Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Partnering for Health

Saudi FDA Newsletter

April – June 2025

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The Spotlight

Leading the Way in Regional Nutrition

The World Health Organization (WHO) has officially designated the SFDA as a WHO Collaborating Centre for Nutrition for the Eastern Mediterranean Region → 22 Countries

Objectives

- Develop optimal healthy food systems
- Support evidence-based policies and health-promoting behaviors
- Strengthen regional collaboration in nutrition policy implementation

Key Initiatives:

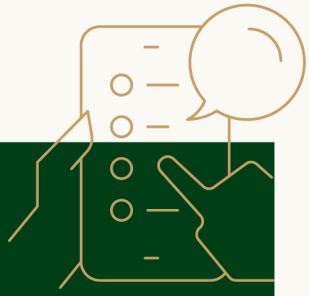
- Reduce salt and sugar consumption
- Eliminate partially hydrogenated oils in the region
- Restrict marketing of low-nutrition foods to children
- Develop a regional nutritional components database

SFDA Elected to the MedDRA Management Committee

Becoming the 6th global regulatory authority to join, with impactful contributions by leading the Arabic translation of 20,000+ MedDRA terms, enhancing pharmacovigilance in the region

01

The Spotlight



SFDA's Digital Employee: 98% Accuracy, Zero Guesswork

Repetitive tasks are now automated using software robots that mimic rule-based human activities, operating according to predefined scenarios.

The Impact:

- Accelerate procedures
- Enhanced work efficiency
- Reduced burden on employees

> The Digital Employee doesn't replace people — it empowers them

International Webinar on Medical Device Evaluation

The SFDA and WHO held a webinar covering ISO 14155 & 20916, case studies, and key concepts in clinical and analytical performance evaluation for medical devices

SFDA Laboratories Earn ISO/IEC 17043 Accreditation

This landmark accreditation empowers them to deliver over 20 proficiency tests across medicines, cosmetics, and herbal products, enhancing safety and quality standards

02

Our Quarter in Review

Accelerating Innovation Through Clinical Trials

Key Approvals for Drug Clinical Trials:

01 **Stem Cell Therapy for Type 1 diabetes to differentiate stem cells into functional insulin-secreting beta cells**

02 **Two New CAR T-Cell Therapies:**

Study (1): Rapcabtagene Autoleucel Versus Comparator	Study (2): Rapcabtagene Autoleucel Versus Standard of Care
Phase 2	Phase 2
120 participants	150 participants
For Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA)	For Systemic Lupus Erythematosus (SLE) with active, refractory lupus nephritis (LN)

Medical Device Innovation in Clinical Trial:

22 Clinical Trial Applications Received & Evaluated

- 11 Studies approved
- Covering pre-market and post-market investigations
- Diverse therapeutic areas, including Implantable Cardiac Devices, Neurotherapy Stimulators, and AI-powered Diagnostic Software

SFDA Breakthrough Medicines Program

Accelerating access to innovative and effective treatments for patients suffering from serious or life-threatening conditions, particularly when existing therapies are inadequate or unavailable.

Second Quarter of 2025

9 Submissions Received

02

Our Quarter in Review

A Targeted Study on Ethylene Glycol (EG)

The SFDA Pharmaceutical Laboratories conducted a comprehensive study to assess EG levels in various liquid pharmaceutical preparations.

100+ Products across diverse drug groups and pharmaceutical forms

Gas Chromatography-Mass Spectrometry (GC-MS/MS) technology for accurate results

International Council for Harmonisation (ICH) alignment

Regulatory Actions and Oversight (Q2 2025)

A Seizures and Closures

154 facilities were closed due to operating without a license

109 facilities were shut down due to violations directly impacting product safety

35 production lines were suspended

19 overseas Manufacturers were suspended

Methane-Based Animal Feed Approval

Saudi Arabia is among the first countries globally to produce methane-fed microbial protein animal feed. The SFDA has approved the registration of two new products, which are produced using advanced biotechnology. These innovative products utilize specific types of bacteria that consume methane gas as their primary food source to create a new, sustainable animal feed.

Why It Matters

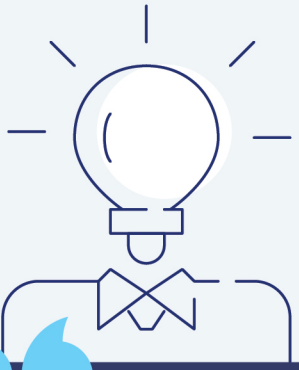
- Supports food security
- Provides a sustainable protein feed source
- Reduces methane emissions

03

Expert Corner

Our collaboration with WHO and the SFDA's designation as a Regional Collaborating Center for Nutrition is a profound recognition of our dedication to global public health. The new center will be instrumental in developing optimal, healthy food system and promoting healthier lifestyles. We'll also share our knowledge and experience to build capacity within WHO Member States, supporting them in reducing salt and sugar, eliminating trans fats, and restricting the marketing of unhealthy foods to children. This designation is a direct recognition of the SFDA's distinguished expertise and Saudi Arabia's proven leadership in implementing impactful nutrition policies, particularly our commendable work in eliminating industrial produced trans fatty acids and salt reduction in food system.

Executive Director of Nutrition
Faisal F. Binsunaid



The integration of Robotic Process Automation (RPA) through the "Digital Employee" tool marks a significant leap in our digital transformation journey. By automating routine tasks, our digital employees are enhancing efficiency, accelerating critical processes like drug side effect assessment and food contaminant analysis, and ultimately freeing our human talent to focus on higher-value, strategic initiatives. Adopting this technology enables us to scale our operations more efficiently. This direction stems from our core belief in putting people first, empowering our employees and delivering better, faster services to our stakeholders. Today, we don't expand our workforce by adding more people; instead, we integrate technology to optimize our existing resources and efficiently absorb what's coming."

Director of Digital Solutions and Innovation
Ashwaq A. Alswayah

04

According to SFDA

New Food Regulations for Healthier Choices

Building upon the efforts to support Saudi Vision 2030, particularly the Health Sector Transformation Program, the SFDA has enforced three significant new food regulations, targeting all menus across restaurants, cafés, and food delivery platforms within Saudi Arabia, effective

July 1, 2025.

The New Regulations:

01

High-Salt Labeling
Displaying a “Salt Shaker” icon next to food items containing over 5g of salt

02

Caffeine Disclosure
Displaying the caffeine content (in mg) per 100ml or per serving, along with a recommendation that the daily limit for adults is 400 mg

03

Physical Activity Labeling
Providing estimated physical activity time needed to burn off the calories in each food item

SFDA's New Regulatory Documents for Medical Devices

01

Guidance for ISO 13485 Requirements and Corresponding SFDA-MDS Requirements (MDS-G24)
To understand and implement the ISO 13485 Quality Management System (QMS), specifically illustrating how its international regulatory requirements align with Saudi Arabia's "Medical Devices Law", its implementing regulations and other regulatory documents.

02

Guidance on Companion Diagnostic IVDs (MDS-G26)
Offers critical clarifications regarding Companion Diagnostic (CDx) In Vitro Diagnostic (IVD) devices. It details the specific requirements for their development, the conduct of clinical studies, and the process for obtaining Medical Devices Marketing Authorization (MDMA) in KSA.

Objectives

- Reduce the risk of chronic diseases
- Raise public awareness about food and beverages content
- Support informed food choices across society

04

According to SFDA

Advancing Gene Therapy: SFDA Contributes to Global rAAV Standards

In a global effort to harmonize standards for the development of life-saving Gene Therapy Products, the SFDA has joined forces with the United States Pharmacopeia (USP) through its AAV Gene Therapy Expert Panel. This collaboration has led to the development of General Chapter (1067), which outlines best practices for the manufacture and quality control of recombinant adeno-associated virus (rAAV) gene therapy products.

What Chapter (1067) Covers:

Design:

Details on construct architecture, including promoters, capsid selection, and regulatory elements.

Production:

Guidance for both small-scale research production and large-scale clinical/commercial manufacturing.

Quality Assurance:

A risk-based control strategy covering:

- Upstream cell culture
- Downstream purification
- Critical in-process and release testing for both active substance and finished product.

Enhancing Cosmetics Safety: New Gulf Standards Developed

The SFDA contributed to the development of two new cosmetic products standards of the GCC Standardization Organization (GSO).

Standard Name	GSO Number and Status
Determination of Primary Aromatic Amines (PAAs) in Hair Dye Products - Methods of Testing and Examination	GSO 2791:2025 (View Standard) - Published and Effective
Determination of Dioxane in Cosmetic Products - Methods of Testing and Examination	Subject to accreditation by the Gulf Standards Organization

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