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PROTECTING AND PROMOTING
PUBLIC HEALTH



الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority



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 efforts to communicate with the public, specialists, and the wider food, drug and medical device industries through a variety of channels, including public awareness campaigns, social media, our website and our workshops. Moreover, you will learn how the SFDA is playing a key supporting role in achieving Vision 2030's goal of transforming the health sector and expanding health care infrastructure.

Amid the backdrop of the Covid-19 pandemic, the SFDA is the body responsible for regulating and approving all the vaccines and drugs that are being used in the Kingdom. We undertook a wide range of activities that have helped not only our citizens but others around the world. In particular, our work in the food, drugs and cosmetics, and medical devices sectors enhanced knowledge and raised awareness in the global effort to alleviate the pandemic.

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Vaccinating the Kingdom

SFDA IN BRIEF

HUMAN RESOURCES

The SFDA had
2120
employees in 2020

There was a
70%
increase in the number of female
employees between 2018 and 2020

CUSTOMER SERVICE

In 2020 the SFDA's customer satisfaction department addressed



217,078
calls



56,505
electronic
correspondence



19,560
emails



LICENCES ISSUED

Marketing Authorisation Licences

Over **183,000** medical devices
have received a licence for marketing
authorisation in the Kingdom to date

Establishment Licences

- There were **9662** licences issued in 2020 to establishments that fall under the SFDA's regulatory responsibilities (food, animal feed, medical devices and products, drugs and cosmetics)
- There was a **62% increase** in licences granted to establishments between 2018 and 2020



PRODUCT REGISTRATIONS

- There was a **52% increase** in completed product registration requests between 2018 and 2020 for food, feed, medical devices and cosmetics
- There was a **118% increase** in drug product registrations between 2018 and 2020
- The SFDA completed the following product registration requests in 2020:



174,606
food products



6309
feed products



6278
medical devices
(medium and high risk)



73,984
cosmetic
products



967
drugs for human
consumption



226
veterinary
drugs



72
herbal
drugs

COVID-19 VACCINES

Over **40m**
vaccine doses
administered as of end
September 2021

More than

28m
PCR tests performed as of
end-September 2021

587
vaccination centres across
the Kingdom

4
approved Covid-19
vaccines as of
December 2021

62%
of the population had
received at least one
vaccine dose as of
mid-August 2021

70%
of the population is
expected to be fully
vaccinated by end-
October 2021

RECENT STUDIES

In 2020 and 2021 the SFDA conducted 12 studies related to food, drugs, cosmetics and medical devices. Our researchers also published 10 peer-reviewed articles and presented their work in 15 international scientific meetings. Examples of the authority's recently published research include:

- "Hand Hygiene Compliance and Effectiveness Against Respiratory Infections Among Hajj Pilgrims: A Systematic Review" (*Infectious Disorders - Drug Targets*, 2020)
- "National Cross-Sectional Study of Community-Based Adverse Drug Reactions in Saudi Arabia" (*Drugs - Real World Outcomes*, June 2020)
- "Hand Hygiene Knowledge and Practices Among Domestic Hajj Pilgrims: Implications for Future Mass Gatherings Amidst Covid-19" (*Tropical Medicine and Infectious Disease*, October 2020)
- "The Occurrence and Dietary Intake Related to the Presence of Microplastics in Drinking Water in Saudi Arabia" (*Environmental Monitoring and Assessment*, June 2021)
- "Willingness and Determinants of Participation in Public Health Research: A Cross-Sectional Study in Saudi Arabia" (*Eastern Mediterranean Health Journal*, January 2021)
- "Consumer Behaviour at Supermarkets During Grocery Shopping in Saudi Arabia: A National Observational Study" (*Nutrition and Health*, March 2021)
- "Public Response, Anxiety and Behaviour During the First Wave of the Covid-19 Pandemic in Saudi Arabia" (*International Journal of Environmental Research and Public Health*, April 2021)
- "SARS-CoV-2, Surgeons and Surgical Masks" (*World Journal of Clinical Cases*, April 2021)
- "Awareness of Isotretinoin Use and Saudi FDA Pregnancy Prevention Program in Riyadh, Saudi Arabia: A Cross-Sectional Study Among Female Patients" (*Saudi Pharmaceutical Journal*, June 2021)
- "Real-World Effectiveness and Safety of Apixaban versus Warfarin in Patients with Acute Venous Thromboembolism: Experience of a Large Tertiary Hospital in Saudi Arabia" (*International Journal of General Medicine*, July 2021)
- "Covid-19 Vaccine Surveillance in Saudi Arabia: Opportunities for Real-Time Assessment" (*Saudi Pharmaceutical Journal*, August 2021)

The SFDA is the national body responsible for protecting the public by regulating the safety of food, drugs, medical devices, cosmetics, pesticides and animal feed. We carry out a wide variety of activities in each of these sectors, and we serve the public, health care providers, companies and investors. In this edition, we have chosen to highlight our awareness and communication work in our coverage of What We Do For You.

AWARENESS AND COMMUNICATION

Awareness-raising and communication are two core aspects of our work in the Saudi market. We communicate with the public, specialists, and the wider food, drug and medical device industries through a variety of channels, including public awareness campaigns, social media, our website and our workshops. We design specialised awareness campaigns

based on the differing needs and levels of awareness of target groups, and coordinate programmes to educate stakeholders on the role and regulations of the SFDA. Some leading examples of our recent communication campaigns include healthy food awareness and antibiotics awareness.

We run regular workshops and lectures for those interested in fields related to food, drugs and medical devices. Many of our workshops are designed for those working in the food, drug and medical device industries, such as manufacturers, distributors, retailers and end users. We provide advice and recommendations, explain essential principles, and lay out the official and technical requirements for the products we regulate.

Some of our recently held workshops include:



- **April 2021** – Safe Use of Medicine During Pregnancy



- **July 2021** – Roles and Responsibilities of Regulatory Bodies in Evaluating and Monitoring of Vaccine Safety: Focusing on Covid-19 Vaccines



- **August 2021** – Preparing Auditors for Halal Auditing



- **August 2021** – Pharmacovigilance and Risk Communication in Saudi Arabia



- **September 2021** – Product Verification and Validation Requirements for Medical Devices

If you would like to attend one of our workshops, please visit the SFDA website to sign up: www.sfda.gov.sa/en/workshop

ACHIEVING EXCELLENCE

As recognition of the SFDA's efforts to drive Vision 2030 forwards and become one of the leading authorities in its field, the organisation has recently been selected for the following awards:

ARAB GOVERNANCE EXCELLENCE AWARD

In November 2020 the SFDA received the Arab Government Excellence Award for "best Arab government entity" in the first-ever iteration of the awards. The awards aim to recognise leading Arab ministries and government authorities for their outstanding work in advancing governance and administrative practices in the region. The awards comprise 15 individual and institutional categories.

KING ABDUL AZIZ QUALITY AWARD

In December 2020 the SFDA was awarded the silver medal of the King Abdul Aziz Quality Award for government authorities and institutions. The award serves to recognise institutional excellence in organisations committed to quality standards and continual improvement. The award recognised the SFDA's administrative leadership and excellence, its strategic direction, its fostering of values and behaviours, and representation as a good role model.

EUROPEAN FOUNDATION FOR QUALITY MANAGEMENT (EFQM)

In February 2021 the SFDA was awarded a certificate of excellence with a four-star rating from the EFQM in recognition of its organisational excellence. The EFQM organisational excellence model evaluates capabilities and results based on nine criteria: leadership; strategy; people; partnerships and resources; processes and services; customers' results; people results; society results; and business results.



SUPPORTING VISION 2030

As the national regulator responsible for protecting and promoting public health in the Kingdom, the SFDA has a key supporting role to play in achieving Vision 2030's goal of transforming the health sector and expanding health care infrastructure. Vision 2030 is an ambitious cross-sector reform agenda that seeks to create a diverse, dynamic and sustainable economy. We aim to be an indispensable partner in these ongoing efforts to lay the foundations for the Kingdom's future.

In 2021 Vision 2030's Health Sector Transformation Programme (HSTP) was relaunched, entering its second phase. This followed the success of the first phase of the Kingdom's various Vision Realisation Programmes between 2016 and 2021. The HSTP aims to produce a comprehensive, effective and integrated health system based on the health of the individual and society, inclusive of citizens, residents and visitors. The programme also seeks to improve harmonisation and coordination among all health sector entities, as well as with other Vision Realisation Programmes and relevant government entities. The SFDA is actively supporting the goals of Vision 2030 and the HSTP by encouraging the expansion of

local manufacturing, building collaborative partnerships, supporting the adoption of emerging medical technologies, promoting spending efficiency and enhancing the quality of services. We are encouraging manufacturers of medical devices and pharmaceuticals to enter the Saudi market, and have been supporting the local manufacture of Covid-19 ventilators and personal protective equipment, as well as developing a series of programmes to support the strategic localisation of generic drug production.

The SFDA assists local manufacturers by broadening their understanding of the regulatory requirements, which helps to streamline their work and improve their experience of operating in the Saudi market. With a population of more than 34 million, Saudi Arabia offers an attractive market for both international and domestic investors, bolstered by a willing and supportive national government that is investing substantially in the health care sector.

The SFDA has worked to build partnerships and alliances at the local and international levels with the government, private, scientific and non-profit

sectors. These collaborative partnerships underpin the policies, strategies and activities of the SFDA, and help us to both achieve our strategic goals and support those of our partners.

In 2021 the SFDA introduced a new initiative to accelerate the regulatory process for emerging technologies and medical devices. We are confident that this approach will help increase the efficiency and effectiveness of the Kingdom's health care system. In both 2019 and 2020 the SFDA received recognition from the Centre of Spending Efficiency for achieving government spending efficiency targets. In December 2019 we launched a new unified electronic system to improve the efficiency of our services to investors. The system, known as GHAD, aims to develop and standardise registration, licensing, inspection, clearance, export and enforcement procedures for investors working in all SFDA-regulated sectors. We are focused on developing processes and systems that establish a culture of quality, excellence and creativity. Our work focuses on implementing the principles and requirements of social responsibility, corporate governance and transparency. By doing so, we are creating a rewarding and encouraging environment for our employees to work in, as well as preparing and developing the next generation of leaders in the Saudi Arabian health care sector.

Last but not least, the SFDA has taken unprecedented steps to support public health and guarantee the safety and effectiveness of the Covid-19 vaccines deployed across the Kingdom. We have ensured a consistent supply of all the necessary products to help limit the spread of the virus, and by doing so, we have helped to bolster the Saudi health sector and develop the Kingdom's expertise when it comes to pandemic preparedness.

The SFDA has a key role to play in Vision 2030's goal of transforming the health sector and expanding health care infrastructure





- FOOD
- DRUGS & COSMETICS
- MEDICAL DEVICES

OUR RECENT EFFORTS

GUIDES TO RAISE AWARENESS

The SFDA's Food Sector produced a number of guides in 2021 to enhance knowledge and raise awareness about food safety and regulations. They were designed to inform investors and consumers of the most important requirements listed under the SFDA's standard and technical regulations for particular products. The publications covered the following products: oats, cheese, vegetable oils and soy sauce. We also released a supplementary guide on how to search for standard and technical regulations on the SFDA website (<https://mwas-fah.sfda.gov.sa>). Moreover, the SFDA produced educational guides on eggs and related products, and honey and processed meat products, as well as infographics on water use and expiration dates for frozen meat. Our work on raising awareness included participating in international Micro-, Small and Medium-sized Enterprises Day, where we shared information on legislation issued by the SFDA and the most pertinent challenges faced by enterprises in this field.

HEALTHY FOOD FOR CHILDREN

Recently, the SFDA has issued a series of guidelines and educational material related to nutrition and healthy diets for children of all ages. For the youngest age group there is a specific guide that

spreads awareness about breastfeeding, and its importance to both infants and mothers. For those a bit older, the SFDA issued a guide for parents about the benefits of healthy food. These included nutritional models for infants and toddlers, and identified types of nutrition that facilitate children's growth and development.

For school-aged children we issued a guide on the importance of providing balanced and healthy meals with the nutrients needed for growth, as well as preventing disordered associations with food. We also focused on enhancing the role of parents in providing and preparing more healthy school meals, and educating them to choose the appropriate quantities of food for the school day.

HEALTHY FOOD INITIATIVES

In December 2020 the UN Food and Agriculture Organisation declared 2021 the International Year of Fruit and Vegetables. The SFDA has supported this initiative by launching its own national campaign. The campaign aims to raise public awareness of the health benefits of fruit and vegetables, and of their contribution to a balanced and healthy diet and lifestyle. The objectives of the campaign include encouraging food establishments and restaurants to add a dedicated fruit

and vegetables section on their menus that carries the International Year of Fruit and Vegetables logo. The authority has also laid out special guidelines for all participating food establishments about the presentation of fruit and vegetables in restaurants in ways that appeal to consumers.

RESEARCH AND STUDIES

In 2021 the SFDA, in collaboration with the World Health Organisation Regional Office for the Eastern Mediterranean (WHO-EMRO), published a review article in the journal *Nutrients* titled "Saudi Arabia's Healthy Food Strategy: Progress and Hurdles in the 2030 Road". The paper summarised key nutritional regulatory programmes established by the SFDA in collaboration with other government agencies as part of a healthy food strategy to reduce chronic diseases and enhance community health. In the same year, a systematic review entitled "Salt Reduction initiatives in the Eastern Mediterranean Region and Evaluation of Progress Towards the 2025 Global Target: A systematic Review" was published in collaboration with the WHO-EMRO.

LECTURES AND WORKSHOPS

The authority held a number of events in 2021, including a lecture on the residual effects of pesticides in food, and their effects on human and

The SFDA has produced a number of guides to raise awareness about food safety that are designed to inform both consumers and investors

animal health at King Faisal University's international virtual symposium. In addition, the authority presented a lecture on the technical regulation of bottled drinking water to investors and Saudi water factories. This covered the latest updates and requirements in technical regulations. Furthermore, the authority organised a workshop on the requirements for importing honey and other bee-related products into the Kingdom. This was part of an ongoing effort in order to ensure that these products are not only safe for consumption but also high in quality and produced in a sustainable and environmentally friendly manner.



UPCOMING INITIATIVES

Public Health Pesticides

We are in the process of launching a campaign to raise awareness of the safe handling of pesticides used by the public. Public health pesticides (PHPs) are pesticides that are used to control pests of public health significance, and include products such as insecticides and acaricides. The SFDA's Food Sector is responsible for ensuring the safety and quality of these products. We do this through scientific evaluation, approving registrations, issuing certificates and monitoring PHPs that are already on the market. Saudi Arabia currently imports more than 1367 tonnes of PHPs, and 248 import permits have been issued for the pesticides. As part of the authority's work to ensure the safe use of PHPs, the SFDA issues an annual report on pesticides that details pesticide poisoning cases based on the Ministry of Health's database and includes recommendations aimed at reducing the risk of pesticides to human health. Our new PHP awareness campaign is scheduled to be launched at the end of 2021.

Global Halal Centre

We are in the process of establishing a Global Halal Centre for food and other halal products. The centre play a central role in the segment by granting halal certificates and accreditation. This initiative will help to further extend Saudi Arabia's leadership position at the heart of the Arab and Islamic worlds, as well as support Vision 2030. To date, we have recognised 74 certification bodies in 41 countries and granted halal certificates to 110 local establishments. In total, the centre has issued 15,474 certificates to different entities. Halal is not only of the utmost importance for practicing Muslims, but it is also a source of interest for non-Muslims. The recognition of halal products as being safe, clean, hygienic and high quality has attracted many non-Muslim consumers.

Pesticide Residue Inspection Centre

The SFDA is creating an inspection centre for pesticide residue. This facility aims to establish, equip and operate laboratories that have the capacity to examine pesticide residues in vegetables and fruit. The authority has already started the programme's operations in Riyadh, Makkah and the Eastern Region.

OUR LATEST INITIATIVES

WHAT WE DO FOR YOU

We ensure the safety and quality of all food, animal feed and pesticides consumed in the Kingdom. This includes all imported food, which currently represents over 80% of Saudi Arabia's food sourced from over 150 countries.

NATIONAL FOOD MONITORING AND CONTROL PROGRAMME (NFMCP)

In collaboration with the Ministry of Environment, Water and Agriculture (MEWA) and the Ministry of Municipal and Rural Affairs and Housing (MoMRA), in 2020 the SFDA introduced a programme designed to better monitor imported and locally produced food. The NFMCP is based on scientific findings from international sources and previous research. It focuses on a variety of food groups, including fruits, vegetables, dairy and baby foods, and analyses chemical contaminants, microbial contaminants,

pesticide residues, veterinary drugs and food additives. As part of the programme, samples of imported food are taken from border inspection points and samples of locally produced food are collected directly from domestic manufacturers. These samples are then distributed to the SFDA, the MoMRA or MEWA, depending on the area of speciality and expertise needed. Samples are also taken from date processing plants around the country. The MoMRA and MEWA collect samples from retailers, central markets and farms. Each year the SFDA, the MoMRA and MEWA release a joint annual report detailing the programme's findings as well as the actions taken for non-compliant samples.



HEALTHY FOOD AWARENESS

The SFDA has initiated several healthy food awareness campaigns in recent years to help the public make healthy eating choices. These include the concept of calories and how to calculate them; reducing your sugar, salt and fat intake; and how to read food labels for healthy choices.

These campaigns are part of the SFDA's Healthy Food Strategy, launched in 2018, and are in support of key national objectives. One of the main goals of Vision 2030 is to improve health and promote healthy food consumption among residents.

The campaigns have offered an abundance of educational material online, including tailor-made guides on the following topics: healthy diets for all community groups, how to minimise sugar consumption, how to reduce salt consumption and how to calculate calories in meals. Various awareness materials were developed, including videos, infographics, podcasts, printed posters and brochures, in addition to interactive booths. The most effective channel of communication has been social media outreach on all the major platforms, including Twitter, Instagram, Facebook and Snapchat.

FOOD CHAIN SAFETY

The SFDA launched a feed contaminant monitoring and control programme targeting domestic production and border crossings. The programme aims to increase the safety and quality of feed, reduce contamination with microbes such as salmonella and clostridium, limit pesticide residues to a maximum residue level, and reduce mycotoxins and heavy metals. Our work is underpinned by the farm-to-table principle, which ensures the highest measures of food safety are implemented at every stage of the food chain. Assessing the safety of animal feed products is one of the starting points for ensuring food chain safety. As part of our work in this field we published 15 technical regulations guides, 95 scientific reports and a risk profile related to animal feed in 2020.

ACCREDITATION

In 2020, for the first time, we received the ISO 17025 accreditation for Drug Laboratory, Medical Devices Laboratory and Food Laboratory in Jeddah; in addition to the ISO 17025 accreditation renewal for Food laboratories in Riyadh and Dammam. Furthermore, our Microbiology Reference Laboratory passed a quality proficiency test from the Technical University of Denmark's National Food Institute.

NEW DETECTION METHODS

Our control and reference laboratories have developed a number of analytical

methods in 2020-21 to enhance our ability to identify chemical and microbial contaminants in the products we regulate. This was done to enhance the laboratories' capabilities and as a response to the needs of other SFDA segments in satisfying their regulatory obligations.

Research we have conducted in this field of study has been published in various peer-reviewed journals, which include the *Arabian Journal of Chemistry*; *Food Additives & Contaminants*; and *Regulatory Toxicology and Pharmacology*. The studies and research covered topics such as detecting synthetic dyes in food products; analysing pesticide residue in bananas; and identifying inorganic arsenic, heavy metals, pesticides and mycotoxins in rice.

CHEMICAL AND MICROBIOLOGICAL TESTING

The SFDA created a proficiency testing programme to conduct chemical and microbiological proficiency tests to empower governmental and private laboratories. The programme focuses on food and cosmetics, and will offer support to ensure the integrity of quality and results of the laboratories within the SFDA network in the form of consultations, proficiency testing and training. In line with the SFDA's private laboratories licensing policies, SFDA technical auditors conduct regular audit according to the international standard ISO 17025. In these audits, our experts take a closer look at the laboratories' quality control processes and document their challenges.



OUR RECENT EFFORTS

COVID-19 SUPPLY AVAILABILITY

In response to the pandemic, we have ensured the availability of essential pharmaceuticals in the Kingdom by expediting the process of assessment of post-marketing variations. Such variations included a variety of changes that can have an impact on the availability of pharmaceutical products, such as shelf life extension and the use of alternative sources of raw materials upon the supply chain disruption the world witnessed during the pandemic. Such actions proved to be crucial in maintaining constant supply of essential products and continuous availability to the public. We have ensured the availability of hand sanitisers by encouraging local production of these products with the aim of reaching self-sufficiency. We developed and published temporary guidance for manufacturers and those specialising in health care products that outline the technical specifications and requirements of these products. As a result, the total number of hand sanitisers registered by the SFDA has increased to 118 products.

The SFDA has directly supervised the manufacturing, storage and marketing of these products to ensure their quality and safety, for both health care and public use. As part of our monitoring efforts, 26 products were recalled for not adhering to the technical specifications stated in this guidance.

PHARMACOVIGILANCE

Drug safety is of the utmost importance for the SFDA's Drugs Sector. Comprehensively evaluating new drugs and monitoring their performance helps to prevent adverse effects of pharmaceutical products. The SFDA's National Pharmacovigilance Centre (NPC) has completed the evaluation of approximately 356,800 adverse drug event reports between the beginning of 2021 and August 2021. Since the establishment of the centre, our inspection team has performed 88 routine inspections, and there have been 116 critical findings, 489 major findings and 182 minor findings. Moreover, the NPC's Signal Detection Team periodically publishes a set of drug safety communications on the SFDA website, which are directed at health care providers. In 2021 the authority published 23 such communications detailing side effects related to medicinal products registered in the Kingdom.

Additionally, the authority published 11 articles in a World Health Organisation (WHO) pharmaceutical newsletter detailing the signals of adverse drug reactions discovered and verified by the team. This surpasses the reporting of many other international organisations. Spanning the 2020-21 period, more than 50 workshops were held to raise awareness about the importance of pharmacovigilance. If users

notice any side effects after taking a medication, they are able to report this to the SFDA through the NPC or the SFDA call centre by dialling 19999.

DRUG SAFETY AND RISK MANAGEMENT

As part of efforts to improve our post-market surveillance of medications, we have introduced the Proactive Drug Safety Monitoring Programme. In 2020 the programme evaluated the safety of 114 medicinal products registered by the authority between 2005 and 2020. A total of 77 comprehensive drug safety reviews were performed for 162 potential safety signals. The SFDA is continuously improving its efforts in risk-management. In 2020, for example, 562 risk-management plans of medicinal products were reviewed by the SFDA's Drugs Sector, and 230 additional risk-minimisation measures were requested and approved. A total of 21,330 health care providers have benefited from these measures.

In 2018 the authority established an electronic track-and-trace system for pharmaceuticals called RSD. The system has helped to ensure that drug distribution can be tracked by the SFDA to guarantee their safety and availability in the market. To date, more than 2.5 billion tracking operations have been electronically recorded across the supply chain, with 15 million units of drugs recalled through the system. This prevented those drug from being dispensed to patients.

The SFDA directly supervises the manufacturing, storage and marketing of hand sanitiser to ensure quality and safety

NITROSAMINE IMPURITIES IN RANITIDINE

SFDA researchers have been helping to advance analytical methods of identifying potentially carcinogenic nitrosamine impurities in medicine and deepen global understanding of the reasons for nitrosamine formation within certain medications.

We have recently tested a new method of identifying impurities in the medicine ranitidine, which lowers the level of acid in the stomach. Leading regulatory agencies have recommended the use of liquid chromatography mass spectrometry (LC-MS) platforms as the only viable method for identifying these impurities, concluding that other platforms such as gas chromatography mass spectrometry (GC-MS) yielded inaccurate estimations of impurities.

However, scientists at the SFDA's reference laboratories have found a way for the GC-MS method to provide more accurate estimations of impurities by utilising a solid phase micro-extraction technique. Researchers at the SFDA found that both LC-MS and the new GC-MS method were able to identify nitrosamine concentrations at comparable levels. We published our results in the *Journal of Pharmaceutical and Biomedical Analysis* in November 2020. Many regulatory authorities around the world, including the SFDA, have recalled medications and suspended the use of ranitidine due to the formation of impurities. In an effort to advance knowledge, SFDA scientists recently reviewed literature on the potential reasons for nitrosamine formation within ranitidine, which is still poorly understood.

Moreover, available data on the possible solutions to counteract the formation of these impurities has been reviewed. We published the results of our own tests in the *Journal of Food and Drug Analysis* in 2021. Industry and researchers may find this journal a valuable resource for further understanding nitrosamine impurities in ranitidine.

COSMETICS SAFETY

Our Department for Cosmetics Safety works to ensure effective control over cosmetic products once they have entered the Saudi market. In 2020 we collected 1741 samples of cosmetic products on the market and sent them for laboratory analysis. The results showed that 36 products did not comply with cosmetic product regulations. Henna products were among the most non-compliant products that year. The most common pollutants in non-compliant products were bacteria and fungi. Eyeliners were some of the most non-compliant products in 2021, with lead found to be the most common pollutant in non-compliant products.

In our 2020 analysis of the products listed in our cosmetic products database, known as eCosma, 185 listed products were analysed. The results showed that 183 products complied with regulations, while two products were non-compliant. In 2020 we recalled 64 cosmetic products that were non-compliant with SFDA cosmetic product regulations. As part of our public awareness efforts for cosmetic product safety, we recently organised 14 public workshops targeting consumers and ran two workshops targeting health care providers. We also participated in a number of national aware-



ness campaigns on social media and International Women's Day, and disseminated a number of awareness publications in cosmetics stores.

REAL-WORLD DATA

The SFDA is investing heavily in expanding its capabilities in the use of real-world data by developing a national database in collaboration with major health care providers. Investing in the generation of real-world evidence based on local data would inform the decision-making process concerning the safety and effectiveness of drugs and medical devices. As of September 2021 the database comprised four hospitals with information on the medical conditions of several hundred thousand patients.

PRICING

The SFDA works to comply with global practices in the regulation and pricing of medicines. We set prices to ensure they are suitable for both society and investors, with no major burden on either party. In 2021 we updated our guidelines for pharmaceutical pricing rules and pharmaco-economic studies. In 2020 and 2021 we published a series of pharmaco-economic articles on areas including H. pylori infections,

non-cirrhotic patients, antibiotics and antimicrobial resistance. At present, the authority is in the process of conducting a number of studies on issues related to pharmaceutical pricing. This includes a study on the association between pharmaceutical pricing and drug shortages in Saudi Arabia. Across 2020 and 2021 the authority participated in several WHO workshops and forums focused on fair pricing, transparency and external reference pricing.

INTERNATIONAL COLLABORATION AND PARTNERSHIPS

We have expanded our membership in prominent international organisations and forums. In July 2020 the authority joined the Pharmaceutical Pricing and Reimbursement Information network; in October 2020 we joined the International Coalition of Medicines Regulatory Authorities (ICMRA) as an associate member; and in June 2021 we joined the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use as a regulatory member.

The SFDA's Drugs Sector is an active member of a number of international conferences and working groups. In November 2020 the authority partici-

ated in the 14th conference of the Veterinary International Conference on Harmonisation, a trilateral EU-Japan-US initiative aimed at harmonising technical requirements for veterinary product registration. Moreover, a visit took place in February 2020 by a delegation from the SFDA – represented by the Veterinary Products Evaluation Department – to the French Authority ANSES, in which a preliminary memorandum of understanding for cooperation in terms of training and attracting consultants from the French side was concluded. Furthermore, a comprehensive applied training programme was prepared in cooperation with the British Veterinary Medicines Directorate for the department's staff, which is scheduled to begin early 2022.

We also participated in the ICMRA Clinical Trials working group; the ICMRA Digital Transformation of Inspection working group; and the WHO-Listed Authorities working group for Registration and Marketing Authorisation and Clinical Trials Oversight. The WHO-Listed Authorities initiative aims to establish and implement a framework for evaluating and designating national regulatory authorities as trusted authorities that practice effective, efficient and smart regulatory activities of medical products.

WHAT WE DO FOR YOU

We have implemented active monitoring of imported batches of Covid-19 vaccines to track the quality of batches over time to ensure the manufacturing consistency and robustness of each batch. This enables early communication with manufacturers in case of quality deviation.

The WHO-Listed Authorities initiative ultimately serves to promote access and supply of safe, effective and quality medicines and vaccines.

SHARING COVID-19 KNOWLEDGE

Since joining the ICMRA we have been an active member in the organisation, sharing our expertise and knowledge with fellow members. Between December 2020 and May 2021 the SFDA shared safety reports to ICMRA members on adverse events following immunisation with the Covid-19 vaccines that were spontaneously reported in the Saudi pharmacovigilance system, known as the NPC. The authority also responded to ICMRA members' queries about adverse events following immunisation of special interest. Additionally, the authority shared its assessment report for the Pfizer-BioNTech Covid-19 vaccine and its deep-dive Emergency Use Authorisation Report. This assessment details the conditional approval requirements for pharmaceuticals and biological products intended for preventing or treating the Covid-19 virus.

The authority's chemistry, manufacturing and controls experts participated in two discussion sessions in a workshop that focused on support-



ing manufacturing capacity during the Covid-19 pandemic. The SFDA presented our experience related to post-approval chemistry, manufacturing and control changes to address manufacturing capabilities for Covid-19 therapeutics and vaccines.

In addition to this, the SFDA have shared its expertise in the field of track-and-trace systems with ICMRA members and have contributed to the review of recommendations on common technical denominators for traceability systems for medicines to allow for interoperability.

RECENT REGULATORY DEVELOPMENTS

Promoting New Medication – As part of our goal to increase the accessibility of new and advanced medications in the Kingdom, the authority is actively working to build regulatory capabilities for Advanced Therapy Medicinal Products, of which an international regulatory system is still not well established. As a result of these efforts, the SFDA has become the first regulatory authority in the region to publish guidelines on the classification of Advanced Therapy Medicinal Products.

Biological Products – In 2020 the authority revised the assessment framework for biological products with the goal of improving the quality and efficiency of assessment processes. The impact of this revision was measured by surveying 14 international companies. The results of the survey revealed a satisfaction rate of 76%, which indicated the positive impact of the revised assessment framework.

ANTIBIOTICS AWARENESS

In 2020 we launched the National Campaign for Appropriate Antibiotic Use in the Community in response to concerns in the country regarding the overuse and inappropriate prescribing of antibiotics which, together, have resulted in increased antibiotic resistance. The nation-wide campaign aims to educate patients and the community about the consequences of misuse and the optimal usage of antibiotics in order to maintain their effectiveness. Online workshops were provided to health care providers and specialists – especially doctors and pharmacists – with the aim of increasing their knowledge of appropriate prescription practices for antibiotics and the importance of explaining these guidelines to their patients. Mass media and social media platforms were also employed by the campaign in order to increase the Saudi public's knowledge and awareness, and decrease patient demand for antibiotics.

INTERNATIONAL COALITIONS

We play an active role in a number of international coalitions, which serve to deepen regulatory harmonisation, expand knowledge transfer and strengthen international communication. Our

proactive participation in these groups is helping to enhance the SFDA's regional and global leadership role and position us to become one of the top-five food and drug authorities in the world.



ICMRA

As part of our international Covid-19 work, the SFDA joined the International Coalition of Medicines Regulatory Authorities (ICMRA) in October 2020 as an associate member. The ICMRA is the largest international coalition of medicine and vaccine regulatory authorities and currently includes 35 regulatory authorities from all over the world. Since becoming a member of the ICMRA, the SFDA has actively contributed to 14 different work streams and groups, and attended more than 76 meetings and workshops that have enabled communication, the exchange of knowledge and information, the transfer of experiences, and the sharing of data related to drugs and vaccines with heads and members of drug regulatory authorities.



ICH

In June 2021 Saudi Arabia, represented by the SFDA, joined the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The ICH brings together regulatory authorities and major pharmaceutical manufacturers and organisations to discuss the scientific and technical aspects of pharmaceutical product development and registration. The ICH aims to promote the development of technical guidelines that relate to the quality, efficacy and safety of pharmaceutical products. As a new regulatory member of the organisation, the SFDA will be able to contribute its expertise to the council's harmonisation work and provide input on the technical and policy environment of the future. Membership will also provide an international forum to build relationships, share experiences and stay highly informed.



Pharmaceutical Pricing and Reimbursement Information Network

In line with the SFDA's focus on compliance with global practices in the regulation and pricing of medicines, the authority joined the Pharmaceutical Pricing and Reimbursement Information network in July 2020. Comprising 90 institutions from 52 countries, it operates as an information-sharing initiative around the topics of price information, pricing policies and reimbursement of medicines.



Arab Industrial Development, Standardisation and Mining Organisation

In April 2021 the SFDA was elected as chair and secretary of the Arab Technical Committee for Health Specifications, Medical Devices and Supplies, which is part of the Arab Industrial Development, Standardisation and Mining Organisation.



Standards and Metrology Institute for Islamic Countries

The authority is spearheading a number of projects and programmes within the technical teams of the Standards and Metrology Institute for Islamic Countries. The SFDA is an active member of the inter-governmental organisation, which seeks to achieve harmonisation of standards among Organisation of Islamic Cooperation countries and eliminate technical barriers to trade. The authority's involvement within the institute serves to support Vision 2030's objective of enhancing Saudi Arabia's position at the heart of the Arab and Islamic worlds, and living by Islamic values.

OUR RECENT EFFORTS

MARKETING AUTHORISATION

There has been a significant increase in marketing authorisations for medical devices used in Saudi Arabia during 2021. In the first quarter of the year we assessed and authorised 2657 new medical devices for marketing, representing a large rise over previous years. This involved boosting our cooperation and communication with international organisations working on the scientific evaluation of medical devices. We share the results of our evaluations with relevant external organisations, and we coordinate with European Notified Bodies that are responsible for assessing the conformity of medical devices before they are placed on the market.

COVID-19 PRODUCTS AND DEVICES

In light of the shortage of medical supplies as a result of the pandemic, the SFDA has made a number of moves to ensure adequate availability. These include evaluating and providing market authorisation for essential products and devices, such as medical masks, thermometers, respiratory apparatuses and tests; conducting meetings with companies that are looking to manufacture medical devices locally; and preparing guidance

that aids manufacturers in fulfilling SFDA requirements for ventilators, masks and respirators. Our support for local manufacturing of ventilators and personal protective equipment helped to ensure no shortage of ventilators in Saudi Arabia, and enabled the Kingdom to provide lifesaving medical devices to other countries in need.

POST-MARKET EFFORTS

As a part of ongoing SFDA activities to ensure the safety, efficacy and performance of medical devices at the post-market phase, the National Centre for Medical Devices Reporting (NCMDR) is devoted to handling safety alerts and complaints, incidents or adverse events from health care providers, manufacturers and the public. In addition, the NCMDR studies these events and works together with manufacturers and suppliers to take the right action. Our laboratories have been diligently assessing and testing Covid-19 products to ensure their quality and safety. Our Medical Devices Laboratory has developed multiple control procedures for medical supplies such as gloves and masks. SFDA scientists and laboratories are ready to proactively address any reports indicating a breach in safety or quality.

INNOVATIVE MEDICAL TECHNOLOGY

We are working to facilitate the entry of innovative medical devices and products, as well as employ the latest technologies. In 2021 an initiative was introduced to identify manufacturers of novel medical devices and persuade them to register with the SFDA and apply for authorisation to enter the Saudi market. The initiative aims to accelerate the regulatory process for emerging technology and medical devices from outside of the Kingdom. We regularly update our guidance documents for devices, products and technologies, and we recently published a document on artificial intelligence in medical software. We are also working to stimulate research and development efforts at private centres, universities and other organisations to develop medical technology.

BUILDING INTERNATIONAL CAPACITY

We aim to strengthen the capacity of other national regulatory authorities, and enhance the safety and efficacy of medical devices worldwide. The SFDA participates in 17 international technical committees related to medical devices, including those under the International Medical Device Regulators Forum, the International Organisation for Standardisation and the GCC Standardisation Organisation. As Saudi Arabia hosts a World Health Organisation Collaborating Centre, we conduct programmes for authorities in the Eastern

In 2021 an initiative was introduced to identify manufacturers of novel medical devices from outside the country and persuade them to register with the SFDA

Mediterranean region and Africa, covering medical device regulations and evaluation. We aim for the centre to become a point of global collaboration in the near future. In addition, as the chair organisation of the Global Harmonisation Working Party, we advance convergence in legislation and regulations for medical devices and products among various countries.

DIAGNOSTIC REFERENCE LEVEL

The SFDA launched the National Diagnostic Reference Level (NDRL) project for diagnostic imaging modalities, and is the first governmental initiative to establish NDRL on a national level in accordance with international guidelines. The NDRL for computed tomography has been published, while NDRLs for mammography and general radiography are still in progress. This project will continuously help monitor and optimise patients' doses across Saudi Arabia while maintaining the image quality and its diagnostic features to protect patients from unjustified excessive radiation doses during examination.



REGULATORY DEVELOPMENTS

We have been overhauling and updating our medical device regulatory system. Some recent noteworthy changes include:

Medical Device Regulatory Scheme

In February 2021 the authority officially introduced a new, overarching medical device law that serves

as the basis of legislative and supervisory control of medical devices used in Saudi Arabia. The Medical Devices and Supplies Regulation replaces the temporary regulation previously in effect, called the Medical Devices Interim Regulation. However, the new law retains most of the previous rules, including articles covering all life stages of medical devices: concept, innovation, design, quality systems, clinical studies and post-market surveillance. The SFDA regularly publishes additional guidelines on specific topics, which are available on its website. Following the release of the Medical Devices Law, the SFDA published explanatory articles of the law which covered the life cycle of medical devices and the new global regulatory trends in innovation. This will support manufacturing process of the emerging technologies and clinical investigations.

Unified Electronic Platform: GHAD

The SFDA launched a new online platform, known as GHAD, which serves as a single portal for submitting medical device applications. Previously, applicants had to use several individual systems. The new online platform allows applicants to complete tasks such as applying for medical device marketing authorisation, enrolling in the Medical Device National Registry and naming a Saudi authorised representative. Guidance issued in July 2021 requests local and foreign medical device manufacturers to register or renew their licences through the new system.

Changes to GHTF Market Access Route

The SFDA is changing the requirements and authorisation process for medical devices that have pre-market approval from other international regulatory authorities, such as those in the EU, US, Canada,

Japan and Australia. These countries make up the former Global Harmonisation Task Force. Whereas devices from these markets previously benefitted from a simplified authorisation process in Saudi Arabia, they will be required to pass through the SFDA's full regulatory process beginning on January 1, 2022.



Devices from markets of the former Global Harmonisation Task Force will have to pass through the SFDA's full regulatory process beginning on January 1, 2022

MEDICAL DEVICE REGISTRATION EXPLAINED

The SFDA is responsible for registering medical devices used in Saudi Arabia. Medical devices can only be placed on the market once they have been registered with the SFDA. The following are the core requirements of the registration process:

Authorised Representative

The SFDA requires foreign medical device manufacturers to assign a local Saudi company as an authorised representative (AR) to act on their behalf in the market at all times. This is the case for all high-risk medical devices. An up-to-date AR licence is required for shipment clearance at the ports. A manufacturer can appoint a different AR for each medical device category or group if they prefer. The AR has to be registered and approved by the SFDA, upon which an AR licence is issued. The AR is responsible for the medical device registration process, compliance with all SFDA regulations and the implementation of the required standards. These actions help to facilitate a smoother marketing and sales process in the Kingdom.

Medical Device National Registry

This database lists all medical devices and related companies that operate in Saudi Arabia. The SFDA requires all medical device establishments, manufacturers, agents and suppliers operating in the country to enrol in this registry. The registry includes a company profile, the products they deal with, their country of origin and any pre-market approval their devices have been granted from other international regulatory authorities.

Medical Device Marketing Authorisation

In order for medical devices to enter the market in Saudi Arabia, they must meet a series of criteria and comply with all SFDA regulations. Local manufacturers and authorised representatives are required to apply for authorisation for each device they intend to offer for sale. The application process collects information such as manufacturer details, product category and country of origin. It also requires the submission of a series of documents detailing the medical device's intended use in Saudi Arabia. Upon successful completion, a market authorisation license will be granted.



UPSKILLING SAUDI TALENT

We aim to be a leading example in the journey to upskill Saudi talent and adopt best practices



The SFDA is deeply invested in its workforce and has a number of initiatives in place for continuously upskilling its staff and enhancing their well-being and job satisfaction. These initiatives are in line with Vision 2030's Human Capability Development Programme, which seeks to create a highly skilled and productive population by instilling values, developing skills and enhancing knowledge. As part of the programme, the Kingdom aims to reach 45th place on the World Bank's Human Capital Index by 2025. The Executive Department of Human Resources (HR) at the SFDA aspires to be a leading example in the journey to upskill Saudi talent and adopt best practices in human capital development. Key priorities include providing and creating an attractive workplace for employees; caring for employee health, safety and well-being; communicating effectively; and training, educating and empowering staff to succeed. The SFDA is always eager for new and creative approaches to attract and nurture top talent in the Kingdom.

LEADERSHIP DEVELOPMENT

We promote the principle that all SFDA leaders should speak the same language of leadership. Our leadership training follows a series of annual developments programmes that focus on a new theme each year. These include trust, coaching and

situational awareness. We encourage our leaders to enable and encourage the talents of their employees in order to improve employee engagement. This has helped leaders at all levels to work with their teams more effectively. In 2021 we introduced the Leading by Trust programme, which aims to increase trust among leaders and their teams, as well as across all levels of the organisation.

COACHING AND MENTORING

We also provide external coaching sessions to all of our leaders, from section heads to the CEO. This helps people in leadership positions at the SFDA overcome challenges and optimise their performance. We see coaching as a leadership tool, and as such, we have trained our leaders to become coaches for their staff. We are aiming to provide this coaching support to all SFDA staff, year-round. We have also instituted a mentoring programme pairing senior staff and leaders with fresh graduates and junior staff. The programme aims to transfer knowledge, establish role models, and create open channels of communication between junior and senior team members.

UPLIFTING SCIENTIFIC CAPABILITIES

The SFDA aims to become one of the top-five food and drug authorities in the world. This has under-

scored the need to provide the latest and most cutting-edge scientific training to employees. A huge proportion of our training budget is directed towards raising teams' scientific capabilities. We have provided myriad learning opportunities, including scholarships to well-recognised international institutions and universities we have partnered with, and blended learning approaches that mix virtual and face-to-face training.

CONTINUOUS LEARNING

To support and encourage continuous learning among SFDA employees, staff are allocated a two-hour break from their usual work schedule each week to undertake an online training course on platforms such as Coursera, Knowledge City, Udemy and LinkedIn. The aim is to enhance both technical and soft skills, and ensure employees have a dedicated window of time for learning that does not eat into their personal lives.

MEASURING EMPLOYEE ENGAGEMENT

We measure job performance to develop HR programmes that support employee development. We have initiated an annual employee engagement survey that aims to measure every factor related to the employee experience at work to discover areas for improvement. Ensuring that our employees are both motivated and effective

in their work, and that their efforts are appropriately valued, helps boost overall organisational performance.

WELL-BEING

Our ongoing efforts to enhance well-being across all teams at the SFDA include providing career counselling sessions to employees and their families, including one-on-one and group sessions; conducting workshops on mental health and well-being at work for employees and their families, especially during the pandemic; and providing a medical clinic inside our building, and home health care services for employees and their families. In addition, we have implemented a weekly mood check, asking employees to rate their mood on an electronic scale in order to track how sentiment changes over time, so we can analyse causes and provide support. We also launched an initiative encouraging handwritten letters of happiness to be exchanged among SFDA employees to foster a culture of motivation; and celebrate international milestones such as Volunteer Day, Happiness Day, Environment Day and others. We strive to enhance employees' quality of life in areas such as travel, health, housing, school and hobbies by hosting internal exhibitions, providing a tourist advisory service, and offering concierge service.

Covid-19 Vaccines

- Timeline of vaccination rollout
- Approved vaccines
- International and national responses
- SFDA response



VACCINATING THE KINGDOM

The SFDA was among the first regulatory authorities in the world to grant conditional approval to the Pfizer-BioNTech Covid-19 vaccine. After an exhausting journey of scientific research, and a vigorous race against the clock, its scientific teams recommended the conditional approval of the Pfizer-BioNTech jab on December 10, 2020, helping to make Saudi Arabia one of the first

countries in the world to receive the Covid-19 vaccine. As the body responsible for regulating and approving all vaccines and drugs that are used within the Kingdom, the SFDA undertook a wide range of activities in order to achieve this historic result. Here we detail the myriad international, national and SFDA efforts that have helped to vaccinate the Kingdom against Covid-19.

TIMELINE OF COVID-19 VACCINATION IN SAUDI ARABIA

March 26, 2020

Saudi Arabia convenes an emergency G20 virtual meeting to discuss ways to unify efforts to reduce the spread of Covid-19

April 2020

The Kingdom announces a \$500 million contribution to support international efforts to address Covid-19

October 2020

Saudi Arabia joins the International Coalition of Medicines Regulatory Authorities (ICMRA), the largest international coalition of medicine and vaccine regulatory authorities

December 10, 2020

The SFDA approves the first Covid-19 vaccine for use in the Kingdom, developed by Pfizer-BioNTech

December 25, 2020 & January 7, 2021

Crown Prince Mohammed bin Salman bin Abdulaziz Al Saud and King Salman bin Abdulaziz Al Saud receive vaccinations on TV, sparking a massive demand for vaccination among the public

APPROVED VACCINES

The following vaccines were approved for use in Saudi Arabia as of November 2021:



- **Pfizer-BioNTech** – Conditional approval for adults aged 18 years and over on December 10, 2020; extended to adolescents aged 12-18 on June 27, 2021 and children aged 5-11 on November 3, 2021.



- **Oxford-AstraZeneca** – Conditional approval for adults aged 18 years and over on May 5, 2021.



- **Johnson & Johnson** – approved for incoming visitors on May 18, 2021; conditional approval for adults aged 18 years and over on March 16, 2021.



- **Moderna** – approved for incoming visitors on May 18, 2021; conditional approval for adults aged 18 years and over on June 27, 2021; extended to adolescents aged 12-18 on August 22, 2021.

The SFDA was among the first authorities in the world to conditionally approve the Pfizer-BioNTech Covid-19 vaccine



WHAT WE DO FOR YOU

The SFDA ensures that Covid-19 vaccines are safe and effective for the public to use. This involves multiple stages of assessment and rigorous testing by the SFDA's scientific departments.



INTERNATIONAL RESPONSE

Race to Find a Vaccine – In our interconnected world, where travel around the globe is possible in a matter of hours, few have been able to avoid the impact of the Covid-19 crisis. Once it became clear that the spread of the virus could not be fully contained or treated through precautionary measures or existing drugs, the race to find a vaccine rapidly got under way. Pharmaceutical companies, universities and the biggest medical research centres in the world geared their operations towards developing a vaccine in the shortest and safest possible time period. Medical research centres have since become an object of global attention and major pharma companies have become household names.

Rapid Development – Through intensive cooperation and unparalleled efforts, the international medical community has been able to develop vaccines for Covid-19 in record time. The accelerated research and development process, which usually takes several years, can be attributed to an enormous commitment of resources from governments, the private sector and the pharmaceutical industry; unprecedented levels of cooperation between myriad organisations; streamlined bureaucracy to expedite clinic trials and approvals; and

cutting-edge technology that has made big strides in recent years and seen significant improvements since previous epidemics and pandemics.

NATIONAL RESPONSE

International Support – Saudi Arabia has taken unprecedented efforts to support the global development of Covid-19 vaccines and ensure the population of Saudi Arabia received vaccinations as soon as possible. In March 2020 the Kingdom used its presidency of the G20 to convene an emergency G20 virtual meeting to discuss ways to unify efforts to reduce the spread of SARS-CoV-2. In April 2020 Saudi Arabia announced a \$500 million contribution designed to support international efforts to address the Covid-19 pandemic.

ICMRA – In October 2020 Saudi Arabia, represented by the SFDA, joined the ICMRA, the largest international coalition of medicine and vaccine regulatory authorities. This facilitated communication with leading regulatory authorities around the world, allowing all members to consider the latest scientific data and news on vaccine development efforts. Saudi Arabia stands as the first Middle Eastern country to participate in this coalition. The Kingdom's involvement has helped to facilitate discussions on a number of topics and enabled

Saudi Arabia to deepen its vaccination expertise through engagement with ICMRA members.

Vaccine Centres – To date, Saudi Arabia has set up 587 vaccine centres around the country. The Ministry of Health (MoH) has provided a number of digital platforms for citizens and residents to book appointments for vaccinations at one of these centres. The MoH has been aiming to achieve herd immunity by vaccinating at least 70% of the Saudi population before the end of 2021. Vaccine uptake has soared since stringent requirements for vaccinated and unvaccinated persons were introduced.

SFDA RESPONSE

Covid-19 Actions – We took a number of steps to ensure the availability of medicines and medical devices during the pandemic through our registration and inspection work. As of mid-September 2021 we had cleared more than 40 million doses of Covid-19 vaccines. Moreover, we have granted more than 4000 import permits for over 2.5 billion products designed to combat Covid-19, including hand sanitisers, masks, eye protection, medical gloves, medical gowns and face shields. This work was conducted around the clock, seven days a week, to issue emergency import requests promptly. We created a special path for requests for imported products, and facilitated the expansion of domestic hand sanitiser and face mask production by issuing priority licences to factories. When curfews were in place, we initiated an electronic platform to issue exemption permits for licensed establishments to allow essential movement so products could be delivered to markets, hospitals and pharmacies.

Proactive Engagement – Since the early stages of the Covid-19 pandemic, the SFDA has actively engaged and communicated with multiple international organisations and authorities. This includes the Medicines and Healthcare Products Regulatory Agency, the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and the ICMRA on the subject of Covid-19 vaccines, and therapeutics and treatments. For example, this has involved sharing information on guidelines, assessment progress and regulatory considerations. Our intensive engagement with international experts in the form of scientific meetings and workshops has helped to accelerate our evaluation work of Covid-19 vaccines.

Monitoring Vaccine Research – As vaccine research got under way in various countries, we began to monitor the various phases in research and development conducted by scientific centres and drug companies closely. We opened direct lines of communication with the companies that undertook clinical tests and we designated points of contact to manage this process.

Research Verification – Before vaccines can be registered in Saudi Arabia, the SFDA carefully examines scientific papers describing the vaccine research and testing conducted by vaccine producers. This is done to verify the safety and efficacy of vaccines. Because of this process, the SFDA has reviewed thousands of scientific papers – a procedure which has required the skill and scientific expertise of the SFDA's top scientists and researchers. Verification requires comprehensively reviewing each stage of the vaccine research and development process. The SFDA then produces an assessment report for the given vaccine, which is required for each new drug application.

Risk Monitoring – The SFDA identifies expected risks from Covid-19 vaccines by analysing risk profiles and participating in the development of plans to mitigate potential negative impacts.

“ Saudi Arabia has taken unprecedented efforts to support the global development of Covid-19 vaccines and ensure the population of Saudi Arabia received vaccinations as soon as possible ”

During clinical trials, vaccine producers list all side effects and then provide regulators such as the SFDA with a risk-management profile that consists of risk-mitigation actions. This covers known risks, potential risks and unknown risks. This information is then conveyed to health practitioners and individuals as educational material in the form of guidebooks, safety messages and alert cards.

Quality Assurance – Quality assurance is of the utmost importance during all phases of vaccine development and manufacturing. The SFDA's experts closely monitor these phases and develop a quality profile for each vaccine. The quality profile consists of all the vaccine development phases, from laboratory tests to the final commercial product. The quality assurance team is divided into three sub-teams: a manufacturing assessment team, an analysis assessment team and a factory assessment team. These teams collectively verify the quality of the product.

Manufacturing Assessment – When assessing manufacturing data, the following is considered: raw materials used in manufacturing, manufacturing procedures and controls, manufacturing outputs and conformity with pre-set quality specifications. Usually dozens of chemical and biological raw materials are used in vaccine manufacturing; in one of the reviewed vaccines, 80 raw materials were used. It is imperative to verify the quality and safety of these materials by reviewing certificates of analysis and verifying their conformity with pharmacopoeias and international benchmarks. The team studies the biological, physical and chemical properties of the vaccine and analyses a set of tests to verify the identity of the active substance and ensure that it is free of any impurities.

Reviewing Packaging – Our teams are responsible for reviewing technical specifications on packaging in order to identify and avoid any possible errors. If products come with missing or unclear information, they will be rejected. In some cases, the SFDA will ask companies to improve the accuracy of information and make amendments. All basic information must be clear to the recipient of the drug, including the name of the drug, the dosage and storage information.

Factory Inspections – The SFDA has conducted a number of inspection visits to international facilities that are producing Covid-19 vaccines. SFDA policies stipulate that manufacturers wishing to import pharmaceutical products to the Kingdom must pass pharmaceutical factory inspections. This is a key requirement for a product to be registered in the Kingdom. Inspections are a specialised and complex process, and most factories are located in remote areas which require our team to travel long distances to access sites. This proved a significant challenge during the pandemic due to travel bans and precautionary measures taken by various countries. SFDA staff had to pass numerous health checks to travel abroad, and in some cases personnel were required to quarantine for 14 days on arrival. During inspections, our inspectors ensure that vaccine manufacturers meet international pharmaceutical industry standards in good manufacturing practices and that all required documents are verified. At the end of each inspection, a detailed technical report of all the observations made during the visit is prepared. This is then sent to the manufacturer, and factories will be required to address any issues before receiving approval to export to the Kingdom. If there are any serious shortcomings at a factory, permission to export will be denied.

Shipment Inspections – Once the vaccine receives registration approval from the SFDA, a new stage of monitoring, analysis and follow-up takes place. In line with SFDA policies, shipments of pharmaceutical products arriving at ports of entry are subject to SFDA laboratory sampling during their inspection. These samples represent the

entire shipment that has arrived and must pass certain tests in the SFDA's laboratories, which serve to verify the safety and quality of the product. We conduct a number of important tests on vaccines in the SFDA's control laboratory, including impurity testing, efficacy testing, active substance testing and preservatives testing. Certificates of release are then issued by the SFDA, and the shipment is able to be sent onwards to vaccination centres.

Monitoring Side Effects – The SFDA is responsible for remaining alert to all expected and emergency side effects of vaccines. Vaccine-related side effect cases are monitored locally and globally. Cases are carefully assessed and studied, and all the risks are examined. Cases are then reviewed by committees of specialised physicians and pharmacists who develop recommendations and take appropriate measures. The SFDA's National Pharmacovigilance Centre is responsible for this work, monitoring the safety of all medicines marketed in Saudi Arabia. The centre runs an online reporting system where health care professionals and the public can report adverse reactions to drugs and pharmaceutical defects. This helps us to introduce preventive measures and mitigate the development of side effects. The most prominent side effects of Covid-19 vaccines



are common symptoms following the admittance of a vaccine, such as fever or pain and swelling at the injection site. To date, no side effects have been monitored that require product withdrawal or suspension.

Monitoring Batches – The SFDA has implemented a stringent policy of actively monitoring imported batches of Covid-19 vaccines to track the quality of vaccine batches over time, and to ensure the manufacturing consistency and robustness of each particular batch. This enables early communication between the SFDA and manufacturers in case of quality deviation.

VACCINE CLINICAL TRIALS EXPLAINED

Clinical Trials on Animals

Companies first test their vaccines on animals in order to verify their safety. These tests consist of three parts:

Stage 1: Immune Response

Studying a vaccine's ability to produce immune responses

Stage 2: Toxicity Testing

Conducting harm or toxicity testing in animals

Stage 3: Effect on Reproduction

Assessing safety in terms of reproduction and a given vaccine's effect on animals' ability to conceive

Clinical Trials on Humans

The next phase is clinical trials on humans. This includes:

Stage 1: Small Group

A small sample of not more than 100 people which aims to verify the vaccine's ability to produce immune responses and make sure that no harm, toxicity or side effects occur. This helps to ensure that the vaccine is suitable for human use.

Stage 2: Larger, Diverse Group

Trials on a larger group of participants with diverse characteristics, including age and health conditions. This helps to verify that the vaccine is capable of producing the adequate immune response required in all of these groups.

Stage 3: Very Large Group

Even larger trials, considered the most important phase of clinical trials by the supervisory authorities assessing the vaccine's efficacy and safety.





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