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الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Enabling Industrial Localisation and Attracting Investment in Saudi Arabia's Life Sciences Sector

Pillars for Strategic Investment in Food and Drugs







Volume 2

Enabling Industrial Localisation and Attracting Investment in Saudi Arabia's Life Sciences Sector

Saudi Arabia's life sciences sector is undergoing a structural transformation driven by the intersecting goals of economic diversification, industrial localisation and health security. Under Vision 2030, the Kingdom has identified pharmaceuticals, biotechnology and medical technologies as strategic industries capable of supporting long-term economic resilience while improving national health outcomes. Central to this transformation is the development of a regulatory ecosystem capable not only of safeguarding public health, but also of enabling investment, facilitating technology transfer and expanding domestic manufacturing capacity.

The Saudi Food and Drug Authority (SFDA) plays a central role within this evolving landscape. While traditionally recognised for its regulatory role in monitoring the safety of food and medical devices, and the safety and efficacy of pharmaceutical, herbal, and veterinary products, the authority has increasingly assumed a broader strategic role within Saudi Arabia's industrial and investment agenda. Its recent reforms reflect a shift towards a more enabling regulatory model designed to advance localisation, strengthen supply chains, and create an attractive environment for both international and domestic investors.

This shift has become particularly significant in the aftermath of the Covid-19 pandemic, which exposed vulnerabilities in global supply chains and reinforced the importance of domestic manufacturing capabilities for critical health products. In response, Saudi Arabia accelerated efforts to reduce dependence on imported medical goods and expand local production across pharmaceuticals, biologics, vaccines and medical devices. Regulatory reform has become a core component of that effort.

The SFDA works closely with a range of stakeholders, including the Ministry of Investment, the Ministry of Industry and Mineral Resources, the Ministry of Health, the National Unified Procurement Company, the Local Content and Government Procurement Authority, and the Saudi Authority for Industrial Cities and Technology Zones. Working together, these entities form an increasingly integrated ecosystem that aligns industrial incentives, localisation priorities and regulatory pathways. The ultimate objective is to attract foreign capital while also ensuring that investment generates sustainable local value creation through manufacturing, workforce development and technology transfer.

A defining feature of Saudi Arabia's localisation strategy has been its effort to align domestic regulatory frameworks with internationally recognised standards. In pharmaceuticals, the SFDA's good manufacturing practice guidelines are closely aligned with those of the Pharmaceutical Inspection Co-operation Scheme. These frameworks establish clear quality benchmarks while enhancing the international credibility of Saudi-manufactured products. For local manufacturers, alignment with globally recognised standards is increasingly important not only for domestic market participation, but also for export competitiveness.

In the medical devices sector, similar reforms have been implemented under the Medical Devices Law. Manufacturers are required to obtain ISO 13485:2016 certification, which is the internationally recognised standard for quality management systems in medical device manufacturing. The SFDA recognises the ISO 13485 certificates that have been issued by accredited certification bodies, including those accredited by bodies recognised within the International Accreditation Forum (IAF) framework. This approach facilitates market entry for international manufacturers by reducing duplication in certification requirements and by recognising internationally established quality management systems.

Drug Registration Volume by Category (2022-2025)

CATEGORY	2022	2023	2024	2025
Generic	269	298	414	558
NCE - New Chemical Entity	80	108	71	103
Biological	67	68	65	91
TOTAL	416	474	550	752

The authority has also introduced measures aimed at strengthening domestic technical capabilities. Pharmaceutical and medical device manufacturers are required to appoint qualified technical and quality managers responsible for regulatory compliance, design verification and quality control. These requirements support the development of local expertise while establishing clearer accountability within manufacturing operations. Risk-based inspections and continuous engagement with manufacturers further reinforce compliance standards without creating unnecessary administrative burdens, while also promoting more consistent implementation across facilities.

Alongside framework modernisation, the SFDA has introduced a range of procedural reforms intended to support industrial localisation and accelerate investment for the pharmaceutical sector. Pre-registration scientific consultations are now available for companies pursuing localisation initiatives, allowing manufacturers to engage directly with regulators before formal submissions are made. Products linked to localisation objectives or included within strategic lists may receive prioritised registration pathways, reducing time-to-market for locally manufactured products.

Recent updates to the pricing guidelines have also been used to incentivise localisation. Locally manufactured products produced under licence from international companies may benefit from price parity with the original product during patent protection periods. For manufacturers transferring production stages into the Kingdom, price stabilisation mechanisms can be applied for periods of up to seven years. These measures create greater commercial certainty for investors undertaking long-term localisation projects.

One of the most significant developments has been the creation of dedicated pathways for advanced and emerging technologies. Under Article 9 of the Medical Devices Law, the SFDA has introduced a specialised pathway for innovative medical devices, providing structured regulatory support for innovators, universities and research institutions. Early engagement mechanisms are designed to allow developers to clarify applicable requirements during the product development stage, reducing regulatory uncertainty for emerging technologies.

In pharmaceuticals, regulatory adaptation has become increasingly important as Saudi Arabia seeks to position itself within advanced manufacturing and biotechnology sectors. The SFDA's evolving frameworks now incorporate accelerated pathways for biologics, biosimilars, advanced therapy medicinal products, complex generics and specialised medical

technologies. Initiatives such as priority review, verification and abridged pathways, as well as the Breakthrough Medicine Program, allow faster regulatory assessment for products addressing unmet medical needs while maintaining rigorous safety and efficacy standards.

The authority has also introduced regulatory processes such as Orphan Drug Designation and the Research and Investigational Drugs Designation (RAID) to facilitate earlier scientific engagement between developers and regulators. Product-specific guidance for advanced therapies, including cell and gene therapies, provides clearer development expectations while encouraging innovation in emerging therapeutic fields.

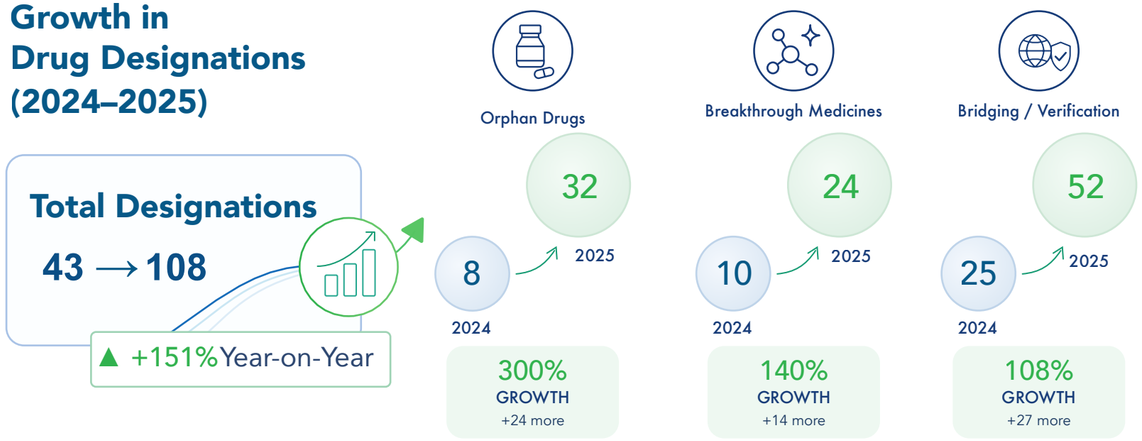
This regulatory evolution reflects a broader ambition to position Saudi Arabia as a regional centre for biotechnology and life sciences innovation. The SFDA's Fourth Strategic Plan (2023-27) includes explicit objectives related to enabling investors, supporting research and fostering innovation. Regulatory reform is increasingly viewed not simply as an administrative function, but as an instrument of industrial policy capable of shaping long-term economic development.

Regulatory predictability and transparency remain central to this effort. Investors in the life sciences sector typically operate within long development cycles that require stable and clearly defined regulatory conditions. The SFDA has therefore prioritised digitalisation, transparency and stakeholder engagement as part of its broader reform agenda. Initiatives such as the Investor Journey platform can provide clearer regulatory pathways for investors, while digital systems such as the Saudi Drug Registration (SDR) and Ghad platform are intended to improve the overall experience for regulated entities.

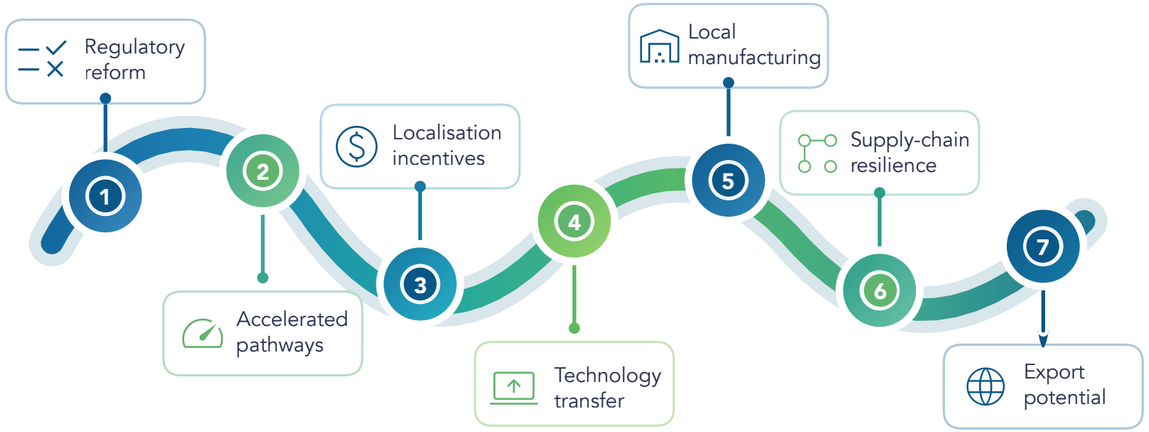
Public-private engagement has also increased considerably. The SFDA regularly engages with private-sector stakeholders to identify operational challenges and gather industry feedback. Scientific workshops, collaborative forums and technical consultations have become increasingly valuable mechanisms for supporting knowledge transfer and strengthening domestic capabilities.

Despite substantial progress, challenges remain in scaling industrial localisation across the life sciences sector. Advanced manufacturing sectors such as biotechnology, cell and gene therapies, and specialised medical technologies require highly skilled workforces, specialised infrastructure and continuous regulatory adaptation. Building sufficient domestic talent pools

Growth in Drug Designations (2024–2025)



How the SFDA enables industrial localisation



in these areas will require sustained investment in education, training and research capacity over the longer term.

Regulatory systems must continue evolving to keep pace with rapidly advancing technologies. Emerging therapeutic modalities, artificial intelligence-enabled medical technologies and advanced manufacturing processes present scientific and regulatory complexities that require increasingly sophisticated oversight frameworks. Maintaining international alignment while adapting to local industrial objectives will remain a delicate balancing exercise.

Nevertheless, the trajectory of reform is significant. Saudi Arabia has already made progress in expanding local manufacturing capabilities, strengthening supply chain resilience, and attracting international partnerships in pharmaceuticals and medical devices. More multinational companies are entering localisation agreements with Saudi manufacturers, while domestic firms are increasingly participating in higher-value sectors of the health care supply chain.

Taken collectively, the SFDA's reforms reflect an expansion of its regulatory role to include stronger enablement and facilitation. By aligning regulatory modernisation with industrial policy, investment facilitation and technological advancement, the authority is helping to establish the conditions necessary for a diversified life sciences sector capable of attracting long-term investment and supporting sustainable industrial growth. As Saudi Arabia continues investing in advanced manufacturing, biotechnology and health innovation, the SFDA is likely to remain central to the Kingdom's ambition to position itself as a regional centre for life sciences production, investment and research.

Taken collectively, the SFDA's reforms reflect an evolution from a traditional regulatory role towards a broader strategic enabling role. This is supported by the role of the SFDA department responsible for investment development and growth, in engaging with investors, addressing regulatory challenges and promoting localisation opportunities. By aligning regulatory modernisation with investment facilitation, industrial localisation and technological advancement, the SFDA is contributing to a more attractive environment for investment, domestic manufacturing and sustainable growth in Saudi Arabia's life sciences sector. As the Kingdom continues to invest in advanced manufacturing, biotechnology and health innovation over the long term, the SFDA will remain an important and strategic enabler of a competitive regional life sciences ecosystem.