OXFORD BUSINESS GROUP

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

# Connecting Global Innovation to Local Markets

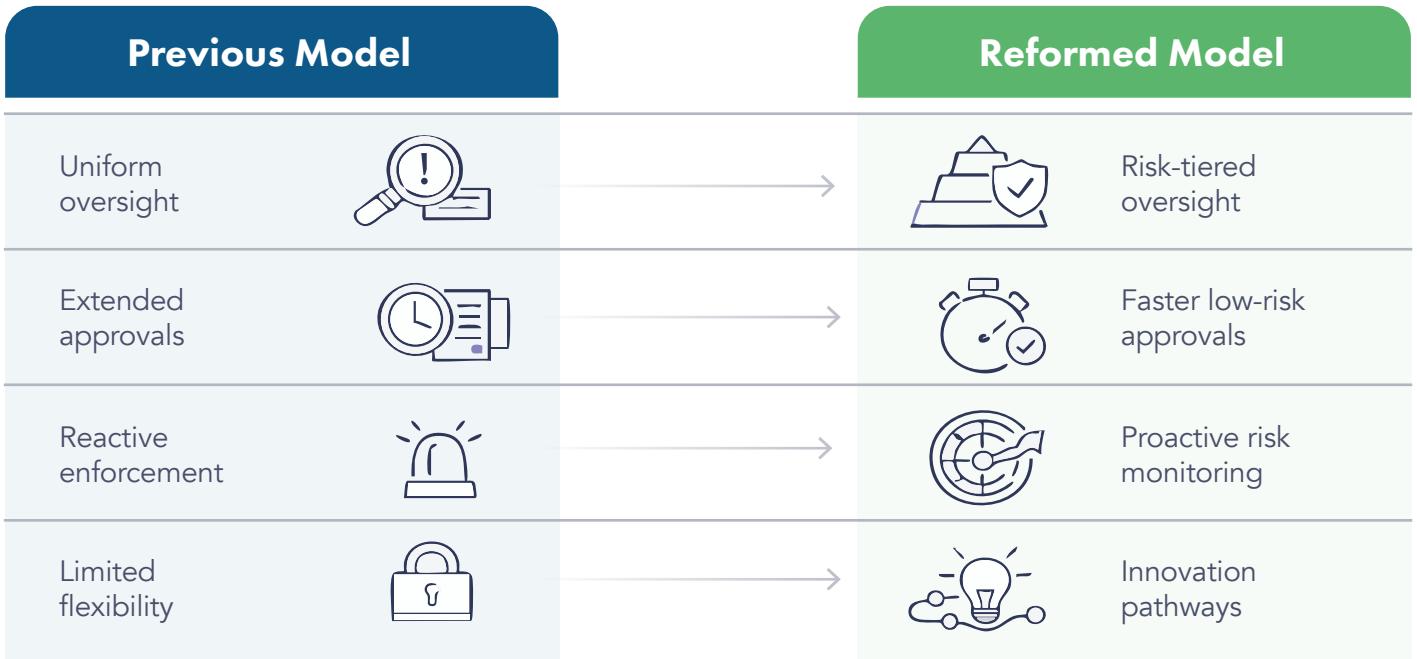
## Pillars for Strategic Investment in Food and Drugs

Volume 1

# Health Care Regulation in Saudi Arabia: Structural Reform and Strategic Direction

Saudi Arabia's health care regulatory framework has undergone significant structural reform over the past decade, driven by the objectives of Saudi Vision 2030 and a deliberate effort to align domestic oversight with international standards. The reforms reflect a shift from a largely compliance-based model towards a risk-informed, enabling framework that simultaneously safeguards public health and facilitates sectoral growth. This has wide-ranging implications for investment, localisation and the Kingdom's long-term position as a global hub for life sciences and health care investment.

## From Compliance to Risk-Based Regulation




## Regulatory Context and Strategic Imperatives

Saudi Arabia's health care sector is expanding rapidly. A growing population, an increasing burden of non-communicable diseases and an accelerating transition towards privatisation are generating sustained demand for pharmaceuticals, medical devices and health related consumer goods. Against this backdrop, the government designated health care as a pillar of Saudi Vision 2030, with the dual aim of improving health care quality for Saudi citizens and residents and reducing the Kingdom's longstanding dependence on imported products.

The Saudi Food and Drug Authority (SFDA) – which oversees the regulation of food, drugs, medical devices, cosmetic products, pesticides and feed – sits at the nexus of these goals. Its regulatory framework shapes the conditions under which global firms enter the Saudi market, domestic manufacturers invest in local production and new health technologies become available

# Cumulative Growth of Local Medical Device Manufacturers

| Year | Manufacturing Facilities | Growth( %) |
|---|---|---|
| 2021 | 14 | – |
| 2022 | 27 | 92.85% |
| 2023 | 52 | 92.59% |
| 2024 | 77 | 48% |
| 2025 | 98 | 27.27% |

to patients. Reforming that framework to keep pace with sectoral growth and global best practices has been a policy priority – one in which measurable progress has been made.

## From Compliance-based to Risk-informed Oversight

The most substantive shift in Saudi Arabia's regulatory landscape is the transition from compliance-driven oversight towards a risk-based model. This approach, aligned with established systems in the EU, UK and US, optimises regulatory resources by graduating intensity based on product hazard. Consequently, lower-risk, well-characterized products benefit from expedited processing, while novel or high-risk products receive a level of scrutiny proportional to their complexity.

In pharmaceuticals, the SFDA has updated Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) requirements to align with the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and International Council for Harmonisation (ICH) guidelines. The (A) requirement for local manufacturers to appoint a qualified person directly accountable for GMP compliance mirrors practice in mature markets and establishes clearer lines of responsibility within manufacturing operations.

In medical devices, the framework has seen similar modernisation. All manufacturers must now hold a Certificate of Conformity to ISO 13485:2016 – the globally accepted quality management standard. The SFDA's recognition of certificates issued by International Accreditation Forum member entities outside the Kingdom reduces the administrative burden on established global manufacturers without compromising the underlying quality requirements. Manufacturers are required to appoint full-time technical and quality managers responsible for design verification, manufacturing quality control and regulatory compliance. The updated Requirements for Inspections and Quality Management System for Medical Devices incorporates risk classification and compliance history into inspection planning, allowing the SFDA to focus oversight resources where risk is highest while offering more streamlined processes to consistently compliant manufacturers.

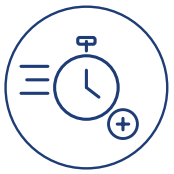
Alongside framework modernisation, the SFDA has introduced

# Market Access and Innovation Pathways

mechanisms to improve the speed and predictability of market access, particularly for innovative and key products. Expedited registration pathways have been established for drugs designated for rare diseases or listed on shortage registers, allowing priority processing without reducing substantive safety and efficacy requirements. Post-approval, accelerated pathways are reinforced by bolstered post-market surveillance, targeted sampling and continuous safety monitoring.

The Regulatory Affairs Innovation and Development (RAID) pathway represents the most significant structural innovation in this area. RAID provides a mechanism for early regulatory engagement between the SFDA and developers of novel therapies, advanced medical technologies and digital health solutions. By enabling scientific and regulatory dialogue ahead of formal submission, the pathway is designed to reduce the uncertainty that has historically extended timelines for innovative products – and to ensure that evidence packages are appropriately structured before the formal review clock begins. The SFDA has also updated its performance measurement tools, publishing defined key performance indicators, service-level commitments and digital dashboards that track application timelines, inspection coverage and the speed of safety alert dissemination.

## Accelerated Access to Medicine Programs



### 1. Breakthrough Medicine Program

**Brief**

Expediting access to treatments for serious or life-threatening diseases

**Benefits to Companies**

- Registration decision within 60 working days
- Specialised scientific consultations
- Facilitate coordination with relevant health authorities

**Results**

**22**
Breakthrough designations

**5**
Registered to date

### 2. Orphan Drugs

**Brief**

Encouraging the development and registration of treatments for rare diseases

**Benefits to Companies**

- Priority evaluation and fast-tracked studies
- Dedicated support and scientific consultations

**Results**

**30**
Drugs classified as Orphan

**6**
Registered to date

### 3. Verification and Bridging Tracks

**Brief**

Utilising scientific evaluations from trusted global regulatory partners

**Benefits to Companies**

- Validation Track: Max 30 working days
- Bridging Track: Max 60 working days

**Results**

**216**
Products registered since 2020

# International Integration and Institutional Recognition

Multilateral Cooperation | Knowledge Exchange | Joint Strategic Initiatives | Regulatory Harmonisation | Innovation and Research Support

A distinctive feature of the SFDA's recent development has been its active pursuit of memberships with the principal international regulatory entities and standard-setting organisations. The SFDA became the first organisation in the Middle East to secure membership with the ICH Management Committee – the entity that oversees the development of harmonised technical guidelines for pharmaceutical development, registration and post-market safety globally. It has since obtained a seat on the MedDRA Steering Committee, participating in the working groups that shape international standards for medical terminology in pharmaceutical regulation. Within the International Coalition of Medicines Regulatory Authorities (ICMRA), the SFDA co-chairs sessions on emerging regulatory themes, including the application of artificial intelligence (AI) in regulatory decision-making. Furthermore, for companies using Saudi Arabia as a regional base, the SFDA's status as the first Arab body to become an official observer at the International Medical Device Regulators Forum (IMDRF) helps ensure a regulatory environment that is perfectly synchronized with international regulatory authorities.

These institutional engagements carry practical significance beyond their symbolic value. ICH membership, in particular, provides early insight into evolving international standards and allows the SFDA to contribute to shaping guidelines before they are finalised, reducing the lag between global standard-setting and domestic implementation.

Bilateral memoranda of understanding with international regulatory counterparts formalise cooperation on food safety, pharmaceuticals, medical devices and regulatory innovation, facilitating knowledge exchange and over time, regulatory convergence that can simplify market access for compliant manufacturers operating across multiple jurisdictions. This global leadership is further underscored by the SFDA's role as Vice-Chair of the Codex Alimentarius Commission (CODEX), which aims to enhance efficiency, inclusiveness, visibility and transparency within food systems.

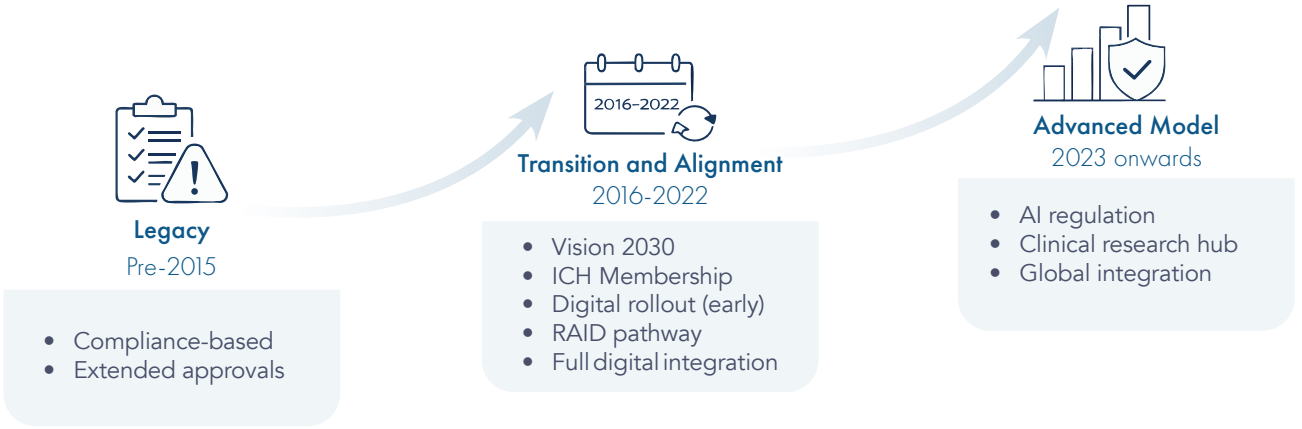
Full mutual recognition is achieved when peer regulators rely substantively on each other's approvals, a status that requires demonstrated consistency in regulatory outcomes. Saudi Arabia is on a credible trajectory towards that standard, and its institutional memberships are accelerating the process, even if equivalence with the most established regulatory authorities remains a medium-term objective.

# Digital Infrastructure and Regulatory Transparency

Digital transformation has been a fundamental enabler of the SFDA's regulatory reforms. The implementation of integrated electronic submission platforms, digital licensing systems and data-driven compliance tools – such as the Drug Track and Trace System (RSD) and the Unified Electronic System (GHAD) – has significantly reduced manual processing while improving traceability. These advancements enable the Authority to maintain continuous, life cycle-based oversight of products within its regulatory mandate. Real-time monitoring capabilities facilitate the early detection of compliance concerns, supporting a strategic shift from reactive enforcement toward proactive risk management.

This digital evolution has, in turn, served as a catalyst for greater transparency. Through the Public Consultation Platform (Istitlaa), the SFDA embeds stakeholder engagement directly into the rulemaking process, enabling regulated entities and the public to review and comment on draft regulations before they are finalised.

Furthermore, safety alerts, recall notices and enforcement actions are published publicly. The SFDA maintains specialised electronic portals through which regulatory decisions and compliance data can be accessed. These measures foster a predictable regulatory environment that strengthens investor confidence and empowers entities to manage compliance more effectively.




# Strategic Priorities and Outlook

The SFDA's priorities for the coming five to 10 years include deepening regulatory digitalisation, expanding innovation-enabling pathways for advanced and cell and gene therapies, developing robust frameworks for clinical research and real-world evidence generation, and further alignment with global regulatory systems. The regulatory governance of AI-powered medical technologies is an area of particular focus – and one where the SFDA's participation in ICMRA discussions positions it to contribute to, rather than merely adopt, the frameworks that will govern these products internationally.

Clinical research infrastructure is also a priority. Developing regulatory frameworks that support clinical trials, data quality standards and real-world evidence generation would reduce reliance on evidence produced exclusively in other markets and, in time, position Saudi Arabia as a contributor to the global clinical evidence base – a meaningful step for a country seeking to establish itself as a life sciences leader rather than primarily a market.

Assessed in aggregate, Saudi Arabia's health care regulatory reform represents a coherent and substantively progressed programme of institutional modernisation. The adoption of risk-based frameworks, alignment with international standards, investment in digital infrastructure and active participation in global regulatory entities collectively reflect a system that is maturing in the right direction.