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HEALTH ASSOCIATION COMPANY
شركة رابطة الصحة

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MARKET ENTRY BRIEF · AUGUST 2026

Placing a medical product in Saudi Arabia

What the regulatory route actually involves, how long it takes, and what a foreign manufacturer needs on the ground. Prepared by Health Association Company for partners considering the Saudi market.

USD 12.3bn
Saudi pharmaceutical market, 2025 — forecast USD 17.6bn by 2033

~SAR 25bn
Annual public procurement through NUPCO, serving 500+ public hospitals

54%
Share of total Saudi healthcare spend that is government purchasing

0
Products a foreign manufacturer may register in its own name — a licensed local representative is mandatory

The rule that governs everything: a manufacturer outside Saudi Arabia cannot register, import or sell a regulated product directly. The SFDA requires a locally licensed Authorised Representative to file, correspond and carry the post-market obligations — so every timeline below starts only once that appointment is in place.

THE TWO REGISTRATION ROUTES

Pharmaceuticals

1. **Classification & strategy** 2–4 weeks
   Confirm the pathway — new chemical entity, generic or biologic — and map Saudi-specific requirements.
2. **eCTD dossier build** 6–12 weeks
   CTD Modules 1–5, CPP, GMP certificates for every site, zone-appropriate stability data, bioequivalence for generics, bilingual SmPC and labelling.
3. **Submission** 2–4 weeks
   Filed electronically through the Saudi Drug Registration portal by the local representative.
4. **Technical & scientific review** 6–14 months
   SFDA assessment and deficiency letters. Published target ~155 working days for a standard generic, ~280 for a new drug (93 / 168 under priority review).
5. **Pricing review** 4–10 weeks
   Committee assessment against published pricing rules and the country-of-origin price certificate.
6. **Marketing authorisation** valid 5 years
   Registration issued and renewable; plan the renewal before expiry, not after.

Realistic end-to-end: 8–18 months. GMP certificates from EMA, US FDA and similar authorities are generally accepted in place of a physical site inspection — the biggest time saver available to a European or US manufacturer.

Medical devices

1. **Classification** 1–2 weeks
   Risk class A, B, C or D. Class A non-sterile, non-measuring devices may go on the national registry instead of full authorisation.
2. **Authorised Representative** 2–3 weeks
   Appointment of an SFDA-licensed AR — annual licence around SAR 2,600.
3. **Technical file** 4–10 weeks
   ISO 14971 risk file, clinical evaluation, design verification, ISO 13485 certificate, Declaration of Conformity, Free Sale Certificate, Arabic/English labelling, UDI data.
4. **MDMA application** 2–6 months
   Filed by the AR through the GHAD portal. Target 35 working days; in practice 60–90 days for lower classes, 120–180 for Class C/D.
5. **Import & distribution** ongoing
   Establishment licence (MDEL) held by the importer/distributor; adverse event reporting and recalls through the AR.

Indicative SFDA application fees run from roughly **SAR 15,000** (lowest risk class) to **SAR 23,000** (highest), excluding VAT; renewal around SAR 5,000.

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Getting paid: how the Saudi market actually buys

Public sector — the majority of the market

- NUPCO runs unified procurement for the Ministry of Health and the health clusters, on framework agreements.
- Suppliers must be NUPCO-registered and hold a valid SFDA establishment licence and product authorisations.
- Etimad government platform enrolment is required to bid.
- Local-content rules favour locally made product, but foreign product still wins where no qualified local alternative exists.

Private sector — faster, and where new brands land first

- Private hospital groups, polyclinics and specialised centres buy directly or through distributors.
- Pharmacy chains and wholesalers cover retail reach across the Kingdom.
- Decision cycles run in months, not years — the practical route to first revenue while a tender position is built.

WHAT A FOREIGN MANUFACTURER MUST HAVE IN PLACE

- **A licensed Saudi representative** — mandatory for filing, correspondence, inspections and safety obligations.
- **A complete, Saudi-specific dossier** — most delay comes from deficiency letters, not SFDA review time.
- **Arabic labelling and packaging artwork** — best resolved before submission, not during review.
- **Compliant storage and distribution** — licensed facility, validated temperature monitoring.
- **A pricing position** — country-of-origin evidence shapes the approved Saudi price; plan it before filing.
- **A renewal calendar** — a lapsed registration removes the product from the market until restored.

WHERE HEALTH ASSOCIATION COMPANY FITS

YOU NEED	WHAT WE DO
A licensed local entity	Fully registered Saudi company — CR 7050223499, VAT 313030707900003, Riyadh Chamber member — headquartered in Riyadh, with desks in the USA, France, Egypt, India and China.
Registration handled	Dossier preparation, submission and follow-through to authorisation across all five categories, plus variations and renewals for the life of the product.
Product stored correctly	Warehousing across ambient, chilled and frozen ranges with continuous monitoring, excursion alerts and batch-level traceability.
Product moved and sold	GPS-tracked refrigerated distribution to hospitals, pharmacy chains and wholesalers, with a medical representative force for promotion and a commercial team for tendering, invoicing and collection.

Talk to us before you commit to a route

If Saudi Arabia is on your 2027 plan, a 20-minute conversation will tell you whether your product has a realistic path, what it will cost and how long it will take — whether or not you appoint us. We are at MEDICA in Düsseldorf, 16–19 November 2026, and glad to meet at your stand.

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Figures and timelines are indicative, compiled from publicly available regulatory and market sources in August 2026, and are provided for orientation only. SFDA requirements, fees and review periods change; confirm current requirements for your specific product before making commercial commitments. Sources include SFDA guidance as summarised by Saudi regulatory consultancies, Grand View Research market data, and published NUPCO procurement guidance. This document is not legal or regulatory advice.