous scientific study, laboratory analysis and scientific evaluation. To work effectively, the SFDA needs to house a range of highly skilled scientific professionals who can effectively exercise the authority's mandate. Before the implementation of the Plan, the SFDA lacked sufficient numbers of specialised scientists to conduct its work.

In 2017, for example, the organisation had only 75 drug evaluators, and the number of food risk assessment staff was limited to 25 employees and scientists. These were well below the numbers needed for the SFDA to operate effectively. The authority also lacked a centre for conducting supervisory studies and research.

The SFDA set out to raise its level of knowledge and skills as part of its performance efficiency strategy. Supporting measures included installing human resource systems and clearly defining employee responsibilities. These are part of the SFDA's efforts to improve its organisational culture and institutional performance to attract talented and high-performing employees.

Meanwhile, the authority continues to support personnel with master's and doctoral degrees – with KPIs focused on increasing the contribution of internal research to regulatory decision-making. Such actions present an opportunity to support Saudi Arabia's Vision 2030 goal of attracting and nurturing talent while simultaneously advancing progress towards the long-term development objectives of the SFDA.

Improving Consumer Confidence

To ensure and maintain consumer trust, regulators must be able to act swiftly to introduce regulations or penalise misconduct in a timely manner. In the years preceding the Plan, there had been delays to some of the SFDA's regulatory decisions. There was also a failure to announce penalties and fines in some cases, leading to demands for improvements from consumers who had seen better practices internationally.

The SFDA's consumer trust pillar aims to address this by increasing transparency and initiating community participation. Objectives towards this end include enhancing trust in the authority's role, locally and internationally; increasing community awareness of the products under the SFDA's remit; and developing dietary legislation to improve nutritional patterns. This also aligns with the authority's objectives of raising consumer satisfaction, such as by increasing the effectiveness of communication with customers. The overall aim was to achieve the highest levels of trust among the community, health practitioners and other regulators.



Increasing Operational Efficiency

During the preparation of the Plan, national economic conditions led to substantial budget cuts: the SFDA budget was reduced by almost 30% across the organisation. These challenges further underlined the importance of improving the SFDA's general efficiency at the day-to-day, operational level. Enhancing performance required new approaches to existing challenges.

Aims included more efficient spending and greater revenue, once again in line with Vision 2030 objectives. The related KPI entailed a 100% solvency ratio, designed to sustain business for a period of six months by the end of the Plan. This sought to improve the authority's ability to meet its long-term financial obligations, thereby promoting a more sustainable business model. Performance-efficiency goals also included enhanced employee engagement and empowerment, along with a more cooperative environment. Meanwhile, the SFDA outlined plans to increase the use of modern technologies for improved business efficiency. KPIs included improving the maturity of the electronic systems and services available to employees and customers, and increasing the number of high-quality databases accessible through shareable online platforms. These support Vision 2030 objectives to strengthen digital infrastructure – viewed as key to long-term economic diversification

Focusing on Results

Another SFDA priority to unlock lasting socio-economic benefits for the Kingdom was the authority's transition towards a results-oriented strategy.

Prior to the Plan, the SFDA's strategic indicators and projects had typically focused on product control. As part of the authority's development towards organisational excellence, leadership determined that strategic indicators must evolve to focus on results that ensure long-term product safety.

This approach focused on measurable impact, underpinning the SFDA's development in the years from 2018 while simultaneously laying the foundation for long-term progress towards the Kingdom's strategic Vision 2030 objectives.



Experiencing challenges during phases of growth and development is part of the natural order of things for major organisations such as the SFDA. There can be no true realisation of success without first experiencing and learning from key challenges.

H.E. Prof. Hisham bin Saad Aljadhey,
CEO, SFDA

The SFDA's Strategic Plans and Their Priorities

First

strategic plan (2007-11)

- Build the regulatory framework
- Develop the necessary capabilities to assume regulatory responsibilities

Second

strategic plan (2012-16)

- Continue building up operational capabilities
- Address gaps in the SFDA's mandate
- Develop organisational capabilities, policies and procedures

Third

strategic plan (2018-22)

- Focus on measurable outcomes and value creation for stakeholders
- Develop efficient and effective operations that utilise existing capabilities
- Rely on scientific evidence and risk assessment
- Work with partners to effectively monitor and control different components of the value chain



2018

Beginning Our Transformation



Restructuring the Organisation

In 2018 the SFDA implemented changes to help lay the groundwork for its third strategic plan, covering 2018-22 (“the Plan”). Three key goals for 2018 were to restructure the organisation, develop the authority’s leadership expertise and centralise SFDA offices in a new purpose-built building. These steps were designed to complement and kick-start the implementation of the SFDA’s new strategy, while also supporting Vision 2030 objectives such as establishing an improved business environment, improving the efficiency of government spending and creating agile organisations.

It was necessary to reform the SFDA’s structure to meet the Plan’s organisational excellence goals, as well as align long-term goals with Vision 2030. Challenges included the fragmented nature of the inspection process, as well as a lack of separation between laboratory procedures, scientific activities and inspection operations.

An internal SFDA committee conducted a study, supported by a number of consultants, to inform a proposal for a new structure and facilitate its implementation. After the proposed restructuring was approved by the Board of Directors, the committee worked on developing the details of the new structure for eight months before rollout and implementation commenced. A dedicated operations division was established with oversight of all inspection processes, routine registrations and SFDA branches. Research activities and laboratory work shifted to a dedicated laboratories and research division, and experts working on planning and promoting institutional excellence were combined in a new planning and excellence division. A department for international cooperation was also established, spearheading the authority's efforts to become a leading international food and drug regulator.

Management positions were reduced by up to 30% in an effort to make the structure more dynamic, ensure that only the most capable and skilled personnel were in managerial positions, and facilitate operational efficiency. Additionally, an initiative was implemented to analyse employee capabilities to help the authority match positions with the right abilities. While the transition period was challenging – requiring considerable effort and time – it helped the SFDA work towards accomplishing its long-term development goals.



Addressing Culture and Training

The creation of an achievement-focused work environment and investing in professional development marked additional steps in the Plan aligned with Vision 2030. With regards to an achievement-focused work environment, the authority focused on embedding SFDA values within the organisation's culture. These include serving the community, instilling a responsible and independent mindset, communicating with partners effectively and transparently, encouraging a positive attitude among staff and striving for continuous development.



In 2018 the authority introduced new measures to support the selection of the most effective leadership.

With respect to professional development, the SFDA previously had an internal training gap – particularly among middle and upper management. The authority implemented advanced training programmes designed to foster a culture of learning. One key objective of this training was to transform the organisational culture away from being primarily focused on enforcing regulations, without considering market impact. This initiative sought to nurture experts who are proactive, responsive and centred on problem-solving, thereby also supporting the Kingdom's human capital development objectives.

Promoting Responsible Leadership

A structured approach to promoting responsible leadership was identified as key to the Plan. In 2018 the authority introduced new measures to support the selection of the most effective leadership and enhance transparency in recruitment. Previously, the appointment of director-level positions was based on nominations by the direct manager of the position to be filled. Changes to help identify the best candidate included an internal announcement of the vacancy, enabling employees to apply and outline their development plans for the role. The revised process includes an interview with a three-person panel: the direct manager for the position, a similar manager from another department and a representative from the human resources department. A leadership behavioural competency test was later added to the process. The nomination of department employees for the position of department head was approved as part of the new system.

The new leadership development process includes regular meetings. Among these are one-on-one weekly meetings between the department head and team members to discuss employees' professional development. Additionally, a monthly meeting was introduced to review the strategic and operational performance of all departments and allow employees to gain a holistic view of the SFDA's performance. A retreat is held for team leaders and confidence-building programmes are organised for teams. A meeting is held at the beginning of each year for all employees to share achievements and plans for the year ahead.

The SFDA's Customer Satisfaction Centre

Aims to



Motivate
investors



Facilitate
procedures



Overcome
obstacles to
investment

By providing the following services



Assign
relationship
managers



Follow up on
requests and
transactions



Use
the Customer
Journey platform



Receive
feedback



Support new
investors



Online guide
service



Video calling
service

Establishing the Customer Satisfaction Centre

Another pivotal task was to establish effective processes to support the private sector and manage their requests. This includes processing requests in a timely and appropriate manner, which is critical in increasing investment levels in the Kingdom. This is also central to Vision 2030 goals for a thriving economy, such as growing the private sector's contribution from 40% to 65% of GDP, raising foreign direct investment from 3.8% of GDP to the international threshold of 5.7%, and becoming one of the top-10 countries in the Global Competitiveness Index, up from 25th position in 2015.

To help support the private sector, the authority established a Customer Satisfaction Centre in each SFDA building to receive and serve private sector representatives. The centre was designed to be a client-facing facility with the necessary amenities to welcome

visitors to SFDA buildings. Security personnel were replaced with receptionists and a team was formed to follow up on customer queries and complaints, and conclude transactions in a timely manner. The Customer Satisfaction Centre provides a variety of services to facilitate business procedures, overcome obstacles to financing and ultimately enhance the authority's relationship with investors. The centre provides support to new investors, assigns relationship managers, and helps to follow up on requests and transactions. Moreover, the facility hosts the Customer Journey platform, providing information related to licensing requirements, product registration and clearance procedures. In addition, the centre offers a feedback and opinion tool, an online guide and a video call solution.



Improving the Call Centre

In another move to improve the quality of client services and communications, steps were taken to enhance the performance of the SFDA Call Centre. These measures included the introduction of key performance indicators to monitor and improve the process of resolving transactions, as well as reviews of the process in order to enhance service quality. This was designed to address the backlog of unresolved reports caused by limitations in the inspection process. The SFDA Call Centre was established to receive and answer questions or complaints about food, drugs and medical devices. Individuals can reach the call centre by dialling 19999.



Establishing New Headquarters

In 2018 the search for a new headquarters began, engaging internal SFDA stakeholders. Staff members had the opportunity to suggest features of the new building via an online platform. This building was designed to be a modern facility that has the comfort and feel of home. Once it was designed, the agency went on to establish suitable training and conference facilities, the Customer Satisfaction Centre and the SFDA Call Centre.



The year 2018 was significant in the transformation of SFDA. It marked a time when we directed our internal efforts toward refining our strengths and addressing our weaknesses. Our aim was to demonstrate to our partners that we were evolving to be better, faster and more flexible than before.

H.E. Prof. Hisham bin Saad Aljadhey,
CEO, SFDA

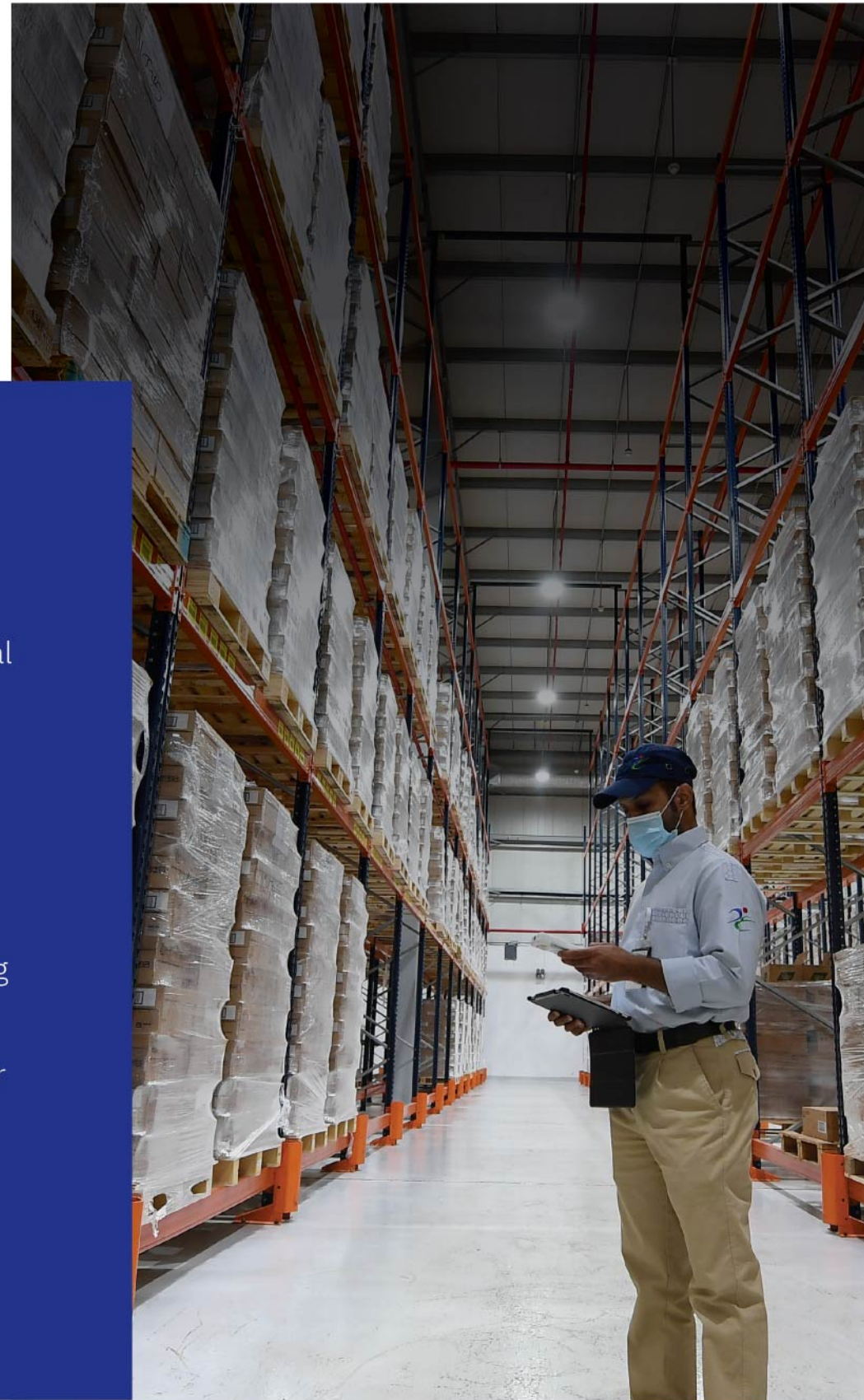
Launching an Annual Conference

In 2017 the authority initiated an annual scientific conference and exhibition designed to gather specialists from sectors regulated by the SFDA. The conference comprises scientific workshops and discussion sessions with experts from different disciplines. Aligned with the Kingdom's Vision 2030 objectives, this event also fosters collaboration between the public and private sectors. In 2018 and 2019 the SFDA Annual Conference and Exhibition became the largest annual event for the Kingdom's food, drug and medical devices sectors. In the latter year the event attracted 20,000 visitors from 35 countries, with the participation of over 200 companies and 80 international exhibitors.



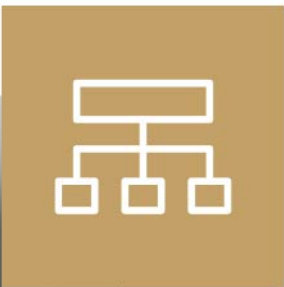
Upgrading our organisational structure was a strategic priority and operational necessity for the SFDA to deliver on its mandate. This included restructuring our internal systems, developing the authority's leadership expertise and enhancing our infrastructure.

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Enhancing Inspections

The authority adopted several executive regulations to enable the easier application of fines for violators, addressing previous shortcomings in inspection procedures and enforcement. This improved the effectiveness and impact of SFDA operations. The first campaign in this effort had been carried out during 2017 in partnership with the Ministry of Commerce, focusing on perfume shops in violation of industry regulations. The impact was substantial in terms of both media coverage and the prevention of violations, underlining the foundational progress made towards the authority's strategic goals as well as the Kingdom's Vision 2030 objectives.




Organisational Structure of the SFDA


The SFDA was restructured in 2018. As of early 2023 seven divisions reported to the Office of the President.



Food




Medical
Devices



Drugs

Office of
the President



Support
Services



Research &
Laboratories



Operations



Planning &
Excellence

2019

SFDA Success Stories



In 2019 the SFDA began to see substantial results in multiple domains related to the third strategic plan (“the Plan”) and organisational restructuring – aligned with Vision 2030 objectives. Throughout the organisation, departments and experts embraced the Plan and were tasked with ensuring comprehensive engagement with internal and external stakeholders.

Activating Regulations

One of the SFDA’s early achievements was the activation of new regulations, followed by the implementation of measures to address violations. Implementing regulations for cosmetic and veterinary medicines were passed, while technical regulations for the food and feed law were approved. Furthermore, extensive efforts were devoted to developing, approving and implementing systems for pharmaceuticals and medical equipment. The implementation of these regulations marked a legislative milestone in ensuring product safety within the Saudi market.

As part of efforts to develop the regulatory system for medical devices and supplies, a medical devices law was issued and several regulatory requirements and guidelines were introduced. These covered topics such as artificial intelligence (AI) and cybersecurity. The requirements outline the compliance standards that factories and companies of medical devices and supplies must meet either prior to entering, or during circulation in, the domestic market – supporting Vision 2030 commitments to focus on public sector planning, as well as regulatory and supervisory roles, in health care to help nurture a vibrant society. The regulatory system developed by the authority and its related documents has since become a model for a host of regional and international regulators.



Mandating Plain Tobacco Packaging

In 2019, under the guidance of the SFDA, Saudi Arabia achieved a significant milestone by successfully implementing plain packaging requirements for tobacco products. As the first country in the Arab world to adopt this regulation, the Kingdom aligned its regulations with the World Health Organisation (WHO) Framework Convention on Tobacco Control and its guidelines.

This move was a crucial component of the national campaign against tobacco use. Plain packaging serves to reduce the risks and attractiveness of tobacco products while also addressing misleading claims. The SFDA issued the new packaging regulations in December 2018, effective from August 2019, and mandates compliance by tobacco product manufacturers and importers.

The introduction of plain packaging requirements initially raised concerns about potential flavour alterations by tobacco companies. However, the authority addressed this through transparent communication with the public via multiple media channels. In addition, the SFDA implemented technical measures to address these concerns further, such as the laboratory analysis of samples and inspections at tobacco manufacturing facilities in Europe. By January 2020 a statement was released disclosing laboratory findings on product features and flavour changes before and after the plain packaging requirement became effective, providing reassurance to consumers.

Despite encountering various regulatory hurdles and individual concerns, the SFDA successfully executed the initiative. This was followed by a notable increase in bookings for Anti-Smoking Clinics. Moreover, the Saudi authority earned designation as a WHO Collaborating Centre for Tobacco Plain Packaging.

In 2019
the SFDA
implemented
key
performance
indicators to
streamline
product
registration
and business
licensing.



Integrating Performance Indicators

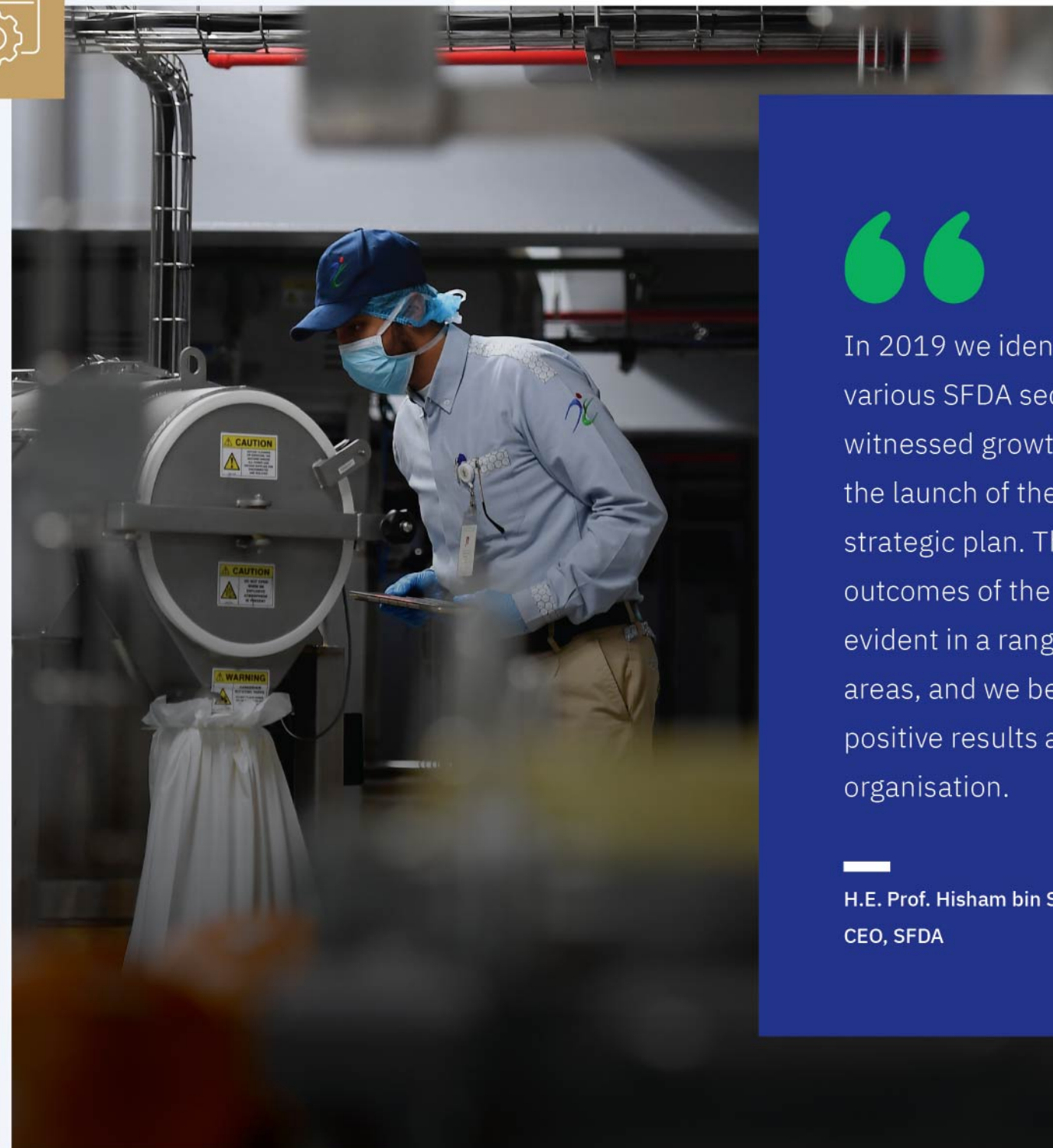
That year the SFDA implemented key performance indicators (KPIs) to streamline the registration process for products and the licensing of companies, marking a significant milestone in the authority's evolution. This was supported by the establishment of a compliance department to help ensure that all internal operations align with SFDA rules and regulations.

By early 2019 the SFDA had developed 314 operational KPIs and had begun tracking these on a monthly basis. These measured business performance across sectors and supported inspection activities. Over time, these KPIs were refined in line with the Plan objectives, distilled down to a total of 135 operational indicators by the end of 2022. These KPIs covered various aspects of the organisation, including the quality of operations, support for inspections and the completion of procedures within the specified time frame. At the end of 2022 the SFDA achieved an impressive target attainment rate of 98% for these KPIs.

One notable success story was the SFDA's strict adherence to the approved registration times for medicines – surpassing set targets, and contributing to an enhanced business environment in the sector. This was made possible through the formation of a crisis management team, comprising representatives from all technical departments. These experts were tasked with swiftly addressing all pending and delayed applications, ensuring that no application would exceed the approved registration time. The SFDA's dedication to meeting approved drug registration times has since been widely recognised.

Introducing New Systems

The year 2019 saw the introduction of new systems to enhance the efficiency of the SFDA's operations. Despite a 30% budget reduction, the authority successfully implemented a rigorous inspection and supervision process. These systems contributed to a substantial increase in the number of inspections conducted within Saudi Arabia. Annual inspections rose from 88,000 to over 130,000 that year, without requiring an increased number of inspectors – underscoring a considerable increase in the authority's efficacy.



In 2019 we identified that various SFDA sectors had witnessed growth following the launch of the third strategic plan. The initial outcomes of the plan were evident in a range of key areas, and we began to see positive results across the organisation.

H.E. Prof. Hisham bin Saad Aljadhey,
CEO, SFDA

To enhance the efficiency of Customs clearances, the authority implemented an electronic system to integrate and connect various Customs points via one unified electronic platform. Benefits include enhanced supply chain efficiency, strengthened control over received consignments, more accurate data to monitor non-compliant products and increased regulatory adherence. This fully digital system enabled the SFDA to eliminate paper-based Customs clearance processes, aligned with the Kingdom's environmental sustainability aims. The year 2019 also saw the introduction of a new integrated electronic system to streamline import and export compliance.



Reducing Costs

In line with a reduced budget, the authority adopted additional measures to reduce operational costs and boost efficiency. Within the research and laboratories sector, this included the launch of a maintenance and calibration department to reduce the costs and time associated with equipment maintenance and calibration, as well as to repurpose old equipment for continued operation – helping to boost the lifespan of materials and supporting sustainability efforts.

Substantial savings of some SR4m were achieved between 2019 and 2022, primarily through reduced labour costs. The launch of the medical devices laboratory and the expansion of analytical capabilities considerably improved the authority's control over medical devices and supplies. It also reduced costs by eliminating the need to send samples abroad for analysis.

Improving Clearance Procedures

The SFDA took steps to facilitate the clearance of consignments while promoting increased compliance. In order to create a suitable environment for receiving and inspecting shipments of food products under SFDA control, the authority introduced an operational plan to appropriately prepare Customs points while also developing infrastructure in collaboration with relevant authorities. This helped to ensure the quality, safety and compliance of products.

An inspection and clearance mechanism in merchant warehouses – for consignments of products controlled by the authority – was designed to enhance alignment with SFDA requirements concerning the transport and storage of products under SFDA supervision. The authority optimised resource utilisation by implementing central clearance procedures and introducing new inspection methods, such as intelligent inspection and the self-evaluation of facilities.

Supporting Investors and Customers

From 2019 the SFDA increased its focus on customer service and investment support, in line with Vision 2030 objectives to unlock high-potential sectors and expand private sector participation. This included the inauguration of a support and development team for national industries. This aimed to increase local content, enhance the regional and international competitiveness of local factories, and raise the efficiency of production processes. The SFDA provided assistance and development to over 590 national factories, which accounted for 39% of the total factories under the authority's purview. With this backing, the number of factories with A and A+ ratings in the Kingdom increased by 200%.

A reception centre was opened on the SFDA's premises for customers, and an integrated system was initiated to conduct customer service operations – including the follow-up of ongoing processes. The authority formed partnerships with private laboratories to facilitate the transmission of samples – an example of efforts to boost collaboration with the private sector and enhance operational efficiency, supporting the Kingdom's long-term development priorities.



Enhancing Scientific Expertise

The SFDA began to place greater emphasis on the scientific dimension of its work from 2019 onwards. Targets included broadening scientific evaluation, launching various research projects and publications, strengthening local and international scientific participation, and developing Saudi Arabia's reference and central laboratories.

Research and Laboratories Sector

In the field of research, the authority successfully completed 11 scientific papers across different fields – comprising six papers on food, three papers about drugs, and two papers regarding tobacco and its products. The SFDA organised a scientific conference that attracted over 20,000 attendees from more than 35 countries, featuring over 120 speakers.

The executive department of research and studies conducted seven internal scientific seminars, in a move to foster knowledge exchange and collaboration, and actively participated in numerous local and international scientific conferences and forums. These were part of efforts to establish the SFDA as a leading global regulatory body, raise the Kingdom's international profile, and to support the transition towards a knowledge-based, diversified economy.

SFDA reference laboratories embarked on a journey to enhance their expertise, placing special emphasis on strategic projects that involve cutting-edge fields such as data analysis, AI, machine learning in genomic sequencing, the identification of unknown compounds, and biological and chemical fingerprinting. These initiatives aimed to improve laboratory testing and analysis, thereby enabling a more precise risk assessment of SFDA-regulated products. Additionally, the authority invested in attracting specialised experts and scientists to enhance expertise within the Kingdom's reference laboratories – while also supporting the development of Saudi Arabia's knowledge-based economy.



Research Achievements, 2019



20,000

attendees from more than 35 countries
attended an SFDA-organised scientific
conference



11

scientific papers completed across
different fields



7

internal scientific seminars
conducted

Medical Devices Sector

Proactive measures were implemented to ensure that medical devices and supplies marketed in Saudi Arabia comply with the SFDA's medical devices regulations, including the development and execution of an annual monitoring plan. Moreover, the authority established and published national reference guidelines to determine diagnostic radiation dose levels for CT-scan devices, as part of efforts to protect patients against medical radiation doses. The SFDA devised a plan to enhance hospital compliance with safety requirements for radiation-emitting medical devices, entailing close coordination with health facilities, and awareness initiatives designed to enhance communication with health practitioners.

The authority introduced an initiative to advance innovation in the realm of medical devices. This aims to engage with interested individuals and experts in medical device innovation, to offer support from the organisation. The initiative focuses on overcoming obstacles faced by innovative, local medical device companies through the SFDA's provision of regulatory support and the clarification of requirements.





Drug Sector

The drug sector also witnessed numerous developments to strengthen the provision of specialist scientific assessments and evaluations. This included implementing a drug evaluation project. Incorporating qualitative training by external experts, the project facilitated the transfer of knowledge and the formation of a network of specialised experts. Improved capabilities and expertise later enabled the authority to more effectively address the Covid-19 crisis by contributing to the Kingdom's readiness to manage vaccines and medicines, and its ability to make supervisory decisions, on the basis of scientific evidence, independent of international regulators.

The SFDA launched the Clinical Studies Advisory Committee, consisting of specialists from various medical fields, to provide advisory opinions on conditions such as heart disease, diabetes, cancer and infectious diseases. Internal specialised committees were established to enhance the evaluation of biosimilars – biological medicines with close similarity to another, approved, biological medicine – and advanced treatments such as cell therapy and gene therapy. A scientific risk-benefit analysis model was developed to help align scientific evaluations with international standards. This focuses on the data integrity, statistical analysis and methodology of clinical trials.

A pre-clinical studies team executed some of the SFDA's key scientific procedures and practices in 2019 – supported by ongoing investment in scientific and professional human capital, aligned with Saudi Arabia's 2030 priorities. The importance of this

organisational unit came to prominence during the Covid-19 pandemic, particularly for the evaluation of vaccines and treatments. The SFDA, meanwhile, contributed to establishing local and international advisory committees to provide scientific opinions on complex pharmaceutical issues, as well as to help set short- and long-term strategic goals for development. The authority took steps to promote the provision of safe and high-quality medicinal herbs and plants. This included simplifying the technical requirements for nutritional supplements and herbal products, and publishing an illustrated list of over 70 prohibited medicinal herbs and plants. The SFDA participated in international working groups, such as the WHO International Regulatory Cooperation for Herbal Medicines, to define the scope and general controls for herbal and complementary-medicine pharmacies.

The SFDA updated the technical requirements for making changes to pharmaceutical products.

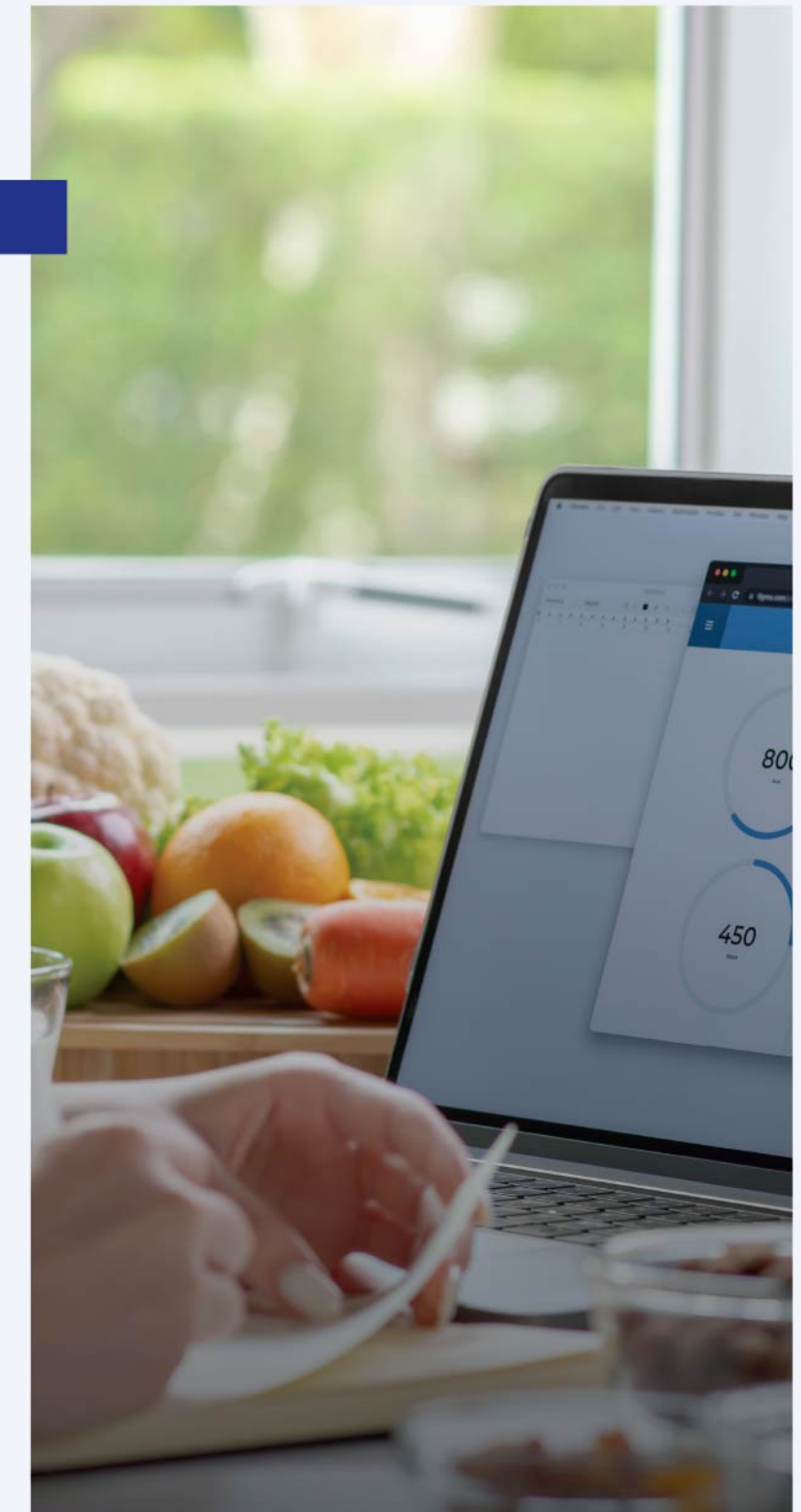
The SFDA re-examined and updated the technical requirements for companies making changes to their pharmaceutical products after receiving regulatory approval, known as guidelines for post-marketing variation. Changes included updated guidelines for extending the shelf-life of products, which later contributed to the availability of therapeutic products during the Covid-19 pandemic. The authority also participated in, and chaired, committees related to drug security, including those centred around shelf-life extension and raw pharmaceutical materials.

Launching a Healthy Food Strategy

In 2017 the SFDA developed a strategic plan for healthy food. This included the formation of the National Nutrition Committee (NNC) and a number of initiatives to reduce the population's consumption of salt, sugar and fat. The introduction of calorie information on restaurant menus, which helped to raise awareness of lower-calorie food options and encourage positive behavioural change, was among the authority's most notable initiatives. The strategy also helped to limit the addition of sugar to fresh juice.

The NNC – a scientific advisory committee focused on improving the nutritional status of Saudi Arabia and promoting a healthy society – serves to provide recommendations and scientific opinions on nutrition to relevant authorities as part of the SFDA's strategy

authorities as part of the SFDA's strategy to promote healthy food. The establishment of the NNC involved collaboration between government and private agencies for public health promotion, chronic disease prevention and the realisation of Vision 2030's pillar for a vibrant society with fulfilling lives. The NNC began by establishing the committee's infrastructure and forming a local scientific advisory council comprised of nutrition experts from Saudi universities and research centres. The committee subsequently conducted extensive research and issued numerous recommendations to enhance the nutritional well-being of Saudi Arabia's society, incorporating considerations such as the population's needs and social habits.



Halal Centre Achievements, 2019



53

organisations granted
halal certification in 25
countries globally



213

establishments received
accredited halal
certificates



63

participants from over 30
countries engaged in halal
training programmes



Opening the Halal Centre

Another key initiative in 2019 was the establishment of the SFDA Halal Centre. The centre made a considerable impact internationally, issuing halal certification to 53 organisations across 25 countries. Additionally, 213 establishments acquired halal certificates for the export of local products to a variety of countries. The centre launched specialised halal training programmes, welcoming 600 participants from 30 countries. The SFDA launched an electronic system for the Halal Certification Centre, while taking steps to enhance coordination and develop laboratories focused on halal products.

The authority introduced a new independent department, the halal regulatory department, in the research and laboratory sector – with responsibilities including the development of halal legislation and specifications. The SFDA also launched an annual monitoring programme to verify the halal compliance of certified products in the Saudi market, among efforts to boost domestic and international confidence in SFDA capabilities.

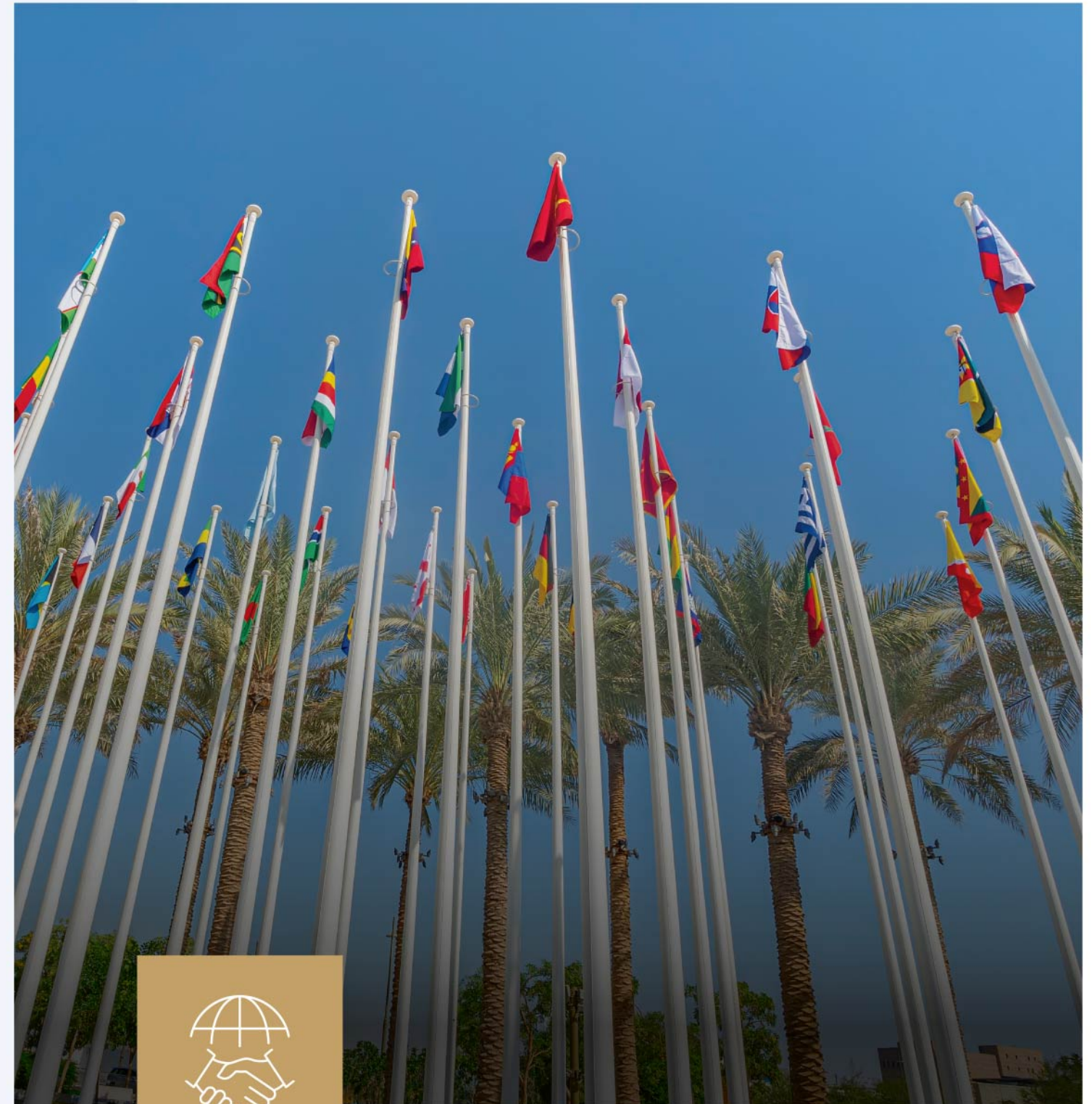
Enhancing International Cooperation

Improving international cooperation became an SFDA priority in 2019. Towards this end, the authority expanded the number of internal experts committed to this objective. By 2023 the SFDA participated in over 150 technical committees globally, maintaining agreements with numerous international organisations and regulatory agencies from a range of countries.

The SFDA began to be appointed to more prominent regional leadership roles during this period. Among these, the authority represented Saudi Arabia as the Regional Coordinator for the 10th meeting of the Near East Committee of the Codex Alimentarius Commission – the international body responsible for setting food standards,

established by the UN's Food and Agriculture Organisation and the WHO. This appointment reflects the commitment of the SFDA, and the Kingdom, to increasing Saudi Arabia's stewardship on the international level.

These success stories signal progress towards the SFDA's goals and Saudi Arabia's Vision 2030 objectives in the years preceding the Covid-19 pandemic. The year 2020 would see related disruption to trade, business and everyday life reshape priorities for the SFDA and for Saudi society, as well as for organisations and populations across the globe, with a lasting impact.



2020-21

The Covid-19 Pandemic



The years 2020-21 marked a period of significant challenge across the globe as individuals and organisations adjusted to the risks posed by the Covid-19 pandemic. Navigating numerous hurdles, the SFDA played a leading role in securing safe and effective vaccines for Saudi Arabia's population in the early phases of the Covid-19 period. Proactive communication with industry and the public facilitated a swift response to the various difficulties posed by the pandemic. Meanwhile, the trust placed in SFDA employees by the Kingdom's leadership played a pivotal role in empowering SFDA experts to pivot effectively to the changing health landscape. This trust, coupled with scientific assessments, helped to enhance cooperation with local and international experts.

The SFDA played a leading role in securing safe and effective vaccines for the population.

In addition, Saudi Arabia was a founding member of the International Heads of Food Agencies Forum (IHFAF), which was established in 2020. The forum, whose secretariat is managed by the SFDA, is committed to promoting food safety, knowledge sharing, capacity-building and policy advocacy. IHFAF goals include establishing international standards, enhancing cooperation among member countries, conducting training programmes for food safety professionals, and raising public awareness about food safety and food-handling practices.

Developing Innovative Solutions

The emergence of Covid-19 prompted the formation of a Supreme Committee, chaired by the minister of health, in the Kingdom. Comprising members from various public bodies, the committee convened in late February 2020 to address the evolving situation. Responsibilities were allocated to various bodies: among these, the SFDA was tasked with leading a subcommittee to ensure sufficient supplies to combat the health and safety risks posed by the novel coronavirus.

SFDA responsibilities expanded to include providing medicine and food, among other essential supplies, for the Kingdom's population. This comprised multiple phases, from sourcing raw materials, to ensuring efficient inter-city logistics and supply chains, and enabling the swift distribution of supplies to retail outlets. Addressing challenges necessitated innovative solutions that offer long-term benefits, such as the establishment of an operations centre, expediting licence issuances and technological integration.

Sourcing Essential Supplies

A number of essential products quickly grew in necessity at the outset of the pandemic. The SFDA was one of the organisations responsible for meeting this demand. The authority worked closely with both the public and private sectors to increase the local production of essential goods. The SFDA also engaged in partnerships with other governments to fast-track the approval process for imported goods, enabling their swift supply to Saudi Arabia and supporting access by the local population.

Working with local manufacturers and the Kingdom's National Unified Procurement Company (NUPCO), the SFDA undertook comprehensive measures to ensure the availability of crucial products. The authority's focus on operational excellence facilitated efficient internal coordination and streamlined processes.

The authority began by identifying products impacted by raw material shortages and evaluating which of these products may be vulnerable to disruption due to their origin. SFDA experts assessed the available quantity of essential products in the domestic market; calculated local demand in light of treatment protocols; and gauged the production capacity of national manufacturers to address any estimated shortfall. The authority analysed the stock of essential medicine, ranking pharmaceuticals according to therapeutic importance.

The SFDA then optimised medicine delivery, addressing demand fluctuations across different regions of Saudi Arabia. Additionally, the organisation developed a directory detailing the availability of essential products at pharmacies for consumers. In a further move to mitigate shortages, private pharmacies were permitted to directly import unregistered and unavailable medicines.

Drugs

To enable drug availability amid supply chain disruptions, the SFDA reviewed requests for extending the validity of medication and for altering active ingredients impacted by pandemic-related disruption. The authority published scientific assessments of medicine and vaccines, providing detailed insights into quality, effectiveness and safety – in a move to enhance transparency, trust and communication with companies, the community and various other stakeholders.

In addition, the SFDA engaged in drug distribution plans, liaising with agents, community pharmacies and beneficiaries, while the Saudi Vigilance System for drug-shortage reporting enabled timely intervention. Follow-up was facilitated by collaboration with pharmaceutical agents via an e-prescription programme under the electronic health service, Wasfaty, as part of NUPCO's Consolidated Purchase Competition Plan for 2020.



Sanitisers

The SFDA assumed direct oversight for sanitiser manufacturing, storage and marketing to ensure the quality of these products and monitor adherence to safety standards. The authority initially faced a substantial challenge in sourcing the necessary raw materials for sanitiser production. Nonetheless, these were successfully procured and transported to Saudi Arabia within a few weeks.

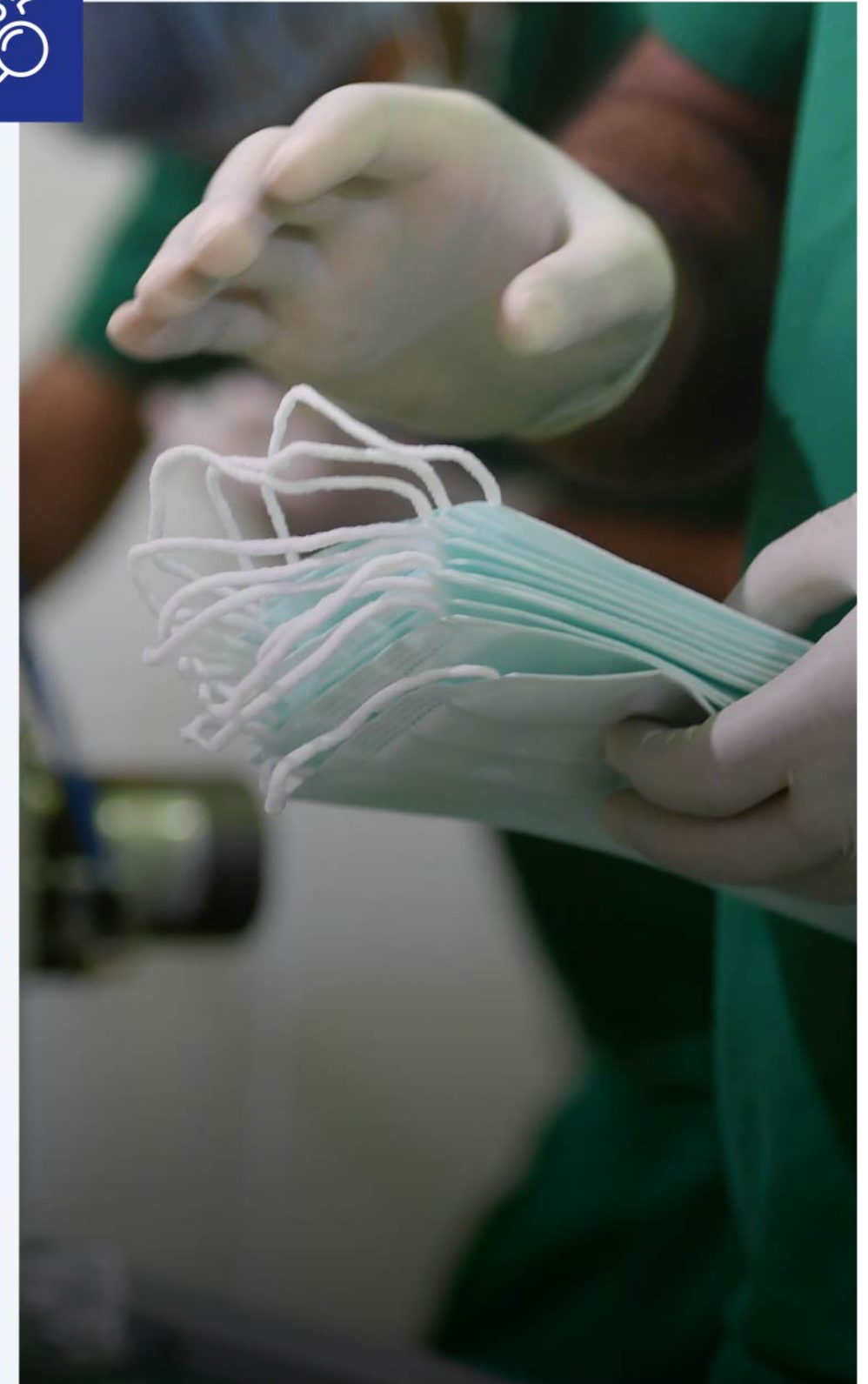
To meet rising domestic demand amid the health crisis, the SFDA issued comprehensive technical guidelines for sanitiser production to local manufacturing facilities. This initiative facilitated a notable increase in local production, fostering greater self-sufficiency. For instance, the number of manufacturers rose from nine to 64, resulting in a total of 118 SFDA-registered sanitiser products. The authority had issued recalls for 26 non-compliant products, underlining its ongoing commitment to quality assurance.

Face Masks

Securing a supply of face masks quickly became one of the Kingdom's standout challenges once movement restrictions were lifted – conditional on wearing a face mask or face covering. Local manufacturers found it difficult to meet demand. Although daily production reached 2m face masks, demand for masks rose to 600m. In collaboration with Saudi Airlines, the SFDA orchestrated airlift operations to swiftly transport the required supplies. This partnership facilitated the provision of 1.2bn masks within a number of weeks. Product availability improved considerably, leading to a reduction in prices – for the benefit of Saudi Arabia's population.

PCR Tests

Securing an adequate supply of PCR tests was another early challenge the SFDA faced during the pandemic. This was compounded by export restrictions on pandemic-essential products in many countries, including the US. The authority's efforts were redirected towards China, where a solution was found – with aircraft allocated to transport these essential products to Saudi Arabia. By the end of September 2021 over 28m PCR tests had been conducted in the Kingdom.



Covid-19 Vaccines in the Kingdom



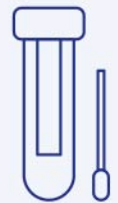
+ 40M

vaccine doses
administered by
end-September 2021



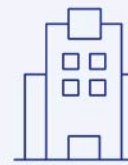
+ 40M

approved Covid-19
vaccines by December
2021



+28M

PCR tests performed
by end-September
2021



587

vaccination centres
across the Kingdom



62%

of the population had received
at least one vaccine dose by
mid-August 2021



Creativity, the
pursuit of alternative
solutions, expertise
and round-the-clock
monitoring were
key elements of our
successful response
to the pandemic.

H.E. Prof. Hisham bin Saad Aljadhey,
CEO, SFDA

Vaccines

Securing a vaccine against the Covid-19 virus – swiftly, and in sufficient quantities – was one of the standout hurdles for governments worldwide in the early phases of the pandemic. To support the Kingdom's efforts to enable access to high-quality vaccines, the SFDA joined the World Health Organisation's (WHO's) National Control Laboratory Network for Biologicals. This network is designed to promote the cooperation and exchange of technical expertise on vaccines. Participation in the network-enabled SFDA laboratories to access the data and test results for vaccines that were already under development in laboratories in other countries.

The authority imposed criteria for vaccine approval to ensure that each decision was grounded in scientific evidence, avoiding administrative influence. This helped to ensure the approval of the safest and most effective vaccines for the national immunisation programme.

Underlining the authority's success, 62% of the population had received at least one vaccine dose by mid-August 2021, with four vaccines approved by that December. Meanwhile, the authority was responsible for ensuring the quality and safety of vaccines entering the Kingdom through monitoring and assessment, in compliance with the highest quality standards. A consistent commitment to scientific rigour allowed Saudi Arabia to be one of the fastest countries in the region to respond to the health threats posed by Covid-19.



Supporting Local and International Partnerships

The SFDA remained steadfast in its support for, and contribution to, international initiatives during the Covid-19 period. One example is the authority's active engagement in the Codex Alimentarius Commission (CAC). The CAC was created by partnership between the UN's Food and Agriculture Organisation and the WHO, and is committed to harmonising international food standards. In 2020 Saudi Arabia was appointed as the CAC's Regional Coordinator for Near East Countries.

Throughout the pandemic, the SFDA continued work to safeguard consumer health and uphold fair practices in the food sector. Despite logistical challenges, the authority also maintained active participation in the CAC's technical activities. Additionally, the SFDA chaired several online CAC working groups for standards, demonstrating its dedication to advancing global food standards and leading progress towards international goals in spite of challenging conditions.

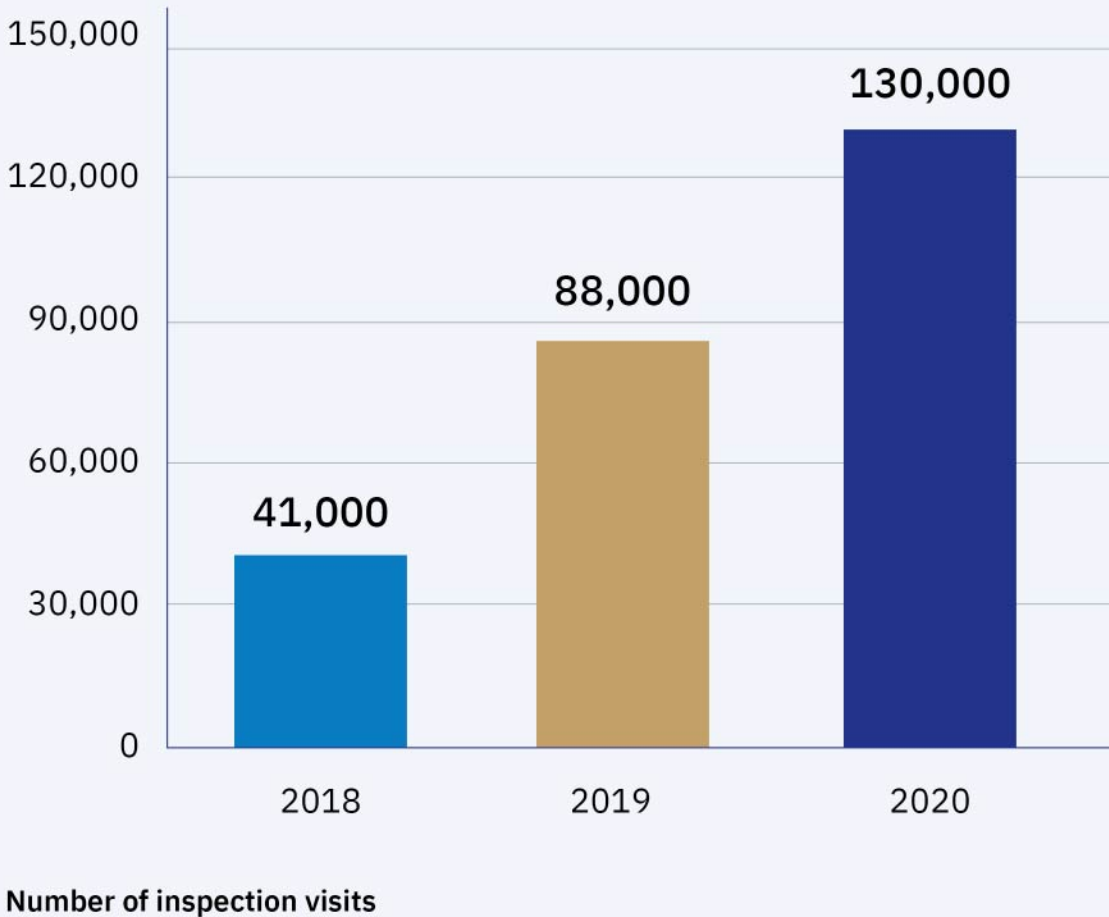
Launching Smart Inspections

The SFDA was expected to uphold its regulatory responsibilities during the Covid-19 period, including the inspection of facilities and products under the authority’s regulatory control. Prior to the pandemic, the SFDA conducted field-based inspections of establishments and products. However, these were restricted and postponed to mitigate virus-transmission risks. The authority implemented protocols for remote inspection via video connection and other remote tools. This allowed the scrutiny of an establishment’s documents, records and operations without the need for an inspector to be physically present. While remote inspections did not entirely replace all on-site visits, they served as a complementary measure – particularly in scenarios where on-site inspections posed health or security risks, travel constraints were enforced, or establishments were situated in locations identified as remote or hazardous.

Despite pandemic-related challenges, SFDA inspection visits increased by some 10% from 2019 to 2020, rising from around 78,700 to exceed 86,700. The SFDA conducted over 3800 smart inspections between the beginning of the pandemic and February 2023. This underscores the vital role remote inspections played, facilitating continuity in SFDA oversight while reducing health and safety risks for inspectors, teams being inspected and the broader community.

SFDA Inspection Visits

The authority’s inspection visits increased by 10% in 2020, despite Covid-19



2022

Recovery and a New Strategic Plan



Having played a pivotal role in Covid-19 pandemic response efforts, the SFDA next began to focus on helping to guide Saudi Arabia on the road to post-pandemic recovery. In 2022 the authority initiated the development of its fourth strategic plan for 2023-27 (“the Plan”). Due to its improved internal capacity, the organisation was able to formulate the Plan without requiring external consultants – relying instead on the expertise of SFDA specialists. The authority also reflected on the key achievements and challenges of the third strategic plan.

Entering the New Normal

The pandemic had altered the trajectory of the Plan, introducing distinctive challenges. Upon containing the pandemic, returning to normal operations became imperative for the SFDA’s pursuit of excellence. Through employee and leadership meetings, the authority gradually resumed regular activities. Some challenges persisted – particularly drug availability due to supply chain disruptions and high demand for medicine after the lifting of restrictions. The SFDA remained steadfast in addressing these ongoing challenges. The disruption brought by the pandemic also led to other lasting changes. For instance, the pressures of the pandemic helped to accelerate the localisation of drug and medical device production, which is a strategic development priority for the Kingdom, along with the advancement of biotechnology (biotech). These sectors now present standout investment opportunities in Saudi Arabia.

Making Progress

Amid the accomplishments of the third strategic plan, the SFDA garnered considerable national and international recognition. This included eliminating industrially produced trans-fatty acids (trans fats) in the Kingdom, achieving World Health Organisation (WHO) maturity level four (ML4) status, and attaining e-services maturity.

Industrially Produced Trans Fats

Through phased regulatory measures aligned with WHO recommendations, the SFDA eliminated industrially produced trans fats from Saudi Arabia's food supply in 2020. Industrially produced trans fats – in contrast to trans fats naturally present in meat and dairy products in small quantities – are commonly added to commercial baked goods and snacks, and fried food. This may be part of efforts to extend product shelf life, alter taste and texture, and reuse frying oils. High levels of trans-fat consumption are linked to cardiovascular disease, obesity, high blood pressure and type-two diabetes.

Progressive phases of the ban included the mandatory labelling of trans-fat content, the introduction of trans-fat content limits, a voluntary agreement with multinational corporations for further content limits and, ultimately, a comprehensive ban. This proactive approach made Saudi Arabia one of the first countries globally to enforce such measures. SFDA standards were adopted regionally in July 2021, promoting unified regulations across the GCC. Through WHO partnerships, Saudi Arabia has shared its experience and provided training for other authorities in the region, thereby contributing to international efforts to eliminate industrially produced trans fats. This aligns with the SFDA's Healthy Food Strategy and signifies a milestone in the Kingdom's nutrition regulation efforts.



WHO ML4 Status

In recognition of its excellence in medicine and vaccine regulation, the SFDA attained WHO ML4 status – the highest accolade in the WHO's classification. This achievement underscores the SFDA's advanced performance and ongoing commitment to improvement. This made SFDA the first regulator in the Eastern Mediterranean, and the third worldwide, to reach ML4. Authorities at ML3 and ML4 level are eligible for WHO-listed authority designation. Authorities with this classification serve as benchmarks for other regulatory bodies, helping to guide their decisions on medical product approval.

e-Services Maturity

The SFDA has made significant strides in enhancing e-services, now offering multiple portals. Among these, the Customer Journey portal enables investors to become acquainted with the procedures and requirements for establishments and products, in addition to offering various other

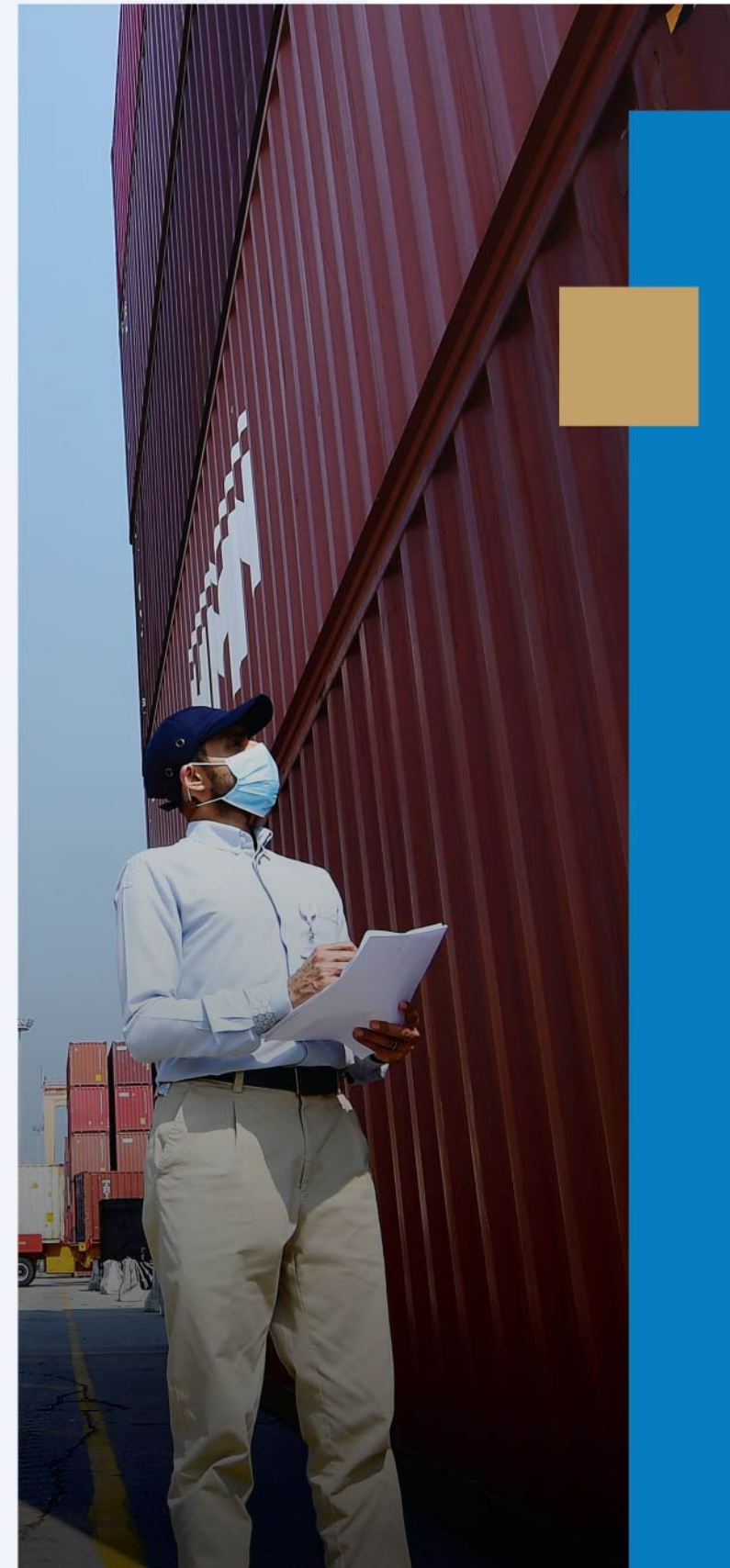
services. The Public Consultation Platform permits public and private sector stakeholders, as well as the general public, to provide feedback and input on proposed regulations, policies and initiatives related to food, drugs and medical devices. This promotes transparency and inclusivity in the regulatory process by inviting public participation and incorporating different perspectives into decision-making.

The authority's Track-and-Trace System, launched in 2018, has helped to ensure drug safety and protect patients. The system monitors the supply of pharmaceuticals, from production to consumption, across Saudi Arabia. This prevents counterfeit products, ensures availability and guarantees safety. By end-2021 over 6000 stakeholders were registered, with more than 3bn transactions recorded and 15m medication boxes recalled.

Central Clearance

Since February 2021 the SFDA has implemented measures to enhance efficiency in clearing goods entering the Kingdom. The authority introduced centralised clearance operations, operating 24 hours a day – even during holidays. This standardised regulatory procedures and reduced consignment clearance times at border ports. Central clearance is aimed at improving operational efficiency, enhancing customer satisfaction, streamlining administrative procedures and expediting decision-making processes. It seeks to optimise the Kingdom's supply chains, facilitate data collection, monitor compliance with SFDA regulations and transition away from paper-based transactions. It enables the swift processing of goods, ensuring their timely availability in local markets through a unified electronic system in collaboration with the Zakat, Tax and Customs Authority.

The SFDA's endeavours have resulted in clearing 95% of goods within two hours, substantially enhancing the Kingdom's performance in global trade metrics. The authority completed over 227,000 food and feed clearance requests in 2022 alone, alongside almost 20,000 requests for drugs and cosmetics, and some 11,000 requests for medical devices that year.



SFDA Clearances Completed in 2022



227,000

food and feed



20,000

drugs and cosmetics



11,000

medical devices

Positioning the SFDA as a Top Regulator

In developing the Plan, the SFDA focused on three key themes aimed at positioning the authority as one of the top food and drug regulators worldwide by 2027. These themes are enhancing product safety; fostering local and international partnerships; and driving operational excellence.

Product Safety

Ensuring product safety is the cornerstone of the SFDA's mandate. This includes the oversight of biological and advanced products, as well as e-commerce and other sectors.

Actions aligned with this pillar in 2022 included inspections of over 8000 drugs, cosmetics and medical devices, as well as over 29,000 food, feed and pesticide products. In addition, the SFDA collected approximately 10,000 food samples from the local market, analysing these in its laboratories, and detected, assessed and responded to some 6000 food alerts. The authority's product safety objectives are:

01

Enhance the regulatory system: refine and govern regulatory procedures concerning product safety across the entire supply chain, and define tasks and responsibilities for all entities involved. Key performance indicators (KPIs) include the percentage of products that comply with standards and requirements; the percentage of compliance among establishments regulated by the SFDA; and the number of individuals affected by food poisoning (per 100,000 people).

02

Strengthen communication and awareness: elevate the standard of communication and levels of awareness among individuals, health care professionals and other relevant stakeholders, and develop tailored communication plans and mechanisms for each group in order to uphold product safety.

Additionally, the SFDA seeks to raise the awareness of product safety by leveraging digital solutions in Arabic, while also enhancing communication in other languages including English and Chinese. KPIs for this goal include the percentage of consumer trust in product safety and the percentage of health practitioner trust in the authority.

03

Develop legislation and oversight for new technology and biotech products: formulate regulations, guidelines and standards to govern emerging products and technology, including biotech and artificial intelligence (AI). The authority also aims to enhance scientific evaluation capabilities and establish relevant laboratories. KPIs include the percentage of new technology and biotech products that are evaluated by the SFDA.



SFDA Inspections Conducted in 2022



8000

drugs, cosmetics and
medical devices



29,000

food, feed and
pesticides

Food Analysis and Alerts in 2022



10,000

food samples collected
from local markets
and analysed in SFDA
laboratories



6000

food alerts
detected, assessed
and responded to



The advancements in
our internal expertise
were crucial as we
pivoted from pandemic
response to recovery,
and embarked on
our fourth strategic
plan, for the period
2023-27.

H.E. Prof. Hisham bin Saad Aljadhey,
CEO, SFDA

Local and International Partnerships

are a focal point of excellence through which the SFDA aims to enhance its global leadership, and ultimately add value to the Kingdom's standing on the international stage.

The authority's objectives for this theme are:

01

Enhance product availability:

increase the effectiveness of legislation regulating the availability of products. Meanwhile, the SFDA seeks to augment the governance and development of control procedures with all relevant authorities throughout the supply chain to support the availability of products. KPIs include the percentage of compliance among

targeted drugs when assessed via field inspection; the percentage of drug contracts with government health authorities that are managed by the National Unified Procurement Company; the percentage availability of registered drugs among agents and suppliers; the percentage of drugs with sufficient stock in the Kingdom to meet demand for three months; and the percentage of domestically manufactured drugs with an adequate inventory of pharmaceutical ingredients for six months.

02

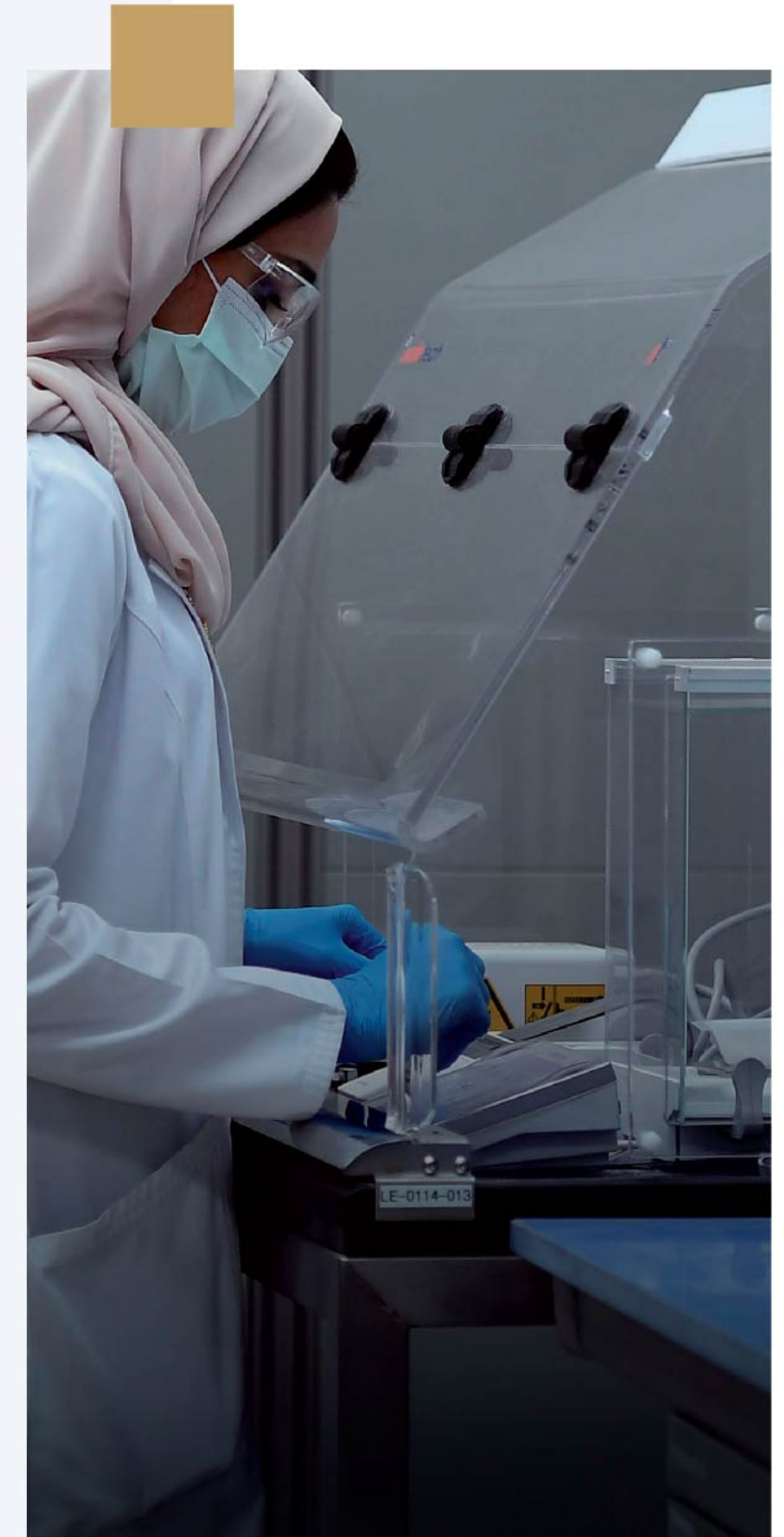
Enhance international leadership: bolster the authority's international presence by forging alliances, hosting high-level meetings, holding leadership positions in international organisations and diversifying participation in international working groups. The SFDA aims to enhance its status as a scientific and technical reference body through offering consultations, providing development programmes and delivering technical training workshops to counterpart regulatory authorities in other countries. KPIs for this objective include the number of pioneering regional and international initiatives that are established by the authority.

03

Support research and innovation: enhance collaboration with research agencies, universities and local manufacturers in order to boost research, development and innovation in the fields of food, drugs and medical devices. This involves fostering innovation pathways, developing enabling legislation and approving clinical studies. KPIs include the number of consultations provided to support researchers and inventors.

04

Empower investors: improve the experience of investors by enhancing communication channels and incorporating customer feedback to raise the level of satisfaction with SFDA services. The authority will identify priority products outlined in national strategies, such as the National Industrial Strategy and the National Strategy for Agriculture, and provide assistance to investors to grow these product lines. KPIs include the percentage of customer satisfaction with SFDA services and the number of consultations provided to private sector clients.



The SFDA's strategic approach looks set to help position the authority as one of the top food and drug regulators worldwide by 2027.

Operational Excellence

Operational excellence is another central aspect of the SFDA's strategic framework for 2023 - 27. The authority aims to integrate AI into its operations and achieve substantial advancement in the development of human capital. The authority's objectives in this regard are:

01



Develop human capital: enhance employee capabilities and motivation through strategic initiatives aimed at achieving operational objectives with high efficiency. KPIs include the percentage of employees participating in development activities; the percentage of vacant critical leadership positions that are filled by target candidates; and the percentage of employment engagement as per the Ministry of Human Resources and Social Development.

02



Diversify income: broaden revenue streams by reducing reliance on service revenues to help ensure the sustainability of financial resources. KPIs for this objective include the percentage of growth in revenue for the authority's subsidiary activities.

03



Increase the use of advanced digital technology: provide seamless and integrated digital services by leveraging advanced technologies and aligning with beneficiary preferences to enhance procedures and service delivery. KPIs include the percentage of compliance with digital transformation standards as per the Digital Government Authority; the number of procedures improved through advanced technology; and the percentage of compliance with basic standards for cybersecurity as per the National Cyber Security Authority.

These aims for the authority's 2023-27 roadmap build upon the lessons learnt in 2017-22. This looks set to help position the SFDA as a top food and drug regulators worldwide by 2027, while supporting progress towards the Kingdom's Vision 2030 goals and international objectives.



We envision a future where the SFDA stands at the forefront of global food and drug regulation, and is one of the top regulators worldwide.

H.E. Prof. Hisham bin Saad Aljadhey,
CEO, SFDA

2017-22

Lessons Learnt



Lessons Learnt

Following our progress during 2017-22, we have dedicated time to reflect on the lessons learnt during our transformative journey of growth. From success to setbacks, each experience has contributed to our collective wisdom. We believe these insights hold value for other organisations navigating their own paths of strategic development and excellence. As the SFDA transitions in the future, we will remain committed to continuing our evolution, reflecting on our journey, and embracing the opportunities that lie ahead.



Pursuing Targets

We recognise the importance of maintaining unwavering focus amid a multitude of challenges. By prioritising clear targets, we have effectively channelled our energies – driving substantial progress and tangible positive outcomes. While acknowledging that not all initiatives may succeed, we have learnt that it is key to pivot and adapt. What truly matters is staying steadfast in the pursuit of your overarching objectives, and ensuring that short- and medium-term aims align with these overarching, long-term priorities for the organisation.



Having a Vision

The importance of a clear vision cannot be overstated. A vision should not be merely a phrase on an organisation's walls; it should reside within the core of every employee. A compelling vision serves as a guiding force, lighting the path forwards and inspiring dedication to shared objectives. A bold vision is essential: it pushes boundaries and fuels innovation, developing aspirations beyond conventional thinking. Encouraging our people to focus on the SFDA's vision has been instrumental to our collective success.



Leadership Resilience

Our journey in recent years has underscored the significance of leadership in times of crisis. True leadership is characterised by accountability, resilience and a willingness to stand alongside teams in the face of adversity. Amid challenges, leaders must lead by example – providing unwavering support and guidance to navigate turbulent waters, avoiding blame in favour of collective problem-solving, and learning from success as well as from setbacks to drive the organisation towards priority objectives for strategic growth.



Empowering Experts

Empowering experts has proven instrumental to our journey's success. When individuals are entrusted with autonomy and responsibility, they are empowered to unleash their full potential. By fostering a culture of empowerment, the SFDA has cultivated a workforce that is not only motivated, but also deeply committed to realising the organisation's collective vision for the future.



Stakeholder Balancing

Navigating the complexities of stakeholder dynamics has taught us the delicate art of balance. Balancing conflicting interests demands diplomacy, empathy and a commitment to seeking common ground. By fostering constructive dialogue and collaboration, the SFDA has cultivated alliances that propel us closer to our shared goals, aligned with national and international development objectives.

