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PROTECTING AND PROMOTING

PUBLIC HEALTH

SFDA

الهيئة العامة للغذاء والدواء

Saudi Food & Drug Authority

Foreword

Welcome to the third edition of the Saudi Food and Drug Authority (SFDA) publication, *Protecting and Promoting Public Health*, where we showcase some of our latest achievements.

As the national authority responsible for regulating the safety of food, drugs, medical devices, cosmetics, pesticides and animal feed across Saudi Arabia, we strive daily to safeguard the health and well-being of the public. Our services cater to the needs of the public, health care providers, companies and investors, and we are always ready to serve their interests.

We take great pride in our accomplishments over the past year, with the implementation of new regulations and the launch of innovative initiatives that bolster our mission – all of which is enabling us to achieve our vision of being among the best food and drug regulators worldwide.

In this edition, you will learn more about our efforts to support the expanding network of local manufacturers within the domains we regulate, in line with Saudi Arabia's national goals. You will also learn about international collaboration and participation in global initiatives in which we share best practices and help to advance international regulatory standards.

As Saudi Arabia progresses towards the ambitious goals of Vision 2030, the SFDA remains steadfast in supporting the transformative changes taking place across the Kingdom. Through the dedicated work of our diverse teams, we are helping to achieve a vibrant society, a thriving economy and an ambitious future.

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SFDA IN BRIEF

PRODUCT REGISTRATIONS

The SFDA completed the following product registration requests in 2022:

150,756
food products

110,145
cosmetic products

42,032
medical device products

3549
feed products

322
drug products for human consumption

126
herbal drug products

64
pesticides

26
veterinary drugs

CLEARANCES

Completed clearance requests in 2022:

227,261
food and feed

19,937
drugs and cosmetics

6676
medical devices

INSPECTIONS

Inspections conducted in 2022:

6546
medical devices

1591
drugs and cosmetics

673
food and feed

FOOD

10,000
food samples collected from local markets and analysed in our laboratories (2022)

5950
food alerts detected, assessed and responded to (2022)

Vision 2030 Achievements

Healthier and happier lives

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

Between 2016 and 2020 average life expectancy in the Kingdom increased from 74.8 years to

75.3 years

Saudi Arabia was ranked

3rd

in the Arab World in the the United Nations (UN) World Happiness Report 2020

> Saudi women are realising their potential at all levels across the organisation. We are working to continuously increase the rate of female participation.

SUPPORTING VISION 2030

Vision 2030 serves as Saudi Arabia's transformation strategy, encompassing the economy and society at large. Since the framework's launch in 2016, Saudi Arabia has witnessed both unprecedented change and remarkable growth. As a key regulatory body entrusted with safeguarding and promoting public health, the SFDA plays a crucial role in realising the objectives outlined in Vision 2030.

Empowering investors and supporting the private sector is one of our top priorities. The government is committed to unlocking the full potential of the food, drug and medical device sectors, and is actively seeking partnerships and investment to expand these key areas of the economy. As part of Vision 2030, we support the government's efforts to create new business opportunities, leverage Saudi Arabia's key strategic assets, and drive economic growth and diversification. At the SFDA we encourage the expansion of local manufacturing, support local enterprises in the sectors we regulate, and assist with the expansion of global businesses in the Kingdom.

The Kingdom's future-orientated economy offers unique business opportunities with significant untapped potential. With a population of over 35 million – of which nearly 60% is under the age of 35 – we regulate the largest market in the GCC and one of the largest in the MENA region. With the implementation of supportive government legislation in recent years, we are becoming one of the most dynamic markets in the region, especially in terms of bolstering the private sector.

The SFDA plays an important role in transforming the health sector and expanding health care infrastructure. Our efforts are guided by Vision 2030's Health Sector Transformation Programme, which is an integral component of the Kingdom's Vision Realisation Programmes. At present, the health care sector is largely publicly financed. Plans for further development focus on achieving greater privatisation of services, fostering public-private partnerships, elevating the quality of care, implementing virtual platforms and enhancing health service through supply chain reform.

At the SFDA, our people are the driving force behind our success. As His Royal Highness Crown Prince Mohammed bin Salman bin Abdulaziz Al Saud said, "Our real wealth lies in the ambition of our people and the potential of our younger generation." We have a team of highly educated men and women who are dedicated to bringing about positive change for the greater public good. Saudi women are now realising their potential and ambitions by working at all levels across the organisation. We are working to continuously increase the rate of female participation.

We are also aiming to achieve a more sustainable future. As such, the SFDA is actively supporting Saudi Arabia's ambition of reaching net-zero carbon emissions by 2060. We are constantly striving for operational excellence by becoming a more dynamic and efficient organisation. Guided by the goals set in the Vision 2030 development roadmap, we are laying a strong foundation for the future.

Saudi Arabia has a distinctive value proposition, offering numerous opportunities for investors to expand in the sectors we regulate. An open Saudi Arabia presents enormous potential. The Kingdom boasts a strategic location at the heart of major trade routes spanning three continents. The country is a G20 economy with a young, highly educated population of over 35 million. The SFDA is ready to support investors at every step of the way. The Saudi Ministry of Investment provides market intelligence and offers consultancy services, visa support and other services to assist investors.

PHARMACEUTICALS & BIOTECH

In the pharmaceuticals and biotech domains, Saudi Arabia is advancing scientific research from early drug discovery to clinical trials. These pursuits aim to enhance manufacturing capabilities and establish the Kingdom as a prominent regional export-oriented centre. Additionally, infrastructure development for a thriving biomedical ecosystem is a key focus, supported by multi-sectoral partnerships, favourable policies, competitive incentives, expertise and sustained financing. Priority areas include clinical research, personalised medicine, value-based health care, artificial intelligence in drug discovery, the localisation of biologics and vaccines, and cell and gene therapy.

$8.5 billion
The value of Saudi Arabia's pharmaceutical market

5.7%
Expected compound annual growth rate between 2023 and 2029, owing to population growth and rising demand for chronic disease treatment

37%
Saudi Arabia's share of the MENA pharmaceuticals market

73%
The mortality rate in Kingdom due to non-communicable diseases (NCDs)

The Kingdom has significant market demand across several pharmaceutical segments, including:

Vaccines	Systemic antibacterial	Oncology	Insulin and analogues	Immuno-suppressants
$641 million	**$631 million**	**$353 million**	**$341 million**	**$313 million**

Saudi Arabia will become a biotechnology and biopharmaceutical centre in the MENA region:

First Mover – New investors have a first-mover advantage given the small number of local production facilities and the limited presence of leading global pharmaceuticals manufacturers

Large Market – Investors can capitalise on local demand and expand their regional footprint by leveraging Saudi Arabia's strategic location and favourable trade agreements with neighbouring countries

NEW OPPORTUNITIES

MEDICAL TECHNOLOGIES & HEALTH CARE

In the areas of medical technologies and health care services, Saudi Arabia is targeting increased usage of medical technology for diagnosis, treatment, and improving individuals' health and well-being. The strategy's objectives include remote consultations and Software as a Medical Device, a software used to carry out medical functions, to serve patients more effectively and efficiently. A key priority is the localisation of medical technologies' supply chains. This offers substantial potential to improve the quality of patient care and reduce costs.

- $5.4 billion – The value of Saudi Arabia's medical technology market in 2021
- 5.8% – The expected compound annual growth rate of the health care services market between 2023 and 2029

The sector offers a strong value proposition:

- Commitment – One of the key goals of Vision 2030 is to increase the quality of life for Saudi Arabia's population
- Future Demand – Saudi Arabia's large, young population represents an incredible market demand not just today, but also for the future
- Substantial Funding – The health care sector accounted for 17.7% of the country's budget expenditure in 2021, making it the Kingdom's third-largest recipient of government funding
- Medical Technology Centre – Saudi Arabia is the region's emerging medical technology centre

AGRICULTURE & FOOD PROCESSING

In the areas of agriculture and food processing, the Kingdom is seeking to establish itself as a leader in the $1.3 trillion global halal industry. Saudi Arabia's food and beverage market is the largest in the Middle East, and the country's food processing sector is poised to expand rapidly in the coming years. Domestic, regional and worldwide demand for Saudi food items has been rising year after year, with seafood, dates and the halal market, in particular, leading the way.

- $42 billion – The value of Saudi Arabia's food and beverage market, making it the largest in the Middle East
- 3% – The expected annual growth rate for the food and beverage market up to 2030
- 85% – The Kingdom's 2030 target for the localisation of food processing

The country offers a large and growing local market, and opportunities for expansion in regional markets.

- Halal Industry – Saudi Arabia is aiming to lead the $1.3 trillion global halal industry
- Future Demand – The food and beverage market is fuelled by a growing population, an increase in the number of Hajj and Umrah pilgrims, and a growing focus on national resilience and food security
- Export Market – Saudi Arabia's unique dates endowment and nutrient-rich soil provide excellent potential for the export of high-quality and distinct dates

Date farms and abundant fish stocks further solidify Saudi Arabia's position as a lucrative export market.

- Dates – Saudi Arabia has 31 million date palms across 123,000 farms and produces over 400 different types of dates
- Top-Three Date Producers – The Kingdom accounts for 18% (1.6 million tonnes) of the global date harvest of approximately 9 million tonnes per year, positioning it among the top-three global producers of dates
- Fish Demand – Domestic consumption of fish is expected to grow by 5% per annum between 2023 and 2030, increasing from 310 tonnes to approximately 436 tonnes
- Fish Stocks – Saudi Arabia boasts a fish capacity of 5 million tonnes, and is able to expand its large production capacities to target high-demand markets such as the EU

LATEST INITIATIVES & PROGRESS

2022 ACHIEVEMENTS: FOOD

10,000 FOOD SAMPLES COLLECTED

In 2022 we collected over 10,000 samples from local markets and analysed them in our laboratories to ensure the safety of products in the food chain as part of the National Programme for Food Monitoring and Control (NPFMC). The NPFMC aims to integrate and streamline efforts in food monitoring and control operations. To further enhance our capabilities, the programme has recently expanded to include packaging monitoring. This addition allows us to gain a better understanding of the sources of food contamination and effectively control the safety of final products.

5950 ALERTS ASSESSED

In 2022 our Rapid Alert Centre for Food (RACF) dealt with 5950 alerts and took appropriate actions in response. The RACF effectively monitors and evaluates food alerts and reports at local, regional and international levels to ensure the safety of food for consumers. A key responsibility of the RACF is managing and maintaining the electronic programme for the Gulf Rapid Alert System for Food and Feed, facilitating information exchange among GCC countries to protect the regional food chain.

The RACF collaborates with regulatory authorities to implement precautionary measures, safeguard consumer health, prevent unsafe food from entering local markets, halt its circulation and issue warnings to consumers. It serves as a contact point for exchanging information with food safety agencies such as the EU Rapid Alert System for Food and Feed and the International Food Safety Authorities Network. This proactive communication ensures swift and effective international coordination to address food chain safety concerns.

ANIMAL FEED

The SFDA launched a programme for monitoring and controlling feed contaminants across markets, factories and border ports. The main objective is to enhance the safety of feed for animals designated for human consumption. Key actions include reducing the presence of mycotoxins, heavy metals and pesticide residue to ensure compliance with maximum residue levels, and minimising contamination by microbes within permissible limits set by the government. Animal feed safety is critical to food chain safety. Through the use of the farm-to-table principle, the SFDA plays a crucial role in safeguarding feed for animals that are later consumed by humans. The SFDA has also launched an educational campaign on pesticide safety. The campaign aims to raise awareness about the proper handling, safe usage and storage of pesticides.

LATEST INITIATIVES: FOOD

The SFDA has implemented a range of initiatives and nutritional policies to tackle obesity and other related NCDs by actively promoting a reduction in sugar, salt and fat intake. The following highlights some key initiatives and policies that have been implemented in recent years:

HIGH-NUTRITIONAL-VALUE LABELLING

In 2021 we introduced the Saudi Nutrient Profiling Model (SNPM) to effectively classify food products as either high or low in nutritional value, based on their nutritional composition. Following this milestone, we implemented detailed regulations pertaining to nutritional labelling, allowing producers to display a high-nutritional-value label on the front of their product packaging if it meets the criteria established by the SNPM. This programme has encouraged producers to reformulate their products and expand the availability of high-nutritional-value food options.

ADVERTISING TO CHILDREN

The SFDA has developed guidelines focusing on controlling and regulating food advertising aimed at youth under the age of 12. Children are frequently exposed to advertising that promotes food products with high levels of saturated fat, salt and sugar (HFSS products). This can influence food preferences and consumption patterns, and result in health conditions including diabetes and obesity. As part of our research, we surveyed popular, local YouTube channels for children featuring advertisements for HFSS food products.

SAUDI DIET AND NUTRITION SURVEY

The recent Saudi Diet and Nutrition Survey in Riyadh collected precise data on food and beverage consumption among individuals aged 12 and older. This data, especially individual-level information, is essential for comprehending dietary patterns, nutrient intake and potential food hazards within the population. This survey data serves as the cornerstone for evidence-based food and nutrition policy development and implementation.

SAUDI TOTAL DIET STUDY

The Saudi Total Diet Study is a strategic food safety initiative aimed at systematically monitoring and assessing contaminants and nutrients present in the typical diet of the Saudi population. The primary objective of this programme is to implement effective control measures that mitigate food safety risks and enhance the overall nutrition of the population. The research involves procuring representative samples of the most commonly consumed food items among the Saudi population. The samples are then prepared following popular cooking and consumption practices, ensuring a realistic and accurate representation of dietary habits.

WORLD FOOD SAFETY DAY

In celebration of World Food Safety Day, on June 7, 2022, the SFDA organised a session focused on the safety and sustainability of modern food. The discussion addressed topics such as the role of biotechnology in food products, the emergence of modern protein alternatives and advancements in food innovation. It provided a platform to discuss the latest developments and challenges in the food industry, and aimed to foster awareness and knowledge regarding food safety and sustainability.

The SFDA actively engages with the public through social media platforms. The authority conducted polls to gauge public interest in new food sources and technologies. Additionally, the SFDA shared information about its pivotal role in ensuring food safety and invited outside participation in the session. The authority also conducted two online webinars. The first focused on raising awareness about antimicrobial resistance, and the second emphasised the importance of individual contributions in building a safe food system and creating a secure society.

FIGHTING ANTIMICROBIAL RESISTANCE

As bacteria develop increased tolerance or resistance to antibiotics, we risk the return to a period when both animals and humans face heightened challenges fighting infection. The SFDA has established a regulatory roadmap aimed at controlling antimicrobial resistance.

TOBACCO PLAIN PACKAGING

In late 2022 the SFDA assumed leadership of the new World Health Organisation (WHO) Collaborating Centre for Tobacco Plain Packaging, leveraging its expertise to support the WHO. This initiative focuses on sharing best practices and offering guidance to countries aiming to implement similar policies for plain packaging of tobacco products, thereby curbing their use. In 2019 Saudi Arabia became the first country in the region to introduce plain packaging for tobacco products, with the SFDA playing a pivotal role in its implementation. Given that smoking is a leading preventable cause of death, claiming around 8 million lives globally each year, reducing smoking rates has become a worldwide public health priority.

A survey conducted by the Ministry of Health revealed a high smoking prevalence in Saudi Arabia, affecting 24% of the population. As a result, the Kingdom actively explores global strategies and practices in the battle against tobacco use.

LATEST INITIATIVES: MILK SAFETY

The SFDA has implemented a series of measures to guarantee the highest levels of safety and international quality in infant formula, follow-up milk and milk intended for medical use

1 Updating technical regulations related to milk for infants and children to align with the most current international standards

The SFDA has approved the update to the Saudi Technical Regulation GSO.SFDA.FD 2106 Infant Milk, Follow-Up Milk and Milk Intended for Private Medical Use

2 Ensuring the presence of the highest international standards of safety and quality in breast-milk-substitute products for infants and children by analysing the products found in the local market, and confirming that they comply with the technical regulations and standard specifications that guarantee the safety and quality of products

3 Conducting studies and research related to breast-milk-substitute products for infants and children

4 Targeting countries and facilities exporting breast-milk-substitute products for infants and children

5 Targeting consignments of breast-milk-substitute products, including the collection of samples and subsequent referral to accredited laboratories for analysis

RECENT EFFORTS: DRUGS & COSMETICS

INNOVATIVE PRODUCTS

We have recently put into effect a number of initiatives to enhance consumer safety for new products. These include implementing stringent regulatory quality standards to effectively mitigate risks associated with nitrosamine impurities; developing more than 30 monographs for herbal and health products through the SFDA's Tameni application; assessing the first oral medication for Covid-19, Paxlovid; and assessing the first novel Saudi herbal product, Healarido, which is derived from myrrha, a traditional Arabian herb.

ADDRESSING MEDICATION ERRORS

The SFDA has taken several measures to tackle medication errors and enhance medication safety. These include evaluating patients' perceptions regarding the clarity of information on the external packaging of paediatric pharmaceuticals, as well as increasing awareness among health care practitioners about pharmacovigilance activities. The SFDA recently joined the International Medication Safety Network (IMSN), which focuses on reducing medication errors, facilitating the establishment of drug safety centres and fostering cooperation among member countries. Being a part of the IMSN allows the SFDA to stay updated with global developments in drug safety, engage in continuous discussions through annual meetings and the network's electronic forum, and contribute to the creation of educational materials on drug safety. Our ongoing work to prevent medication errors includes developing naming and packaging guidelines for pharmaceutical products, reviewing packaging and verifying information. The SFDA actively monitors medication error reports associated with registered products.

NATIONAL PHARMACOVIGILANCE CENTRE

In 2022 the contribution of the National Pharmacovigilance Centre (NPC) to drug safety included publishing over 20 validated signals on the SFDA website. The NPC has also taken the initiative to translate the international Medical Dictionary for Regulatory Activities into Arabic, in collaboration with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. This translation serves the dual purpose of allowing individuals to report adverse drug reactions in their native language and facilitating the technical structuring of the national database.

The NPC has recently joined various regional and international working groups, including the UK-based Drug Safety Research Unit's international working group on new developments in pharmacovigilance and the WHO's regional advisory network for the pharmacovigilance of Covid-19 vaccines for Eastern Mediterranean countries. Through these memberships, the NPC actively contributes its expertise, collaborates with other stakeholders and keeps abreast of the latest advancements in pharmacovigilance practices.

WHODRUG GLOBAL LICENCE

The SFDA recently expanded its contract with WHODrug Global Licence by adopting the use of WHODrug Insight, an advanced software tool. WHODrug is a standardised drug coding dictionary designed to facilitate the classification and coding of drugs. This addition aims to enhance the evaluation process of trade names, and further improve the safety and efficacy assessment of drugs before their registration.

WARNING LABELS

In line with our proactive stance on medication safety, we have taken effective measures to address concerns in this area. Specifically, we have introduced prominent warning labels on the packaging and labels of registered pharmaceutical products classified as neuromuscular blocking agents. These labels explicitly state that the product is a paralysing agent. Our objective is to bolster post-marketing safety, mitigate the risk of medication errors and minimise the occurrence of serious side effects.

> Our efforts to prevent medication errors include developing naming and packaging guidelines for pharmaceutical products.

INTERNATIONAL COOPERATION

To enhance international cooperation, the SFDA has signed a memorandum of understanding with the French Agency for Food, Environmental and Occupational Health & Safety. Additionally, an initial agreement has been established with the UK's Veterinary Medicines Directorate.

LATEST INITIATIVES: DRUGS & COSMETICS

GENERIC QUALITY ASSESSMENT

The SFDA recently initiated multiple projects to improve the evaluation process of our generic drug quality assessment work. These initiatives involve comprehensive screening studies of all chemicals used in synthesis routes, along with predicting potential mutagenic impurities during the stability period of the active pharmaceutical ingredient and in the finished pharmaceutical product.

PRE-MARKET COSMETICS EVALUATION

Introducing an optional service, the authority allows for the evaluation and verification of cosmetics claims prior to their market placement. This process provides an additional layer of scrutiny to ensure the accuracy and validity of claims made by cosmetic products.

COSMETICS CONSUMER KNOWLEDGE

Through awareness campaigns, the SFDA aims to educate consumers on the safe usage of cosmetics. This includes conducting informative workshops targeted at university students and health care providers, equipping them with essential knowledge regarding the proper and safe use of cosmetics, as well as publishing awareness materials across the SFDA's media channels to disseminate valuable information to a wider audience, and promote responsible and informed cosmetics usage.

COSMETOVIGILANCE SYSTEM

The authority has implemented a dedicated cosmetovigilance system for the safety monitoring of cosmetic products. The system helps in the detection of cosmetics with adverse effects, allowing us to promptly respond appropriately to prevent and mitigate potential risks.

LOCALISATION OF CLINICAL TRIALS

The SFDA is advocating for the localisation of clinical trials, including bioequivalence studies, with the objective of increasing the number of trials conducted within Saudi Arabia. This initiative is expected to have a positive impact on the development of the pharmaceutical industry, as well as on research and innovation.

RISK COMMUNICATION FOR MEDICINES

To enhance risk communication regarding medicines in Saudi Arabia, the SFDA has put in place several initiatives. These efforts include collaborative efforts with regional pharmacovigilance centres and hospitals, as well as conducting visits to promote awareness and ensure the proper implementation of risk minimisation measures. Additionally, the Tameni app provides concise summaries of risk mitigation measures in both Arabic and English, serving as a valuable resource for patients.

The SFDA proactively gathers feedback and recommendations from health care professionals and patients through surveys to improve the content and design of risk minimisation measures. The authority conducts stakeholder workshops with the aim of enhancing the implementation and communication of risk reduction strategies. The SFDA also publishes articles on vaccine safety, including guides for parents, to increase public awareness. Furthermore, the organisation is currently developing an electronic platform for health care professionals to evaluate the effectiveness of digital materials related to risk mitigation techniques.

RECENT WORKSHOPS

To enhance communication with industry and provide regulatory updates, the SFDA has held several workshops and events. Our workshops target local and global companies, as well as regional and international regulatory authorities. These have included:

- A hybrid training session on stability testing for drug substances and drug products
- A hybrid workshop on quality variation in pharmaceutical products: requirements and conditions
- A hybrid workshop on biosimilars from a development and regulatory perspective. This presented the fundamentals of biosimilar development. It also included extensive discussions on the SFDA's regulatory requirements for biosimilar registration.
- Two workshops focused on measuring clinical outcomes in trials of haematological and oncologic diseases. The workshops aimed to consult with local and international stakeholders to establish the best clinical outcomes for these diseases.
- A symposium on modelling and simulations, which was shared with the International Coalition of Medicines Regulatory Authorities
- A technical workshop on the quality, safety and efficacy of herbal and health products
- A technical workshop on post-marketing changes concerning pharmaceutical products

The SFDA has played a leading role in numerous events, fostering knowledge exchange with relevant stakeholders. Some instances have included:

- Participation in an industrial hackathon to support innovative ideas and solutions aligned with the needs of national drug manufacturers. This initiative aimed to address challenges specifically related to product manufacturing.
- Involvement in the annual meeting with the WHO and International Regulatory Cooperation for Herbal Medicines, where the SFDA is ranked among the leading regional agencies in the field of herbs and medicinal plants
- Engagement in a regional WHO workshop on the quality of traditional and complementary medicine
- Contribution to multiple working groups of the International Pharmaceutical Regulators Programme, including nanomedicine, quality control, biosimilars, cell and gene therapies, and e-labelling

RECENT EFFORTS: MEDICAL DEVICES

CUPPING DEVICES

Due to their increased usage, the SFDA has successfully proposed a new international standard for the safe use of cupping devices. Existing international standards have focused on industrial requirements and neglected device safety. The initial proposal – which includes requirements for device safety, addressing reuse restrictions, sterility, cleaning and disinfection, packaging and label checks, disposal, and user manual and leaflet verification – was presented in 2018 and became an international standard in November 2022.

WHO COLLABORATING CENTRE

In 2022 the WHO re-designated the SFDA as a WHO Collaborating Centre for Medical Devices Regulation for the next four years. Additionally, the facility received approval to elevate its status from a regional to a global centre covering the Eastern Mediterranean Region and Africa. As a WHO Collaborating Centre, the authority supports the WHO's scientific and technical endeavours around the world. The centre's primary objective is to assist other countries in regulating medical devices and building capacities in this critical field.

OUR LATEST INITIATIVES

Clinical Trials

Significant progress was made in 2022 in the SFDA's Clinical Trials initiative. Six events and workshops were held that focused on guidance and requirements for clinical trials involving medical devices. An electronic system was also developed to expedite the evaluation of applications and ensure regulatory compliance. The aim of the initiative is to increase the number and quality of clinical trials for medical devices in Saudi Arabia by addressing any challenges in the clinical trials system and establishing effective regulatory policies for studying medical devices.

The SFDA has evaluated 160 applications since 2015, resulting in 94 approval letters for clinical trials. In 2022, 44 applications were received, leading to 25 approvals, while eight applications remained under review and the SFDA rejected the other 11. Furthermore, four approvals were granted for trials involving innovative medical devices and in vitro diagnostics (IVDs), fostering the local development of such technologies. The initiative is in line with the SFDA's goal of studying all medical devices in the Kingdom to collect data regarding their safety and performance.

Local Manufacturing

In 2022 the SFDA conducted 20 workshops and held over 35 meetings to support local manufacturers. The workshops covered a number of different topics, such as requirements for authorising the marketing of medical devices and risk classification rules, while the meetings clarified requirements and licensing procedures.

Following the implementation of the new Medical Device and Products Law in August 2021, the SFDA launched an initiative to support investors and manufacturers in localising the manufacturing of such devices. This initiative aims to clarify the necessary technical procedures and regulatory requirements for manufacturing, targeting investors, local manufacturers, research centres and authorised representatives of overseas manufacturers. The SFDA is also working together with government entities to facilitate market entry for potential investors.

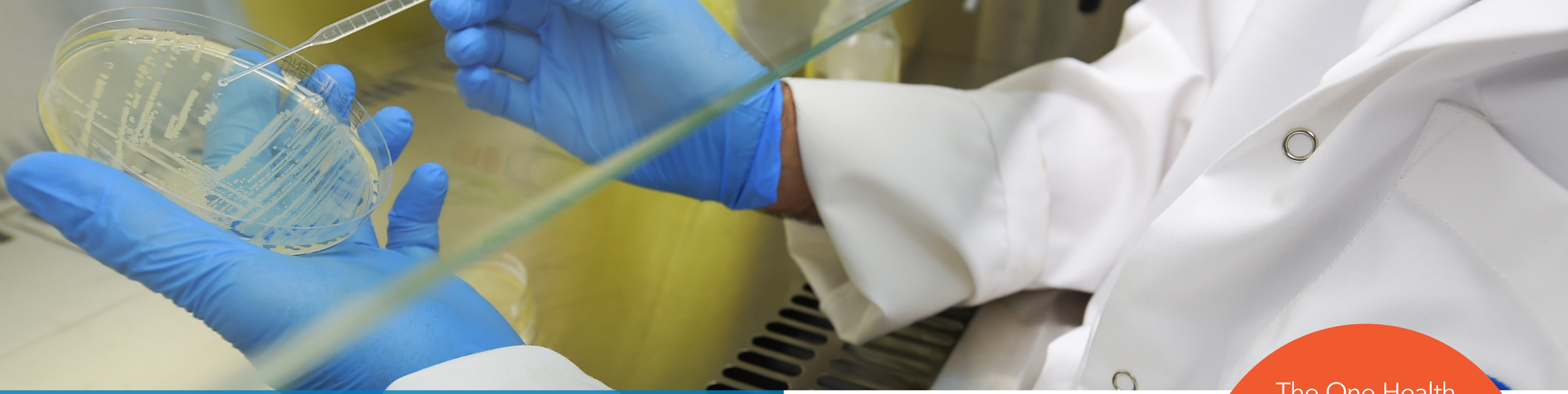
After a new law regulating medical devices took effect at the end of 2022, the SFDA granted approval to 14 local manufacturers. These approvals resulted in 26 authorisations for marketing medical devices, covering 269 products. These products, manufactured in Saudi Arabia, have various risk classifications, including high-tech items such as catheters, ventilators, Covid-19 tests and glucometers. With the number of local manufacturers rapidly increasing, the SFDA has received numerous requests for the local manufacturing of medical devices. The authority intends to promote the development of local manufacturers that are capable of producing competitive products for both the domestic and international markets.

Innovative Medical Devices and IVDs

In 2022 the SFDA organised a series of workshops to introduce a pathway for the regulatory approval of locally developed medical devices. This brought together researchers from universities, inventors, manufacturers of innovative medical devices and authorised representatives. The workshops were part of an initiative to support the development of local innovative medical devices and IVDs as part of efforts to localise the medical device industry.

The goal of the initiative is to familiarise Saudi inventors with the regulatory process and provide them with scientific evaluation support to enhance their chances of success in developing local medical devices. The authority targets specific manufacturers of novel devices, for obtaining registration and marketing authorisation to expedite the regulatory process for patients to access the latest technologies. Having access to such advanced technologies can greatly enhance the efficiency and effectiveness of the Kingdom's health care system.

The success of the initiative has led the SFDA to endorse and evaluate several locally developed innovative medical devices and IVDs. These devices include diagnostic devices that are designed to measure and evaluate the efficiency of the human respiratory system and its disorders; devices that are able to assess an individual's sense of smell; and non-invasive blood glucose level sensors that utilise advanced machine learning and artificial intelligence algorithms.



RECENT EFFORTS: LABORATORIES

REFERENCE LABORATORY FOR FOOD CHEMISTRY

One of the key successes of the reference laboratory for food chemistry (RLFC) is the timely response to enquiries from the SFDA's food department enabled by the compilation of detailed technical reports. The laboratory has also made progress in developing and validating food chemistry methods, with a focus on establishing a way to determine the presence of natural toxins, such as pyrrolizidine alkaloids, in honey and herbs. Furthermore, it conducted a study to investigate the occurrence of pesticides in herbal supplements, and the findings were shared with the appropriate authorities.

The RLFC also employs artificial intelligence techniques to predict unknown chemical compounds in food using well-established scientific libraries. In addition to ensuring the authenticity and integrity of halal products, the RLFC safeguards export products, and is developing a system and national database to detect and prevent food fraud.

Collaboration with local research centres resulted in a comprehensive study investigating levels of inorganic metals in rice in Saudi Arabia. The results of this study are anticipated to provide risk assessors with valuable information, thereby facilitating the establishment of appropriate regulatory limits and the effective mitigation of risks associated with the consumption of this essential food item.

REFERENCE LABORATORY FOR FOOD MICROBIOLOGY

Notable successes of the reference laboratory for food microbiology (RLM) include an ongoing collaboration with local partners to implement the One Health approach. This unified approach is aimed at sustainably balancing and optimising the health of people, animals and ecosystems.

To support the authority's research initiatives, the RLM at the SFDA established a biobank containing some 4000 isolates at its facility. This biobank is an ISO 20387:2018 certified biorepository that collects, processes, stores and investigates microbial isolates for research. The biobank grants SFDA researchers access to samples collected either internally from all SFDA laboratories, or externally from various public and private labs across the Kingdom.

At the RLM, antimicrobial testing now includes novel organisms, aligning with the lab's commitment to advancing testing capabilities. It has established a national antimicrobial resistance surveillance system for foodborne bacteria, standardising data collection, analysis and dissemination. Using shotgun metagenomics sequencing, the RLM has studied microbial communities in various food matrices like poultry, milk, honey and water. These studies lay the foundation for a deeper understanding of the microbiome, aiding in the identification of solutions to enhance food safety. Additionally, the RLM has developed bioinformatics pipelines to analyse bacterial genomics, improving the identification of microbial and resistome communities. They also apply microbial genomic epidemiology to investigate foodborne pathogens.

REFERENCE LABORATORY FOR MEDICINES AND COSMETICS

The lab recently made progress by assessing the risks posed by benzene and lyral, hazardous chemicals found in cosmetic products. These findings have helped inform the regulatory decisions made by the SFDA's drug department.

In 2022 the SFDA and Taif University started a joint initiative to assess the quality and safety of locally produced rose water, aimed at supporting local products. As part of this, they developed a method using gas chromatography-mass spectrometry (GC-MS) to analyse samples that offers a thorough comprehension of rose water composition, ensuring product integrity. The project is expected to progress further in 2023 and beyond.

"The One Health approach is aimed at sustainably balancing and optimising the health of people, animals and ecosystems."

In 2022 the SFDA and other regulatory authorities made a significant investment in laboratory capabilities due to the risk of nitrosamine contamination. This funding facilitated advanced techniques for testing and quantifying impurities. In response to global concerns, prompted by a WHO report, the SFDA took action. The reference laboratories developed a precise method utilising GC-MS/MS to accurately measure glycol concentrations in children's cough syrups.

In addition to these initiatives, the laboratory expanded its professional expertise by partnering with a local facility to test for illicit drugs in seized materials. This collaboration has enhanced the laboratory's competency and enabled the accurate identification and analysis of illicit substances.

NUTRITION

NUTRITIONAL RECOMMENDATIONS

National Nutrition Committee (NNC) – The NNC is a scientific advisory body under the auspices of the SFDA that is dedicated to enhancing the nutritional and health status of the Kingdom. Its primary objective is to provide expert recommendations and scientific opinions in the field of nutrition to the relevant authorities.

Low-Carbohydrate Diet – The NNC recently undertook a comprehensive review of scientific evidence on low-carbohydrate diets and their impact on health. Recent epidemiological studies have indicated a potential association between high-fat diets and conditions such as obesity and coronary heart disease. Our findings concluded that the recommended fat intake for healthy adults should not exceed 35% of total energy intake. Furthermore, the resesarch determined that a low-carbohydrate diet does not result in a decreased incidence of diabetes, cardiovascular disease, cancer or kidney failure. We also found that the current evidence is limited and insufficient to support the use of a low-carbohydrate diet to achieve weight loss.

Obesity – The NNC, the World Bank and the Public Health Authority collaborated to produce a comprehensive book addressing the prevalence of obesity in Saudi Arabia, its consequences and solutions. Several NCDs such as diabetes, cardiovascular diseases and cancer have increased in recent decades, making them the leading causes of disability and mortality in the Kingdom. The country has implemented various interventions designed to combat these challenges.

The book presents new evidence and analysis on obesity in Saudi Arabia, supporting strategic planning for prevention. It explores the concept of a food system approach that encompasses the connection between human health and the environment. A key focus of the book is the need for a Saudi-specific nutrient profiling model, which serves as a tool to guide nutrition and obesity-related policies. The book offers insights and evidence-based strategies for addressing NCDs, thereby fostering improved health outcomes and a sustainable food system.

WHAT WE DO FOR YOU

We ensure the safety and quality of all food, animal feed and pesticides consumed within the Kingdom, including among imported products and domestically produced food.

RECENT STUDIES

Dietary Intake for Pregnant Women

The SFDA conducted a study on the diets of pregnant Arab women before and during the Covid-19 pandemic, assessing dietary patterns and adherence to the US Department of Agriculture's pregnancy guidelines. Surveying pregnant women in five Arab countries, it was found that prior to the pandemic, these women had inadequate diets and low adherence to dietary guidelines. During the pandemic, there was an increase in the consumption of cereal, dairy, fruits, meat, nuts and vegetables, but adherence to guidelines remained low. These findings highlight the significance of nutritional education during prenatal visits for optimising maternal and foetal well-being.

Dietary Intake After Childbirth

A similar study was conducted on post-partum dietary intake, which revealed consistent consumption patterns. However, adherence to the dietary guidelines during the pandemic marginally increased among those sampled.

Dietary Diversity During Covid-19

The SFDA led a cross-sectional study to assess the impact of the pandemic on food consumption patterns and household dietary diversity in 10 Eastern Mediterranean countries. The pandemic exposed the fragility of the region's food system, posing significant challenges to maintaining a healthy and sustainable lifestyle. The findings highlight the area's lack of preparedness in dealing with a health crisis. Aggressive containment strategies, while necessary, had a detrimental effect on dietary diversity and led to poor nutritional outcomes. Steps to address these challenges will need to involve promoting sustainable food systems, ensuring access to a wide range of nutrient-dense foods and providing education on healthy eating habits.

Dietitians' Experiences During Covid-19

The SFDA led a study between November 2020 and January 2021 to evaluate the impact of the pandemic on the roles and responsibilities of dietitians in hospitals and clinics in five Arab countries. Among surveyed dietitians, 18.7% reported being assigned additional tasks within their facilities, while 46.9% shifted to remote nutrition consultations, leading to a 21% decrease in in-person consultations. About 58.9% provided nutrition care to Covid-19 patients, with 48.4% having access to protective equipment. Additionally, 17% supported Covid-19 patients with enteral and parenteral nutrition.

Disparities in Dietary Diversity and Consumption

The SFDA led a study examining disparities in food consumption patterns between men and women, exploring dietary diversity and factors influencing self-reported body weight changes before and during the pandemic in 10 Arab countries. Results indicated a 1.9% decline in dietary diversity among females during the pandemic compared to a 0.4% decline among males. Overweight participants experienced a 1.5% decrease in dietary diversity compared to their counterparts. These findings highlight the need for gender-sensitive strategies and policies to address weight gain, and promote dietary diversity during emergent crises.

INTERNATIONAL ENGAGEMENT

The SFDA is actively working with the Codex Alimentarius Commission (CAC) to promote fair practices in international food trade, operating under the UN Food and Agriculture Organisation and the WHO. The Codex Alimentarius, also known as the "Food Code," includes a comprehensive set of international standards, guidelines and codes of practice designed to safeguard consumer health and ensure fair practices in the food industry. These standards serve as a global benchmark for food safety and help to harmonise national regulations across countries.

Since October 2020, Saudi Arabia, represented by the SFDA, has been spearheading the efforts of CAC's Coordinating Committee for the Near East. The SFDA plays an active role in CAC committees, subcommittees and online working groups. Notably, the SFDA co-chairs the working group responsible for fresh dates and chairs a project focused on harmonising regional food additives standards with general standards.

REGULATORY DEVELOPMENTS: DRUGS

WHAT WE DO FOR YOU

We ensure the safety, efficacy and quality of all pharmaceuticals consumed in the Kingdom. This includes all types of pharmaceuticals, including human, veterinary and herbal drugs and cosmetics.

GUIDELINE FOR CLINICAL TRIALS

The SFDA has released a draft guideline to facilitate the execution of clinical trials in Saudi Arabia. This initiative is part of the Kingdom's broader effort to promote and attract clinical trials. The guideline outlines the authority's requirements for the submission of chemistry, manufacturing and control information for cell-based clinical trial applications.

MANUFACTURING GUIDELINES

The SFDA Good Manufacturing Practice guidelines have been revised to better align with the authority's wider objective of strengthening the commitment of manufacturers and companies to adherence with international best practices to guarantee the safety of pharmaceutical products.

ORPHAN DISEASES

We recently published a guideline on recognising orphan diseases (i.e., rare conditions), and providing insight into possible incentives for their development and registration. This guideline serves as a valuable resource for stakeholders, offering detailed information and encouraging advances in innovation, research and development.

COSMETICS GUIDELINES

The SFDA has guidelines for regulating traditional cosmetics in Saudi Arabia, including amber, musk products and miswak (i.e., teeth-cleaning twigs). The authority also published guidelines for reporting the negative side effects caused by cosmetics products, including manufacturing errors.

PHARMACOVIGILANCE

The SFDA released an updated guide on good pharmacovigilance practices. The new version includes some major changes in the regulation of pharmacovigilance practices in the Kingdom, addressing key areas such as the submission of reports detailing adverse reactions to drugs and the handling of signal detection.

It also included the introduction of requirements for registering the Qualified Person Responsible for Pharmacovigilance (QPPV) and the deputy QPPV. The intent of these updates is to improve the monitoring of drug safety, and foster enhanced cooperation between the SFDA and its marketing authorisation holder partners.

VETERINARY PRODUCTS

The authority has made significant updates to the guidelines and requirements in veterinary medicine. The new developments include the establishment of data requirements for specifications and test procedures, as well as acceptance criteria for new veterinary drugs and medicinal products, including herbal medicines.

DRUG SAFETY PROGRAMMES

Drug safety and risk management are key focus areas for the SFDA, and there are numerous initiatives in place to ensure the safe use of drugs and vaccines. These initiatives include the proactive monitoring of drug safety, assessments of the safety of medications during pregnancy and evaluations of drug interactions.

Proactive Drug Safety Monitoring

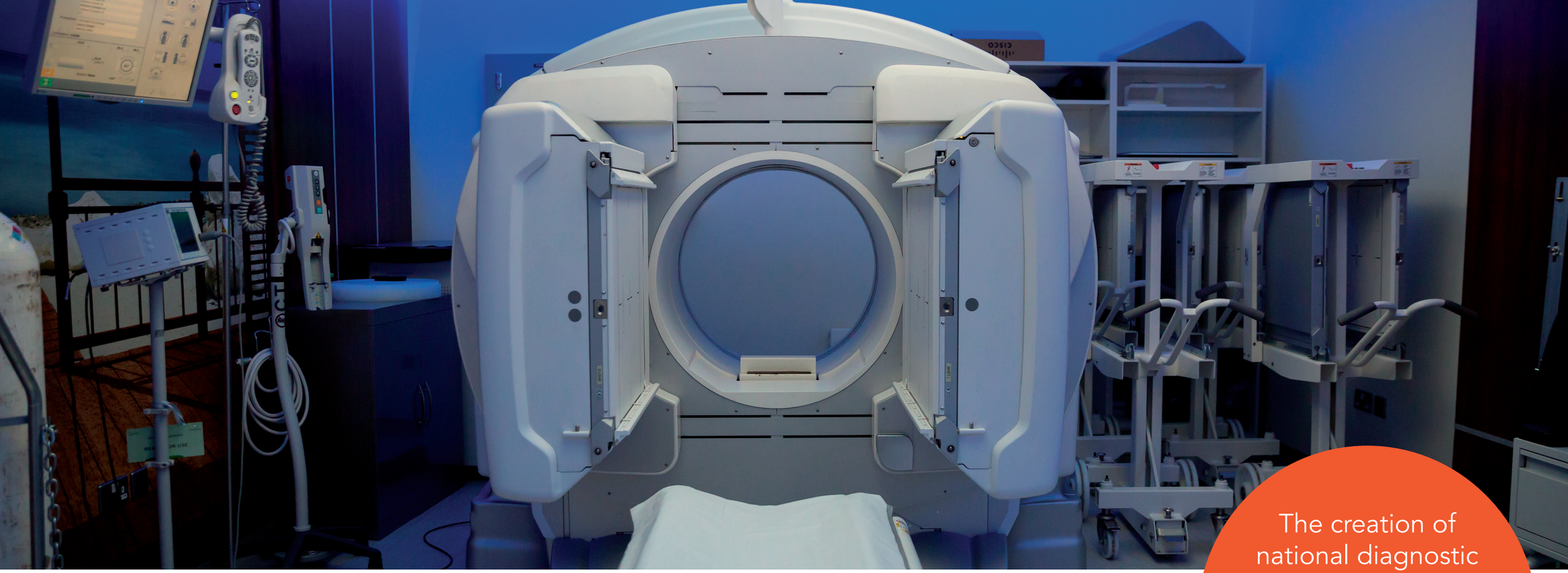
Launched in 2019, this programme improves the post-marketing monitoring of all registered medications, including biosimilar and orphan medications. The initiative utilises global and local cases from the WHO and the National Pharmacovigilance Centre, along with literature reviews and regulatory evaluations. The programme evaluates safety signals in targeted drugs using the WHO-Uppsala Monitoring Centre's causality assessment system and the Bradford Hill criteria for causation. Based on the findings, regulatory actions include updating product safety information, changing the marketing status, implementing risk minimisation measures, requesting data and routine monitoring.

Medication Safety During Pregnancy and Lactation

This project addresses the need for post-marketing data on the potential risks medications pose to pregnant and breastfeeding women. Although post-marketing data is excluded from clinical trials, it is crucial in assessing the safety of medications during these periods. The project involves evaluating fertility, pregnancy and lactation information from SFDA-registered products for potentially teratogenic substances. If necessary, updates to local product information are implemented using available evidence.

Drug Interaction Project

This project aims to identify safety signals associated with herb-drug interactions and drug-drug interactions. Through scientific assessment and evidence-based evaluations, this project focuses on ensuring the safe use of medications and herbal products. The assessment process involves analysing global and local cases, and a systematic review of literature to gather information on unlabelled herb-drug interactions and drug-drug interactions. The outcomes of this project contribute to raising awareness among health care providers and the public regarding these interactions.



REGULATORY DEVELOPMENTS: MEDICAL DEVICES

NATIONAL DIAGNOSTIC REFERENCE LEVELS (NDRLS)

In 2022 the SFDA published a second version of its NDRLs for routine examinations that involve various imaging modalities. The updated levels included CT scans for adults and children, general x-rays and mammography. This version of the NDRLs involved collecting radiation dose indices from 44 major hospitals in the Kingdom, representing a variety of patient populations and geographic locations. These data collection efforts were then followed by a rigorous analysis that was conducted on 29,672 cases. The SFDA has presented several workshops to introduce and discuss the updated NDRLs.

Prior to this effort, in 2020 the SFDA established the NDRLs for adult CT scans. Four workshops were held in 2021, leading to the monthly collection and analysis of dose data from over 70 health care facilities, encompassing more than 26,000 cases. The ongoing implementation of NDRLs aims to continuously monitor and optimise patient doses, ensuring the highest standards of image quality and diagnostic accuracy, while safeguarding individuals from excessive exposure to radiation during their examinations.

The NDRLs were developed by a national committee that was formed and chaired by the SFDA. The members of this committee comprised qualified professionals in medical physics, biomedical engineering and related fields. As part of its work, the committee periodically reviews the NDRLs to ensure that they continue to remain both effective and relevant.

The following are technical and regulatory requirements that the SFDA published in 2022 in relation to medical devices:

- Requirements for Medical Devices Marketing Authorisation (MDS-REQ 1);
- Requirements for Clinical Trials of Medical Devices (MDS-REQ 2);
- Requirements for Safe Use of Medical Devices Inside Health Care Facilities (MDS-REQ 3);
- Requirements for the Import and Clearance of Medical Imaging Materials and Particle Accelerators Used in Radioisotopes Formation for Medical Applications (MDS-REQ 4);
- Requirements for Importation and Shipments Clearance of Medical Devices and Supplies (MDS-REQ 5);
- Requirements for Importation and Re-Exportation for Radioactive Materials Used in Medical Applications (MDS-REQ 6);
- Requirements for Unique Device Identification (UDI) for Medical Devices (MDS-REQ 7);
- Requirements for Advertisement Approval and Launching Awareness and Charity Campaigns for Medical Devices (MDS-REQ 8);
- Requirements for Licensing of Medical Devices Establishments (MDS-REQ 9);
- Requirements for Inspections and Quality Management System for Medical Devices (MDS-REQ 10);
- Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ 11); and
- Requirements for Transporting and Storage of Medical Devices (MDS-REQ 12).

> The creation of national diagnostic reference levels involved analysis conducted on 29,672 cases.

WHAT WE DO FOR YOU

We ensure the safety, efficacy and performance of medical devices used in Saudi Arabia by regulating products across their entire life cycle.

GUIDANCE FOR MEDICAL DEVICES

The following are guidelines that the SFDA published in 2022 in relation to medical devices:

- Guidance for Visual Materials to Raise Awareness of the Safe Use of Home Medical Devices (MDS-G001);
- Guidance on Innovative Medical Devices (MDS-G002);
- Guidance on Extending the Expiration Dates for Medical Devices During Crises, Supply Shortages and Similar Events (MDS-G003);
- Guidance for Requirements of Surgical and Medical Examination Gloves – Recognised Standards (MDS-G004);
- Guidance for Requirements of Sterile Single-Use Hypodermic Syringes – Recognised Standards (MDS-G005);
- Guidance for Requirements of Blood Glucose Metering Devices and Strips for Home Use – Recognised Standards (MDS-G006);
- Guidance for the Operation and Use of Radiation-Emitting Medical Devices (MDS-G007);
- Guidance on Medical Devices Classification (MDS-G008);
- Guidance for Points of Care (POC) Medical Devices Manufacturing (MDS-G009); and
- Guidance for Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices (MDS-G010).

POST-MARKET SURVEILLANCE OF MEDICAL DEVICES

Post-market surveillance is a key component in ensuring the ongoing safety and effectiveness of medical devices. It involves the continuous monitoring and collection of data on device safety and performance, and efficacy, after devices have been released on the market.

Post-market surveillance encompasses both reactive and proactive activities to ensure the safety and effectiveness of medical devices.

Reactive Activities

The SFDA established the National Centre for Medical Devices Reporting (NCMDR), which manages a database of reports related to adverse events, complaints and safety alerts regarding medical devices. These reports are submitted by users, health care providers and establishments. The centre evaluates and studies these reports, and works with manufacturers, authorised representatives, importers and distributors to take necessary action and promote the safe performance of these devices.

Reactive measures include responding to adverse events or complaints, with actions including investigations and analysis to identify root causes. These actions may also involve fault detection, publishing safety alerts on the SFDA website, and working with manufacturers and authorised representatives to implement corrective actions.

To sum up, in 2022 the NCMDR published 420 safety alerts affecting the Saudi market – ranging from low to high risk, with different corrective actions – across a total of 3.4 million medical devices. In addition, the centre managed 127,632 reports of adverse events and complaints.

Proactive Activities

Proactive activities focus on anticipating potential hazards or harm before they occur, and taking the necessary measures to avoid or eliminate risks. This process involves collecting and analysing relevant information to evaluate the signals, assessing the associated risks, and preventing or mitigating the risks. Actions include:

- Conducting risk analysis reports and clinical evaluation studies for any safety signals that have been identified; and
- Preparing an annual plan to monitor medical devices in the Saudi market.

One proactive activity that the authority undertakes is the annual laboratory testing of specific medical devices collected from points of sale and health care facilities. This ensures compliance with the SFDA's technical specifications and requirements, as well as device effectiveness, safety and intended purpose. The SFDA evaluates the compliance of health care providers with safe use requirements through workshops, site visits and other proactive measures, such as issuing awareness materials related to the safe use of commonly used home medical devices.

Audits

Auditing clinical investigations into medical devices is also an important aspect of post-market surveillance. Auditors perform this task through the following:

- Reviewing study protocols, institutional review board communications and approvals, informed consent documentation and investigator agreements to ensure there was compliance with sponsor requirements; and
- Assessing source documentation for protocol adherence, and for the comprehensive evaluation and reporting of adverse device effects.

Risk Communication Activities

Risk communication with manufacturers, health care providers and the public is a major part of our work. This involves enhancing our understanding of device risks and providing guidelines to mitigate or eliminate risks. Our communication outputs include safety alerts and awareness materials to explain device safety for various tools.

SFDA LABORATORIES: WHAT WE DO

STRUCTURE

The SFDA's laboratories fall under the remit of the authority's research and laboratories division. Their core mission is to provide laboratory-based scientific assistance to the technical departments of the SFDA, which helps the authority in its regulatory decision-making. They achieve this through a range of complementary activities within two designated departments, namely the central laboratories and reference laboratories.

CENTRAL LABORATORIES

The central laboratories focus on testing products to verify their safety and adherence to international standards and guidelines like Codex, ICH, ISO and pharmacopoeias. They also engage in ad hoc activities such as organising training programmes and workshops, and coordinating analytical method validation protocols. These facilities receive samples for various purposes, including routine inspections, post-market surveillance programmes and samples related to customer complaints.

The central laboratories are accredited according to ISO 17025 and communicate with relevant sectors inside the SFDA to ensure accurate and precise interpretations of analytical results. They also participate in the planning of annual monitoring and post-market surveillance programmes. There are three central laboratories: one dedicated to food, one for drugs and cosmetics, and another facility for medical devices.

The central laboratories for food conduct thorough testing on various commodities to safeguard against chemical and microbiological hazards. In 2022 the SFDA participated in international events and presented four scientific papers, underscoring the laboratories' contributions to food safety control.

There is a specialised section dedicated to biopharmaceutical testing within the central laboratory for drugs and cosmetics. This section evaluates the quality and safety of biological products, including vaccines, products related to blood and antivenoms. The authority is in the process of upgrading this section in order to meet the requirements of a biosafety level-three compatible laboratory. In 2022 the SFDA successfully coordinated three international programmes to enhance the technical capabilities of staff involved in biopharmaceutical testing.

The central laboratory for medical devices focuses on setting standards for single-use sterile syringes and provides technical assistance to improve the capacities of medical device laboratories in other GCC countries, thus aiding in regional collaboration.

REFERENCE LABORATORIES

The main purpose of the reference laboratories is to provide in-depth technical expertise to the SFDA's central laboratories and private laboratories across the Kingdom. The reference laboratories are home to some of the most experienced personnel and cutting-edge equipment.

The reference laboratories have several responsibilities, such as providing continuing education, analyst training and workshops; ensuring access to necessary tools; conducting proficiency testing for other laboratories; validating methods for regulatory challenges; reviewing testing appeals from stakeholders; establishing best practices and standards; and conducting research.

At the SFDA, there are three main reference laboratories: one for food chemistry, one for food microbiology, and one for medicines and cosmetics. During 2021-22 the laboratories conducted 47 proficiency tests with 518 participants around the Kingdom. These tests covered the fields of food chemistry, food microbiology and cosmetics.

The reference laboratories have a programme to improve the quality of products manufactured by local industry in the areas of food, feed, cosmetics, botanicals and pharmaceuticals, wherein they completed 144 voluntary site visits to various industry laboratories such as poultry, water, dates, honey, drugs and others – in an effort to enhance the internal quality for these quality control laboratories. The SFDA's positive response to these visits has prompted us to expand this exercise in 2023 to include a broader range of industry laboratories.

In 2022 the laboratories welcomed 16 graduate students and 105 visiting researchers to participate in research projects aimed at enhancing food and drug regulations, and policies to improve consumer health in the Kingdom. We also expanded our global reach by participating in 26 local and international scientific conferences and publishing more than 25 articles in peer-reviewed journals.

INTERNATIONAL EFFORTS

Saudi Arabia has consistently championed international economic and social collaboration, empowering both government agencies and the private sector to engage with global partners. Our objective is to strengthen the Kingdom's international presence through effective engagement, scientific contributions, long-term partnerships and knowledge exchange.

The SFDA has been expanding its international presence in recent years to strengthen its position as a leading food and drug authority with a significant global reach. Through these efforts, the authority has become a prominent partner in decision-making within international food and health regulatory organisations. The SFDA now plays a crucial role in shaping and influencing global policies, facilitating effective knowledge exchange and promoting collaboration among regulatory authorities worldwide.

Through its collaborations with national and international organisations, the SFDA is actively working to enhance cooperation and trust among regulators worldwide and improve regulatory harmonisation between countries. The authority has been working closely with a number of international partners to promote common interests regarding the safety and efficacy of food and medicine for both human and animal consumption on a global scale.

Our work extends to policy development and support for numerous international initiatives, with our experts ready to provide assistance. We actively participate in various international committees, expert panels and working groups, continually expanding our involvement in global programmes. Through this process, we share best practices, help deepen regulatory harmonisation, strengthen international communication channels, and drive advancements in regulatory processes and standards. These efforts ultimately serve to benefit the global community.

This level of engagement enhances the SFDA's regional and global leadership role, demonstrating the authority's effective presence worldwide, offering its scientific contributions, and proactively working with peers and international partners. The SFDA's role in the international community is guided by our strategic goal of becoming one of the top-five food and drug authorities in the world.

SUSTAINABLE TARGETS

The authority is committed to supporting the UN Sustainable Development Goals (SDGs) and Saudi Arabia's contribution towards these international efforts. The SDGs, which were formulated under the UN's 2030 Agenda for Sustainable Development, are closely in line with the stated goals of Saudi Arabia's Vision 2030, emphasising human development and prosperity. These shared objectives inform the SFDA's outlook and collaborative approach.

The SDGs encompass health, the environment and social well-being – all areas that are of major significance for the SFDA as an important regulatory body in Saudi Arabia. We recognise the role the authority plays in realising these goals, as the SFDA understands that sustainable development is a fundamental component of the Kingdom's various international efforts.

Many of the authority's efforts are closely aligned with SDG 2 and SDG 3. The former is concentrated on the eradication of hunger to achieve food security, improve nutrition and promote sustainable agriculture, while the latter emphasises achieving universal health coverage, ensuring healthy lives and promoting well-being for individuals across all age groups.

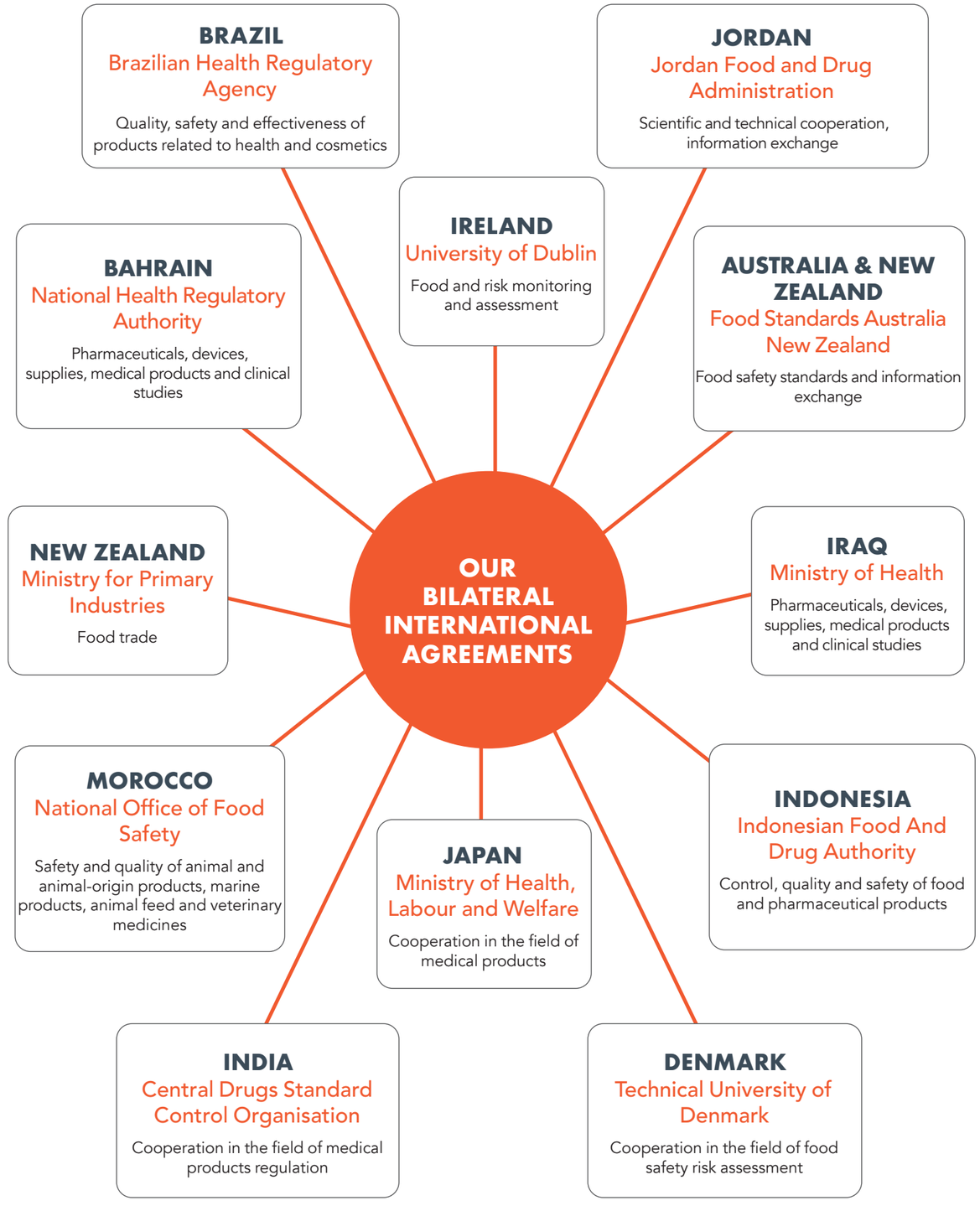
The work undertaken by the SFDA also contributes to SDG 12, which covers responsible consumption and production. We promote sustainable practices in the food and drug sectors by helping manufacturers and suppliers adopt environmentally friendly processes. This involves reducing waste generation, implementing efficient resource management systems and promoting the use of sustainable packaging materials. By doing so, the SFDA helps mitigate the environmental impact of these industries and promotes sustainable consumption patterns among businesses and consumers.

The SFDA places a strong emphasis on SDG 17, in terms of forming partnerships to achieve the UN's goals. Recognising that achieving the SDGs requires cooperation, we collaborate at both national and international levels. By working with international regulatory bodies, scientific institutions and industry stakeholders, the SFDA facilitates the exchange of knowledge, best practices and professional expertise.

The authority's commitment to the SDGs underscores its dedication to the welfare of the Kingdom's population, and the sustainable development of Saudi Arabia and the world.

BILATERAL AGREEMENTS

The SFDA is continually building specialist international partnerships with regulatory agencies from different countries. We have also established formal partnerships with a number of our international counterparts to increase cooperation and knowledge exchange in a wide range of subject matters.



INTERNATIONAL MEMBERSHIPS & PARTICIPATION

The SFDA collaborates with international organisations and scientific institutions through participation in technical committees, expert panels and working groups. By engaging in these organisations, the authority aims to develop international guidelines and align its regulations with coalition members. The SFDA also provides the support of its own qualified professionals in various scientific fields.

CODEX ALIMENTARIUS COMMISSION (CAC)

The SFDA represents Saudi Arabia on this commission, with the Kingdom acting as its focal point. The Codex Alimentarius is a collection of standards, guidelines and codes of practice adopted by the CAC. The commission was established by the UN Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO) to protect consumer health and promote fair practices in food trade. The commission is responsible for all matters regarding the implementation of the joint FAO/WHO programme on food standards. Saudi Arabia, which is represented by the SFDA, presides over the Coordinating Committee for the Near East.

GULF HEALTH COUNCIL

The primary function of the Gulf Health Council is to advance GCC cooperation in the health care sector, strengthen integration and promote the health of all citizens in member countries. The council is responsible for developing proactive initiatives and responding to regional and global health challenges. The SFDA has a seat on five technical committees that cover drug registration, health systems and policies, the registration of veterinary preparations, the registration of herbal and health products, and the pricing of pharmaceuticals.

ARAB INDUSTRIAL DEVELOPMENT, STANDARDISATION AND MINING ORGANISATION (AIDSMO)

AIDSMO is dedicated to promoting harmonised standards and specifications among countries in the Arab world in order to eliminate technical barriers and facilitate trade. The organisation focuses on industrial coordination, integration, and the fostering of sustainable and inclusive industrial development. Headquartered in Rabat, Morocco, the organisation is affiliated with the League of Arab States and has 21 members. AIDSMO has a total of 15 committees. The SFDA has held the presidency and secretariat of the Arab Technical Committee for Standardisation of Medical Devices and Supplies since 2020. The SFDA is also a member of the organisation's Arab codex delegation.

GCC STANDARDISATION ORGANISATION (GSO)

The GSO aims to unify the various standardisation activities that are taking place within GCC member states. The organisation does this by cooperating and coordinating with these countries' national standardisation bodies. The SFDA is a participant in 12 GSO technical committees that cover topics such as food, drugs and medical devices, and tobacco products.

WORLD TRADE ORGANISATION

The SFDA is the chair of the Committee on Sanitary and Phytosanitary Measures, and is also an active member of the Committee on the Technical Barriers to Trade Agreement.

INTERNATIONAL REGULATORY COOPERATION FOR HERBAL MEDICINES (IRCH)

The IRCH is a global network of regulatory authorities that is responsible for the regulation of herbal medicines. Membership in the network is open to national regulatory authorities and regional/sub-regional bodies. The SFDA has been a member of the network since 2009.

GLOBAL HARMONISATION WORKING PARTY (GHWP)

The GHWP aims to study and propose strategies for harmonising medical device regulations across member countries. A key priority for the organisation is assisting emerging countries in establishing their regulatory frameworks. The SFDA has held the chairmanship of the GHWP since 2018, and is actively engaged in all nine scientific and technical working groups. The SFDA leads two working groups: one that is focused on determining pre-marketing requirements for medical software, and the other on developing and overseeing quality management systems for medical devices, specifically audits and evaluation.

INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC)

The IEC is the world's leading organisation for the preparation and publication of international standards for all electrical, electronic and related technologies. The SFDA has been a member since 2013, and participates in the technical committee for electrical device specifications in medical applications and the technical committee for electro-medical devices.

INTERNATIONAL ORGANISATION FOR STANDARDISATION (ISO)

The SFDA's involvement in the organisation encompasses its participation in numerous technical committees that are dedicated to medical devices, in addition to technical committees focused on tobacco products and methods of microbial analysis in food and feed. The SFDA oversees national work teams that align with international committees, comprising representatives from relevant governmental and private entities.

STANDARDS AND METROLOGY INSTITUTE FOR ISLAMIC COUNTRIES (SMIIC)

The SMIIC seeks to achieve the harmonisation of standards among the countries within the Organisation of Islamic Cooperation and eliminate technical barriers to trade. Saudi Arabia, which is represented by the SFDA and Saudi Standards, Metrology and Quality Organisation, joined in 2013. The Kingdom participates in nine working groups and technical committees, spanning halal food, halal supply chains, halal management systems and conformity assessments.

INTERNATIONAL HEADS OF FOOD AGENCIES FORUM (IHFAF)

The IHFAF is a platform in which leaders of food regulatory agencies from around the world come together to discuss and collaborate on food safety and regulatory issues.

The role of the IHFAF is to act as an annual gathering of international food safety agencies to share best practices regarding food safety and advance collaboration in key initiatives, including establishing international standards and addressing common challenges. The forum's first meeting was held in Riyadh in 2020, following its establishment by the authorities of Saudi Arabia, Ireland, Australia and New Zealand.

WHO-NATIONAL CONTROL LABORATORY NETWORK FOR BIOLOGICALS (WHO-NNB)

The WHO-NNB serves as a platform for sharing quality and technical information about pre-qualified vaccines, thereby promoting global accessibility to vaccines. The SFDA became a member of the network in 2020 and actively participates in the network's regular meetings.

INTERNATIONAL PHARMACEUTICAL REGULATORS PROGRAMME (IPRP)

The IPRP brings together pharmaceutical regulatory authorities to promote the convergence of regulatory approaches for pharmaceutical medicinal products intended for human use. The SFDA has been a member since 2020 and participates in nine technical committees spanning areas such as nanomedicine and generic drug quality.

INTERNATIONAL COOPERATION ON COSMETICS REGULATION (ICCR)

The ICCR is an international group of cosmetics regulatory authorities. The SFDA joined as an observer in 2020 and actively participates in a joint working group on consumer awareness and the microbiome, specifically addressing the effects of cosmetic products on skin bacteria.

INTERNATIONAL COALITION OF MEDICINES REGULATORY AUTHORITIES (ICMRA)

The ICMRA is the largest international coalition of medicine and vaccine regulatory authorities in the world. The SFDA joined in 2020 and participates in three working groups: the Working Group on Pregnant Women Research, which investigates complications of Covid-19 in pregnant women, related treatments and vaccine safety; the Pharmaceutical Quality Knowledge Management System Working Group; and the Action Group on Microbial Resistance.

THE INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE (ICH)

The ICH aims to promote the development of technical guidelines that relate to the quality, efficacy and safety of pharmaceutical products. The SFDA joined in 2021 and participates in eight working groups and technical committees, including planning and design, clinical trials, bioequivalence, evaluation and monitoring, and pharmacoepidemiology.

PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME (PIC/S)

PIC/S is a cooperative arrangement between regulatory authorities to ensure good manufacturing practices for medicinal products that are intended for human or veterinary use. It aims to harmonise inspection procedures by developing common standards in good manufacturing practice and by providing training opportunities to inspectors. The SFDA became a member in July 2023 and participates in annual meetings.

INTERNATIONAL MEDICATION SAFETY NETWORK (IMSN)

The IMSN is an international network of practice centres to improve patient safety. This is achieved by medication error reporting programmes and guidance to minimise harm from medicines. The SFDA joined in 2022 and participates in the network's regular meetings.

EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTH CARE (EDQM)

The EDQM is a leading organisation that protects public health by facilitating the development, assisting in the implementation, and monitoring the application of quality standards for medicines and their safe use that are recognised as a scientific benchmark and are used globally. The SFDA has maintained ongoing communication with the EDQM since signing an agreement in 2020. This collaboration has proven beneficial, providing support in multiple facets of quality assessment for active pharmaceutical ingredients in generic pharmaceutical products.

THE INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR VETERINARY USE (VICH)

The VICH aims to promote the development of technical guidelines that relate to the quality, efficacy and safety of pharmaceutical products. The SFDA joined in 2019 and participates in the VICH Outreach Forum.

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Saudi Food & Drug Authority

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