The Saudi Healthcare Market

A Guide to Entry and Growth

Navigating Opportunity, Partnerships, and Market Access

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The Saudi Healthcare Market: A Guide to Entry and Growth

A Strategic Guide for International Healthcare Companies

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How to Use This Report

A practical market-entry guide for international healthcare, life sciences and pharmaceutical companies

Saudi Arabia's healthcare market is undergoing a structural transformation driven by Vision 2030, the Health Sector Transformation Program, increased private-sector participation, localisation, digital transformation and the corporatisation of public healthcare delivery. For international healthcare, life sciences and pharmaceutical companies this creates significant opportunities. However, market entry requires more than identifying demand for a product or service.

This report is therefore designed as a practical market-entry guide, moving from the strategic case for entering Saudi Arabia to the specific requirements for establishing and growing a presence in the Kingdom. It follows a deliberate sequence, summarised on the next page, and each section opens with a short introduction explaining what it covers and how it builds on the sections before it.

The central message: approach Saudi Arabia as a strategic, long-term market and not simply as an export destination. Understand the regulatory sequence, engage the right decision-makers and align with the Kingdom's localisation and saudisation priorities.

Key Acronyms at a Glance

Core institutional, regulatory and market-entry terms used throughout the report.

MOH – Ministry of Health: policy, regulation and facility licensing.

HSTP – Health Sector Transformation Program: Vision 2030 health reform.

HHC – Health Holding Company: state delivery platform for regional clusters.

MISA – Ministry of Investment: foreign-investor licensing and registration.

SFDA – Saudi Food and Drug Authority: medicines and medical-device authorisation.

NUPCO – National Unified Procurement Company: central public-sector procurement.

CNHI – Center for National Health Insurance: public payer and value-based purchasing.

IA – Insurance Authority: insurance-sector regulator, including health cover.

NPHIES – National platform for eligibility, pre-authorisation and insurance-data exchange.

Qiwa – MHRSD labour platform: contracts, visas and saudisation administration.

ZATCA – Zakat, Tax and Customs Authority: tax, VAT, customs and e-invoicing.

LCGPA – Local Content and Government Procurement Authority: local-content preferences.

MDMA – Medical Device Marketing Authorization: SFDA approval before market entry.

AR – Authorised Representative: Saudi-licensed representative for foreign manufacturers.

LLC – Limited Liability Company: common entity for direct foreign control.

Why Saudi Arabia?

Understanding the Investment Case

01

Section One

Why Saudi Arabia?

A practical market-entry guide for international healthcare, life sciences and pharmaceutical companies

Saudi Arabia's healthcare transformation is part of a broader national economic strategy rather than a short-term response to cyclical market conditions. This section establishes why the Kingdom has become a priority market for international healthcare and life sciences companies, examining the scale of healthcare expenditure, Vision 2030, demographic and disease-burden trends, infrastructure requirements and the expansion of private-sector participation.

It also places the current opportunity in context by examining the transformation from a predominantly public-provider model towards a more diversified, digitally enabled and increasingly private-sector-supported healthcare system. Long-term presence of international companies already operating successfully in Saudi Arabia shows how sustained local presence, partnerships, technology transfer and localisation can support long-term market development.

Section logic: why the market is attractive → why the opportunity is growing → how the system is changing → what successful international entrants have done.

The Core Investment Thesis

Saudi Arabia is both the region's largest healthcare market and its most active policy-led transformation success story.

The transformation of Saudi Arabia's healthcare sector is one of the most ambitious globally.

Under Vision 2030's Health Sector Transformation Program, the Kingdom is shifting from a mainly public-provider model to a mixed system to expand private-sector participation, attract foreign capital and expertise, localise pharmaceutical and medical-device manufacturing, digitise care delivery, and raise quality and standards.

The opportunity is large and shaped by policy. The annual health and social development budget for 2026 is US $69bn.

Private participation is a stated aim of the Health Sector Transformation Program: more care delivered with private providers, investors and operators alongside the public system. Foreign companies that commit to a local presence, Saudisation and technology transfer are the ones positioned for long-term supply relationships. Entry is through licensing, registration, cluster relationships and the relevant procurement channel.

US $69bn+

Health and Social Development Budget 2026

Bottom Line

Foreign healthcare, life sciences, and pharma companies that regard Saudi Arabia as a strategic long-term market rather than solely an export destination and that invest in local presence, talent development, and manufacturing/technology transfer will enter a welcoming, high-growth environment with strong government sponsorship.

Sources

Based on GHS research and estimates

Information Classification: General

Why Saudi Arabia Matters Now

Saudi Arabia is a large, structurally committed market. The government has embedded healthcare transformation into national economic policy through its Vision 2030 to ensure resilience to oil-price cycles.

Structural Demand Drivers

Scale of Spend

Largest healthcare market by healthcare expenditure in GCC; government allocations have grown in recent budgets.

Demographics & Disease Burden

A young but steadily ageing population, with rising rates of diabetes, cardiovascular disease, hypertension, obesity and cancer.

Infrastructure Gap

Significant additional bed capacity and speciality infrastructure are required by 2030, especially outside the core urban centres.

High Coverage, Insurance Market Still Growing

95.9% of the population has some form of coverage: state entitlement for citizens plus mandatory employer-funded cover for expatriates and private-sector staff; this is not private-insurance penetration. Demand is shifting from access to quality as insurance expansion and National Platform for Health and Insurance Exchange Services (NPHIES) grow the insured spend pool.

Increasing Quality & Accreditation

Government is raising standards (CBAHI accreditation) and introducing value-based, digital models that favour sophisticated international operators.

The market opportunity is real but it is shaped by policy. Any entry strategy must align with government priorities and not just commercial demand.

Sources

[1] https://www.trade.gov/country-commercial-guides/saudi-arabia-healthcare
[2] https://www.stats.gov.sa/en/w/gastat-100-of-saudis-have-basic-healthcare-coverage

Structural Reasons to Enter Now

An aggressive drive for localisation, together with a fast-growing uptake in high-opportunity segments like digital health and AI, means that Saudi Arabia's healthcare market presents a combination of unmet consumer demand and sustained government capital and policy support.

Localisation of Manufacturing a National Priority

- Partnerships with PIF entities (e.g., Lifera), technology transfer, and local production unlock significant commercial and strategic advantages.
- At Global Health Exhibition 2025, for example, Pfizer Saudi Arabia and Lifera signed an MoU to explore local drug manufacturing, technology transfer, and workforce development.[5]

High Growth, High Alignment Opportunity Clusters

- Digital health, AI, speciality care, home care, rehabilitation, diagnostics, and biopharma manufacturing.
- Clusters like digital health and AI are experiencing double-digit CAGR.

100% Foreign Ownership [2]

- Available for a vast majority of healthcare-related activities (services, manufacturing, trading, consulting, digital health) under a Ministry of Investment Saudi Arabia (MISA) investment registration.

Clear Sequential Registration Pathway for Ease of Business [3]

- MISA Investment Registration → Commercial Registration (Ministry of Commerce) → Sector licences (MOH for facilities; SFDA for pharmaceuticals, medical devices, cosmetics) → Tax/GOSI/Qiwa/municipal registrations.

SFDA: A Credible, Internationally Respected Regulator [4]

- SFDA, Saudi Arabia's drug and device regulator, is recognised by the World Health Organization as one of the world's most mature regulatory authorities - a distinction achieved by a select number of countries.

Sources

[1] https://investmentpolicy.unctad.org/investment-policy-monitor/measures/5539/saudi-arabia-launches-the-national-privatisation-strategy

[2] https://misa.gov.sa [3] https://eservices.misa.gov.sa

[4] https://www.who.int/news/item/30-10-2023-saudi-arabia-regulatory-system-becomes-third-to-reach-who-maturity-level-4

[5] Pfizer Saudi Arabia – Lifera MoU, announced at Global Health Exhibition 2025, Riyadh: gulfnews.com/business/markets/pfizer-saudi-arabia-pifs-lifera-to-explore-local-drug-manufacturing-1.500322851

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Localisation of Manufacturing a National Priority

- Partnerships with PIF entities (e.g., Lifera), technology transfer, and local production unlock significant commercial and strategic advantages.
- NUPCO, Sanofi and Novo Nordisk have partnered on insulin localization programs with local manufacturing partners. These arrangements have moved beyond the original agreements toward technology transfer and local production. [1]

High Growth, High Alignment Opportunity Clusters

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Sources

[1] https://www.spa.gov.sa/en/N2193470

[2] https://misa.gov.sa [3] https://eservices.misa.gov.sa

[4] https://www.who.int/news/item/30-10-2023-saudi-arabia-regulatory-system-becomes-third-to-reach-who-maturity-level-4

Information Classification: General

The Saudi Healthcare Ecosystem

Procurement decisions are increasingly made at a cluster, payer, or centrally-procured portfolio level as opposed to hospital by hospital.

Since 2024, Insurance Authority regulates the private health insurance market[1]

01

Ministry of Health: Central government licensing authority

02

Health Holding Company:Care delivery and regional health clusters

03

Local Content and Government Procurement Authority

04

SFDA: Pharmaceuticals and medical devices regulation

05

NUPCO: Centralised public-sector procurement

06

Council for National Health Insurance: Public payer

07

CBAHI: ility accreditation and quality standards

08

Insurance Authority: Health insurance regulator

09

NPHIES: Unified eligibility, pre-authorisation and claims exchange

10

Etimad: Government platform for tenders, contracts and payments

11

SCFHS: Practitioner classification and licensing

Commercial implication

Map the buyer, regulator and reimbursement gate separately before committing to entering the market.

Source

[1] https://gccbdi.org/legal-updates/saudi-insurance-authority-has-now-become-sole-regulator-insurance-sector-ksa

Healthcare Transformation

The healthcare sector in Saudi Arabia has pivoted from a Ministry-centric to a distributed, cluster-based delivery model.

2016	2017	2022	2026
Vision 2030 Launch	First health cluster	Health Holding Company Established	SFDA signs MOU with Singapore's HSA

01 — 2016

Vision 2030 announced. Health is a national priority: access, quality, prevention and a larger role for private providers.

02 — 2016 - 2020

Health Sector Transformation Program (HSTP): expanded private-sector participation, cluster-based care model introduced

03 — June 2022

Health Holding Company (HHC) established, now the delivery platform running 20+ regional health clusters

04 — 2022–Present

NPHIES (National Platform for Health and Insurance Exchange Services): mandatory for providers and insurers; handles eligibility, pre-authorisation, and claims exchange

05 — 2024

First wave of health clusters transferred from the Ministry to the Health Holding Company. Health insurance market regulation moved to the Insurance Authority

06 — February 2025

New Investment Law: One framework for Saudi and foreign investors. reduces the time and friction of market entry compared to the pre-2025 regime.

07 — September 2026

SFDA and Singapore's Health Sciences Authority signed a MOU on regulatory cooperation, including novel products in biotechnology and AI

Source

Vision 2030; Health Holding Company, health.sa (first cluster 2017, company established 2022, 20 clusters by end-2023, first-wave transfer 2024); Council of Health Insurance notice, 4 March 2024; Investment Law in force February 2025. NPHIES was rolled out in phases

https://sfda.gov.sa/en/news/19512

Information Classification: General

Case Studies: Foreign Companies Already Operating Successfully

Long-term, localised strategies have already proven successful in the Kingdom. The following public examples illustrate different successful models:

01

Companies: Novo Nordisk (Denmark) and NUPCO (Saudi Arabia)

Segment: Pharmaceuticals/Insulin localisation

Novo Nordisk partnered with NUPCO and local manufacturing partners on insulin localization. The program has progressed from agreement toward technology transfer and local production.

02

Companies: Shilpa Biologicals (India) and SOIMACO Bio (Saudi Arabia)

Segment: Pharmaceuticals/Bio-similars

Exclusive MENA licensing for PD-1 bio-similars. Shilpa manufactures and transfers technology. SPIMACO leads regulatory and commercial work in Saudi Arabia and the region.

03

Companies: Sysmex (Japan)

Segment: Diagnostics/Devices

Direct affiliate since 2022 and a regional headquarters in Riyadh. 2025 memorandum for a diagnostic-reagent factory and logistics hub.

04

Companies: ezCaretech (Korea) and Ministry of National Guard Health Affairs

Segment: Digital Health/Hospital IT

Supplied an integrated hospital information system to the Ministry. Later formed the Saudi Korean Health Informatics Company joint venture in Riyadh.

05

Companies: Fosun Health (China) and Fakeeh Care Group (Saudi)

Segment: Healthcare Services/Digital Hospital

Memorandum covering specialty development, digital hospital solutions, preventive care with wearables, and regenerative medicine.

Source

Publicly reported information

Market Overview

From Market Potential to Commercial Opportunity

02

Section Two

Market Overview

From Market Potential to Commercial Opportunity

Understanding the size of the opportunity is only the starting point. International companies also need to understand where demand sits, how healthcare is delivered and funded, who the principal buyers are and which segments offer the strongest opportunities.

This section therefore moves from headline market metrics into the structure of the Saudi healthcare system.

It examines infrastructure and workforce capacity, the changing procurement architecture, public and private buyer types and the principal segment opportunities across pharmaceuticals and biosciences, medical devices and equipment, digital health, and healthcare services. It also considers special economic and trade zones as potential platforms for investment, manufacturing and localisation.

Section logic: How large is the market → how is it structured → who buys → where are the opportunities → where can investment be located?

Market Size and Key Metrics

US $69bn +

Annual government health and social development budget for 2026; one of the largest single budget lines in the Kingdom at 20% of total 2026 budget [1]

US $33bn+

Strategic partnerships and investments announced by Ministry of Health on the opening day of Global Health Exhibition 2025, including US$8.4 billion in hospital and infrastructure projects [2]

97.5%

Strategic Share of population clusters covered by essential healthcare services, including remote areas[3]

79.7 Years

Life expectancy reported in the Health Sector Transformation Report 2025, against a Vision 2030 target of 80 [4]

US $69bn+

Annual gov Health and Social Development budget 2026[1]

US $33bn+

Strategic Partnerships and Investments

Sources

[1] Ministry of Finance, Budget Statement / Mid-Year Budget Report FY 2026 (mof.gov.sa)

[2] Ministry of Health news, 29 October 2025 (moh.gov.sa)

[3] HSTP 2025 report

[4] Ministry of Health news on the 2025 HSTP report (moh.gov.sa)

Infrastructure and Workforce

Saudi Arabia is not a greenfield market and already has a scaled, functioning healthcare system:

- **516** hospitals and **23.4 beds** per 10,000 people [1]
- **82,721** total hospital beds, including **20,624** beds in private-sector hospitals [1]
- **20+** HHC health clusters determine public-sector procurement [3]
- **129,772** physicians, **243,336 nurses**, and **46,856** pharmacists [1]

The Health Sector Transformation Program is expanding capacity and workforce. The Ministry of Health and the Saudi Commission for Health Specialties report that registered healthcare practitioners now exceed 800,000 [2].

516
Hospitals
(2024 baseline)

23.4
Beds/10k population

800k
Healthcare practitioners

20+
Health clusters, Public delivery network

Sources

[1] Current facility, bed and workforce counts: MOH Statistical Yearbook 2024.

[2] scfhs.org.sa.

[3] Cluster count: https://www.health.sa/en/clusters/list

Procurement and Buying Behavior

Who buys depends on the product, and on how far that part of the system has moved. Build the sales plan around the actual buyer for that category, not around a single public channel.

Usual first step

Dealer & Distributor

Most foreign companies still start here, especially for devices and consumables, before they sit down with any of the buyers below.

This opens several routes. Public buying is not one counterparty.

Public Sector

Several buyers, not one

The Ministry of Health, the Health Holding Company and its clusters, NUPCO, and other government channels all buy - which one depends on the category and the stage of transfer.

Tender windows can be weeks; price benchmarked against regional/global references.

NPHIES

Eligibility layer

Determines eligibility, pre-authorisation, and reimbursement decisions.

Mandatory connectivity for all providers and insurers.

Increasingly influences formulary access and device reimbursement.

Private Hospitals & Groups

Usually the faster route

Buying is structured. Clinical evidence, price and a clear service commitment all matter, and decisions tend to move faster than in the public system.

Examples include: Saudi German, Dr. Sulaiman Al Habib, Mouwasat, Dallah.

Insurers & TPAs (Third-Party Administrators)

Dominant Payers

Examples include Bupa Arabia, Tawuniya, and Medgulf.

Formulary and reimbursement decisions are increasingly centralised.

NPHIES integration is a prerequisite.

Sources

SFDA/NUPCO procurement guidance; Trade.gov Saudi Arabia Country Commercial Guide; Council of Cooperative Health Insurance (CCHI/Insurance Authority) NPHIES documentation

The Saudi Healthcare Market: Key Segment Opportunities (2026 Outlook)

Driving value through Vision 2030 Localisation, and Digital Transformation

Pharmaceuticals & Biosciences

Market: Priority sector on Invest Saudi. Focus on biologics, vaccines, and cell and gene therapy.

Opportunity: Local manufacturing and technology transfer with nation partners, including PIF vehicles such as Lifera.

Entry Path: MISA registration, then SFDA authorisation.

Medical Device & Equipment

Procurement: Buying is distributed across the Ministry, HHC clusters, NUPCO and other channels

Regulatory: Early SFDA engagement. MDMA required before sale.

Hot Spots: Advanced diagnostics, complex surgical hardware, high-volume consumables.

Digital Health (New Segment)

Catalyst: SEHA Virtual Hospital linking 220+ hospitals nationwide.

Program Target: Unified digital medical record for 100% of the population.

Opportunity: Electronic Health Records (EHR), remote monitoring, AI-supported diagnostics, NPHIES-compliant eligibility & claims tools.

Healthcare Services & Care Delivery

Delivery: Public care runs through the Health Holding Company's 20+ clusters.

Models: Private operators alongside the public system in specialty, home health, rehabilitation and longer-term care.

Entry Path: MISA registration, Ministry of Health facility license, and cluster relationships where relevant.

Key Commercial Note: Digital health is a new and rapidly growing segment with significant government backing

Sources

Future Market Insights (Pharma 2026), IMARC Group (Digital Health), NIDLP / Vision 2030 localisation targets, Ministry of Health / Seha Virtual Hospital official data, NUPCO & SFDA regulatory frameworks, Health Sector Transformation Program

Special Economic and Trade Zones for Pharmaceutical & Healthcare Companies

Government support through multiple special zones for Pharmaceutical and MedTech companies

King Abdullah Economic City (KAEC) SEZ [1]

- **Target sectors**: Pharmaceuticals and MedTech, alongside advanced manufacturing, automotive, ICT, and logistics
- **Tax incentives:** 5% corporate income tax for up to 20 years, 0% withholding tax on profit repatriation, customs duty suspension, and VAT zero-rating on goods within the zone
- **Geostrategic Red Sea position connecting Asia, Europe, and Africa**, with an existing logistics and light-manufacturing hub in Industrial Valley
- KAEC has a proven pharma track record, as this is where **Pfizer's manufacturing and packaging facility is located**

Riyadh Integrated Special Logistics Zone (SILZ) [2]

- Target sectors: Global logistics, Pharmaceuticals, Nutritional and Medical Supplies, alongside Luxury Goods, Aviation, Consumer Electronics and Computer Systems
- Tax incentives: 0% corporate income tax for up to 50 years, 0% withholding tax on profit repatriation, customs duty suspension, and others
- Strategic positioning of Riyadh Integrated, only 8km from the King Khalid International Airport, allows companies to expedite the arrival of goods at the zone in order to access the largest consumer market in the Middle East

Key Commercial Note: Each zone serves different strategic objectives, so the appropriate location will depend on the company's intended activity and long-term goals

Sources

[1] https://www.kaec.net/kaecsez/

[2] https://silz.gaca.gov.sa/business/about-us

Public and Private Healthcare Landscape

Care is divided between a large public system and a fast-growing private sector, with each offering different entry points and mandatory insurance reconfigure demand.

Dimension	Public sector	Private sector
Role & scale	~60% of beds under Ministry of Health (MOH); universal, largely free care for Saudi nationals	~25% of beds and rising, driven by insurance and expatriate demand
Key players	MOH health clusters, Ministry of National Guard Health Affairs (MNGHA), military & university hospitals	Dr. Sulaiman Al-Habib (HMG), Mouwasat, Dallah, Saudi German, Fakeeh
Funding	State budget	Mandatory cooperative insurance for expats and private-sector staff
Direction	Corporatisation of public assets via Public Investment Fund (PIF) / Health Holding Co.	Rapid expansion; capacity, technology and specialty-care gaps
Where you fit	Framework contracts, Public-Private Partnership/Joint Ventures, clinical services to clusters	Equipment, digital health, speciality and staffing partnerships

Takeaway: make contact with public clusters through framework contracts, and private groups through equipment, digital health and speciality partnerships.

Source
MOH; sector market data

Entry Requirements

Understanding the Route into the Market

03

Section Three

Entry Requirements

Understanding the Route into the Market

Saudi Arabia offers multiple routes into the healthcare market, but the appropriate model depends on the product or service, regulatory requirements, capital commitment, desired level of control and long-term ambition. Entry is therefore not a single decision but a sequence of regulatory, commercial and structural choices.

This section explains the principal regulatory and licensing pathways and compares the main entry models available to international companies,

from distributors and authorised representatives to direct entities, joint ventures, BOT structures and manufacturing or localisation.

Section logic: What must be approved → what legal and commercial structure is appropriate → how much control and investment is required → where additional opportunities are created

Regulatory & Licensing Pathways

Sequencing is critical, as commercial activity cannot commence prior to core registrations being completed. The steps below indicate the critical path and where limited parallel work is possible.

Indicative Official Processing Windows

5-10 Days	35 Days	15 Days	5-14 Days
MISA registration	SFDA MDMA (GHAD)	Hospital Operating License	SCFHS licensing

01 Entity Establishment (MISA + Ministry of Commerce)

- MISA investment registration (5-10 days) → Commercial Registration (30–90 days)
- Preferred form: LLC | 100% foreign ownership available for most healthcare activities

02 Product Registration (SFDA) - Critical Path for Devices & Pharma

- **Medical Devices:** Medical Devices Marketing Authorization (MDMA) submitted through GHAD. Review window for a complete file is 35-60 working days. A Saudi-licensed Authorized Representative is required for foreign manufacturers.
- **Pharmaceuticals:** Separate drug registration pathway. Timelines and documentation differ from the device pathway. Confirm current requirements with SFDA before submission.

03 Facility Licensing (Ministry of Health)

- Hospital license issued within 15 working days of a complete application. Prior steps such as commercial registration, municipal license, inspection and building approvals determine the overall timeline.

04 Practitioner Licensing by Saudi Commission for Health Specialties (SCFHS)

- Final registration 5–14 days once classification and exam are complete
- Full DataFlow + classification + exam journey typically takes 3–8 months

05 Operational Readiness

- ZATCA, GOSI, Qiwa contract authentication, bank account, NUPCO prequalification (where applicable)

All figures referenced above reflect official processing windows for the final review/registration stage only, not end-to-end timelines.

Sources

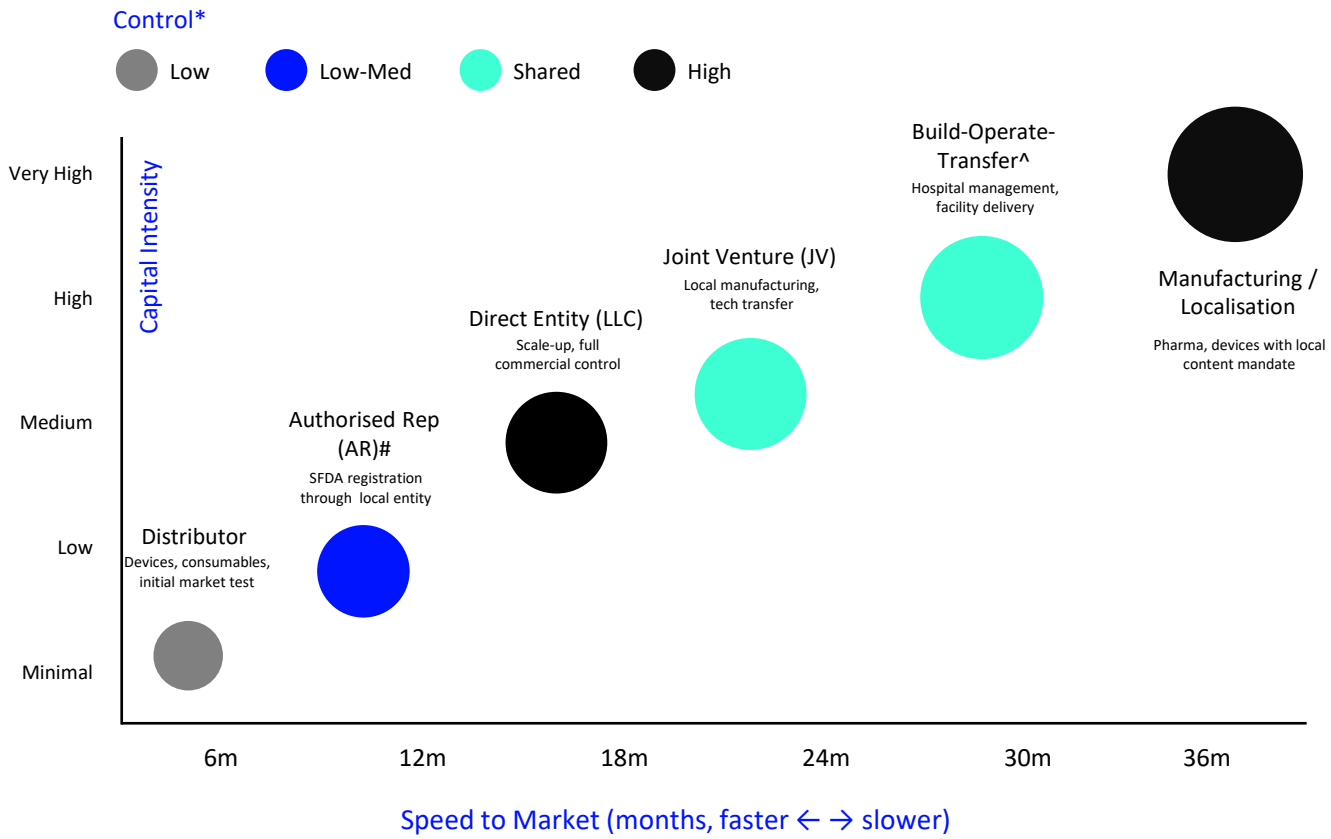
Market-Entry Models

The correct entry model depends on the product type, regulatory pathway, capital availability, and long-term market ambition. Most companies begin with a distributor or authorised representative and upgrade their presence as the market matures.

6
Entry models compared

3-6m
Fastest route: distributor

2025
New investment law simplifies entity setup



***'Control'** in the chart above refers to how much operational and commercial decision-making authority the foreign company retains: pricing, branding, staffing, strategy, and how the product or service is positioned in-market.

#**Authorised Representative**: A mandatory local entity that acts as the official legal liaison between a foreign medical device manufacturer and the Saudi Food & Drug Authority (SFDA)

^BOT: Build-Operate-Transfer models are the central pillars of Saudi Vision 2030 to drive economic diversification and infrastructure development

Source

SFDA/MISA guidance; Trade.gov Country Commercial Guide; White & Case and CMS market-entry advisories

Stakeholder Map

Knowing Who Makes the Decisions

04

Section Four

Stakeholder Map & the Regulatory Gate

Knowing Who Makes the Decisions

One of the most important changes in Saudi healthcare is the shift from a predominantly Ministry of Health-centric system towards a more distributed, cluster-based delivery and purchasing architecture. As a result, knowing the formal regulator is not necessarily the same as knowing the organisation or individual that controls the commercial decision.

This section maps the institutional landscape and clarifies the roles of the Ministry of Health, Health Holding Company and regional health clusters, SFDA, NUPCO, payers and insurance platforms, professional and accreditation bodies, investment institutions and procurement authorities, helping companies distinguish between regulatory gates, purchasing gates, delivery organisations and investment partners at each stage of market entry.

Section logic: Who regulates → who pays → who procures → what SFDA requires → how approval is kept..

Who Does What: Institutional Roles

Market access is not one door. Policy, delivery, procurement sit with different institutions, and the split is still moving. Read the map in that order before you decide who to call.

Institution	What it actually does	Why it matters
Ministry of Health (MOH)	Sets National health policy and regulation, and is shifting out of day-to-day provision.	Strategy, licensing of facilities, and the rules the rest if the system works under. moh.gov.sa
Health Holding Company (20+ Health Clusters)	HHC is the state delivery platform. These health clusters run public hospitals and primary care in their regions.	These are the operating customers for many products and services. health.sa
Saudi Food & Drug Authority (SFDA)	Authorizes medicines, medical devices and food before they can be sold.	No registration, no sale. WHO maturity level 4 for medicines and vaccines. sfda.gov.sa
Insurance Authority (IA)	Regulates the private insurance market, including health cover.	Sets the rules for payer coverage and conduct. ia.gov.sa
Saudi Commission for Health Specialties (SCFHS)	Licensing and classification of health professionals.	Governs whether your clinical staff can practice. scfhs.org.sa
Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI)	National accreditation body for healthcare facilities.	Quality bar your provider partners must meet. cbahi.gov.sa
Center for National Health Insurance (CNHI)	CNHI is the public payer. Buys care from accredited providers for beneficiaries covered by state-funded insurance.	A buyer of services, not a regulator. Distinct from the Insurance Authority. cnhi.gov.sa
National Platform for Health and Insurance Exchange Services (NPHIES)	NPHIES is the national platform for eligibility, pre-authorization and claims exchange.	Providers and Insurers have to be NPHIES integrated to transact. nphies.sa
National Unified Procurement Company (NUPCO)	PIF-owned company that aggregates demand and buys medicines, devices and supplied for many government facilities.	Often the counterparty for public product. nupco.com
Etimad	The Ministry of Finance platform where government tenders are published.	Where you find and submit broader public bids. etimad.sa
Local Content Authority (LCGPA)	Sets local-content rules for government procurement	Local-content score can change who wins a tender. lcgpa.gov.sa
Ministry of Investment (MISA)	Licenses foreign investors.	First gate for 100% foreign ownership in most healthcare activities. misa.gov.sa
Lean Business Services (PIF)	Builds and operates national digital health platforms, including Sehhaty, Seha and the health-information exchange.	A technology partner and digital enablers of healthcare in Saudi Arabia. lean.sa

Sources

Ministry of Health; Health Holding Company: SFDA; Insurance Authority; Center for National Health Insurance; SCHS; BAHI; NUPCO; Etimad / Ministry of Finance; LCGPA; Ministry of Investment; PIF portfolio page for Lean Business Services.

Saudi Food & Drug Authority (SFDA)

The Critical Gatekeeper for Pharma & Medical Device Market Access in Saudi Arabia

SFDA is the sole regulator controlling market entry for pharmaceuticals, medical devices (including SaMD), and biologics in Saudi Arabia. No product can be imported, distributed, or sold without SFDA authorisation. It is the critical path item for NUPCO tenders, hospital access, and commercial scale-up under Vision 2030.

35-60 days
Official MDMA review tar get

3 years
MDMA Validity
Renewable

US $700
Annual Authorised Representative fee
Mandatory for Foreigners

US $4k-6k
Application fee — SAR 15,000–23,000 (excl. 15% VAT)
Fee scales with risk class A–D; renewal SAR 5,000, minor label update SAR 1,100

SFDA MDMA Registration Process

01 Classify the device
Determine risk class A–D based on invasiveness, duration of use and harm potential

02 Appoint authorised rep
Mandatory for foreign manufacturers without a Saudi legal entity; SAR 2,600/year

03 Prepare technical file
CE/FDA certificate, ISO 13485 QMS, engineering data, Arabic/English labels

04 Submit via Unified Electronic System (GHAD)
Electronic filing through SFDA's Medical Devices Registration System

05 Pay fees & technical review
SADAD payment; on-site Good Manufacturing Practice (GMP) inspection required for class III/IV

06 MDMA certificate issued
Medical Devices Marketing Authorization
Valid 3 years, renewable; device listed on SFDA's approved register

Commercial takeaway: Dossier quality and Authorised Representative discipline determine whether the 35-60 business-day target is achievable or becomes a cascading delay.

Sources

SFDA, "Evaluation Fees of Medical Device Marketing Authorization (MDMA)" fee schedule (sfda.gov.sa/sites/default/files/2025-05/MDMA-Fee4En.pdf); SFDA Authorised Representative licensing guidance.

SFDA MDMA regulations (MDS-G008); GHAD registration system. Fees exclude 15% VAT; USD conversion at SAR 3.75 peg

Inside the Technical File:

What SFDA Actually Reviews

The technical file is the primary route to a Medical Device Marketing Authorization, and its completeness determines whether registration lands at the fast or slow end of the stated range. External approvals such as CE or US FDA may be submitted in support but are not mandatory. ISO 13485 certification is.

Technical File Contents

Part 1

General information

- Manufacturer and design facility details, including any critical subcontractors
- External approvals (CE, US FDA) — **optional**, submitted in support only
- Device and accessory information: labels, instructions for use, marketing material
- Product variants, with model numbers and SKUs listed under a parent product
- SFDA classification (Class A–D)
- Manufacturing process, design traceability, design stages and manufacturing structure
- **ISO 13485 QMS certificate — mandatory**, with latest audit report accepted within 12 months

Part 2

Technical Documentation

- **Essential Principles checklist — mandatory**, on the SFDA template and manufacturer letterhead
- Complete risk management file: plan and report
- Clinical evaluation plan and report
- Stability, shelf-life and product testing data
- Post-market surveillance plan and report — **plan only where the product is new to market**
- Declaration of Conformity
- Any additional supporting documentation

50 products maximum per application — but only if they share no more than 5 technical files. Where each product carries its own separate technical file, the ceiling falls to 5 products per application.

Bundling Categories

Category	Condition
Medical device family	Same classification and same intended use
Medical device system	Sold and used as a single system
Procedure pack / kit	Supplied as a combined pack
IVD products	In-vitro diagnostic grouping

MDMA Fee Schedule

Device class	SFDA fee
Class A	US $4,000
Class B	US $4,800
Class C	US $5,600
Class D	US $6,135
Renewal / update	US $1,335

Fees exclude 15% VAT. MDMA validity is three years, renewable; the certificate may be updated within its term to add products or models.

Two decisions made before submission — how products are bundled, and whether the file is genuinely complete — set both the cost and the duration of Saudi market entry.

Sources

SFDA, "Evaluation Fees of Medical Device Marketing Authorization (MDMA)" fee schedule (sfda.gov.sa/sites/default/files/2025-05/MDMA-Fee4En.pdf); SFDA Authorised Representative licensing guidance.

SFDA MDMA regulations (MDS-G008); GHAD registration system. Fees exclude 15% VAT; USD conversion at SAR 3.75 peg

SFDA After Approval: UDI, Vigilance & Launch Readiness

SFDA relevance does not stop when the MDMA certificate is issued. International entrants must show that the local representative and distributor can support UDI submission, adverse-event reporting, recall coordination, import clearance and post-market surveillance across the commercial life of the product.

UDI Readiness

Mandatory since Dec 2024 — Applies across device Classes A–D. UDI data must come from an accepted issuing agency (GS1, HIBCC or ICCBBA) and be submitted through the Authorised Representative holding the product certificate. No SFDA fee is stated for UDI.

Post-Market Reporting Deadlines

Event type / trigger	Deadline
Serious public-health threat	2 working days
Unanticipated death or serious injury	10 working days
Event not associated with high risk	30 calendar days
SFDA-initiated adverse-event report	5 working days

Post-Approval Obligations

Responding to the regulator

Separately from initial vigilance reporting, the manufacturer and Authorised Representative must respond to SFDA's National Center for Medical Devices Reporting (NCMDR) within 2–5 working days on adverse events occurring in the Kingdom, and on recalls — including where the manufacturer has determined that a global recall does not affect Saudi Arabia. The confirmation is required either way.

MDIL / demonstration licence

Product brought into the Kingdom solely for exhibition, demonstration, training or research does not require MDMA. A Medical Device Importation Licence (MDIL) covers demonstration use and must be kept separate from commercial sale.

Bottom Line

Treat SFDA as a market-access system, not a single approval milestone.

Sources

KSA Healthcare Market Access (SFDA); GHS analysis. Amounts shown in SAR; VAT and external advisory fees excluded unless stated.

Market Entry Execution

Turning Market Entry into an Executable Plan

05

Section Five

Market Entry Execution

Turning Market Entry into an Executable Plan

The strongest market-entry strategy can fail if regulatory, commercial and operational dependencies are not sequenced correctly. Saudi Arabia's healthcare market requires companies to plan around approval timelines, procurement requirements, workforce obligations, localisation expectations and partner readiness rather than treating these as separate workstreams.

This section brings the report's earlier findings together into a practical execution framework. It examines entry timelines and dependencies, saudisation, taxation, incentives and banking, before identifying common commercial and regulatory pitfalls, concluding with a practical 12-month roadmap and guidance on selecting and managing local partners.

Section logic: What can delay entry → what must be prepared → what can go wrong → how to sequence the first 12 months.

Practical 12-Month Roadmap

This is the only sequence the guide asks you to follow. Other pages are context, not alternative plans.

Saudi healthcare entry takes longer than most companies expect because each step depends on the one before it. The roadmap below is illustrative as actual timelines depend on product complexity, regulatory dossier quality, and partner readiness.

01

Phase 1 : Foundation

- Market prioritisation and segment selection
- SFDA dossier gap assessment (longest-lead item, start immediately)
- MISA entity setup initiation (5–10 working days registration; 30–90 days full setup)
- Partner longlist and initial due diligence
- HHC cluster mapping and stakeholder identification

02

Phase 2 : Registration

- SFDA product registration submission
- SCFHS practitioner registration (if applicable)
- CBAHI accreditation planning (if facility-linked)
- Stakeholder engagement: MOH, HHC cluster management, NUPCO contacts
- Insurer/TPA mapping for private-sector channel

03

Phase 3 : Market Readiness

- NUPCO prequalification application
- KOL and key account mapping
- Pilot account selection (private sector for faster access)
- NPHIES integration planning (if digital health or HIS)
- Partner shortlist to 2–3 candidates; begin commercial negotiation

04

Phase 4 : Commercial Activation

- Public-sector tender bids (if NUPCO pre-qualification complete)
- Private-sector pilot launches
- Reference site development
- 90-day go/no-go expansion review

4	12 Months	SFDA	90 Days
Phases from setup to scale	Planning horizon	Critical path [Longest-lead item]	Go/no-go review [Post-activation check]

Tax, Incentives, Banking and Capital Considerations

The Zakat, Tax, and Customs Authority (ZATCA) is responsible for the oversight of tax in Saudi Arabia and regularly issues updates to laws, regulations, and guidelines. Taxation for special economic zones is outlined below:

VAT (Value Added Tax)

15% standard rate. Registration mandatory above threshold; e-invoicing (Fatoora) compulsory.

Corporate Income Tax

20% on taxable income for foreign-owned entities (2.5% **Zakat** may apply in mixed ownership). Standard regional rate.

Withholding Taxes

5%-20%. Apply on certain cross-border payments; treaty network should be reviewed.

Incentives

Industrial / manufacturing projects may access Saudi Industrial Development Fund (SIDF) financing, Saudi Authorities for Industrial Cities and Technology Zones (MODON) land, customs exemptions, and local content preferences. Regional HQs and certain strategic investments have historically received attractive packages.

Banking

Corporate accounts require full KYC/AML (Know Your Customer/Anti-Money Laundering); expect thorough documentation. Capital contribution evidence is required.

Repatriation

Generally permitted subject to tax compliance and central bank rules; no blanket foreign exchange controls of the restrictive type.

It is advised to model tax and incentive scenarios with a specialised Saudi tax advisor. The structure (entity type, financing, IP holding, supply chain) has a material impact.

Sources

https://eservices.misa.gov.sa/en/resources/taxLawsRegulationOverview

Commercial Risks and Pitfalls

The most common market-entry failures in Saudi healthcare are not caused by bad products but by sequencing errors, stakeholder misreads, and foreseeable compliance gaps.

Regulatory Sequencing Failure

Starting commercial activity before SFDA registration, NUPCO prequalification, or CBAHI accreditation is complete. These are sequential dependencies and not parallel tracks.

Outdated Stakeholder Maps

Purchasing is distributed across the Ministry of Health, HHC clusters, NUPCO and other channels. Identify the actual buyer for the product category before committing

NUPCO Prequalification Gap

Missing prequalification means zero access to public-sector tenders. This is a binary gate and not a competitive disadvantage.

Saudisation Compliance Risk

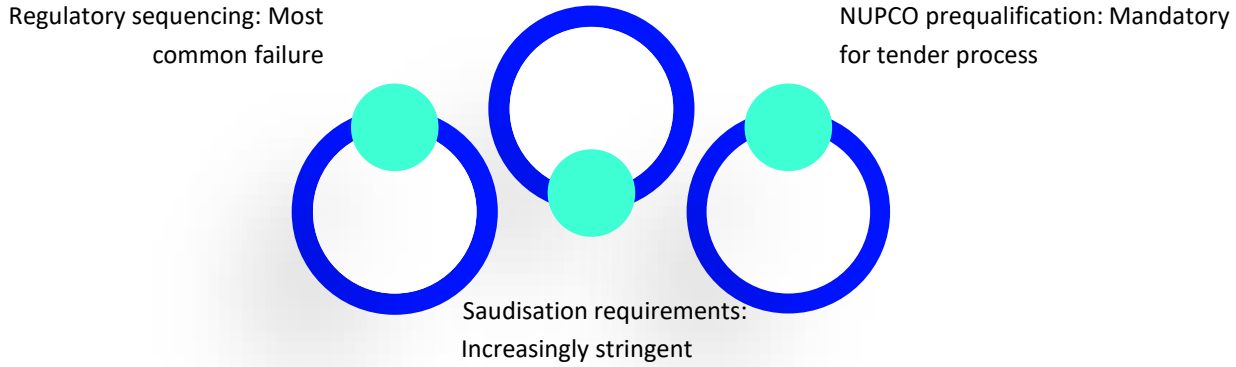
Requirements expanded in 2025. Companies must budget for recruitment, training, and compliance overhead across clinical and commercial roles.

Single-Tender Concentration

Over-reliance on one NUPCO category or one HHC cluster creates fragile revenue. Diversify across buyer types and clusters.

No commercial commitment should depend on an approval that does not yet exist.

Key Risk Categories



References, Abbreviations & Checklists

06

Section Six

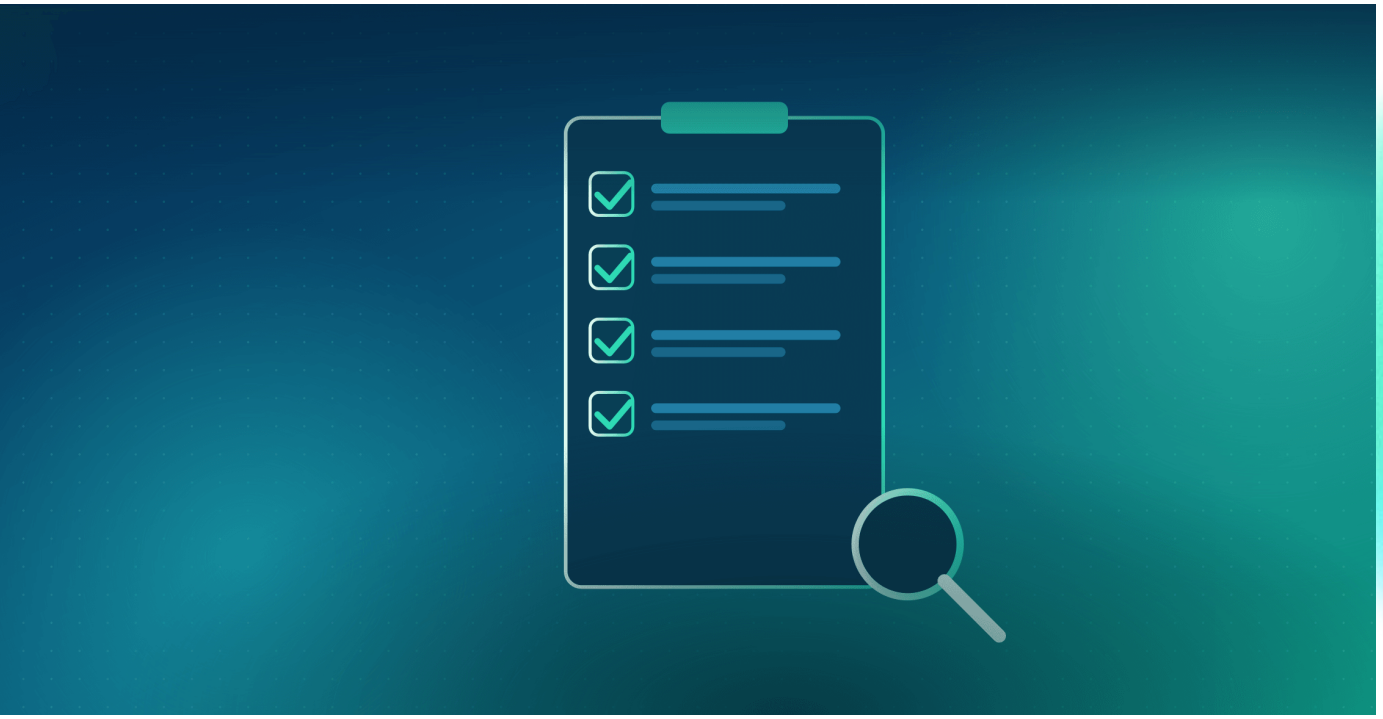
References, Abbreviations & Checklists

From Strategy to Action

The final section converts the report into a practical reference tool. Before committing capital or entering the market, companies need to test their assumptions against regulatory requirements, partner credentials, procurement eligibility, localisation obligations and the specific characteristics of their chosen market segment.

The Final Strategic Checklist provides a concise pre-entry review covering regulatory readiness, entity structure, saudisation, NUPCO prequalification, health-cluster relationships, NPHIES requirements and partner due diligence. The accompanying glossary and reference material provide a common language for the terminology used throughout the report and direct readers to the relevant official portals for further verification.

Section logic: Check your readiness → verify your assumptions → understand the terminology → go to the authoritative source.



Abbreviations and Glossary (1/2)

Institutional acronyms and organisations referenced in the Saudi healthcare market-entry roadmap.

Core market institutions

GCC – Gulf Cooperation Council: Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the UAE; used for regional comparison.

MOH – Ministry of Health: Saudi Arabia's central healthcare policy, regulation and facility licensing authority.

HHC – Health Holding Company: State-owned delivery platform operating Saudi Arabia's regional health clusters.

HSTP – Health Sector Transformation Program: Vision 2030 programme driving reform, prevention and digital health.

MISA – Ministry of Investment of Saudi Arabia: Primary authority for foreign-investor registration and licensing.

SFDA – Saudi Food and Drug Authority: Regulates medicines, devices, cosmetics and product market authorisation.

NUPCO – National Unified Procurement Company: Centralised procurement company for public-sector medicines, devices and supplies.

CBAHI – Central Board for Accreditation of Healthcare Institutions: National facility-accreditation and quality body.

SCFHS – Saudi Commission for Health Specialties: Classifies, licenses and regulates healthcare practitioners.

CNHI – Center for National Health Insurance: Public payer.

CCHI – Council of Cooperative Health Insurance: Legacy health-insurance authority referenced in older materials.

IA – Insurance Authority: Regulator overseeing health insurance after the 2024 transfer of responsibilities.

Regulators, funds & local-content bodies

NCA – National Cybersecurity Authority: Sets cybersecurity controls for cloud, SaaS and digital health systems.

ZATCA – Zakat, Tax and Customs Authority: Administers tax, zakat, VAT, customs and e-invoicing.

MHRSD – Ministry of Human Resources and Social Development: Labour authority for saudisation, Nitaqat and employment compliance.

HRDF / HADAF – Human Resources Development Fund: Employment-support fund for national hiring and workforce development.

LCGPA – Local Content and Government Procurement Authority: Sets local-content policy and procurement preferences.

PIF – Public Investment Fund: Saudi sovereign wealth fund and strategic investor in healthcare localisation.

SIDF – Saudi Industrial Development Fund: Financing support for qualifying industrial and manufacturing projects.

MODON – Saudi Authority for Industrial Cities and Technology Zones: Develops industrial cities and manufacturing zones.

MIM – Ministry of Industry and Mineral Resources: Oversees industrial policy, incentives and localisation.

GOSI – General Organization for Social Insurance: Administers social insurance registration and employer obligations.

Note: verify official names, mandates and portals against current Saudi government sources before market-entry decisions.

Abbreviations and Glossary (2/2)

Operating platforms, regulatory terms and commercial-entry acronyms used across the report.

Digital, regulatory & procurement platforms

NPHIES – National Platform for Health and Insurance Exchange Services: Mandatory eligibility, pre-authorisation, claims and insurance-data exchange platform.

Qiwa – MHRSD labour-compliance platform for contract authentication, visas and saudisation administration.

Etimad – National government platform for broader digital tendering and procurement.

GHAD – SFDA electronic submission portal for regulated products and related procedures.

MDS-REQ – Medical-device requirements series issued by SFDA.

MDMA – Medical Device Marketing Authorization required before a device can be placed on the Saudi market.

SaMD – Software as a Medical Device: Clinical software regulated as a medical device.

HIS – Hospital Information System: Enterprise platform for hospital operations, administration and clinical workflows.

EMR – Electronic Medical Record: Digital clinical record used by providers and care teams.

BOT – Build-Operate-Transfer: structure where a private partner builds, operates and then transfers an asset.

Commercial, legal & finance terms

TPA – Third-Party Administrator: Entity administering insurance claims and payer-provider processes.

KOL – Key Opinion Leader: Influential clinical or scientific stakeholder shaping evidence and procurement.

IKTVA – In-Kingdom Total Value Add: Local-content framework demonstrating contribution to the Saudi economy.

LLC – Limited Liability Company: Common Saudi legal entity for direct foreign commercial control.

JV – Joint Venture: Shared ownership or operating structure with a local or strategic partner.

AR – Authorised Representative: Saudi-licensed representative often required for foreign manufacturers.

PHC – Primary Health Centre: Front-line facility category relevant to delivery planning.

NTP – National Transformation Program: Vision 2030 programme for infrastructure, reform and delivery targets.

KYC / AML – Know Your Customer / Anti-Money Laundering: Banking checks for account opening and cross-border payments.

VAT – Value Added Tax: Saudi Arabia's standard 15% consumption tax.

SAR – Saudi Riyal: The official currency of Saudi Arabia.

Note: verify official names, mandates and portals against current Saudi government sources before market-entry decisions.

Final Strategic Checklist

Saudi Arabia rewards evidence-led preparation and disciplined sequencing. The checklist below covers the minimum conditions for a credible commitment to entering the market.

Before Committing Capital

- Confirm SFDA dossier gaps and realistic registration timeline
- Check MISA entity setup timing and structure (LLC vs. branch)
- Confirm saudisation requirements for your specific roles and company size
- Verify NUPCO prequalification status and requirements for your product category
- Map target HHC clusters: Identify cluster management contacts, not just the MOH
- Confirm NPHIES integration requirements if product impacts claims, eligibility, or reimbursement
- Assess local partner NUPCO status, SFDA track record, and saudisation compliance
- Confirm the current buyer for your category with the Ministry, the relevant cluster and NUPCO.

Before First Market Visit

- Shortlist 3–5 prequalified local partners with verified NUPCO and SFDA credentials
- Prepare realistic regulatory timelines. Do not promise what approvals cannot yet deliver
- Map HHC clusters and payer relationships relevant to your segment
- Confirm which buyer type (public, private, insurer) is your primary channel
- Prepare a localisation narrative: IKTVA (In-Kingdom Total Value Add), technology transfer, or saudisation plan

Official Portals & Source References

Primary Official Portals (Verify All Requirements Here):

- Ministry of Investment (MISA) / Invest Saudi: misa.gov.sa / investsaudi.sa
- Ministry of Health – Healthcare Licensing & Investor Services: moh.gov.sa (electronic licensing services)
- Saudi Food & Drug Authority (SFDA): sfda.gov.sa (GHAD system, MDS-REQ regulations, drug registration)
- Ministry of Commerce / Saudi Business Center: mc.gov.sa / business.sa
- ZATCA (Tax): zatca.gov.sa
- MHRSD / Qiwa (Labour & saudisation): qiwa.sa / hrdf.org.sa (HADAF)
- Vision 2030 / Health Sector Transformation Program: vision2030.gov.sa
- SCFHS (practitioner classification): scfhs.org.sa
- CBAHI (accreditation): cbahi.gov.sa
- NUPCO (procurement): nupco.com
- Local Content & Government Procurement Authority (LCGPA)

Key Reference Categories

- Vision 2030 official publications and Health Sector Transformation Program targets.
- MISA investment licensing guidance and 2026 reform announcements (ownership, fees, Commercial Register Law).
- SFDA Medical Devices Law, implementing regulations, MDS-REQ series, and GHAD procedural guidance.
- MOH Healthcare Investor Licensing resources and electronic facility licensing service descriptions.
- MHRSD Nitaqat 2026 cycle updates and health-profession saudisation decisions (radiology, labs, physiotherapy, pharmacy, etc.).
- Market Scenario: Ministry of Health, Ministry of Finance, MISA, HSTP. Global Health Exhibition investment announcements
- Company-specific public disclosures and press releases.
- Practitioner and legal analyses from specialised firms (for process sequencing and practical timelines) – always cross-checked against official sources.

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