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Kingdom of Saudi Arabia
Saudi Food & Drug Authority

PROTECTING AND PROMOTING PUBLIC HEALTH

Saudi_FDA
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Foreword

Welcome to the latest publication on the Saudi Food and Drug Authority (SFDA) and the work we do. As the regulator of food, drugs and medical devices in Saudi Arabia, we play a vital role in protecting and promoting public health, both in the Kingdom and internationally.

In this publication, you will learn about the SFDA's role as a regulatory authority, as well as our efforts to increase food and drug safety in support of Saudi Arabia's goal of creating healthier citizens. We are improving regulations, enabling businesses to grow and leading international alliances.

H.E. Prof. Hisham bin Saad Aljadhey
CEO, Saudi Food and Drug Authority

In the following pages, we will showcase our international presence and outreach, which has put the SFDA on the world map as a leading member of a global community.

2020 was a year like no other in recent history, as we detail in a special section on Covid-19 in this publication. Saudi Arabia's Covid-19 response has been achieved through incredible cross-governmental collaboration, with the SFDA at the centre throughout. Our efforts have included implementing an effective public communications campaign, expediting regulations, and fast-tracking emergency-use authorisation for essential drugs and medical devices to combat the virus. At the outset of the pandemic, we were quick to expedite the import, registration, approval and distribution of personal protective equipment, test kits, N95 masks and pharmaceuticals to keep our residents safe and prevent transmission.

We are an approachable authority, ready to share our knowledge, enthusiastic to engage and equipped with a dynamic workforce. As such, we have designed this publication to be useful for specialists and non-specialists alike, recognising that we would not be able to do the work we do without the support of the public, our partners in industry and our colleagues in other government organisations. We aim to become one of the top-five food and drug authorities in the world, helping to build an attractive environment for both local and international investors to participate in Saudi Arabia's development. We urge you to get involved, get in touch, and engage with us and our work.

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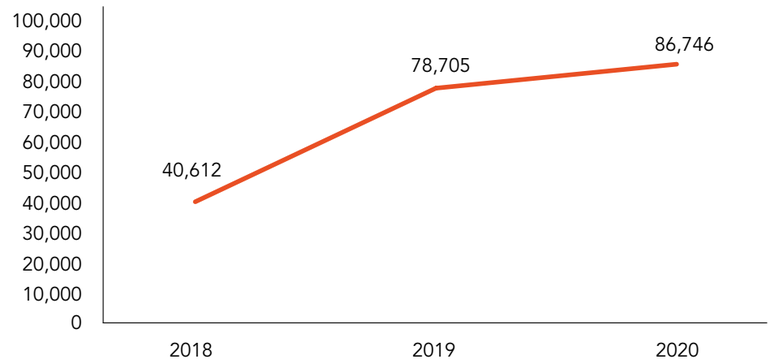
Inspections and Product Registrations

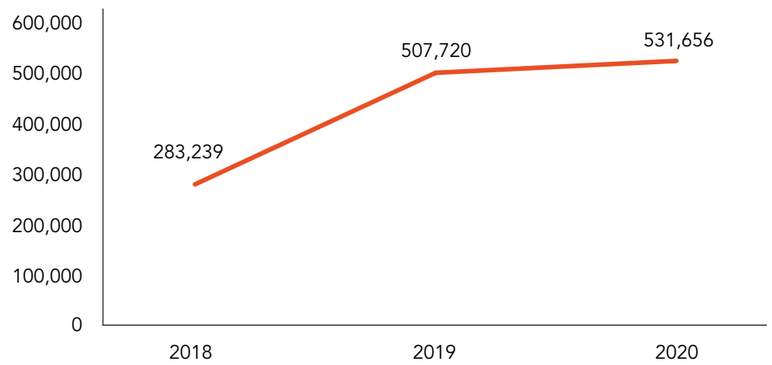
INSPECTION VISITS

The number of inspection visits **increased** by **94%** in **2019**



CLEARANCES

The number of received items handled by the SFDA **increased** by **79%** in **2019**



PROCESSING TIME

The number of consignments processed **within two hours** in **2020 increased** by **93%**

REGISTRATION PERIODS

The number of days needed to register products **decreased dramatically between 2018 and 2020**

	2018	2019	2020
Food Products average registration period	10.5 days	6 days	1 day
Fodder Products average registration period	163 days	116 days	15 days
Cosmetic Products average registration period	22 days	15 days	1 day

10,000 FOOD SAMPLES COLLECTED

The SFDA collected and analysed over **10,000 food samples** in 2020 in cooperation with the Ministry of Environment, Water and Agriculture, and the Ministry of Municipal and Rural Affairs as part of the National Programme for Food Monitoring and Control

70,000 DRUG SAFETY REPORTS ADDRESSED

In 2020 the SFDA received and addressed approximately **70,000 drug safety reports**, up from 58,000 in 2019 and 47,000 in 2018

COVID-19 RESPONSE

- Distributed **150,000 travel permits** on the first day of curfew to ensure that the manufacturing and supply chain of food, drugs and medical devices continued
- Created a new Covid-19 products approval website in **less than 12 hours**
- **167 Covid-19-critical products** received emergency-use authorisation and medical devices marketing authorisation
- Issued **3765 import permits** for more than **2.5m Covid-19-critical preventive products**
- Worked **24/7** to process **urgent import requests** to ensure availability of **critical supplies**
- Connected consumers via the **SFDA Tameni app** with more than **1000 pharmacies** throughout the country where sanitiser and masks could be bought

About SFDA

Our Vision

To be a leading international science-based regulator, protecting and promoting public health

Our Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and animal feed

Supporting Vision 2030

The SFDA is an active partner for, and drive of, Saudi Arabia's Vision 2030. As part of the Vision, key sectors that the SFDA regulates are undergoing major transformational reforms. In the health sector, these are aimed at delivering substantial improvements in quality, efficiency, value and safety. The country envisages healthier citizens, with the aim of increasing the average life expectancy from 75 years in 2015 to 80 years by 2030. These goals will be achieved in part by increasing private sector participation in the health care sector.

Vision 2030 is also targeting industrial expansion and investment support. This includes localising key industries and increasing the local manufacture of essential products. The National Industrial Strategy (NIS) has identified pharmaceuticals, medical supplies and food processing as key segments for domestic manufacturing expansion. By 2030 the NIS is targeting the development of a pharmaceutical, biopharmaceutical and medical supplies industry, and the development of industrial clusters for food.

At the heart of ongoing health sector reforms is the Ministry of Health's Healthcare Transformation Strategy. The strategy focuses on providing value-based health care, with the objectives of raising the overall standard of service, improving access to medical care, ensuring better value and strengthening preventive measures against the main threats to the health of residents. The latter includes enhancing prevention of non-communicable diseases such as heart disease, stroke, diabetes, respiratory disease, mental health and congenital diseases, while also mitigating the risk of major outbreaks of communicable diseases that remains substantial, especially during the annual Hajj pilgrimage.

This comes as the demographics of the country are continuing to grow and change. By 2030 the population is expected to reach 39.5 million, up from 33.5 million in 2018, while the number of elderly (aged 60-79) is expected to increase from 1.96 million to 4.63 million.

Part of the Kingdom's role in health provision is caring for the large number of non-Saudi residents as well as the many overseas visitors the Kingdom welcomes each year. As part of Vision 2030 the government has a target of expanding the annual pilgrimage from 8 million to 30 million pilgrims visiting by 2030. This will require an agile health care system with the highest standards of safety and regulation.

The SFDA is positioning itself to support and deliver on Vision 2030's objectives in order to ensure a new and healthier Saudi Arabia.

As our population grows, we face a number of health and food safety challenges that the SFDA is ready to meet

WHAT WE DO FOR YOU

Who We Are

The Saudi Food and Drug Authority (SFDA) is a government agency that protects the public by regulating the safety of food, drugs, medical devices, cosmetics, pesticides and animal feed. Safe consumption of these products ensures that the health of our community is maintained.

The SFDA was established in 2003 and its headquarters are located in Riyadh. We employ over 2000 experts and specialists from food and health backgrounds in facilities across the country, including in Riyadh, Dammam, Abha, Makkah and Skakah.

The authority is made up of five main sectors: the Food Sector, the Drugs Sector, the Medical Devices Sector, the Research and Laboratories Sector, and the Operations Sector. We also have an investment support centre that helps private companies invest and set up facilities in the Kingdom.

The SFDA works in close coordination with the Ministry of Health and other government entities with mandates in the health and food sectors. The SFDA is headed by a Board of Directors and reports directly to the Cabinet of Saudi Arabia, the Council of Ministers.

Our Responsibilities

The SFDA carries out a wide variety of activities related to food, drugs and medical devices. These include setting standards; creating regulations to ensure the safety, quality, effectiveness and performance of products; monitoring and inspecting both imported and locally manufactured goods; supervising licensing of factories; running consumer-awareness campaigns; conducting research and applied studies; and working with local and international scientific bodies and regulatory agencies.

As our population grows, we face a number of health and food safety challenges that the SFDA is ready to meet. These include addressing the increased incidence of lifestyle-related diseases, protecting a population that will exceed 39 million by 2030 and 44 million by 2050, and protecting the health of a growing number of visitors to the Kingdom each year. These challenges make it more important than ever to have high standards in food, drug and medical device regulation and controls.

As the economy continues to develop, the SFDA is positioning itself to respond to the rapid pace of innovation, the tighter integration of global supply chains, and the increasing demands of our citizens for safe and healthy products. We expect to meet these challenges with informed decisions based on scientific evidence, and by building partnerships with the private sector, other government entities and our international partners. We are committed to earning the community's trust by engaging proactively with the public and by building a high-performing, efficient and innovative organisation that allows our staff to be the best at all that they do.

The Products We Regulate

Highlighting What We Do

Consumer Awareness

The SFDA is in charge of consumer awareness on all matters related to food, drugs and medical devices, and communication with the public is a major part of its work. The SFDA call centre exists to receive and answer questions or complaints related to food, drugs and medical devices.

Inspections

We inspect both imported and locally manufactured goods. Saudi Arabia imports 80% of its food, 60% of its medication and more than 90% of its medical devices. Ensuring that only safe products enter the market is of paramount importance.

Post-market Surveillance

We monitor the quality and performance of products and devices once they have entered the market, as well as in hospitals. We do this through a wide network of health care providers and regulatory officers.

Setting Regulations

We set standards and develop regulations for the products we are responsible for. This includes standards for production, distribution, importation and registration of food products, drugs and medical devices. We set hygiene standards that food industry facilities and related workers should abide by, and we supervise licensing procedures for food, drug and medical device factories.

Research

We conduct research and apply studies to identify health problems and their underlying causes, and determine their impact on the public. We partner with scientific centres and external research bodies such as King Abdulaziz City for Science and Technology and university research centres.

Collaborating with Others

We collaborate closely with other Saudi government entities engaged in food and drug affairs. We also disseminate and exchange information with local and international scientific and legal agencies.

OUR GLOBAL PRESENCE

The SFDA operates at a global level to represent Saudi Arabia and share its expertise with the international food and health regulatory community. In addition to being an active leader and organiser of global food safety and health summits, it is continually building specialist international partnerships with regulatory agencies from other countries, alongside worldwide food and health governance organisations.

RECENT GLOBAL SUMMITS

Sustainable Production in the Health Sector Global Forum 2020

Saving lives Sustainably
GLOBAL FORUM 2020
SUSTAINABLE PRODUCTION IN THE HEALTH SECTOR
18–19 November 2020

In November 2020 Saudi Arabia hosted the Sustainable Production in the Health Sector Global Forum 2020 on the sidelines of the Kingdom's staging of the G20 Summit. The event was organised by the SFDA and the Saudi Secretariat of the G20, in collaboration with global partners such as the UN Development Programme. The forum, which focuses on sustainable production in the health sector, addressed health care supply chain issues in areas including procurement and logistics. The event took place both physically and virtually, with over 50 international expert speakers and moderators leading the dialogue. It was the biggest G20 international conference held alongside the G20 Summit.

Its theme, "Recovering Better after Covid-19", provided an opportunity for suppliers, manufacturers, policymakers, technical experts, academia, civil society organisations and others active in the global health sector to share best practices based on their experience with Covid-19. Participants were able to explore new pathways to move ahead with the sustainable procurement and manufacturing of health commodities, in addition to reviewing the latest public and private innovations in the sector.

International Leaders' Meeting

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

November 2020 also saw the virtual International Leaders' Meeting of the Global Harmonisation Working Party (GHWP), of which Saudi Arabia is the international leader. The Kingdom is also an active participant in all of the organisation's technical and scientific working groups.

HEADS OF FOOD AGENCIES MEETING

FOOD STANDARDS Australia New Zealand · Food Safety Authority of Ireland · الهيئة العامة للغذاء والدواء Saudi Food & Drug Authority · World Health Organization · CODEX ALIMENTARIUS · Food and Agriculture Organization of the United Nations

In January 2020 the SFDA initiated the first of a series of annual global forums on food safety, known as the Heads of Food Agencies Meeting. Convened in Riyadh and organised by a number of international food authorities, the forum offered a unique opportunity for global heads of food agencies to come together to work to protect public health and identify emerging issues of food safety.

Initially organised in collaboration with the respective authorities of Ireland, Australia and New Zealand, the initiative has since expanded to include authorities from France, Japan, China, Morocco and Kuwait. The initiative is also supported by the World Health Organisation and Codex Alimentarius.

In August 2020 the SFDA convened an emergency meeting of the forum which was part of the programme of international conferences on the sidelines of the Kingdom's presidency of the G20. The meeting served to advance efforts to ensure food safety in the face of Covid-19. The forum helps to fill a vital gap in international collaboration on food safety issues and positions Saudi Arabia as a proactive and inclusive leader in the field. The forum helped to increase international dialogue, the exchange of information, and the adoption of best practices and regulations throughout the sector.

OUR INTERNATIONAL PARTNERS

The following are among the organisations the SFDA has specialist international agreements with:

CDSCO · Ministère chargé des Transports (Liberté Égalité Fraternité) · BADAN POM · Jordan Food & Drug Administration · وزارة الصحة العراقية · University College Dublin · Ministry for Primary Industries Manatū Ahu Matua · FOOD STANDARDS Australia New Zealand · Global Harmonization Working Party GHWP Towards Medical Device Harmonization · nhra BAHRAIN · الهيئة الوطنية لتنظيم المهن والخدمات الصحية NATIONAL HEALTH REGULATORY AUTHORITY · ANVISA · edqm · Council of Europe · Conseil de l'Europe · MHLW JAPAN

The SFDA is a member and active supporter of the following international organisations:

World Health Organization · Food and Agriculture Organization of the United Nations · World Trade Organization · WIPO World Intellectual Property Organization · ICCR International Cooperation on Cosmetics Regulation · ICH harmonisation for better health · ICMRA

Our Sectors

- Food
- Drugs
- Medical Devices
- Research and Laboratories
- Operations

FOOD

The SFDA's Food Sector is responsible for ensuring the safety and quality of all food, animal feed and pesticides. Saudi Arabia currently imports over 80% of its food from more than 150 countries. The SFDA is responsible for ensuring the safety and quality of these imports, as well as all food produced domestically.

Food and agriculture have an important part to play in the non-oil economy's expansion. As the sector rises in economic importance, the Kingdom's population is continuing to grow, which means the SFDA's remit for ensuring food safety will expand. One of the main objectives of Vision 2030 is to improve health and promote healthy food consumption among residents. This comes at a time when food safety and ensuring the quality of food are becoming more important from both a consumer and public health perspective.

Food safety and nutrition are key determinants of human health, and these are underpinned by effective regulatory decisions and controls. Food regulators are called upon daily to address issues and serve as the source of reference for food business operators, traders and consumers. By ensuring food safety, we are actively supporting the national priority to create healthier citizens.

Environmental factors like climate change are already challenging the global food supply in the face of an increasing number of mouths to feed: the UN estimates an additional 2 billion people will be added to the world's population by 2050. In this vein, the Kingdom will need to be a part of efforts to produce more food sustainably and safely, and connect consumers to the food they eat. Reducing waste will be a major task to ensure a more sustainable food system.

WHAT WE DO FOR YOU

In 2020 the Kingdom drastically reduced the amount of pesticide residue introduced to combat the contamination of imported food.

FOOD SAFETY

The SFDA is committed to reducing any potential food contaminants that can pose a threat to people's health, and ensuring that any pesticides, chemicals and microbiological products used in the food production process are safe, in accordance with regulations and within standard permissible limits. These are important preventive measures for health problems.

As the main food safety regulator in the Kingdom, the SFDA is implementing a national food-monitoring programme in 2020, covering the whole food chain. The programme is conducted by the SFDA, the Ministry of Environment, Water and Agriculture, and the Ministry of Municipal and Rural Affairs. It is designed to collect more than 10,000 samples across all the Kingdom's regions, including both locally produced and imported goods. There are 11 programmes focused on monitoring chemical contaminants in food contact materials. In addition, the SFDA has conducted more than 15 monitoring programmes on food contaminants, such as food additives, heavy metals, mycotoxins and PAHs, with more than 4000 samples collected to date.

Some of the food safety measures introduced include the Gulf Rapid Alert System for Food. The Food Rapid Alert Centre was established to manage this system, and is where reports and alerts related to food safety are exchanged in the GCC. Incident reporting is an important aspect of food safety, thus the SFDA's vigilance programme for receiving mentions of food poisoning allows for the tracking of foodborne illnesses by individuals, health facilities and practitioners submitting reports.

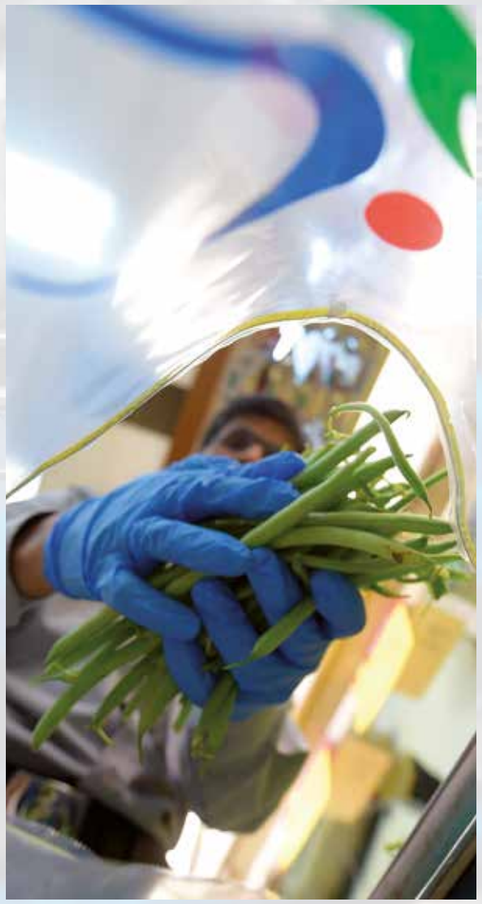
> The Kingdom is committed to modernising food systems locally and globally to ensure food safety and sustainability
>
> ”

The SFDA has adopted the Food Safety Risk Analysis Framework, an internationally recognised systematic approach for making food safety decisions. It consists of three interconnected components: risk assessment, risk management and risk communication to ensure food safety regulatory decisions are science-based and transparent. This enables the SFDA to identify the risk level and nature based on the evaluation of scientific evidence, and provide decision-makers with scientific opinions to take interventions to mitigate risk. It also supports the exchange of information, encouraging input and opinions from relevant stakeholders throughout the process. The framework contributes to the robustness of the food safety system, with the aim of supporting consumers' health and fair practices in the food trade.

Risk communication is another important aspect of food safety. Our work involves communicating food risks and benefits to consumers to help them make informed decisions. This helps ensure effective food regulations and a wider understanding and acceptance of risk-management decisions. To enable people to make informed food safety decisions, we conduct several webinars focused on consumer concerns, especially during the Covid-19 pandemic. We use several tools and methods to understand consumers' needs and concerns, including surveys that evaluate consumers' food safety knowledge and practices, and help identify their concerns related to food risks and their sources of food safety knowledge. The SFDA is also committed to improving the maturity of food safety control systems. This means achieving the highest performance protocols in line with international standards. We are designing flexible and adjustable measuring tools to improve the effectiveness of the food safety system – for example, by benchmarking and reviewing the best available systems and practices used by international organisations.

QUALITY CONTROL

We monitor locally processed food items both before and during production for quality and compliance purposes. In addition, as part of our efforts to address food fraud, we work to prevent deliberate and intentional deception such as substitution, addition, tampering or misrepresentation of food, ingredients or packaging. To this end, we are developing our laboratory detection capabilities, establishing working mechanisms and raising awareness of the danger of food fraud.



PESTICIDE CONTROL

We seek to protect consumers from the adverse effects of crop pesticides and aim to guard against pesticide residue that may remain on or in food. This is also important for crops consumed by animals. If animal feed contains pesticide residue, it may end up in humans if they consume products or meat from the animal.

The SFDA has developed and implemented a number of national programmes in order to monitor contaminants and pesticide residue in food, and between 2012 and 2020 more than 30,000 food samples from a variety of regions we collected and analysed.

HEALTHY EATING

The SFDA and the Ministry of Health are working together to tackle the increased incidence of non-communicable diseases that is impacting national health and well-being.

Major conditions include diabetes, respiratory illnesses like asthma, cardiovascular diseases such as heart disease and stroke, and obesity. These are often linked to eating habits, thus boosting the nutritional value of food products and encouraging healthy eating is essential. The SFDA is developing nutritional policies in collaboration with government entities and private sector players. Through our Healthy Food Strategy, launched in 2018, we are encouraging companies to voluntarily commit to reduce salt, sugar and fat content in products. We also encourage them to transparently indicate calorie content on packaging and provide healthier food options to promote public health. As part of our efforts, we launched the What We Eat in Saudi Arabia project to collect food consumption data. We also issue nutritional recommendations and scientific opinions to the relevant authorities through the National Nutrition Committee, a scientific advisory body established by Cabinet decision in 2018 under the organisational structure of the SFDA.

FOOD WASTE

The SFDA is working with the Saudi Grains Organisation and the National Programme to Reduce Food Loss and Waste on campaigns to reduce waste and raise community awareness.

INTERNATIONAL COLLABORATION

The SFDA recently joined a number of international bodies in the field of food safety, including the International Liaison Group for Methods on Risk Assessment of Chemicals in Food, the International Risk Communication Liaison Group, and the organisational coordinating committee of the Global Network for Determining Genotypes of Foodborne Pathogens – or PulseNet – for Eastern Mediterranean countries under the supervision of the World Health Organisation (WHO) and the US Centres for Disease Control and Prevention.

The SFDA has bilateral agreements that includes a memorandum of understanding with the University College Dublin for collaboration in monitoring and assessing microbial risks associated with food; and a cooperation agreement with the Australia and New Zealand Food Authority.

The authority is also involved in an initiative to share data on pollutant concentrations in food, among other things, through the GEMS FOOD platform of the WHO. It participates in major conferences such as the Dubai International Food Safety Conference, the Shenzhen Food Safety Forum and the International Association for Food Protection.

DRUGS

The Kingdom aims to provide affordable, accessible and high-quality health care for all – with an emphasis on preventive care

The Drugs Sector is responsible for ensuring the safety, efficacy and quality of pharmaceuticals consumed in the Kingdom. Ensuring the highest standards are met and maintained, while also adhering to competitive timelines, is of paramount importance for the sector.

The prevalence of certain chronic diseases such as type 2 diabetes, hypertension, hyperlipidemia and asthma has created a need to produce more drugs locally, alongside securing other therapeutic methods and essential medications. As part of Vision 2030 and the Health care Transformation Strategy, the Kingdom aims to provide affordable, accessible and high-quality pharmaceutical and biotechnology products for all – with an emphasis on preventive care – while ensuring the adequacy and responsiveness of medicinal supplies. Saudi Arabia has a large, well-developed domestic pharmaceuticals industry, and many local and multinational companies have production facilities in the Kingdom. While the majority of pharmaceuticals remain imported, the SFDA is working to support national targets to boost domestic production from 20% of the total in 2019 to 40% by 2030. This will help to reduce dependence on imports, and ensure a consistent and adequate supply of medicine for residents. Pharmaceuticals has been identified as a key expansion segment for the industry, which will help raise the level of domestic manufacturing under the goals of Vision 2030. Over the long term, the industrial sector targets pharmaceutical export growth and the development of new drugs. Scientists within the SFDA's drug specialist teams are ready to provide support and guidance to all companies that want to further engage with the Saudi pharmaceuticals industry. Our priority is to uphold international best practices in safety, while improving the experience for investors and research and development firms.

The SFDA is working to support national targets to boost domestic pharmaceutical production from 20% of the total in 2019 to 40% by 2030

WHAT WE DO FOR YOU

In 2020 the SFDA received and addressed 70,000 adverse drug event reports, up from 58,000 in 2019.

REGIONAL LEADERSHIP

We have an important role in leading our region in drug safety and quality control. Most neighbouring countries follow the general recommendations of the SFDA and may apply these recommendations in their respective countries. For example, if the SFDA recalls a product, other countries often follow. The SFDA is part of a GCC pharmaceuticals committee that makes collective decisions on drug-related topics. The committee recently worked to stabilise medication prices across all GCC member nations.

REGULATIONS AND GUIDELINES

We create and review laws, regulations and manuals related to pharmaceuticals. We monitor narcotics, psychotropic substances and controlled pharmaceuticals, and ensure their compliance with the relevant laws and procedures. We also publish guidelines on popular local products such as oud oil and miswak. The Drugs Sector updates its guidance frequently and ensures overall regulatory harmonisation.

are very competitive compared to other pharmaceutical authorities. Its scientific evaluation practices are up to international standards, and all submitted data are reviewed and scientifically critiqued.

CLINICAL STUDIES

We organise clinical studies of drugs that are not registered in the Kingdom and register all clinical studies that take place on drugs in line with our related goal of increasing the accessibility of new medications. The Saudi Clinical Trial Registry is mandated to conduct all phases of clinical trials.

SCIENTIFIC EVALUATION AND APPROVAL

The SFDA manages the registration, approval and renewal of licences related to medicinal products. As registration is instrumental to ensuring safety, efficacy and quality, the authority has sped up this process by implementing the Saudi Electronic Drug Registration System (eSDR). All products go into the registry after a comprehensive online application has been filled out. The eSDR aims to build a database of all pharmaceutical facilities in the Saudi market, including manufacturers, agents and batch distributors. The authority works to minimise the time needed to review and evaluate supporting documents, and its timelines

COSMETICS

Ecosma is another electronic system, regulating the Saudi cosmetics market through a comprehensive database of locally manufactured or imported cosmetic products. Ecosma is used by importers and manufacturers of products marketed in Saudi Arabia to notify the SFDA about their products to make sure they are compatible with local standards, namely in terms of ingredients.

PHARMACOVIGILANCE

In order to ensure drug safety, or pharmacovigilance, the SFDA consistently evaluates the safety, efficacy and quality of all types of pharmaceuticals in the Saudi market, including human, veterinary and herbal drugs. The authority tracks drugs throughout the whole supply chain – from manufacturing to sale and consumption – in order to combat fraud and enhance supply, availability, safety, quality and security. Comprehensively evaluating new drugs and monitoring their performance helps to prevent adverse effects of pharmaceutical products.

The SFDA's post-market surveillance work involves monitoring medications in the market by checking their safety, efficacy and quality in order to ensure that they meet the required standards and specifications. This also involves detecting and controlling side effects, and preventing adverse effects of pharmaceutical products, including both expected and unexpected reactions. The SFDA has advanced systems that run full assessments on products. The authority has been working to institute a culture of reporting on side effects to enhance drug safety and reduce the risks related to medicines. We also supervise and support the risk-reduction and precautionary measures of health agencies and hospitals that prescribe and dispense risk-related drugs.

The SFDA's pharmaceutical track-and-trace system ensures faulty medication can be identified easily, which helps to prevent fraud as well as other unsafe discrepancies. Ensuring the safety and quality of generics to increase consumer confidence is another important priority. We have a dedicated quality-assurance project for locally marketed generics that conducts specialised safety and efficacy tests on these lower-cost versions of in-demand medications.

> The eSDR aims to build a database of all pharmaceutical facilities in the market

PRICE REGULATION

We are responsible for setting the prices of pharmaceuticals and reviewing them on a regular basis according to the published pricing rules. We implement regular price cuts based on comparative safety and efficacy studies, pharmacoeconomic studies and prices in marketed countries. Re-evaluation of drug prices is also conditioned to their consumption and the availability of alternatives. We set prices to ensure they accommodate both society and investors, with no major burden on either party.

SUPPLY AVAILABILITY

The SFDA secures the availability of pharmaceuticals in the Saudi market and ensure that there is no shortage for patients, especially medication for chronic diseases. These efforts were more pronounced during the Covid-19 pandemic, with efforts focused on assuring the availability of essential medicines, masks and hand sanitisers.

COMMUNICATION

We provide drug information to the public and medical providers, and implement awareness campaigns on the rational and safe use of drugs and cosmetics, leveraging technology to provide accurate and actionable information regularly.

MEDICAL DEVICES

The SFDA's Medical Devices Sector plays a pivotal role in ensuring the safety, efficacy and performance of medical devices under a comprehensive legislative and regulatory framework aligned with international best practices for harmonisation and convergence. As part of this role, it chairs the GHWP and is an active member in a number of technical committees at the International Medical Device Regulators Forum (IMDRF) and the International Organisation for Standardisation (ISO).

Medical device regulation covers the entire product lifecycle, starting from the initial design concept, through to manufacturing and the product reaching the end user.

In addition, this regulation involves monitoring the performance and safe use of medical devices. The medical devices sector performs a series of regulatory activities, including reviewing medical devices' technical files, clinical trials, post-market surveillance plans, quality and other technical documents prior to granting the marketing authorisation. It also monitors approved devices via a well-designed model of post-market surveillance with a risk-based approach, analysing field safety notices, adverse events and other safety signals in order to ensure a high degree of safety and efficacy.

Medical devices play an essential role in screening, diagnostics and treatment, which means their efficacy and accuracy are crucial for quality care

Communicating effectively with health care providers is another facet of its role, sharing updated safety communication recommendations and vigilance reports.

Furthermore, the sector oversees and monitors medical radiation-emitting devices, medical radioactive material, and radiation protection and safety among health care providers, ensuring the compliance of radiology departments, nuclear medicine, radiotherapy, dermatology and dental clinics with the SFDA's regulatory requirements.

In conjunction with the WHO, the medical devices sector manages the SFDA-WHO Collaboration Centre, which provides international services to the WHO and other countries such as training, workshops and the active participation of SFDA experts in many projects.

WHAT WE DO FOR YOU

Since 2007 we have operated the National Centre for Medical Devices Reporting (NCMDR), an online portal designed for reporting problems with medical devices and products in order to ensure they work both safely and efficiently.

SAFETY VERIFICATION

Medical devices are expected to perform according to the best international standards from the concept design phase to the production phase through to actual use

Saudi Arabia intends to raise the local manufacture of medical devices and equipment from 6% in 2019 to 16% by 2025

in diagnostics and treatment. The SFDA's priority is to verify the safety and accuracy of medical and diagnostic devices wherever they are used.

This involves both pre-market assessment and post-market surveillance. Assessment of medical devices before they enter market includes evaluating the device's accompanying technical documentation, such as information on clinical studies, risk assessment analysis and a quality portfolio.

The post-market surveillance stage involves risk analysis, addressing any complaints and safety issues related to medical devices, as well as conducting post-market clinical evaluation.

Based on these studies, many regulatory decisions have been made on a number of medical devices to protect patients and users. We continuously conduct quality checks on devices in the market to ensure safe performance.

Another part of our role is to conduct safety and radiation protection assessments for radiological devices. This includes assessing the safe use of medical devices in x-ray, nuclear medicine and radioactive therapy departments, as well as dermatology, dental and plastic procedure clinics. The SFDA has established National Diagnostic Reference Levels across the country to monitor and optimise patient dosages while preserving image quality and diagnostic usefulness. This protects patients from unjustified excessive radiation doses during examination.

> At the end of 2019 the SFDA introduced its own independent approval standards for medical devices

MONITORING AND GUIDANCE

Our monitoring and guidance work includes maintaining a comprehensive database of all registered companies licensed to operate in the Kingdom, including manufacturers, suppliers and maintenance companies. We ensure suppliers and distributors comply with SFDA standards and that products are stored correctly. As part of our post-market surveillance work, in 2020 we developed a new code-based registering and tracking system that connects the SFDA, factories, medical companies and health care providers to make it easier to search for and track medical devices after sale.

We create rules for the safe use of medical devices in diagnostics and treatment, as well as requirements for companies in charge of device maintenance in hospitals and clinics. This enhances facilities' ability to apply international safety standards for medical devices. It also raises the quality and efficiency of care by adopting the best methods in medical device management across health institutions. In 2019 we developed an annual monitoring plan for medical devices to verify that marketed medical devices comply with the technical specifications and requirements of the SFDA. In addition, to ensure their effectiveness, efficiency and safety, we conduct annual lab testing on specific medical devices collected from the point of sale or health care facilities. We also work to ensure robust communication with health practitioners through the NCMDR. Health practitioners are provided with the latest recommendations and safety updates to help improve the safe use of medical devices and equipment, and they can communicate any problems, incidents and adverse events they may experience to the SFDA.

SFDA APPROVAL

At the end of 2019 the SFDA introduced its own independent approval standards for medical devices. These are harmonised with international regulations but underpinned by national mandates, which negates the need to utilise the approval process of medical device regulators in other countries. This will help to grow the local medical device industry in support of Vision 2030. SFDA approval is recognised in GCC nations and most of the African market. We aim for SFDA approval to be recognised as among the highest international standards and reach the same level of international recognition as approval from the US Food and Drug Administration.

REGULATIONS AND STANDARDS

We draft oversight legislation and regulations for medical devices, and establish procedures for their registration. We set standards that determine radioactive reference levels to protect patients against radioactive doses that exceed international limits. We are responsible for enhancing legislation pertaining to devices and products, and take the necessary decisions on devices deemed unsafe for users. The SFDA has been particularly active to ensure harmonisation of regulations among GCC states.

INTERNATIONAL LEADERSHIP

The SFDA leads and supports several international organisations and authorities focused on medical device regulation. We work with international bodies such as the WHO, and global forums like the IMDRF and the GHWP. The SFDA currently serves as chair of the GHWP – with the vice-president of the Medical Devices Sector, Ali Al-Dalaan, serving as its chairman – marking a big achievement for the authority. SFDA personnel are leaders and members of many groups within the ISO that are working to unify medical device regulations. This presence allows the SFDA to weigh in on oversight decisions and share the Kingdom's successes with other countries.

Due to our institutional experience, the SFDA has been designated a WHO Collaborating Centre, focused on helping different countries with medical device regulation by providing counsel or organising lectures and workshops. WHO Collaborating Centres carry out activities in support of WHO programmes; there are currently more than 800 centres in over 80 member states and they play an important role in supporting the implementation of health technologies resolutions, as well as contributing to the work of the Global Initiative on Health Technologies.

The SFDA is on the Expert Committee of the WHO's Technical Advisory Group on Personal Protective Equipment (PPE) for Covid-19. The authority has attended meetings and participated in developing a guidance document on technical specifications for Covid-19 PPE. It also participated in the development and finalisation of the integration of medical devices such as in-vitro diagnostic medical devices into the WHO's Global Benchmark Tool.

Additionally, the SFDA has supported the WHO in a consulting capacity in its efforts to enhance medical device regulation in Africa through the African Medical Device Forum. The SFDA's proactive engagement efforts on this front are helping to promote international confidence in the authority.

RESEARCH AND LABORATORIES

Testing ensures compliance with international requirements and certifies that products are free of prohibited substances

The SFDA Research and Laboratories Sector conducts analysis on research and laboratory activities, and develops tests in the fields of food, drug and medical devices. We help to conduct research and apply studies to identify health problems, their causes and the impact on the public. Testing activities are conducted in either SFDA laboratories or appointed private laboratories in accordance with SFDA regulations. The data produced supports and determines the authority's regulatory decisions.

The SFDA has a number of laboratories specialising in different fields and each have sub-branches across the country. Our laboratories include the Food Laboratory, Drug Laboratory, Medical Devices Laboratory, Reference Drug Laboratory, Food Chemistry Reference Laboratory and Food Microbiology Reference Laboratory.

We are also helping to empower the private sector through our work. We have licensed private laboratories to provide analysis services, and have appointed some to conduct analysis on behalf of the SFDA in accordance with its regulations. This serves to support Vision 2030's drive to increase the involvement of the private sector in key industries.

> The SFDA has started engaging the private sector more deeply and contracting out certain tasks to accredited private laboratories
>
> ”

WHAT WE DO FOR YOU

We carried out 23 major research studies in 2020 aimed at ensuring the safety of products supervised by the SFDA.

TESTING

We conduct multiple types of tests on the products the SFDA is responsible for to ensure their compliance with international standards and certify that products are safe. We do this through the sector's central laboratories located in the Kingdom's main cities, or its sub-laboratories located in air-, sea- and land ports.

Ensuring the quality and safety of vaccines for human use is often achieved by testing on laboratory animals and issuing the necessary reports. We test on laboratory animals according to international standards and partake in the Laboratory Animal Care Programme. Our reference laboratories also conduct tests for chemicals and micro-organisms in food.

We test factory products to uphold quality and standardisation. We also conduct various tests on products in the market to determine their conformity with the required international standards. For example, tests have been conducted on hair removal products, skin care products, talc powder products and oral care products, such as determining the percentage of alcohol in mouthwash. In terms of food, the SFDA collected and analysed over 10,000 food samples in 2020 in cooperation with the Ministry of Environment, Water and Agriculture, and the Ministry of Municipal and Rural Affairs as part of the National Programme for Food Monitoring and Control.

Novel testing methods are continuously being developed. The sector's microbial genome analysis tests have produced a quantum leap in understanding and tracking the transmission of microbes from food, and linking them to microbial infections that occur in a specific community or even hospitals.

The microbial genome analysis technique enables epidemiological control of pathogenic microbes in food and enhances our knowledge of their main source so we can work to stop or reduce them. This has a great impact on easing the economic and health burden that may be caused by foodborne diseases, whether viral or bacterial.

Furthermore, since 2019 the SFDA Reference Drug Laboratory Department has been working to develop methods of analysis, such as analysing nitrosamine contaminants in three drug groups – blood pressure drugs, acidity drugs and diabetes drugs – which has already yielded results.

> The SFDA has been working to develop a method for analysing nitrosamine contaminants in three drug groups

RESEARCH STUDIES

We prepare scientific reports and systematic reviews to investigate the effectiveness and safety of the products the SFDA regulates. We carry out studies to monitor and identify product risks, as well as studies that are related to consumer behaviour in order to assess societal trends.

We conduct research studies related to the safety of food products and develop analysis methods to increase the safety of food on the market. Our prior research has included a study on the detection of microplastics in the drinking water in Saudi Arabia.

We also measure the awareness of Saudi society about food safety, which helps to assess consumer confidence in food quality control. In 2020 we published more than 12 papers in international scientific journals. We participate in a number of international conferences to share the latest results of research carried out by the SFDA.

CRISIS MANAGEMENT

Our Crisis Management Department serves to address any crisis that may emerge in relation to food, drugs and medical devices – as such, it played a crucial role throughout the Covid-19 pandemic. The department has created a mechanism to help it efficiently manage crises, ensure the readiness of the SFDA to continue its work and coordinate with external parties in a time of crisis.

ENGAGEMENT

We partner with external research bodies, hospitals, local and international private laboratories, key national institutions such as the King Abdulaziz City for Science and Technology, and other university research centres. We are working to establish a national network of food laboratories in the Kingdom. We are also developing scientific partnership programmes to boost research collaboration between SFDA and universities.

We have recently signed agreements with three main government hospitals in the Kingdom, as well as hospitals and insurance companies in the private sector, to unify patient databases in the National Database for Pharmacoepidemiology. As the first of its kind in the region in terms of design and objectives, we are conducting four research projects to evaluate and develop the National Database for Pharmacoepidemiology, and assess the impact of the SFDA's regulatory legislation.

Microbial genome analysis tests have produced a quantum leap in understanding and tracking the transmission of microbes from food

OPERATIONS

One of the most important aspects of ensuring the safety and quality of products is inspections

The SFDA Operations Sector handles all procedural matters for the authority, including the issuance of operational licences for establishments under the purview of the SFDA; registering products; and issuing clearances for imported products coming in through Saudi Customs points. The Operations Sector also monitors establishments and products for compliance, and imposes legal penalties on violators. It devises strategies to accomplish various missions, and receives consumer complaints and queries about products.

WHAT WE DO FOR YOU

We have safely fast-tracked the average registration period for food products from 10.5 days in 2018 to 1 day in 2020.

INSPECTIONS

We inspect local and international manufacturers of food, drugs and medical devices, as well as retailers of these products. We strive to ensure all food, animal fodder, pesticides, drugs, cosmetics, and medical equipment and products made or imported to the Kingdom comply with regulations, safety standards and consumer requirements.

The Operations Sector inspects drug factories and warehouses. We also conduct inspections of companies in order to confirm that the medical devices in health facilities subject to maintenance by these companies operate at the highest level of quality and efficiency to ensure the safe use of such devices.

One of the most important aspects of ensuring food safety and quality is inspections. We carry out inspections to verify the accuracy of the stated ingredients of circulated foodstuff. We inspect foodstuff during Customs clearance, in production centres such as animal slaughterhouses and food plants, and in the market in places such as restaurants and retail centres. We also inspect butcheries and other meat sale outlets. This is done in coordination with the Ministry of Municipality and Rural Affairs.

The SFDA's inspection work is present throughout the production chain. It doesn't start from the port, but from the point of origin by following the path to producers and manufacturers abroad. These inspections ensure activities are being done at international standards to guarantee safety for the public. Wherever the journey starts, you will find the SFDA there.

REGISTRATION AND LICENSING

We issue licences for establishments that fall under the SFDA's purview, which include import and export licences. We oversee e-services for supplier registration of medical devices, cosmetic products, foodstuffs and animal fodder, and we receive appeals filed against product classifications and open accounts in the classification system.

We have overseen a rapid reduction in the time it takes to register and process products. The number of days needed to register food products has decreased dramatically between 2018 and 2020, from 10.5 days to just 1 day. For fodder products, this was reduced from 163 days in 2018 to 15 days in 2020. The time needed to register cosmetic products, meanwhile, fell from 22 days to 1 day over the same period.

COMPLIANCE AND ENFORCEMENT

We ensure that food, drug, cosmetic, animal fodder, pesticide and medical device companies and importers comply with laws and regulations. We also monitor the compliance of technical sectors with laws, regulations and circulars. The SFDA supervises the application of penalties against violators, which are issued by the Ministry of Trade. Penalties can include direct or indirect actions, and involve giving instructions and suspending products from sale.

HALAL

The SFDA is working to support the expansion of halal industries in Saudi Arabia and make it a hub for the global halal sector. The SFDA Saudi Halal Centre analyses food to make sure it aligns with Islamic regulations and awards halal certificates for food-related service providers. We issue regulations for appointing halal certification bodies; auditing halal facilities; authenticating certificates issued by accredited bodies; and regulating the use of the halal logo and any relevant follow-up compliance. We conduct studies related to halal in order to update and develop specifications. A recent study focused on stun shock for poultry. This was carried out in cooperation with King Faisal University's College of Veterinary Medicine.

SUPPORTING INVESTMENT

The SFDA's Executive Directorate of Investment Development is the voice representing the private sector within the authority. It seeks to expand the SFDA's customer services and incorporate the priorities of the private sector into SFDA regulations. The executive directorate was established in August 2020 in support of Vision 2030, which calls for the private sector to play a pivotal role in transforming health care. A core target of Vision 2030 is boosting foreign direct investment and strengthening national industry by localising more production in the Kingdom, with close coordination and alignment between the Ministry of Investment and the SFDA to ensure cohesive efforts to achieve health care objectives.

This is especially the case in health-related industries. One of the key national goals for reforming the health sector is to optimise government costs and increase private sector investment. The Ministry of Health intends to privatise 290 hospitals and 2300 primary health care centres by 2030. In doing so, the government aims to reduce the burden of public spending while still advancing the quality and capabilities of the sector. Recent regulatory changes mean foreign companies can operate with 100% ownership of health care companies and participate in public-private partnership projects. Having recently implemented a decentralisation model and health service delivery clusters, the sector is committed to enhancing transparency, efficiency and competition in pursuit of quality care.

The executive directorate helps enhance confidence in the SFDA's role locally and abroad by increasing the effectiveness of communication and responsiveness with customers, and boosting international cooperation and participation. By helping develop private sector activity, the centre is also ensuring the availability of food, drugs and medical devices through its support for localisation of industry. Its main objectives are enhancing the effectiveness of communication between the SFDA and customers; improving the investment process; ensuring strong business relationships with investors; and building investment partnerships with other Saudi government bodies. It is also responsible for conducting collaborative partnerships with local government entities. These partnerships are critical to achieving Vision 2030 goals.

WHAT WE DO FOR YOU

The Executive Directorate of Investment Development is the voice that represents the private sector in the SFDA.

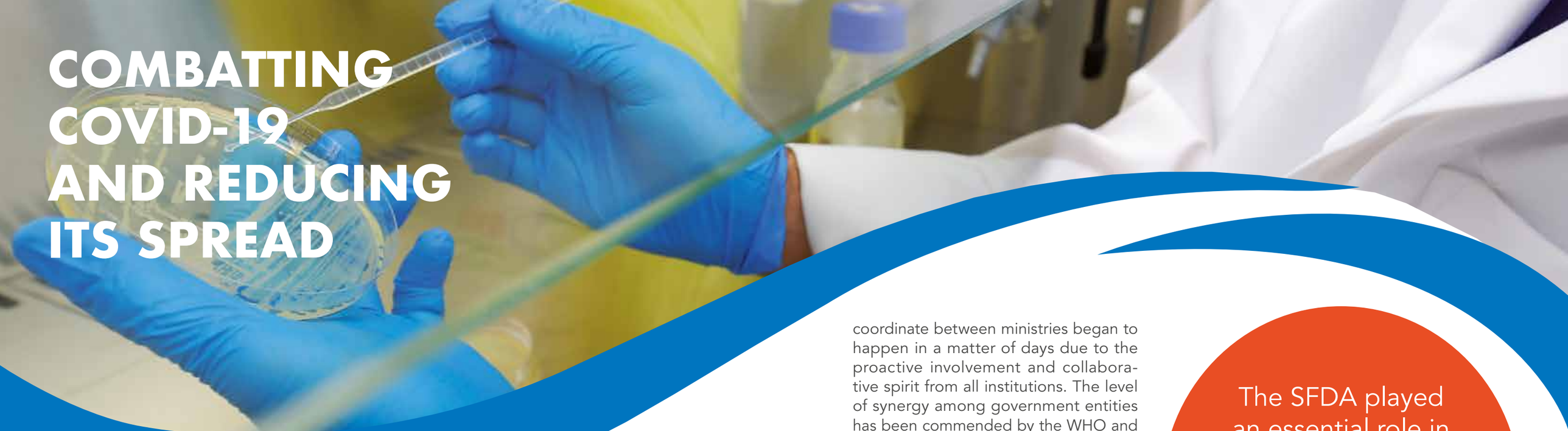
SUPPORTING COMPANIES

We ensure all inputs and opinions of the private sector are constantly incorporated into new regulations, and we help to convey the voice of companies when crafting legislation. Our work is focused on increasing the satisfaction customers feel when engaging with the SFDA in areas such as licensing and registering products. We are contactable on our toll-free number to answer enquiries, covering everything from how to import, to what is and is not permitted according to the regulations.

> The Ministry of Health intends to privatise 290 hospitals and 2300 clinics by 2030

Covid-19 Response

- Timeline
- National Actions
- SFDA Actions
- Future Preparation



COMBATTING COVID-19 AND REDUCING ITS SPREAD

TIMELINE OF THE COVID-19 PANDEMIC IN SAUDI ARABIA

- December 31, 2019 – China alerts the WHO of a pneumonia-like illness in Wuhan with an unknown cause
- January 7, 2020 – China identifies outbreak as a new coronavirus and signs of international spread emerge
- January 2020 – Saudi Arabia forms emergency Covid-19 committee headed by the Minister of Health
- March 2, 2020 – First Covid-19 case recorded in Saudi Arabia
- March 4, 2020 – National restrictions start to be introduced, including the suspension of the Umrah pilgrimage and public gatherings; schools, universities and workplaces move online
- March 15, 2020 – National curfew introduced
- April 25, 2020 – Curfew restrictions start to ease and safety precautions remain in place
- December 10, 2020 – SFDA approves the first Covid-19 vaccine for use in the Kingdom

WHAT WE DO FOR YOU

The SFDA has helped to ensure the continued supply of food, medicines and medical devices for citizens and residents throughout the pandemic.

NATIONAL RESPONSE

Saudi Arabia has made huge efforts to combat Covid-19. Since cases were first reported in China, the government has proactively introduced strict precautionary and preventive measures to combat the virus and reduce its spread.

The Kingdom formed an ad hoc Covid-19 committee at the end of January 2020 to monitor and follow developments of the pandemic. The committee comprised 24 government entities and was presided over by the Minister of Health. Cross-government coordination among state agencies became essential to ensure an integrated and effective crisis management response. What would previously have taken months to organise and coordinate between ministries began to happen in a matter of days due to the proactive involvement and collaborative spirit from all institutions. The level of synergy among government entities has been commended by the WHO and several specialised organisations globally.

SFDA RESPONSE

The SFDA has been at the centre of the government's efforts to counter Covid-19. As a leading actor in the Kingdom's defence, the SFDA has worked throughout the duration of the pandemic to ensure the continued supply of food, medicines and medical devices for citizens and residents. It has done so in cooperation with partners in the government, as well as actors from across the public and private health care sectors.

SUPPLY AVAILABILITY

During the peak of the crisis, the three major areas that the SFDA regulates – food, drugs and medical devices – were in particularly high demand at a time of unprecedented supply chain disruptions. The Kingdom's manufacturing base needed to be repurposed and supply chains made operational again both inside and outside the Kingdom, all while ensuring industry and distribution activities were Covid-safe. The SFDA played an essential role in ensuring supply chains were both operational and following new safety guidelines.

The SFDA played an essential role in ensuring supply chains were both operational and following new safety guidelines

The SFDA has taken steps to ease import restrictions, accelerate registration processes, and provide support to local factories and distributing companies to ensure regulations do not obstruct the manufacturing or supply of products that could save lives. This involved a number of new regulatory interventions.

Monitoring Stocks: The SFDA monitored national stocks to facilitate the availability of medicines and products that were in high demand. This has involved daily follow-up and coordination with major pharmacy chains to collect data on the stock of sanitisers and masks. We conducted a national study on the behaviour of citizens and residents in the use of masks and sanitisers to help estimate the level of consumption and future needs with regard to these products.

Expediting Approvals: The SFDA expedited the evaluation and authorisation process for PPE such as masks, medical gloves and gowns, ventilators and IVD diagnostic kits. It was one of the first regulators to give emergency-use authorisation for Covid-19 diagnostic tests.

The SFDA issued more than 3700 permits to import more than 2.5 billion Covid-19 preventive products from the beginning of the pandemic through to the end of June 2020.

Fast-tracking Imports and Accelerating Processing Times: The SFDA created a fast track for the clearance of vital drugs and medical devices required for the treatment of Covid-19. The authority's efforts included expedited approvals of alternatives for out-of-stock active pharmaceutical ingredients.

The SFDA also created fast-track approvals for manufacturing and importing sanitisers. It was particularly important to ensure that diagnostic kits entered the country as quickly as possible and did not stay in transport for too long.

Repurposing Aircraft: The SFDA worked with representatives of Saudi Airlines' cargo operations on logistics efforts and had over 16 aircraft bringing supplies to the country every day.

Enhancing Guidance Given to Producers and Manufacturers: The SFDA worked closely with producers and manufacturers, and published an emergency pharmaceutical registration guide. In addition, we supported local scientists and researchers who worked on developing diagnostic options for Covid-19. We worked 24/7 to process urgent import requests, which involved addressing thousands of inquiries and challenges facing the private sector, such as hurdles to producing critical supplies. These were dealt with immediately over all days of the week and around the clock.

Maintaining and Increasing Local Production: Major efforts were taken to boost production capacity at local factories. The SFDA worked with the Ministry of Industry and Mineral Resources, the National Industrial Clusters Programme, the Saudi Industrial Development Fund and the Local Content Authority to boost the output of prevention products.

We helped to oversee an expansion of Saudi medical manufacturing – especially for PPE – to cover a large share of domestic demand. We produced guidance for manufacturing medical devices during the pandemic and helped to ensure the availability of raw materials to avoid supply line disruptions. The authority coordinated with the National Industrial Clusters Programme and Saudi Basic Industries Corp (SABIC) regarding the provision of raw materials related to the manufacture of masks and sanitisers. We also strengthened partnerships with the private sector to ensure abundant food supplies.

Furthermore, the SFDA reviewed fodder stocks and the production capacity of facilities to minimise interruption along the value chain. In the medical devices segment, we facilitated international collaboration by encouraging Saudi medical device manufacturers to work closely with Korean manufacturers to develop Covid-19 tests.

Issuing Travel Permits: The SFDA was responsible for issuing letters that allowed key industry personnel to travel during the curfew in order to facilitate manufacturing and monitor the supply chains of food, drugs and medical devices.

Suspending Exports: On March 2, 2020 Saudi Arabia suspended the export of pharmaceuticals and medical devices to ensure their availability for citizens and residents. The SFDA noticed that a lot of travellers were taking large quantities of PPE out of the country at the beginning of the crisis, and the authority brought a rapid stop to this.

Keeping Pace with Global Regulations: We adopted global changes in medical device regulation and regularly met with key bodies, including the GHWP and the IMDRF.

Sanitiser: Ensuring the availability of sanitiser in the Kingdom required significant efforts. At the beginning of the pandemic Saudi Arabia was at risk of depleted stocks for hand sanitiser, with nine local manufacturers of the product. The SFDA worked with SABIC and Saudi Aramco to bring in raw materials and within a few weeks was able to secure more than 11,000 tonnes from outside the Kingdom. The authority also helped boost local production of sanitiser so that 70 manufacturers were producing more than 4 million litres.

Masks: Demand rose from 100,000 masks per day to 4 million-5 million per day. The SFDA was able to import nearly 1 billion masks in one month.

> "The SFDA was responsible for issuing letters that allowed key industry personnel to travel during the curfew in order to facilitate manufacturing and monitor the supply chains of food, drugs and medical devices"

VACCINE PREPARATION

The SFDA went to great lengths to make sure a safe and effective Covid-19 vaccine would be available to the country. This included proactive engagement with vaccine producers to combat obstacles that might cause supply shortages. We created a fast track to evaluate pre-clinical and clinical studies of Covid-19 vaccines, and issued a weekly scientific report intended for vaccine and pharmaceutical stakeholders. Another fast track was established to review clinical trial protocols and approve an international joint clinical trial for treating Covid-19.

PUBLIC AWARENESS CAMPAIGNS

The SFDA launched an effective public communications campaign to enhance Covid-19 awareness. This targeted health workers, biomedical and clinical engineers, food specialists, workers in food production facilities and consumers.

Initiatives under the campaign included enhancing the SFDA Tameni app by creating a Covid-19 information page that shared updates, warnings, initiatives and measures taken by the authority. The app also allowed consumers to locate pharmacies where sanitisers and face masks were available to purchase. The April-May 2020 Ramadan At Home initiative focused on following a healthy diet and avoiding food poisoning during the month of Ramadan, in addition to safe and correct practices to taking medicine.

The SFDA produced leaflets on shopping safely to prevent the spread of Covid-19 during essential trips to the store. These detailed how to prevent transmission of the virus and offered advice for delivery representatives. We published awareness material online to promote public health during the pandemic, including nutrition advice and how to maintain a healthy lifestyle. Moreover, the authority conducted online webinars on topics such as the safe use of medical devices, as well as online workshops to alleviate the public's concerns that food might be a vehicle for the virus.

SAFETY MONITORING

The SFDA carried out a number of tests on important products to fight the pandemic, including a test for detecting microbial contamination of medical masks; waterproofing tests for medical gloves; and a test on sterile medical products packaging.

We also verified the safety and compliance of sanitising products. As these products shot up in importance and demand, we launched a programme to test the quality of sanitisers and look at potential toxicity levels in ingredients. It was found that some manufacturers were using ethanol, which is toxic. As a result, orders were made to withdraw substandard products from the market.

Relying on technology, the SFDA instituted virtual inspections for some institutions and manufacturers – a move that protected the health of the SFDA team, created efficiencies and expedited the application of technology in more operations. Instead of traveling 200 km, SFDA teams arranged virtual meetings so that assessments could be made.

SAFETY GUIDANCE

We enhanced communication with manufacturers and published a number of guides on new safety protocols. Examples include a clinical study guide for pharmaceuticals during the pandemic and guidance for protective measures in fodder facilities to ensure continued operation. We reached out to manufacturers to ensure the safety, efficacy and performance of medical devices, and conducted maintenance if needed. Additionally, we distributed safety guidance for health care practitioners that included best practices when using medical face masks, ventilators and isolation units. We also produced recommendations on how to support business remotely.

ADAPTING OUR SUPPORT

Within a week the SFDA moved its call centre online and gave all staff the ability to work from home to protect the health of employees.

SUPPORTING OTHERS THROUGH INTERNATIONAL ASSISTANCE

The SFDA has worked with and supported the international community during the Covid-19 crisis. This included supporting other countries, sharing knowledge and experiences, and providing consultations to ensure others were equipped to respond. Support was given across the GCC, the eastern Mediterranean and worldwide. Efforts included participating in the WHO consultative task force on regulating PPE, and studying and adopting PPE specifications – including for face masks – with the GCC Technical Committee 11 on Medical Devices and Supplies. We supported countries in medical device regulation through the SFDA-WHO Collaboration Centre for Medical Devices.

In May 2020 the SFDA participated in a WHO meeting in support of the African Medical Devices Forum. The SFDA provided its expertise on medical devices in areas including Covid-19 tests, PPE, ventilators and post-market surveillance reporting. We convened an emergency Heads of Food Agencies Meeting in August 2020 where each country shared challenges they faced and their business continuity plans, which proved to be a success.

PREPARING FOR FUTURE PANDEMICS

The SFDA learned a lot from the Covid-19 pandemic. We now have the experience and knowledge to ensure national stocks of food, drugs and medical devices, and can protect the safety of employees in the event of a future crisis. We are continuing to work on several policy regulations and collaborating with the international community to share as much information as possible on lessons learned and preparations for the future. In this vein, we can rely on technology much more than previously thought to communicate during a crisis.

> The authority created a fast track to evaluate pre-clinical and clinical studies of Covid-19 vaccines

The SFDA is engaged with a lot of projects, including on national security for medication, medical devices and food. We are assessing where there were gaps that need to be plugged and what investment is required to do this. So far we know that more focus is needed on local manufacturing of medication and medical devices, thus we continue efforts on our long-term goal of bringing businesses into the Kingdom to set up manufacturing operations, especially for PPE.

The country also needs to further diversify its food supply chains and expand the sources it buys food from to avoid single-source products. Advanced international collaboration in this and other regards will be critically important.

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