

GCC registration and tender guides: the visitor pack.

Nine briefs written for the buyer's side of the table, by M Care Exports, an Indian pharmaceutical merchant-exporter supplying originator brands and WHO-GMP sourced generics since 2003. Each brief states where its facts come from. Figures and portals change; confirm the current version with the regulator or with us before you file.

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MARKET ENTRY · 12 MIN READ · PUBLISHED 6 JULY 2026 · BY DR. RAJAT BHATT,
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Importing Indian Generic Medicines into the UAE: How EDE Registration Works After MOHAP

If you are a UAE importer or procurement buyer planning to bring Indian generic medicines into the country, the first thing worth getting straight is that the regulator you probably have in mind no longer runs drug registration. On 29 December 2025, the Ministry of Health and Prevention (MOHAP) transferred its pharmaceutical registration services, including product registration and import and export permits, to the Emirates Drug Establishment (EDE). If you have been searching for MOHAP registration, you are looking at the old name for what is now an EDE process. The rules underneath it carry over, but the front door has moved.

The second thing worth getting straight is who holds what. Under Federal Decree-Law No. 38 of 2024 on Medical Products, the registration that lets a product be sold in the UAE is held by a UAE-licensed pharmaceutical establishment, not by the Indian factory and not by M Care Exports. We are an India-based merchant-exporter, a sourcing and trading house, not a manufacturer and not your UAE licence holder. What we supply is WHO-GMP finished product from qualified Indian manufacturers, plus the dossier and CTD documentation your registration needs, working through your appointed UAE local agent.

This guide walks through the pieces that actually decide whether your product can be imported and sold: the MOHAP-to-EDE handover and what it changes, who holds the registration and the

new multi-agent rules, what goes into the dossier, what the fees and timelines realistically look like, and how import permits and free-zone stock work. Where the public record is transitional or unconfirmed, and in mid-2026 quite a lot of it is, we say so plainly rather than asserting.

Where M Care fits, and where it does not.

M Care Exports is an India-based pharmaceutical merchant-exporter. We do not own the plants that make the medicines, and we do not hold, and cannot hold, a UAE product registration. Under Federal Decree-Law No. 38 of 2024, registration is filed by a UAE-licensed pharmaceutical establishment (such as a medical warehouse, drug store, or scientific or marketing office) acting as the local marketing authorisation holder or authorised representative. A foreign Indian manufacturer cannot register products with the Emirates Drug Establishment directly, and neither can a foreign trading house. That establishment must hold a valid pharmaceutical-facility licence before it can file any product application.

What we do is the supply side of that structure. We source finished product from WHO-GMP manufacturing from qualified Indian manufacturers, assemble the CTD documentation, manufacturer certificates, stability data and samples the registration file needs, and work alongside your UAE local agent so the dossier can be built and filed in the Emirates. The agent files; we make sure the agent has a complete, defensible file to work with.

This guide is written from that position. It is not a regulatory affairs consultancy pitch, and where a fee, timeline or procedure has not been officially published by the EDE, we tell you that rather than quoting a consultancy figure as if it were law.

MOHAP to EDE: what changed on 29 December 2025.

The Emirates Drug Establishment was created under Federal Decree-Law No. 38 of 2024 on Medical Products, which took effect on 2 January 2025. It became operational as the UAE's federal drug authority when MOHAP transferred its pharmaceutical regulatory services to it in late December 2025. The EDE is now responsible for drug approval and registration, marketing authorisation, pharmacovigilance and inspection. Import and export permits moved across in the same handover.

In practice, the continuity matters as much as the change. Executive regulations and guidelines issued under the previous framework (Federal Law No. 8 of 2019 and MOHAP guidance,

including labelling rules) remain in force to the extent they do not conflict with the 2024 law. The fee schedule you will encounter is largely inherited from MOHAP. The law's one-year transitional compliance period has since run its course, so MOHAP-era requirements continue to apply under EDE administration until the EDE issues replacement guidance.

What this means for you as a buyer: keep using MOHAP-era documents and expectations as your baseline, but treat every portal step, fee and processing time as transitional. The typical sequence in 2026 is: your UAE local agent holds or obtains its pharmaceutical-establishment licence; the Indian manufacturing site is registered with the regulator; the agent files the product dossier through the digital portal (login via UAE PASS); technical review of quality, safety and efficacy follows; then a pricing decision and issue of the marketing authorisation; and finally an import permit before each shipment. Because the services moved to the EDE so recently, confirm the current workflow with your UAE agent or the EDE before filing rather than relying on any published walkthrough, including this one.

The EDE route, after MOHAP

MOHAP services moved to the EDE on 29 December 2025.

Federal Decree-Law No. 38 of 2024, in effect 2 January 2025

STAGE 1 · THE HOLDER

A UAE-licensed establishment holds it

Not the Indian factory, and not the exporter.



STAGE 2 · THE DOSSIER

eCTD through the EDE portal

CTD, bioequivalence, GMP, CPP, Zone IVb stability.

Dossier in English. Labelling and artwork in Arabic.



STAGE 3 · THE OFFICIAL TARIFF

AED 100 application · AED 7,000 registration

The legacy MOHAP tariff. Confirm the current figure on the EDE portal at the time of filing.



STAGE 4 · EVERY SHIPMENT

Import permits are per shipment

1. Initial permit, ~3 business days → 2. Shipment clearance

AED 100 per application. Registration must exist first.

M Care Exports supplies the product and the exporter-side file.

The route on one card. Every stage is unpacked below.

Who holds the registration, and why you now need more than one importer.

The registration never sits with the Indian side. A UAE-based authorised agent, which must be a licensed pharmaceutical establishment (typically a medical warehouse or marketing office), submits the marketing-authorisation application via the EDE portal and manages post-market obligations such as regulatory affairs and pharmacovigilance on the manufacturer's behalf. Foreign companies cannot hold UAE pharmaceutical facility licences or import permits, so every consignment must also be imported by a UAE-licensed establishment authorised on the product's registration.

There is a structural change here that many buyers have not yet priced in. Article 22 of Federal Decree-Law No. 38 of 2024 requires the marketing authorisation holder to appoint at least two licensed importers and one or more distributors for each product. This carries forward a requirement first introduced by Federal Decree-Law No. 11 of 2023. Advisory guidance additionally indicates that one designated pharmaceutical establishment should be nominated as responsible for regulatory affairs, pharmacovigilance and quality management across the product lifecycle; confirm that designation requirement with the EDE or your agent, as the detailed conditions await executive regulations.

On 24 February 2026 the EDE announced the activation of a mechanism, described in its own announcement as a first of its kind, obliging pharmaceutical companies to appoint more than one authorised agent for each medical product marketed in the UAE. The EDE framed the move as breaking single-exclusive-distributor monopolies and strengthening pharmaceutical security, with Director General Dr. Fatima Al Kaabi stating it will help regulate medical product distribution and improve supply-management efficiency.

Two honest caveats. First, as of early July 2026 no published transition timeline, product-category carve-outs or penalty schedule for existing exclusive-agent arrangements has been located, so if you currently sit inside an exclusive arrangement, confirm your position with the EDE or UAE counsel. Second, the mechanism is designed to allow additional agents to operate alongside an existing distributor rather than displacing the incumbent, which opens the door for new entrants on already-registered products. But the exact EDE procedure for adding an agent

to an existing registration has not yet been published, so that route should be scoped case by case rather than assumed.

What goes into the dossier: CTD, bioequivalence, GMP, CPP and Zone IVb stability.

The dossier follows the ICH Common Technical Document structure, submitted electronically (eCTD) through the EDE digital portal, with your local agent logging in via UAE PASS. The technical dossier is prepared in English; Arabic is required for product labelling and patient-facing information, and some administrative documents are submitted bilingually. Regulatory consultants consistently flag poor Arabic translations as a common cause of registration queries and delays, so professional Arabic artwork review before submission is money well spent.

For a generic, bioequivalence with the reference product must be demonstrated. BE studies conducted to internationally recognised standards (GCC, EMA or FDA guidelines) are expected, but confirm the accepted reference product and study design against current EDE and GCC guidance before commissioning anything. The product must also be confirmed as not infringing UAE intellectual-property and trademark protections.

GMP evidence is required for the manufacturing site. Under the current framework this can be a GMP certificate issued by the EDE (or previously MOHAP), or, per current regulatory guidance, a certificate from the competent authority in the country of origin or an EDE-recognised reference authority may be accepted. Indian sites should expect the possibility of a UAE GMP inspection or desk assessment regardless. Alongside that sits the Certificate of Pharmaceutical Product (CPP) issued under the WHO scheme by the country-of-origin regulator, for India typically CDSCO or the state licensing authority; advisory sources indicate a Certificate of Free Sale may be accepted in limited cases where a CPP is unavailable. Key certificates must be legalised, including attestation by the UAE Embassy in India, before submission.

Stability data is where Indian exporters most often discover a gap. The UAE falls in climatic Zone IVb (hot and very humid), so registration stability data must include long-term studies at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \text{ RH} \pm 5\%$ and accelerated studies at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \text{ RH} \pm 5\%$, per the GCC stability guideline. If your manufacturer holds only Zone III or EU-condition data, additional Zone IVb studies will usually be needed, and that costs months. Ask this question before you shortlist a product, not after.

The dossier must also include a pharmacovigilance plan (advisory guidance indicates this is reviewed and must be acceptable before the marketing authorisation is issued), quality-control documentation and product samples. Labelling must be bilingual Arabic and English, covering the full ingredient list in international nomenclature, dosage instructions, batch and registration numbers, manufacture and expiry dates, storage conditions and health warnings, with the patient information leaflet available in Arabic. Packs must carry GS1-compliant 2D DataMatrix codes encoding GTIN, randomised serial number, expiry and batch, because nothing moves through the UAE supply chain without Tatmeen, the national track-and-trace platform that has been mandatory since December 2022 and now sits under EDE supervision by law while still operating on the same MOHAP-built processes.

Fees, timelines and validity: what is official and what is guesswork.

Here is where we owe you plain speech, because most published guides quote figures with more confidence than the record supports. On fees: under the schedule inherited from MOHAP, the application fee is AED 100 and registration of a conventional pharmaceutical product is AED 7,000. Those two figures come from the official legacy tariff. Advisory firms cite additional line items such as product analysis (around AED 3,500), the pricing certificate (around AED 500) and pharmacovigilance-plan evaluation (around AED 1,000), with all-in per-product budgets of roughly AED 10,000 to 20,000, but those additions are consultancy figures, not published tariff. Because the services transferred to the EDE in late December 2025, confirm the current official tariff on the EDE portal at the time of filing.

On timelines: there is no officially published EDE approval timeline. Consultancy estimates range from about 45 working days (the legacy MOHAP service standard) to 3 to 6 months for a complete, well-prepared dossier, and 6 to 12 months where queries, laboratory testing or pricing negotiations intervene. Our advice as the exporting side of these projects is to plan around a realistic 6 to 12 month runway from dossier submission to first import permit, and to treat any single quoted figure as indicative only.

An expedited review route exists, but probably not for you. Advisory sources describe it as covering lifesaving, critical-care, innovative or orphan products, with reviews reported in as little as around 25 days. Standard generics do not automatically qualify, so if you are importing a routine generic range, plan around the standard pathway unless the EDE confirms priority

eligibility for a specific product. Similarly, US FDA or EMA approval does not by itself shortcut UAE registration of a generic. As of mid-2026 we could not verify any published EDE reliance pathway that abridges the full dossier requirement for generic finished products; the confirmed reliance elements are acceptance of GMP certification from recognised authorities and reference to international bioequivalence standards. The 2024 law does give the EDE latitude to develop reliance mechanisms, so check current guidance rather than assuming either way.

Pricing is integrated into registration: the approved public price is fixed as part of obtaining the marketing authorisation, so pricing documents belong in the dossier from the start. Once granted, a UAE product registration is valid for five years, and renewal applications should be filed at least 90 days before expiry to avoid a lapse.

Import permits, free zones and actually moving stock.

Registration gets you a marketing authorisation. It does not move a single carton. Imported medicines must already hold EDE marketing approval before an import permit is granted, and permits are issued per shipment, having become an EDE service in the December 2025 handover. Limited exceptions exist under separate EDE services, such as named-patient and personal-use import routes, but for commercial generic supply the registration comes first, full stop.

The permit process runs in two stages via the EDE portal. First, an initial import permit is filed before the goods ship, supported by the proforma or commercial invoice, with a published processing time of around 3 business days and a fee of AED 100 per application. Second, a shipment clearance request is filed once the air waybill or bill of lading exists, with a published processing time of around 2 business days. Permits are valid for 2 months from issuance, and release of the consignment remains subject to inspection at customs clearance. As with everything post-handover, treat published fees and timings as indicative and confirm on the EDE portal at the time of filing.

Free-zone routing remains a live strategy in 2026. The 2024 law defines import as bringing medical products from outside the country or its free zones into the mainland, so stock held in JAFZA or DAFZA (see the [UAE market desk](#) for how we run bonded free-zone stock) sits outside the regulated mainland market until formally imported. For imports from fenced free zones, the EDE adds specific conditions: an active marketing-office licence for the marketing authorisation holder, a valid EDE Good Storage Practice certificate, and a minimum of 12

months remaining shelf life on the goods. That last condition is worth planning around when you negotiate manufacturing lead times with the Indian side.

On duty: goods in a bonded free zone are duty-suspended until released to the mainland, the standard UAE and GCC rate is 5% of CIF value on release, and re-exports from the free zone attract no UAE duty. In practice, however, medicines registered with the UAE health authorities are generally exempt from customs duty under the applicable tariff exemptions. So for pharmaceuticals the free-zone advantage is chiefly regulatory and logistical (regional hub stock, deferred commitment to the mainland market, re-export flexibility) rather than a duty saving. Confirm duty treatment per HS code and per product registration status.

If you are weighing the UAE against a wider Gulf rollout, note that the GCC centralised registration route under the Gulf Health Council remains available alongside national EDE filing: one GCC-CTD dossier reviewed centrally, with GCC GMP inspection of the site, across the UAE, Saudi Arabia, Kuwait, Bahrain, Oman and Qatar. Central approval is not a marketing authorisation by itself; registration must still be finalised nationally in each state, including national pricing. Most sponsors treating the UAE as the priority market file nationally with the EDE and keep the GCC route for multi-country plans.

FAQ

Can you register our products with the EDE yourselves?



No, and you should be wary of any Indian exporter who says yes. Foreign companies cannot register products with the EDE directly and cannot hold UAE pharmaceutical facility licences. Registration is filed by a UAE-licensed establishment acting as the marketing authorisation holder or authorised representative, which in practice means your appointed local agent. What M Care does is supply the WHO-GMP product, the CTD dossier documentation, stability data and samples that your agent files with.

Do we still apply through MOHAP, or is it all EDE now?



It is EDE now. MOHAP transferred its drug-registration services, including product registration and import and export permits, to the Emirates Drug Establishment on 29 December 2025. The underlying MOHAP-era regulations and guidelines remain in force where they do not

conflict with Federal Decree-Law No. 38 of 2024, so your existing documentation expectations largely carry over, but filings, permits and fee payments go through the EDE portal.

Who holds the marketing authorisation, us or the Indian manufacturer?



Neither the Indian manufacturer nor M Care. The marketing authorisation sits with a UAE-licensed pharmaceutical establishment, typically the medical warehouse or marketing office appointed as local agent. That establishment manages regulatory affairs and pharmacovigilance for the product, and any transfer of a marketing authorisation to a new owner requires EDE approval.

Do we really need to appoint two importers for one product?



Under Article 22 of Federal Decree-Law No. 38 of 2024, the marketing authorisation holder must appoint at least two licensed importers and one or more distributors per product, and in February 2026 the EDE activated an enforcement mechanism requiring more than one authorised agent per product. What has not been published yet is the transition timeline, penalties, or the procedure for adding agents to existing registrations, so structure new agency agreements with the two-importer rule in mind and confirm treatment of existing exclusive contracts with the EDE or UAE counsel.

Our shortlisted product is US FDA approved. Does that shortcut UAE registration?



Not on any pathway we can verify. As of mid-2026 there is no published EDE reliance route that abridges the full dossier requirement for generic finished products. What recognised-authority approval does help with is the GMP-evidence element and bioequivalence standards. The 2024 law gives the EDE room to develop reliance mechanisms, so it is worth checking current guidance at filing time, but do not build your launch plan on a shortcut that has not been published.

How long will registration take, and what should we budget?



Honestly: no official EDE timeline exists. Consultancy estimates run from about 45 working days to 3 to 6 months for a clean dossier, and 6 to 12 months when queries, lab testing or pricing negotiation intervene; we advise buyers to plan on 6 to 12 months from submission to first import permit. On cost, the inherited official tariff is AED 100 application plus AED 7,000 registration, with advisory firms citing all-in budgets of roughly AED 10,000 to 20,000 per

product including analysis, pricing certificate and pharmacovigilance-plan line items. All fees are transitional after the EDE handover, so confirm the current tariff on the EDE portal before filing.

Can we hold stock in JAFZA or DAFZA while registration is under way?



Yes, free-zone stock sits outside the regulated mainland market until it is formally imported, which makes it a workable regional hub position. When you do move goods to the mainland, EDE conditions for imports from fenced free zones apply: an active marketing-office licence for the marketing authorisation holder, a valid EDE Good Storage Practice certificate, and at least 12 months remaining shelf life. Note the product still needs its EDE marketing approval before any mainland import permit is granted.

What stability data do you supply for the UAE, and will EU data do?



The UAE is climatic Zone IVb, so the registration file needs long-term stability at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \text{ RH} \pm 5\%$ and accelerated data at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \text{ RH} \pm 5\%$ per the GCC guideline. Manufacturers holding only Zone III or EU-condition data will usually need additional Zone IVb studies, which takes months. We screen for existing Zone IVb data when qualifying Indian manufacturers for Gulf projects, and we flag the gap before you commit to a product rather than after the dossier bounces.

MARKET ENTRY · 12 MIN READ · PUBLISHED 29 JUNE 2026 · BY DR. RAJAT BHATT,
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Sourcing Indian Generic Medicines into Saudi Arabia: How SFDA, Your Local Agent, and NUPCO Fit Together

If you are a procurement buyer or importer planning to bring Indian generic medicines into Saudi Arabia, the first thing worth getting straight is who holds what. The marketing authorisation that lets a product be sold in the Kingdom is not something a foreign factory in India holds directly, and it is not something M Care Exports holds either. It sits with a locally registered Saudi entity, usually the authorised agent or distributor you appoint.

Understanding the split between SFDA registration, your local Saudi agent, and NUPCO listing early saves a lot of confusion later. Saudi Arabia is one of the largest pharmaceutical markets in the Gulf, and it runs more than one gate before an imported generic can be sold and then procured by a government hospital. This is how those gates fit together, written from the position of a sourcing house that supplies product and documentation, not a manufacturer and not your Saudi licence holder.

Where M Care fits, and where it does not.

M Care Exports is an India-based pharmaceutical merchant-exporter. We are a sourcing and trading house, not a manufacturer. We do not own the plants that make the medicines, and

we do not hold a Saudi registration. What we do is supply WHO-GMP finished product from qualified Indian manufacturers, pull together the dossier and CTD documentation a registration needs, and work alongside your local Saudi agent so the regulatory file can be built and filed in the Kingdom. This guide is written from that honest position.

Below we walk through the four things that actually decide whether your product can be sold and procured in Saudi Arabia: SFDA marketing authorisation and who holds it, NUPCO supplier registration and catalogue listing as a separate step, the Vision 2030 local-content rules that quietly disadvantage pure imports, and the documentation, labelling and pricing set you have to assemble. Where the public record is unclear or evolving, we say so rather than guessing.

SFDA registration, and why the authorisation never sits with the Indian factory.

To legally market an imported generic medicine in Saudi Arabia, the product has to obtain Marketing Authorization, the registration granted by the Saudi Food and Drug Authority (SFDA). The SFDA is the body that regulates pharmaceutical products in the Kingdom and sets the registration and post-marketing requirements. No SFDA registration means the product cannot be placed on the Saudi market, full stop, and SFDA clearance is a prerequisite before any government procurement route opens.

Before a single product application is filed, the establishment behind it has to be on file. Local and international companies, manufacturers, agents and wholesale distributors first register in the SFDA Drug Establishments National Registry (DENR), an electronic system that builds a national database of drug establishments. DENR registration provides the login credentials needed to access SFDA electronic drug services and to start the Saudi Drug Registration process. It helps to read DENR as a registry, a national database of entities registered or licensed in the Kingdom, rather than as a licence in itself. Holding DENR access is not the same as holding an SFDA establishment licence, which is a separate status worth confirming directly.

Here is the part most buyers underestimate. A foreign manufacturer in India cannot submit a registration application directly to the SFDA. It has to appoint a local authorised representative or authorised local agent inside Saudi Arabia, and that local entity is the one that handles regulatory submissions, communication with the SFDA, pharmacovigilance and

safety monitoring, and ongoing compliance. The Saudi authorised representative must be a legally registered entity in the Kingdom. It acts as the regulatory point of contact, receives official SFDA correspondence, and is accountable for post-approval obligations on behalf of the foreign company across the product lifecycle.

Who formally owns the Marketing Authorization Holder (MAH) status, the legal owner of the authorisation in Saudi Arabia, depends on the submission pathway chosen. Regulatory-affairs advisers generally recommend keeping the MA under the manufacturer's own SFDA account rather than a distributor's, but that is consultancy practice, not a fixed SFDA rule, and you should decide it deliberately rather than by accident. International companies are reported to have several routes into the system: establishing a local legal entity through the Ministry of Investment (MISA), setting up a scientific office for direct submissions, submitting through a local distributor on a shared SFDA account, or using an SFDA-approved local consulting firm running a dedicated account. Treat these as reported pathways from advisory sources and confirm the current options against the live SFDA position.

WHO-GMP product plus dossier, working through your agent.

Given all of that, an Indian merchant-exporter has a clear and limited role, and it is worth being precise about it. M Care does not hold the Saudi authorisation, does not become your MAH, and does not replace the local agent the SFDA requires. What we supply is the finished product from WHO-GMP manufacturing and the dossier and CTD support that the registration file is built from. We work with and through the Saudi authorised agent or distributor you appoint, rather than around them.

Manufacturing sites that supply SFDA-registered drugs are subject to GMP requirements. The SFDA applies a risk-based approach here: a physical site inspection (with inspection fees) may be required, but a valid GMP certificate from a recognised authority such as the EMA, US FDA or ANVISA can be accepted in place of an on-site inspection. The base requirement is straightforward, a valid GMP certificate should be submitted, and the waiver mechanics around recognised authorities and GCC frameworks are described by advisory sources rather than quoted regulation. Our part is to source from manufacturers whose GMP status and certificates stand up to that scrutiny.

Generic-product applications are submitted electronically in eCTD (Common Technical Document) format through the SFDA portal, and bioequivalence study data is a standard

requirement for generic products. Where the reference product is not already registered with the SFDA, the dossier also has to carry a comprehensive literature review of the active substance in Module 2.5 (Clinical Overview). These are the pieces an Indian sourcing house helps assemble from the supply side: the eCTD-ready modules, the bioequivalence data, the manufacturing and quality documentation, handed to your local agent to file under their SFDA access. The fast-track Verification and Abridged routes, by the way, are not available for generics; they apply only to new chemical entities and new biologics, so a generic file follows the standard route.

NUPCO: a second, separate registration before you can sell to government.

SFDA registration gets a product onto the market. It does not, on its own, get it into a government hospital. That is the single most common misread we see from first-time buyers. Selling into the Saudi public health system runs through NUPCO, the National Unified Procurement Company, and registering with NUPCO is a distinct step from SFDA registration, with its own portal and its own requirements.

NUPCO was established in 2009 by Royal Decree with a registered capital of SAR 1.5 billion and is fully owned by the Public Investment Fund (PIF). It is the largest centralized company in Saudi Arabia for the procurement, logistics, warehousing and distribution of medication, medical devices and supplies for the government health sector, serving public-sector health entities including the Ministry of Health and other government health authorities. It maintains a Unified Catalogue, an electronic guide of medicines, devices and supplies with regularly updated technical specifications and pricing references, used across government health agencies.

Two things have to happen here that SFDA registration does not cover. First, suppliers must register with NUPCO before bidding on its tenders, through NUPCO's supplier-registration portal, which asks for standard company details including a Saudi Commercial Registration (CR) number and SFDA status. Second, a product must actually be listed in NUPCO's Unified Catalogue to be procurable by government hospitals. Products that are not in the catalogue are generally unavailable through government procurement channels, which makes catalogue inclusion a commercial requirement that sits on top of SFDA registration, not

inside it. In short, SFDA registration is the prerequisite, not the finish line; NUPCO supplier registration plus catalogue listing are additionally required to win government tenders.

A few practical notes. An approved SFDA pharmaceutical marketing authorisation is valid for five years from the date of authorisation, with renewal required ahead of expiry; the renewal window opens around 180 days before expiry, and the SFDA does not provide a grace period once a registration lapses, so the local agent has to track this. NUPCO also runs additional platforms, including a digital healthcare Marketplace and the Wasfaty service that routes government prescriptions to private community pharmacies. Some secondary write-ups put NUPCO's annual procurement somewhere in the region of SAR 21 to 25 billion and describe multi-year Framework Agreements organised by therapeutic area as a primary procurement mechanism, but those figures and mechanics come from consultancy sources rather than a primary NUPCO disclosure, so treat them as approximate and confirm the current mechanism with NUPCO directly.

Vision 2030 local content: why a pure import competes uphill.

This is the part that changes the commercial maths, and it is worth understanding before you commit to a pure import-and-distribute model. Saudi Arabia runs a government-procurement local-content preference system administered by the Local Content and Government Procurement Authority (LCGPA), applying across public-sector buying including health. It has two core instruments: a Mandatory List of national products that covered government entities and their contractors must buy locally, and a price-preference mechanism that treats a qualifying local product as the lowest bid when its price is within a set margin of the cheapest offer.

The standard local-content price preference is 10 percent. A qualifying national product priced within 10 percent of the lowest offer is treated as the lowest bid in a government tender. (During COVID-19 this was temporarily raised to a maximum of 30 percent by sector standards, then reverted to 10 percent.) For medicines specifically, the LCGPA pharmaceutical-sector initiative adds a preference of up to 20 percent on top of the standard 10, so a qualifying local product can carry a combined edge of up to around 30 percent versus foreign products: 10 percent for being on the initiative list, plus a further up to 10 percent where the product contains a domestically manufactured Active Pharmaceutical Ingredient (API).

The eligibility rules are where pure imports lose ground. To qualify for the additional pharmaceutical preference, a product needs a valid SFDA registration certificate, and it is not eligible if it has undergone only secondary packaging in Saudi Arabia, unless it also contains a locally manufactured API or has had clinical or bioequivalence studies carried out in Saudi Arabia. In healthcare the LCGPA Mandatory List is reported to include about 623 pharmaceutical and medical-device items from roughly 90 manufacturers, items that covered government entities have to buy locally. NUPCO is the central buyer that operates inside this framework, while the LCGPA price-preference and Mandatory-List rules are the formal instruments.

The plain implication for an Indian exporter is this. A finished-goods import that is registered with the SFDA can compete in NUPCO tenders, but it competes without local-content preference, it is excluded from the Mandatory List, and it does not qualify for the additional pharma preference. It can therefore be beaten by a qualifying local product priced meaningfully higher. Local presence sits on a spectrum: secondary packaging alone is the weakest and does not by itself earn the additional preference; local fill-finish combined with local API or Saudi bioequivalence studies qualifies; and full local manufacturing maximises both procurement preference and certain SFDA pricing advantages. That spectrum is analysis drawn from the LCGPA and SFDA rules together, and it is the honest frame for deciding whether a pure-import play fits your volumes or whether you should be planning a local-content step over time. We do not publish specific Vision 2030 localisation-percentage targets because the public sources conflict and none is cleanly attributable to an official document.

The documentation, labelling and pricing set you have to assemble.

The registration file itself is structured, and the current governing guidance is the SFDA document Data Requirements for Human Drugs Submission, Version 4.0, issued 3 August 2025. The dossier goes in as eCTD/CTD. Module 1 (Regional Administrative Information) carries the cover letter, application form, product information (SmPC, labelling, the patient information leaflet, artwork mock-ups and samples), pharmacovigilance, certificates and pricing. One important update under Version 4.0: a Certificate of Pharmaceutical Product (CPP) or free-sales certificate is now optional and no longer required for new Marketing Authorization applications across all regulatory pathways. If you are working from older

guidance that lists the CPP as mandatory, that requirement was reversed. A valid GMP certificate, on the other hand, should still be submitted in Module 1.7.

Arabic-language patient information is mandatory. The leaflet has to be provided as both an Arabic and an English version, alongside the SmPC, labelling and artwork. On secondary (outer) packaging, regulatory-affairs guidance describes a fairly detailed requirement set: product name in Arabic and English on more than three non-opposing faces of the box, the active substance qualitatively and quantitatively, pharmaceutical form and contents, route of administration, special warnings such as keep out of sight and reach of children, storage conditions, and the manufacturer and MAH name and address, with all excipients stated for parenteral, topical, eye or inhalation products. On primary packaging such as blisters and strips, the product name and strength, the MAH or brand name, manufacturing and expiry dates and the batch number are expected, and once labelling is SFDA-approved it must not be altered. The generic INN name is reported to be required at a size at least 50 percent of the trade name, a point that appears across regulatory-affairs sources rather than in the official text we reviewed, so treat it as practitioner guidance.

Saudi Arabia also operates a barcoding and traceability regime that your manufacturer has to meet. For market distribution the SFDA requires a GTIN-14 encoded in a GS1 DataMatrix barcode carrying, at minimum, the GTIN, expiry date and batch or lot number, with companies registering with GS1 Saudi Arabia to obtain a GS1 Company Prefix and generate GTINs. The Kingdom runs a national track-and-trace system, RSD or Rassd, under the SFDA, which is GTIN- and serial-number-based, and stakeholders need a unique Global Location Number (GLN). These are upstream obligations that a sourcing house and manufacturer prepare for, with the local agent handling the Saudi-side registrations.

Pricing is approved before market entry, and it is its own exercise. The SFDA uses a hybrid method: Internal Reference Pricing against comparable registered alternatives, External Reference Pricing against a basket of comparator countries, plus pharmacoeconomic input and price negotiation. The published rules list around 16 reference countries (a basket narrowed over time from 30 to 20 and then to 16). A price certificate, Form 16, documents ex-factory, CIF and public or retail prices and is checked against lower prices in reference markets. Generic ceiling prices are tiered below the originator: the first generic at a maximum of 70 percent, the second at 65 percent, and the third and subsequent at 60 percent, with the innovator price reduced 25 percent on first generic entry. For government procurement, the CIF price determined by the SFDA, without profit margin, is the ceiling for

tendering and the starting point for negotiated reductions through NUPCO. We do not quote specific SFDA registration timelines or government fees as fact, because we could not locate an official, dated service-level or fee schedule; consultancy estimates exist but they vary and should not be read as a published standard.

FAQ

Does M Care Exports hold the SFDA registration for the products it supplies?



No. M Care is an India-based merchant-exporter and does not hold Saudi marketing authorisations. The SFDA marketing authorisation is held through a locally registered Saudi authorised agent or distributor that you appoint, since a foreign manufacturer cannot submit a registration application directly. M Care supplies the WHO-GMP finished product and the dossier and CTD support, and works with and through that local agent.

Is SFDA registration enough to sell into Saudi government hospitals?



No. SFDA registration is the prerequisite, not the finish line. To sell into the public health system you also have to register as a supplier with NUPCO and get the product listed in NUPCO's Unified Catalogue. Both are separate steps from SFDA registration, and a product that is not in the catalogue is generally not procurable through government channels.

Who needs to be appointed in Saudi Arabia, and what do they do?



A foreign manufacturer must appoint a local authorised representative or agent that is a legally registered entity in Saudi Arabia. That agent handles regulatory submissions, communication with the SFDA, pharmacovigilance and safety monitoring, receives official SFDA correspondence, and is accountable for post-approval obligations across the product lifecycle. M Care supplies product and documentation to support that agent, rather than replacing them.

Why does a pure import compete at a disadvantage in NUPCO tenders?



Saudi Arabia runs a local-content preference system under the LCGPA. A qualifying national product priced within 10 percent of the lowest offer is treated as the lowest bid, and medicines can carry an additional preference of up to 20 percent. A pure finished-goods

import that is only SFDA-registered competes without that preference and is excluded from the Mandatory List, so it can be beaten by a qualifying local product priced meaningfully higher.

Is a CPP (Certificate of Pharmaceutical Product) still required for the dossier?



Under the current SFDA guidance, Data Requirements for Human Drugs Submission Version 4.0 issued 3 August 2025, submission of a CPP or free-sales certificate is optional and no longer required for new Marketing Authorization applications across all regulatory pathways. A valid GMP certificate, however, is still expected in the dossier. If you are working from older guidance that lists the CPP as mandatory, that requirement was reversed.

Does the manufacturing site always need an SFDA inspection?



Not necessarily. The SFDA applies a risk-based approach to GMP. A physical site inspection with fees may be required, but a valid GMP certificate from a recognised authority such as the EMA, US FDA or ANVISA can be accepted in place of an on-site inspection. M Care sources from WHO-GMP manufacturers whose certificates are intended to stand up to that review.

What is the documentation and labelling set in practice?



The dossier is submitted in eCTD/CTD format and, for generics, includes bioequivalence data. Labelling requires both Arabic and English patient leaflets, with detailed outer and primary packaging content, and a GS1 GTIN-14 DataMatrix barcode for traceability under the SFDA's RSD track-and-trace system. Pricing is approved before market entry via Internal and External Reference Pricing and a Form 16 price certificate, with generics tiered below the originator price.

Can you tell me the exact timelines and government fees for SFDA registration?



We do not state specific SFDA registration timelines or government fees as fact, because we could not locate an official, dated service-level or fee schedule to cite. Consultancy estimates circulate, but they vary by source and should not be treated as a published standard. Your appointed local agent is the right party to confirm current timelines and fees directly with the SFDA for your specific product and pathway.

QATAR MARKET ACCESS · 9 MIN READ · PUBLISHED 1 SEPTEMBER 2026 · BY DR. RAJAT BHATT, MANAGING DIRECTOR

Qatar's Ministry of Public Health registers every medicine through its Pharmacy and Drug Control Department before it can be imported or sold.

Every medicine sold in Qatar needs marketing authorisation from the Ministry of Public Health's Pharmacy and Drug Control Department, held by a Qatar-registered local agent. Importing it afterwards needs its own set of licences, separate from the product approval itself. This guide sets out how registration, GCC central registration, and Hamad Medical Corporation's tenders fit together for an Indian supplier.

One ministry regulates medicines in Qatar, through one working department

The **Ministry of Public Health (MOPH)** is Qatar's medicines regulator. It has held that role since 2016, when the Emir disbanded the Supreme Council of Health and folded its functions back into MOPH.

Inside MOPH, the working unit for medicines is the **Pharmacy and Drug Control Department (PDCD)**. PDCD reviews and approves marketing authorisation applications for finished pharmaceutical products, licenses drug stores and pharmacists, and runs its own **PDCD E-System** portal for electronic submissions, including eCTD dossiers.

No medicine can legally be marketed, imported, or distributed in Qatar until PDCD has approved it under a named local marketing authorisation holder. That single point of control

is worth understanding before an Indian supplier commits to a Qatar order, whether the buyer is a hospital, a wholesaler, or a private pharmacy chain.

A foreign medicine needs a Qatar-based marketing authorisation holder before PDCD will register it

An Indian manufacturer, or M Care Exports acting as its export partner, cannot register a product in Qatar directly. PDCD requires a **Qatar-registered local agent** to act as marketing authorisation holder (MAH): the entity that submits the dossier, holds the approval once granted, and answers for later variations and pharmacovigilance reporting.

The registration file follows the CTD structure and is submitted electronically through the PDCD E-System. It needs a legalised, valid **Good Manufacturing Practice (GMP) certificate** and manufacturing licence from the health authority in the product's country of origin, stability and analytical data, and Arabic-language labelling and patient information.

Building that file correctly the first time matters more in Qatar than in most markets, because PDCD works from a fixed CTD structure and does not iterate informally on a rejected submission. See how M Care Exports prepares a [CTD dossier](#) for exactly this kind of filing.

Registering the product is not the same as being licensed to import it

Product registration and import licensing are two separate approvals in Qatar. Once PDCD has approved a medicine, only a licensed Qatari entity may actually bring it into the country and distribute it. Under PDCD's published importer conditions, that entity needs:

- a valid **Drug Store licence**, issued by PDCD's inspection function
- a valid **Pharmacist licence**, issued by MOPH
- a **Commercial Registration** from the Ministry of Commerce and Industry that names trading in medicines as a permitted activity

Controlled and narcotic-classed drugs carry extra conditions on top of this standard route, with additional approvals and handling rules that go beyond a routine consignment. An

Indian exporter should confirm the current requirements for any scheduled product with the Qatar-side importer before committing to a shipment.

For an Indian exporter, this means the buyer or agent on the Qatar side has to hold current licences in their own name, not just a registered product. M Care Exports checks an importer's licensing status as a standard step before confirming an order.

GCC central registration can shorten Qatar's review, it does not replace it

Qatar takes part in the **Gulf Health Council's central registration system**, the regional mechanism that lets a pharmaceutical product be reviewed once for multiple GCC member states rather than filed separately in each. The Council runs this as its Central Registry for human medicines, medical devices, and veterinary medicines.

Where a product already holds a valid, GCC-executive-office-stamped central registration certificate, PDCD offers a faster assessment track for the Qatar filing, provided the applicant submits that certificate and confirms the product information matches the GCC-approved version exactly.

That fast-track shortens Qatar's own review; it does not substitute for it. The national requirements still apply in full: a Qatar-registered local agent, Arabic labelling, and PDCD's own approval before the product can be marketed or imported. For the broader question of when a regional pathway actually speeds up a national filing, see our note on [WHO prequalification versus national registration](#).

Hamad Medical Corporation is Qatar's largest pharmaceutical buyer, and it tenders only to registered vendors

Hamad Medical Corporation (HMC) runs Qatar's public hospital network on a shared formulary, managed centrally by its Supply Chain Management division. HMC sources medicines through periodic tenders and standing or blanket purchase agreements for formulary lines, plus ad hoc emergency procurement to cover shortages.

A supplier cannot bid without first completing HMC's own vendor registration, credentialed to the relevant product category for pharmaceuticals. Every drug quotation submitted

through HMC's e-tendering platform must carry a valid MOPH registration certificate for that specific product, while implants carry their own separate registration requirement.

Shipment conditions are exacting. Controlled and narcotic drugs need copies of the supplier's valid import and supply licences attached, biologic products such as those derived from human blood or plasma typically carry an additional certification requirement from the country-of-origin regulator, and standard shipping paperwork, legalised where required, has to accompany every delivery. M Care Exports builds tender responses and shipment files against these HMC-specific conditions rather than a generic export template. See our [tender response support](#), and the wider [Qatar market page](#) for buyer-by-buyer detail.

The Indian half of the file has to match what PD CD and HMC actually ask for

For a shipment from India, the document pack an exporter assembles typically includes:

- a **WHO-GMP certificate** for the manufacturing site, where the product is a generic sourced from a WHO-GMP certified Indian plant, or the relevant manufacturing and marketing authorisation where the product is an originator brand moved through licensed Indian channels
- a **Certificate of Pharmaceutical Product (CPP)** in WHO format, issued by India's Central Drugs Standard Control Organisation
- a batch-wise **Certificate of Analysis**
- a **Certificate of Origin** from an Indian Chamber of Commerce
- a commercial invoice and packing list matching the product, quantities, and HS codes on the shipment exactly

Because both Qatar Customs and HMC call for legalised paperwork, and Qatar is not a party to the Hague Apostille Convention, the Certificate of Origin and invoice typically need attestation through the Qatar Embassy in India, or through India's Ministry of External Affairs and Qatar's Ministry of Foreign Affairs where no consulate covers the shipment.

M Care Exports has supplied 49 markets since 2003 and builds this pack against each product's actual manufacturer file, not a standard template, because PD CD and HMC both

reject documentation that does not match the registered product exactly. Buyers evaluating a specific molecule can start with a [medicine request](#) or open a [trade account](#) to move straight to sourcing.

Frequently asked

Which authority registers medicines in Qatar?



Qatar's Ministry of Public Health (MOPH) is the country's medicines regulator. Registration is handled by MOPH's Pharmacy and Drug Control Department (PDCD), which reviews and approves marketing authorisation applications, licenses drug stores and pharmacists, and runs its own PDCD E-System portal for electronic and eCTD submissions. No medicine may legally be marketed, imported, or distributed in Qatar until PDCD has approved it under a named local marketing authorisation holder.

Can an Indian manufacturer sell directly into Qatar without a local partner?



No. PDCD requires every product to have a Qatar-registered marketing authorisation holder, and separately, the entity that physically imports and distributes the product needs its own Drug Store licence, a Pharmacist licence, and a Commercial Registration from the Ministry of Commerce and Industry naming medicines trading as a permitted activity. In practice, an Indian exporter works through a licensed Qatari importer or agent. M Care Exports prepares the Indian-side dossier and shipment documentation that partner needs to take the product through PDCD and, where relevant, through Hamad Medical Corporation's tender process.

Does GCC central registration mean a product is automatically approved in Qatar?



Not automatically. Qatar takes part in the Gulf Health Council's central registration system, and PDCD offers a faster assessment track for products holding a valid, GCC-executive-office-stamped central registration certificate. The applicant still has to submit that certificate and confirm the product information matches the GCC-approved version exactly. What it does not remove is the national file: a Qatar-registered local agent, Arabic labelling, and PDCD's own approval are all still required before the product can be marketed or imported into Qatar.

How does Hamad Medical Corporation buy medicines?



Hamad Medical Corporation runs Qatar's largest public hospital network on a shared formulary, managed centrally by its Supply Chain Management division. It buys through periodic tenders, standing and blanket purchase agreements for formulary lines, and ad hoc emergency procurement to cover shortages. A supplier has to complete HMC's own vendor registration and hold pharmaceutical credentialing before it can bid, and every drug quotation submitted through HMC's e-tendering platform must carry a valid MOPH registration certificate for that specific product.

What documents does an Indian exporter need to prepare for Qatar?



The pack typically includes a WHO-GMP certificate for the manufacturing site for a generic, or the relevant Indian manufacturing and marketing authorisation for an originator brand, a WHO-format Certificate of Pharmaceutical Product from India's Central Drugs Standard Control Organisation, a batch-wise Certificate of Analysis, a Certificate of Origin, and a commercial invoice and packing list, usually legalised through the Qatar Embassy in India. M Care Exports assembles this against the actual manufacturer file for each product, because PDCD and Hamad Medical Corporation both reject documentation that does not match the registered product.

Is it worth registering a product in Qatar for a small order?



Registration is a national requirement, not a per-order one, so it only pays for itself against volume a buyer can commit to, typically a hospital network or a licensed wholesale importer with an ongoing formulary need, rather than a single trial shipment. Many Indian suppliers start by responding to a Hamad Medical Corporation tender, or an importer's request for a molecule that is already registered in Qatar, then build toward registering additional products once demand is established.

KUWAIT MARKET ACCESS · 9 MIN READ · PUBLISHED 13 SEPTEMBER 2026 · BY DR. RAJAT BHATT, MANAGING DIRECTOR

Kuwait requires Ministry of Health registration and a licensed local agent before any imported medicine reaches a pharmacy or hospital shelf.

Kuwait's Ministry of Health controls which medicines enter the country, and no foreign manufacturer can register a product without a Kuwaiti company standing behind it as local agent. Gulf-wide central registration can strengthen the technical review, but the national filing, pricing step and import licence still run through Kuwait alone. This guide sets out who regulates what, what an Indian exporter's document pack looks like, and where the process actually slows down.

Kuwait's Ministry of Health is the single registering authority

Kuwait's Ministry of Health controls which pharmaceutical products can be sold in the country. Registration dossiers are submitted to a dedicated administration, the Medicine and Medical Products Registration and Regulatory Administration, and Ministerial Decree No. 341 of 2025 sets out what a CTD or eCTD registration file submitted to that administration must contain.

Dossiers follow the Common Technical Document format, aligned to the ICH M4 structure across five modules, with a Kuwait-specific Module 1 covering administrative documents, certificates and the manufacturer's letter of authorisation. The scope runs across new chemical entities, generics, biologicals, biosimilars, hormonal products and combination

products, so the same framework applies whether the product is an originator brand or a WHO-GMP generic.

See our [Kuwait market page](#) for the fuller picture of how registration, pricing and hospital procurement fit together, and our [CTD dossier preparation service](#) for how we build the file itself.

Registering a foreign company's products, not the company itself

A foreign manufacturer does not register directly with Kuwait's Ministry of Health. The product is registered through a Kuwaiti entity acting as marketing authorisation holder and local agent, working from a document pack the manufacturer supplies: a legalised manufacturing licence, a legalised Good Manufacturing Practice certificate from the country of origin, and a site master file covering the facility, its equipment and its quality systems.

Manufacturing sites need GMP acceptable to the Kuwaiti and wider Gulf authorities. That is the bar M Care Exports applies before it will offer a molecule out of India: generics come only from WHO-GMP certified manufacturers, and originator brands move through their own licensed Indian marketing channels, so the manufacturing evidence a Kuwaiti registration file needs is already in place before a quote goes out.

Once granted, a registration certificate runs for five years and needs renewal at least six months before it lapses; a product without a current certificate cannot legally be imported, tendered for or dispensed, so the renewal calendar matters as much as the first approval.

Why every shipment needs a licensed Kuwaiti agent

Kuwait does not allow direct-to-market import. Every product needs a local agent: a Kuwaiti company holding a Ministry of Commerce and Industry licence that covers medicine sales, alongside the relevant Ministry of Health drug licence for import and storage. The manufacturer appoints that agent through a legalised letter naming it sole or exclusive agent, and the agency agreement itself is registered under Kuwait's commercial agency law.

The local agent is not a formality. It is the entity that files the dossier locally, holds the import permit, signs for customs, and is the counterparty on any hospital or tender contract. A

licence that has lapsed, even briefly, stalls a shipment at the port regardless of how complete the registration dossier is. **M Care Exports** checks agent licensing status before a first shipment moves, not after.

Our [MOH product registration service](#) covers how we work alongside a Kuwaiti agent on filing and renewals.

Where GCC central registration helps, and where it does not

Kuwait is a founding member of the Gulf Health Council, alongside Saudi Arabia, the UAE, Qatar, Bahrain and Oman. The Council runs a central drug registration route through a rotating Central Gulf Committee for Drug Registration, based in Riyadh, letting a single technical dossier be reviewed on behalf of participating states rather than filed separately in each one.

Central approval strengthens a Kuwait filing but does not replace it. Pricing, the local agent appointment, the import licence and Arabic-label approval still run through Kuwait's own Ministry of Health administration at country level. A product with GCC central approval enters the Kuwait queue in a stronger position; it does not skip the queue.

Our note on [WHO prequalification versus national registration](#) covers the same reliance-versus-national-filing question from a different angle, and is worth reading alongside this one.

How Kuwait's public sector buys medicines

Kuwait's Ministry of Health owns and runs most of the country's hospitals and polyclinics, and buys the medicines that stock them. Storage and distribution to those facilities runs through the Central Medical Stores Administration, the Ministry's dedicated warehousing and distribution arm. Procurement itself runs two ways: medicine-specific tenders are published and run through the Ministry's own electronic tenders channel, while larger, cross-ministry contracts route through Kuwait's Central Agency for Public Tenders, the state body responsible for government-wide tendering.

Either way, the Ministry evaluates the registration status of the offered brand alongside price. A tender response needs a current registration number, Certificate of Analysis,

Certificate of Origin, GMP certificate, stability data and Arabic-approved artwork ready before the tender opens, not assembled after an award.

See our [GCC tender response service](#) for how we prepare that pack.

The document pack an Indian exporter prepares

From the Indian side, a Kuwait registration file typically draws on: the manufacturer's CDSCO or state drug-licensing authority manufacturing licence, a WHO-format Certificate of Pharmaceutical Product or free sale certificate, the current GMP certificate, a Certificate of Analysis for the specific batch, stability data, and, where the product needs one, a Drug Master File for the active ingredient.

Kuwait has not joined the Hague Apostille Convention, so these documents cannot simply be apostilled. They need consular legalisation instead: attestation through India's Ministry of External Affairs, followed by legalisation at the Kuwait Embassy in New Delhi, before the Kuwaiti agent can submit them to the Ministry.

M Care Exports assembles this pack from its Mumbai regulatory desk and routes the legalisation steps directly, so the file that reaches the Kuwaiti agent is ready to submit rather than needing a second round of corrections. If you are evaluating a specific molecule, [tell us what you need](#) or [open a trade account](#) to start the conversation.

Frequently asked

Who actually registers a medicine with Kuwait's Ministry of Health, the exporter or the local agent?

The filing is made by the Kuwaiti local agent, working from documents the exporter supplies. A foreign manufacturer has no direct standing to register a product in Kuwait; it appoints a Kuwaiti company as marketing authorisation holder and local agent, and that company submits the Common Technical Document dossier, holds the import licence, and is the entity the Ministry of Health corresponds with. The exporter's job is to supply a complete, correctly legalised document pack, so the agent's filing goes through without deficiency queries.

Does GCC central registration mean I don't need to register separately in Kuwait?



No. Kuwait is a founding member of the Gulf Health Council's central drug registration route, and a centrally reviewed product enters Kuwait's own queue in a stronger position. But pricing, the local agent appointment, the import licence and Arabic-label approval still have to be completed through Kuwait's Ministry of Health at country level. Central registration speeds and strengthens the technical review; it does not replace the national filing.

What licences does a Kuwaiti import agent need to hold?



A Ministry of Commerce and Industry licence that specifically covers medicine sales activity, plus the relevant Ministry of Health drug licence covering import and storage. The agency agreement between the manufacturer and the agent is registered under Kuwait's commercial agency law, and the agent's authorised signatures need to be legalised through the Kuwait Chamber of Commerce and Industry. If either licence lapses, shipments stall at the port even when the product's own registration is current.

Can I send Kuwait an apostilled document instead of a legalised one?



No. Kuwait has not joined the Hague Apostille Convention, so an apostille is not accepted for documents used there. Manufacturing licences, GMP certificates and other supporting documents need consular legalisation instead: typically attestation through India's Ministry of External Affairs, followed by legalisation at the Kuwait Embassy in New Delhi. Building this into the production schedule early avoids it becoming the item that delays a filing that is otherwise ready.

How does Kuwait's public sector actually buy medicines?



Kuwait's Ministry of Health owns most of the country's hospitals and polyclinics and buys directly. Medicine-specific tenders run through the Ministry's own electronic tenders channel; larger, cross-ministry contracts go through the Central Agency for Public Tenders. Successful suppliers deliver into the Central Medical Stores Administration, the Ministry's central warehousing and distribution arm, which then supplies individual hospitals and health centres. A current registration number is a precondition for bidding, not a detail to sort out after an award.

Can M Care Exports supply both branded and generic medicines into Kuwait?



Yes. M Care Exports supplies originator brands through licensed Indian marketing channels and generics sourced from WHO-GMP certified Indian manufacturers, both against the same Kuwait registration and local-agent framework. M Care Exports does not manufacture and does not hold WHO-GMP itself; it is a merchant-exporter that builds the registration and shipping file around whichever product, branded or generic, a Kuwaiti buyer actually needs, and sources the manufacturing evidence from the plant that made it.

OMAN MARKET ACCESS · 9 MIN READ · PUBLISHED 25 SEPTEMBER 2026 · BY DR. RAJAT BHATT, MANAGING DIRECTOR

Oman registers medicines through the Ministry of Health's Drug Safety Center, and every foreign product needs a locally licensed agent to file the application.

Oman's Drug Safety Center runs product and company registration through its own e-portal, with a fast-track lane for products already cleared under the Gulf Health Council's central registration route. No foreign manufacturer or exporter can apply directly: an Omani-licensed agent must be appointed as the applicant of record before a dossier is submitted.

Who regulates medicines in Oman

Oman's national medicines regulator sits inside the Ministry of Health as the **Drug Safety Center (DSC)**. Older material, including a 2016 mission report from the International Narcotics Control Board, refers to the same function under an earlier name, the Directorate General of Pharmaceutical Affairs and Drug Control. The Ministry's current service pages and its own 2025 dossier-submission guideline both use Drug Safety Center, so that is the name a supplier should work from today.

Two legal instruments sit behind the DSC's work: the Pharmacy Practice Law (Royal Decree 41/91), which governs pharmacy and warehouse licensing, and Minister of Health Decision No. 113/2020, whose Articles 63, 66, 68 and 69 set out registration, re-registration and variation of medicinal products. Registration and pricing decisions are made by the **Technical Committee for Registration and Prices (TCR&P)**, which can approve an application, reject

it, ask for more information, or set an approved price that is lower than the one the applicant requested.

Registering a product sourced from India

A new Marketing Authorisation Application (MAA) is submitted through the MOH e-portal, with the product dossier uploaded in eCTD format against the components the DSC publishes on its own site. Every submission goes through technical and business validation before assessment starts, and the DSC allows up to three rounds of written queries (a "wave") per application.

The DSC sorts new applications into two lanes:

- 1. Fast track**, for new chemical entities with Stringent Regulatory Authority approval, vaccines with SRA approval or WHO Prequalification, biologicals and biosimilars with SRA approval, locally manufactured products, first and second generics, and products already registered under the Gulf Health Council's central drug registration route.
- 2. Normal track**, for everything else.

The DSC's own performance targets (working days, excluding inspection time and any period an application is waiting on the applicant) are 90 days for a fast-track application processed on reliance, 180 days for a fast-track application needing full assessment, and 280 days for a normal-track full assessment. A locally submitted certificate is valid for five years; a renewal request is due six months before that certificate expires. Once a product is on the market, any change is filed as a variation: minor Type IA changes are notified within 14 days of implementation, Type IB changes wait 120 working days for the DSC's response before going ahead, and major Type II changes need prior approval, targeted at 180 working days.

Why a local agent is not optional

An Indian manufacturer or exporter cannot file a dossier with the DSC directly. Registration in Oman runs as two gated steps: a pharmaceutical company must first be registered with the DSC, and only that registered entity can then submit a product's Marketing Authorisation Application. In practice this means an Omani-licensed agent is appointed as the applicant

and local sponsor of record, and stays in that role for the life of the registration, not just for the initial filing.

This isn't a formality. Pharmacy and pharmaceutical warehouse licensing in Oman runs through the DSC's own framework under the Pharmacy Practice Law (Royal Decree 41/91), so the agent has to be a properly licensed Omani pharmaceutical entity, not simply a distributor holding a general trade licence. Getting this relationship right before the first submission avoids the common failure mode: a dossier stalled or rejected because the party of record on file with the DSC has no standing to respond to a query. [M Care Exports](#) works alongside the buyer's appointed Omani agent to keep the dossier, the query responses and the agent's filings aligned through assessment.

How the GCC central registration route fits in

Oman is a founding member of the region's central drug registration system, run by the **Gulf Health Council** and referred to in Oman's own regulatory guideline by both of its short forms, GHC-DR and GCC-DR, with published guidance issued out of Riyadh. A product that already holds a GCC-DR registration certificate qualifies for Oman's fast-track lane, and the validity of the Omani marketing authorisation is then aligned to the GCC certificate's own validity rather than run as a separate five-year clock.

Oman also operates a narrower reliance route inside its own process: a product with an existing approval from the Saudi FDA, the UAE, or Kuwait (backed by a Certificate of Analysis) within the last two years can be assessed on reliance rather than full review, provided the submitted product information is declared identical to what the reference authority approved. Either route still requires stability data run to the GCC's guideline for a hot, humid climate (climatic Zone IV), which is a different test condition to the temperate-zone data some Indian manufacturers hold as their default package. See our note on how [reliance pathways compare with a full national dossier](#) for the wider Gulf and Africa picture.

How Oman's Ministry of Health buys medicines

DSC registration and public procurement are two separate gates. Bulk purchasing for MOH-affiliated hospitals and health institutions runs through the **Directorate General of Medical**

Supplies (DGMS), which manages receipt, storage and distribution from central warehouses in Muscat, Nizwa and Salalah, plus an emergency reserve.

Before a company can bid on an MOH tender, it has to be pre-qualified by the DGMS under Ministerial Decision No. 109/2008, a separate technical and quality review from the DSC's product registration. A supplier can hold a valid DSC marketing authorisation and still not be pre-qualified to tender, and the reverse can also stall a shipment if the two approvals fall out of step. Our [tender-response support for GCC public procurement](#) is built around keeping registration status and pre-qualification status moving together rather than treating them as one step.

The document pack an Indian supplier needs to assemble

Most of the delay in an Oman filing comes from documents that were prepared for a different market and need reworking, not from the DSC's own review clock. A typical pack includes:

- A Certificate of Pharmaceutical Product (COPP) or free sale certificate from the Indian licensing authority (CDSCO or the relevant state FDA) for the actual manufacturing site.
- The manufacturing licence and current GMP evidence for that site, whether the product is a generic from a WHO-GMP-certified manufacturer or an originator brand supplied through a licensed Indian distribution channel.
- Batch Certificates of Analysis matching the samples submitted.
- Stability data generated for the GCC's hot, humid Zone IV conditions, not a temperate-zone package.
- A CTD dossier built to the DSC's eCTD components, with Module 1 documentation and any additional data the guideline calls for.
- A signed local agent appointment letter naming the Omani entity as applicant of record, plus notarisation and consular legalisation of the corporate and product documents as the agent's filing requires.

M Care Exports does not hold WHO-GMP certification itself and does not manufacture; as a merchant-exporter it assembles this pack from the actual manufacturing site's certificates for generics, or from the licensed Indian channel's documentation for originator brands, and hands the buyer's Omani agent a dossier built to the DSC's current format rather than a

generic CTD template. Our [dossier preparation service](#) covers this rework, and a buyer can start with a [specific product request](#) or set up a [trade account](#) to move straight to sourcing once the regulatory path is confirmed. Our [Oman market page](#) covers the categories we supply to Omani agents and hospitals.

Frequently asked

Does M Care Exports hold WHO-GMP certification itself?



No. M Care Exports is an Indian merchant-exporter, not a manufacturer, and it does not hold WHO-GMP or WHO-PQ status in its own name. For generic products it sources from WHO-GMP-certified Indian manufacturers and passes their certificates through to the buyer's dossier. For originator brands it sources through licensed Indian distribution channels. The manufacturing site's own GMP status, not M Care's, is what the Drug Safety Center reviews.

Can an Indian generic use the GCC reliance pathway for Oman registration?



Yes, if it qualifies. Oman's fast-track lane covers first and second generics on their own merits, and separately recognises products already registered under the Gulf Health Council's central registration route (GHC-DR/GCC-DR) or holding a recent approval from the Saudi FDA, the UAE, or Kuwait with a Certificate of Analysis. A generic without any of those doesn't lose eligibility to register, it is simply assessed on Oman's normal track, which carries a longer target timeline.

Who can act as the local agent for an Indian exporter's product in Oman?



It has to be an Omani-licensed pharmaceutical entity: pharmacy and pharmaceutical warehouse licensing in Oman runs through the Drug Safety Center's own framework under the Pharmacy Practice Law. The agent submits the registration request, is recorded as the applicant, and stays the point of contact with the Drug Safety Center for the life of the marketing authorisation, including renewals and variations.

How long does it take to register a medicine in Oman?



The Drug Safety Center's own working-day targets, excluding inspection time and periods waiting on the applicant, run from 90 days for a fast-track product assessed on reliance up

to 280 days for a normal-track product needing full assessment. The Ministry's public e-portal listing for a standard product registration service states an end-to-end target of 360 working days. A locally issued certificate is then valid for five years, with renewal due six months before expiry.

Does DSC product registration automatically qualify a supplier for Ministry of Health tenders?



No. Product registration with the Drug Safety Center and company pre-qualification for Ministry of Health tenders are handled by two different directorates. Tender eligibility runs through the Directorate General of Medical Supplies under Ministerial Decision No. 109/2008, a separate technical and quality review. A registered product still needs its manufacturer or agent to complete DGMS pre-qualification before it can be offered into a public tender.

What stability data does Oman require for a hot climate?



Oman applies the Gulf Health Council's stability testing guideline for climatic Zone IV, the hot and humid zone, in Modules 2 and 3 of the product dossier. This is a different storage and testing condition to the temperate-zone (Zone II) data that some manufacturers hold as their default stability package, so Indian exporters targeting Oman should confirm their stability programme covers Zone IV conditions before submission rather than after a query is raised.

BAHRAIN MARKET ACCESS · 9 MIN READ · PUBLISHED 1 OCTOBER 2026 · BY DR. RAJAT BHATT, MANAGING DIRECTOR

NHRA registers every pharmaceutical product sold in Bahrain, and Indian exporters need a Bahrain-licensed distributor to bring one to market

Bahrain's National Health Regulatory Authority (NHRA) reviews and licenses every medicine before it reaches a pharmacy shelf or a hospital tender. For an Indian supplier, the route runs through a Bahrain-based importer, not a direct filing from Mumbai or Ahmedabad. M Care Exports sets out how the pieces fit together, from product registration to Ministry of Health procurement.

NHRA is the single regulator for medicines in Bahrain

The National Health Regulatory Authority (NHRA) is the government body that licenses healthcare facilities, health professionals and pharmaceutical products across the Kingdom of Bahrain. Within NHRA, the Pharmacy and Pharmaceutical Products Regulation section is the one that matters for an exporter: it runs product registration and pricing, product inspection, and parcel clearance for medicines entering the country.

NHRA reviews quality, safety and efficacy data before any medicine, health product, or complementary/alternative medicine can be sold in Bahrain. Applications and supporting checklists differ by product category, and NHRA operates its licensing transactions through online systems it calls Munshaat and Mehan. A supplier does not deal with these portals

directly. The Bahrain-licensed distributor holding the marketing authorisation application does.

For a wider view of how registration differs from a WHO listing status, see [WHO prequalification vs national registration](#).

What product registration actually requires

NHRA's registration process asks for a technical dossier covering manufacturing, quality control, stability and clinical/bioequivalence data, built around the current guideline in force for the product category. This is the same discipline used across most Gulf regulators: a structured Common Technical Document (CTD) format dossier, not a loose file of certificates.

Because the review sits with the local applicant, the quality of the dossier the Indian manufacturer or M Care Exports hands over decides how smoothly the file moves. Gaps in stability data, inconsistent batch documentation, or a Certificate of Pharmaceutical Product that does not match the exact product presentation are the most common reasons a submission stalls. See [dossier preparation in CTD format](#) for how this gets built before it ever reaches Bahrain.

Renewals, variations (a new pack size, a labelling change, a manufacturing site change) and re-registration all run through the same section, so the relationship with the Bahrain distributor needs to survive beyond the first approval, not just the first sale.

Company registration and the local distributor requirement

NHRA licenses pharmaceutical establishments as well as products, and that establishment licence sits with a Bahrain-registered company. In practice, an Indian exporter without a Bahrain presence works through a locally licensed pharmaceutical importer or distributor: that entity holds the establishment licence, submits the product registration file, and takes on the regulatory and pharmacovigilance obligations NHRA expects of a marketing authorisation holder based in Bahrain.

This is the standard pattern across the Gulf, not a Bahrain-specific hurdle. An Indian principal that already has a good relationship with a licensed Bahraini distributor, or is willing

to build one, moves faster than one hunting for a partner mid-registration.

M Care Exports works with the Bahrain-side applicant of record to keep the paperwork consistent between what the Indian manufacturing site issues and what NHRA's file requires, rather than leaving that reconciliation to the distributor alone.

GCC membership does not replace NHRA's own review

Buyers sometimes ask whether an approval in Saudi Arabia, the UAE or another Gulf state carries over into Bahrain. It does not. NHRA runs its own national dossier review and issues its own marketing authorisation, independent of where else in the region a product is registered. A prior Gulf approval can support a Bahrain file as reference evidence, but it is not a substitute for it.

Treat Bahrain as its own registration project with its own timeline, even when the same product is already moving through registration elsewhere in the GCC. Confirm the current position on any regional harmonisation directly with NHRA or with the Bahrain-based distributor handling the file, since procedures are updated from time to time.

Ministry of Health tenders run through the Bahrain Tender Board

Government procurement in Bahrain, including Ministry of Health purchasing, runs primarily through the Tender Board and its eTendering portal. Suppliers bid through that system, and the Tender Board's published user guides for suppliers set out the account and submission steps.

A foreign manufacturer or exporter participates through its local registered agent or distributor, the same entity that typically holds the NHRA product registration. Registration and tender eligibility tend to move together in Bahrain: a product generally needs its NHRA marketing authorisation in place before it can be offered into a Ministry of Health tender line.

See [GCC tender response support](#) and [Ministry of Health registration across the GCC](#) for how M Care Exports lines up registration status with tender timing across the region, including Bahrain's neighbours covered in [unlicensed medicines in GCC hospitals](#).

What M Care Exports prepares on the India side

The Bahrain distributor's registration file is only as good as the underlying Indian documentation. M Care Exports assembles this pack before the file goes to Bahrain, whether the product is a WHO-GMP certified generic or an originator brand moved through licensed Indian channels:

- Certificate of Pharmaceutical Product (CoPP), issued in WHO format by the Indian licensing authority for the specific product and manufacturing site
- Current manufacturing site GMP certificate, matched to the product being registered
- Free Sale Certificate covering the export shipment
- Certificate of Analysis for the batch, plus stability data supporting the claimed shelf life
- Product labelling, package insert and artwork in the format NHRA expects for review
- Commercial documentation: proforma invoice, packing list, and certificate of origin for each shipment

Because M Care Exports has supplied both generic and originator-brand product into regulated Gulf and African markets since 2003, the pack is built around what a receiving regulator's reviewer actually asks for a second time, not just what the first submission requires. Buyers can start a specific product enquiry through [request a medicine](#) or set up ongoing sourcing through a [trade account](#). The [Bahrain market page](#) sets out the categories we supply to Bahraini distributors and hospitals.

Frequently asked

Can an Indian exporter register a product with NHRA directly, without a Bahrain company?



No. NHRA licenses pharmaceutical establishments, and that licence sits with a Bahrain-registered company, so in practice the marketing authorisation application is submitted and held by a Bahrain-licensed importer or distributor. An Indian manufacturer or merchant-exporter such as M Care Exports supplies the product dossier and manufacturing documentation, but the applicant of record on the NHRA file is the Bahrain-based company. Building that local relationship early avoids losing time once the dossier is ready.

Does a product already registered in Saudi Arabia or the UAE get approved faster in Bahrain?



Not automatically. NHRA runs its own national review of quality, safety and efficacy data and issues its own marketing authorisation, regardless of a product's status elsewhere in the Gulf. A prior Gulf registration can be useful supporting evidence in the file, but Bahrain still needs its own dossier submission and its own decision. Treat it as a separate registration project with its own timeline rather than an automatic extension of another country's approval.

How does Ministry of Health tendering work for imported medicines in Bahrain?



Government procurement, including Ministry of Health purchasing, runs through the Bahrain Tender Board's eTendering portal. A foreign supplier bids through a local registered agent or distributor, usually the same entity holding the product's NHRA registration. Because eligibility and registration status tend to be linked, a product generally needs its NHRA marketing authorisation secured before it can be offered against a Ministry of Health tender line.

What documents does M Care Exports provide for an NHRA submission?



The core pack is a WHO-format Certificate of Pharmaceutical Product matched to the exact product and manufacturing site, a current GMP certificate for that site, a Free Sale Certificate, batch Certificates of Analysis with supporting stability data, and product labelling and artwork in the format the reviewing authority expects. Commercial paperwork (proforma invoice, packing list, certificate of origin) is prepared alongside it. The pack is assembled before the file goes to the Bahrain-based distributor, to reduce back-and-forth once NHRA starts its review.

Can M Care Exports supply both generic and branded originator products for the Bahrain market?



Yes. M Care Exports is a merchant-exporter, not a manufacturer: it sources WHO-GMP certified generics and originator brand products through licensed Indian distribution channels, and supplies both into regulated markets including Bahrain. The registration route and document pack differ slightly between a generic and an originator brand, but both go through the same NHRA product registration and Bahrain distributor structure described above.

Does WHO-GMP certification on the manufacturing site guarantee NHRA registration in Bahrain?



No. WHO-GMP status on the manufacturing site is one input into the dossier, evidence of manufacturing quality, but NHRA still conducts its own review of the specific product's safety, efficacy and quality data before granting a marketing authorisation. The two are related but separate: see how WHO listing status and national registration differ in more detail at </insights/blog/who-prequalification-vs-national-registration/>.

REGISTRATION · 12 MIN READ · PUBLISHED 26 APRIL 2026 · BY DR. RAJAT BHATT,
MANAGING DIRECTOR

GCC Central Registration in 2025: one dossier, six states, and the catches nobody puts in the brochure.

The six GCC states, Saudi Arabia, the UAE, Kuwait, Oman, Qatar and Bahrain, share a single centralised drug registration route called **GCC-DR**, run by the Gulf Health Council from its Riyadh secretariat. One CTD, one lead-country review, an authorisation that the other five states recognise. It is the pathway a regulatory affairs manager picks when a 6-country launch matters and a 3-to-5-year serial-filing calendar does not work. This post is what we tell regulatory colleagues over coffee when they ask whether *gcc central registration 2025* is the right route for their molecule: what it actually is, who runs it, where the timelines land, and the three or four places where a first-time applicant will lose six months if nobody flags the catch.

A centralised regulatory pathway sounds simple on paper. One dossier, one review, one authorisation. The GCC-DR route earns most of that billing, but the parts that do not scale across the six states are exactly the parts that decide whether a product actually launches on time. This is M Care Exports' walkthrough of the mechanism, the timeline, the cost, and the edge cases.

What GCC-DR actually is, in 2025.

GCC Drug Registration, usually written GCC-DR, sometimes GCC Central Drug Registration, is the harmonised marketing authorisation route for pharmaceuticals across the six Gulf

Cooperation Council states. A single CTD is submitted via the Gulf Health Council's e-portal. The GHC assigns a lead country. The lead country conducts the scientific assessment. Once the lead approves, the other five states issue their own national registration numbers against that harmonised decision, with shared labelling, shared SmPC and, in principle, a shared ex-factory price.

What GCC-DR is *not*: a single marketing authorisation number across six states, and not a single commercial launch date. Each of the six member states still issues its own MA number. Each runs its own pricing committee. Each signs off its own local-agent-of-record. The scientific review collapses into one. The administrative cascade does not.

The route sits alongside the national pathways, SFDA in Saudi Arabia, MOHAP in the UAE, MoH Pharmaceutical Department in Kuwait, DGPA&DC in Oman, MoPH Pharmacy in Qatar, and NHRA in Bahrain. An applicant can still file each country separately. Most serious multi-country launches since the mid-2010s have moved to GCC-DR.

The Gulf Health Council and the six regulators.

The **Gulf Health Council (GHC)**, seated in Riyadh, is the body that governs pharmaceutical harmonisation across the GCC. Older documents may reference it as the GCC Executive Board of the Health Ministers' Council, the name changed but the role did not. The GCC-DR Committee is the working group inside GHC that runs the central registration pathway day to day. Yemen is a non-GCC member but has historically been included in GHC's pharmaceutical workstreams, so older guidance references seven states.

The six national regulators the applicant will touch:

- **SFDA**, Saudi Food and Drug Authority, Riyadh. The largest market, the deepest review bench, and historically the default lead for biologics and NMEs.
- **MOHAP**, Ministry of Health and Prevention, UAE. Federal pharmaceutical regulator; DHA (Dubai) and DoH (Abu Dhabi) overlay emirate-level pharmacy licensing.
- **Kuwait MoH Pharmaceutical Department**, Kuwait City.
- **MoH Oman DGPA&DC**, Directorate General of Pharmaceutical Affairs and Drug Control, Muscat.
- **MoPH Qatar Pharmacy Department**, Doha.

- **NHRA**, National Health Regulatory Authority, Bahrain.

The GHC assigns the lead country based on product type, the applicant's preference and, crucially, the workload queue at each regulator at the time of filing. SFDA is the rigorous default. It is also, at most points in the cycle, the most back-logged. MOHAP and NHRA have gained traction as leads on faster-moving technical reviews.

When GCC-DR beats single-country filing.

The decision is narrower than it looks. GCC-DR is the right route when the commercial plan genuinely covers four or more GCC states, when the product is eligible for the central pathway, and when the applicant can live with the lead-country queue. It is the wrong route when the first launch is a single-country tender with a short deadline, or when the product has an obvious national-pathway shortcut, a local MoH priority listing, for instance.

A simple rule of thumb from the desk:

1. Launching in **one or two GCC states** in the next 18 months, file nationally. The GCC-DR calendar is longer than the combined national calendars at that scale.
2. Launching in **three states**, the decision is genuinely split. It depends on which three, and whether the lead-country queue on GCC-DR is currently shorter or longer than the parallel national queues.
3. Launching in **four or more states**, GCC-DR almost always wins on wall-clock time, and wins heavily on total regulatory effort.

There is one more case where GCC-DR is the right answer even for a narrower launch: when the applicant plans to add states later and wants to avoid re-authoring the dossier each time. A GCC-DR approval lives as a single file across all six national registrations, so adding Oman or Bahrain three years after Saudi launch is a ratification step, not a fresh assessment.

The 12-18 month timeline, step by step.

A clean generic with a complete dossier, a sensible lead-country choice, and a responsive applicant will close inside 18 months from submission to lead-country approval. Biologics and new molecular entities sit at the upper end, 18 to 24 months is realistic, longer if the RTQ cycle opens non-trivial quality questions. Here is where the months actually go:

- 1. Pre-submission, 4–8 weeks.** Lead-country selection, GHC e-portal registration, eCTD validation, bilingual labelling mock-up, apostille and destination-legalisation of the CDSCO CoPP and site WHO-GMP.
- 2. Submission and administrative validation, 2–4 weeks.** The GHC checks the file for completeness before the technical clock starts. Missing pieces, apostille endorsement, Arabic labelling draft, Zone IVb stability, bounce the file here.
- 3. Lead-country technical review, 9–14 months.** Drug substance, drug product, non-clinical, clinical package, risk management plan. RTQs (requests-to-query) arrive in waves; each round consumes 30–60 days of the clock. Responsive applicants close the review inside the window. Slow or defensive responses push the review into extra rounds.
- 4. Lead-country approval and notification to the other five states, 2–4 weeks.** The decision is shared with SFDA, MOHAP, Kuwait MoH, Oman DGPA&DC, MoPH Qatar and NHRA.
- 5. National ratification, 2–6 months per state.** Each of the six states issues its own MA number, finalises local artwork, registers the local agent-of-record. States run this step in parallel; the slowest one defines the launch date for full six-country availability.
- 6. Pricing file and first launch, 2–6 months.** The GCC Unified Pricing submission sets the reference ex-factory price; each state's pricing committee then applies local rules. Pricing is a discrete clock and does not run in parallel with technical review.

Fast-track exists for priority products, WHO-PQ reference, orphan designation, public-health-priority anti-infectives, at GHC's discretion. It compresses the technical review but not the national ratification cascade.

The cost picture and where the saving sits.

The fee saving on GCC-DR is real but smaller than marketing copy suggests. GHC charges a central filing fee. Each member state then charges a national-inscription fee at the point of ratification. Compared with six parallel single-country filings, six full submission fees, six dossier-handling fees, six national-agent retainers across an extended filing window, the net fee saving typically lands in the **30–45%** range. The real saving, by a wide margin, is wall-clock time and regulatory effort.

Six sequential or parallel national filings, authored to six different national formats and defended through six separate RTQ cycles, is a 3-to-5-year programme. A single GCC-DR filing, authored once, defended once, is a 12-to-24-month programme. That wall-clock

difference is the reason CFOs sign off on GCC-DR even before anyone calculates the fee delta.

On the commercial side, the saving is a launch-window saving, not a price saving. Each national pricing committee still applies its own reference-pricing rules and its own trade margins. A unified ex-factory price does not produce a unified retail price.

The four catches most applicants miss.

These are the four places where an otherwise clean GCC-DR programme loses six to twelve months. All four are manageable with planning. None of them is well-advertised in the official guidance.

- 1. Pricing decoupling across states.** Applicants assume that because the dossier is unified and the GCC Unified Pricing Framework exists, the commercial price will be uniform across six markets. It will not. Each state's pricing committee can and does apply local reference-pricing rules and local margin caps on top of the GHC reference price. Budget for six pricing negotiations, not one.
- 2. Arabic artwork variations.** The GHC harmonised template covers most bilingual labelling, but state-specific annex labelling, especially for controlled substances, narcotics and certain biologicals, still needs country-specific work. Saudi Arabic usage differs in places from Emirati usage. Plan the artwork as a harmonised base plus six annexes, not as a single master.
- 3. Lead-country choice on workload, not prestige.** SFDA is the rigorous default. It is also, at most points in the cycle, the most back-logged. Choosing SFDA as lead because the first launch is in Saudi Arabia can add six to nine months over picking MOHAP or NHRA as lead when those benches are lighter. The right question is not "which regulator is strictest" but "which regulator has the capacity window that matches my timeline".
- 4. Pricing file submitted late.** The Unified Pricing submission is technically separate from the technical MA dossier, and it runs on its own clock. Applicants who treat pricing as a post-approval afterthought lose three to six months of first-launch window. Prepare the pricing file in parallel with the last lap of technical review, not after approval lands.

One further point that does not fit in a numbered list: post-approval variations. These are classified under the GCC Variation Guideline as Type IA, IB or II, broadly parallel to the EU model. They route centrally through the lead country when the variation affects harmonised aspects (Module 3 quality, specifications, manufacturing site), and nationally when the

variation is label-only or pricing-only. Our [documentation-chain post](#) covers the Indian-end paper that feeds those variations.

FAQ

Does a single GCC-DR approval mean a simultaneous launch in all six states?

No. The lead-country technical approval is recognised across all six states, which collapses the scientific review into one. Each member state still issues its own MA number, signs off local artwork, registers the local agent-of-record and completes its pricing negotiation. In our experience, the gap between lead-country approval and full six-state commercial availability is 2-6 months, with the slowest state defining the launch window.

Which lead country should an applicant choose for GCC-DR?

The right lead is the one whose review-capacity window matches the commercial timeline, not the most prestigious regulator. SFDA is the rigorous default and sits deep on biologic expertise, but its queue is usually the longest. MOHAP and NHRA have been used increasingly for faster-moving technical reviews. The choice is applicant-led but subject to the lead regulator's capacity at the moment of filing. We advise on the trade-off rather than prescribe a default.

What documents must come from the Indian side for a GCC-DR submission?

The core Indian-end pack is the CDSCO-issued CoPP in WHO format, a site- and dosage-form-specific WHO-GMP certificate, the manufacturing licence (Form 25 or 28 as applicable), the Site Master File, full CTD Module 3 quality data, ICH Zone IVb stability (long-term 30°C / 75%RH), a bioequivalence report for generics, and Indian-apostilled and destination-legalised copies of the statutory certificates. All of it is prepared to GCC technical expectations, not Indian national expectations.

How does GCC-DR compare with filing in each country separately?

Six sequential or parallel national filings is a 3-to-5-year programme with six full fee stacks and six parallel RTQ cycles. GCC-DR is a 12-to-24-month programme with a single technical review and a 30-45% net fee saving. The single exception is a one- or two-country launch

on a short deadline, where the national queue may be shorter than the GCC-DR queue. For a genuine 4-to-6-country launch, GCC-DR wins decisively on wall-clock time and regulatory effort.

GCC TENDERS · 14 MIN READ · PUBLISHED 30 MAY 2026 · BY DR. RAJAT BHATT, MANAGING DIRECTOR

Seven documents that travel with every GCC MoH tender submission.

When a Saudi **NUPCO**, Kuwait **CMSPS**, Qatar **HMC**, UAE **MOHAP**, Oman **MoH** or Bahrain **NHRA** tender opens to an Indian generic supplier, seven documents, not ten, not five, travel with every bid. Skip any of these and the submission sits in clarification limbo while the buyer awards to whoever sent the complete package on day one. This is the working list our Mumbai desk runs through before any GCC tender bid leaves the office, with the catches buyers most often surface in clarification rounds.

A GCC ministry-of-health tender is not won on price alone; it is won on whether your package is complete the day it lands. Across Saudi Arabia, the UAE, Qatar, Kuwait, Oman and Bahrain the document set is broadly the same seven items, but each state bends the freshness windows, the format and the local-representative rule its own way. Here is the working list M Care Exports uses, document by document, with where Indian bids actually stall.

I. The CTD dossier itself, Modules 1 through 5.

The Common Technical Document is the backbone. Module 1 is country-specific (each GCC state has its own administrative overlay), while Modules 2 through 5 are broadly harmonised under ICH guidance. Saudi SFDA, UAE MOHAP and the GHC e-portal for GCC Central Registration accept eCTD format; Qatar MoPH and Kuwait MOH-DFC accept hybrid (eCTD or

paper plus electronic copies); Bahrain NHRA still accepts pure paper for first-time-applicant tenders but is migrating to e-submission through 2026.

The Module 1 overlay matters most. Saudi SFDA requires an Arabic-language SmPC summary plus a price-justification annex; UAE MOHAP requires a UAE-trade-mark certificate; Kuwait MOH-DFC requires a Kuwait-specific pharmacovigilance commitment letter; Qatar MoPH requires a Qatar Pricing Committee submission form bundled into M1; Oman MoH and Bahrain NHRA have their own variants. The dossier preparation team at our Mumbai desk runs through the CTD dossier preparation workflow per country; one master CTD with six Module 1 overlays is how we keep the package consistent.

Where bids stall: Module 1 overlay missed on one state. We have seen submissions with strong M2 to M5 sit for weeks because the Saudi PC pricing annex was not attached. Lead country reviewers do not raise the issue until the substantive review begins, so the clarification clock is wasted.

2. CoPP, the WHO Type Certificate of Pharmaceutical Product.

The CoPP is the destination-country regulator's gateway acceptance signal. Issued in India by the Central Drugs Standard Control Organisation (CDSCO), the CoPP names the destination state on its face. A CoPP for Saudi Arabia is not interchangeable with one for the UAE, even though the underlying manufacturing licence is identical. CDSCO issues batches typically every two to four weeks; a master list of destination countries gets stamped together when the manufacturer files via Form 29.

Freshness window: Saudi SFDA, UAE MOHAP, Qatar MoPH, Oman MoH and Bahrain NHRA require the CoPP to be within twelve months of tender submission. Kuwait MOH-DFC accepts up to eighteen months. Mature partners renew CoPP every nine months as standard practice to avoid the edge case. The WHO-GMP compliance service line manages this renewal cycle plus the underlying Site Master File and inspection-report bundle that supports CoPP issuance.

Where bids stall: a generic India CoPP not naming the destination GCC state, or one issued more than twelve months before tender bid date. Both are treated as missing documents, not clarification items.

3. Authorised Local Representative (ALR) appointment letter.

Every GCC state requires a licensed local entity to act as the legal liaison between the foreign manufacturer and the destination MoH. The ALR is not a distributor in the commercial sense; it is the regulatory address for variation filings, pharmacovigilance reports, recall coordination and post-marketing commitments. Saudi SFDA requires the ALR to hold a current Saudi-incorporated pharmaceutical Establishment Licence; UAE MOHAP requires a Federal Pharmaceutical Trading licence; Qatar MoPH requires registration with the Department of Pharmacy and Drug Control (DPDC); Kuwait MOH-DFC requires a Kuwait-licensed warehouse and a pharmacist-in-charge endorsement; Oman MoH and Bahrain NHRA each have their own variants.

The single most expensive misconception in new-applicant GCC tender bids: one ALR letter does not cover all six states. GCC Central Registration consolidates the scientific review across the six member states but does NOT collapse the ALR requirement. Six separate ALR letters need to sit in Module 1, one per destination. Our [MoH registration, GCC](#) service line carries an ALR-network panel of vetted pharmaceutical distributors across the six states.

Where bids stall: an ALR letter naming an entity whose licence has lapsed between drafting and tender submission. Two-to-six-week clarification holds are common. Verify ALR licence currency via the destination regulator's public register on the bid submission day, not the dossier preparation day.

4. GMP certificate and manufacturing licence.

The manufacturer's CDSCO-issued WHO-GMP certificate is the lower bound. Above that, GCC tenders increasingly weight EU-GMP or PIC/S-recognised inspectorate certification (TGA Australia, Health Canada, ANVISA Brazil) as a tiebreaker for award. Saudi SFDA NUPCO tenders and Qatar HMC oncology tenders explicitly score on this in their technical evaluation matrices. The manufacturing licence (Form 25 or 28, depending on category) issued by the relevant Indian state Drugs Control Department must be current and name the dosage form on the licence.

Freshness window: GMP certificate must be within eighteen months for Saudi SFDA, UAE MOHAP and Qatar MoPH; twenty-four months for Kuwait, Oman and Bahrain. Re-inspection cycle drives this; a manufacturer with a 2024 inspection holds a valid CDSCO WHO-GMP

through 2026 for most categories, but injectables and biologicals tighten to annual renewal. The WHO-GMP compliance service tracks renewal scheduling and inspection-readiness ahead of tender opening windows.

Where bids stall: an outdated GMP certificate where the original inspection was clean but the renewal was delayed by CDSCO scheduling. We have seen otherwise-strong bids fall to clarification because the GMP cert was three weeks past its eighteen-month window on the day the tender closed.

5. Site Master File, PIC/S format.

The Site Master File describes the manufacturing facility in PIC/S Annex 4 structure: site layout, organisation chart, personnel qualifications, equipment inventory, validation matrix, utilities, computerised systems, complaints handling, change control, and self-inspection programme. Saudi SFDA, UAE MOHAP and the GCC Central Registration lead-country reviewers all expect PIC/S format. SMFs prepared to other formats (legacy WHO Site Master, individual quality manuals) are accepted but flagged for substantive clarification rounds.

Freshness window: SMF must be updated within twelve months of tender submission for Saudi SFDA and UAE MOHAP, eighteen months for Qatar MoPH and Kuwait MOH-DFC, twenty-four months for Oman and Bahrain. The SMF revision cycle should follow the manufacturer's annual self-inspection programme, with a formal SMF re-issue every twelve months. The CTD dossier preparation service line keeps the SMF on the same review calendar as the Module 3 quality dossier.

Where bids stall: SMF not in PIC/S format. This is the single most common reason for clarification holds across our GCC tender history. SMFs prepared to WHO Site Master format pass for some destinations but trigger automatic clarification at Saudi SFDA and UAE MOHAP.

6. Batch CoA and ICH Climate Zone IVb stability data.

Three consecutive production batches' Certificates of Analysis (CoA) plus a stability data package are mandatory. ICH Q1A long-term stability at ICH Climate Zone IVb conditions (30 degrees Celsius / 75 percent relative humidity) is the GCC baseline; most Indian manufacturers default to Zone II stability (25 degrees Celsius / 60 percent relative humidity)

which alone is insufficient for Saudi SFDA, UAE MOHAP and Qatar MoPH. Bahrain NHRA accepts Zone IVa (30 degrees Celsius / 65 percent RH) as a fallback for non-thermolabile products; the others do not.

The acceptable stability package: twelve to twenty-four months Zone IVb long-term data, plus accelerated stability at 40 degrees Celsius / 75 percent RH for six months. For thermolabile injectables and biologicals, 2 to 8 degrees Celsius long-term data plus excursion-tolerance studies replace the Zone IVb requirement. Cold-chain dossier overlays (qualified shipper specs, temperature excursion data, conformance to USP 1079 and PDA TR 39) sit in Module 3.2.P. The cold-chain validation service line manages the excursion-tolerance documentation for sensitive products bound for Doha Hamad International, Riyadh King Khaled International, Dubai International and Kuwait International airports.

Where bids stall: Zone II stability data submitted for a Zone IVb destination, where the manufacturer believed the WHO-GMP CoPP would be sufficient. It is not. Saudi SFDA and UAE MOHAP have rejected otherwise-strong bids for Zone IVb stability gaps on a binary pass-fail basis.

7. Pricing reference list with International Reference Pricing (IRP).

Each GCC state has a Pricing Committee that sets ceiling ex-factory prices using International Reference Pricing benchmarks. Saudi SFDA's Pricing Committee references prices in Saudi Arabia, UAE, Jordan, Egypt, Lebanon, France, Spain, Italy, Turkey and the originator's home country. UAE MOHAP, Qatar MoPH, Kuwait MOH-DFC and Bahrain NHRA each use overlapping but not identical reference baskets. GCC Central Registration adds a unified-pricing layer on top: the lead country's Pricing Committee sets the ceiling and that ceiling must hold across the six states.

For NUPCO tenders in Saudi Arabia, the published unified-pricing ceiling is the upper bound; tender bids come in twenty to thirty percent below the ceiling for established generic molecules. Submitting different ex-factory prices to different GCC states triggers a Pricing Committee investigation. The pricing reference list submitted with the tender must show: (a) the ex-factory price proposed, (b) the unified-pricing ceiling, (c) the IRP basket reference prices used to derive the ceiling, (d) any locked-in prices from prior GCC tender awards. Our

GCC tender response service line prepares this comparison table per molecule per tender opening.

Where bids stall: the IRP basket reference prices not current. Reference prices update through the year; an out-of-date reference price submitted with the tender is treated as a pricing-misrepresentation flag and triggers a separate Pricing Committee review track outside the technical evaluation. Verify reference prices the week of tender close, not the week of dossier preparation.

Pre-bid checklist, the night before tender close.

1. CTD M1 overlay

Six country-specific Module 1 overlays current. Saudi PC annex attached. UAE trade-mark certificate verified. Qatar PC submission form bundled.

2. CoPP destination

Destination state named on the face. Issued within twelve months (or eighteen for Kuwait). CDSCO seal current.

3. ALR letter currency

ALR entity's local licence verified on the destination regulator's public register the day of tender submission, not the day of dossier preparation.

4. GMP certificate window

WHO-GMP cert within eighteen months for Saudi, UAE, Qatar; twenty-four months for Kuwait, Oman, Bahrain. Form 25 or 28 manufacturing licence current.

5. SMF freshness

6. Zone IVb stability

Site Master File in PIC/S format, revision date within twelve months for Saudi and UAE, eighteen for Qatar and Kuwait, twenty-four for Oman and Bahrain.

Long-term Zone IVb data twelve to twenty-four months, plus accelerated 40/75 six-month data. Excursion-tolerance for cold-chain SKUs.

7. IRP basket

Reference prices verified current the week of tender close. Unified-pricing ceiling calculated. Tender bid price compared against unified ceiling and prior award prices.

FAQ

Can one ALR letter cover all six GCC states?



No. Each GCC member state requires a separate Authorised Local Representative, licensed as a pharmaceutical distributor inside that country. Saudi SFDA insists on a Saudi-incorporated ALR; UAE MOHAP requires a UAE-incorporated ALR holding a Federal Pharmaceutical Trading licence; Qatar MoPH, Kuwait MOH-DFC, Oman MoH and Bahrain NHRA each require their own. GCC Central Registration (GCC-DR) does NOT collapse the ALR requirement; the lead-country reviewer accepts the dossier, but six ALR letters still need to sit in Module 1.

How old can the CoPP be when submitted?



Saudi SFDA, UAE MOHAP and Qatar MoPH require the WHO-type Certificate of Pharmaceutical Product (CoPP) to be issued within the last twelve months of submission. Kuwait MOH-DFC accepts up to eighteen months; Oman MoH and Bahrain NHRA follow the twelve-month rule. Each CoPP must be country-specific (the destination state named on

the certificate); CDSCO issues these in batches with a two-to-four week turnaround. Build a thirty-day buffer into the submission timeline.

What climate zone stability is required for the GCC?



ICH Climate Zone IVb (hot and very humid: 30 degrees Celsius / 75 percent relative humidity long-term) is the GCC baseline. Most Indian Zone II stability data is insufficient on its own. Acceptable packages combine Zone IVb long-term (12 to 24 months) plus accelerated 40 degrees Celsius / 75 percent RH for six months. Saudi SFDA is the strictest on this; Bahrain NHRA accepts Zone IVa as a fallback for some non-thermolabile products. Always confirm with the lead country before lodging.

Does GCC Central Registration replace single-country MoH filings?



Partially. GCC-DR replaces six parallel scientific reviews with one lead-country review (typically Saudi SFDA, UAE MOHAP or Bahrain NHRA). The lead country's positive opinion is then mutually recognised across the other five. However, each state still issues its own Marketing Authorisation, sets its own price under its own Pricing Committee, requires its own ALR appointment, and prints its own Arabic-bilingual artwork. GCC-DR cuts dossier-review time by twelve to eighteen months; it does NOT cut per-country administration.

What is the GCC unified pricing rule and how does it interact with NUPCO bids?



GCC unified pricing requires the same ex-factory price across the six member states, indexed to a basket of five reference countries (commonly Saudi Arabia, UAE, Egypt, Jordan and a benchmark European market). The Pricing Committee in the lead country sets the ceiling. For NUPCO tender bids in Saudi Arabia, the unified ceiling is the upper bound; bids can come in below the ceiling but never above. Bid awards in NUPCO are typically twenty to thirty percent below the unified ceiling for established generics.

Which document do bids most often stall on?



From our experience submitting through Indian generic manufacturer partners across the six GCC states: the Site Master File. SMFs not in PIC/S format, or older than the eighteen-month freshness window, are the single most common reason for clarification holds. Site Master File issues add two to four weeks of clock-stop per occurrence. Second most common: an

outdated GMP certificate. Third: ALR letter naming an entity that is no longer licensed in the destination.

REGULATORY · 12 MIN READ · PUBLISHED 15 APRIL 2026 · BY DR. RAJAT BHATT, MANAGING DIRECTOR

The unlicensed medicines playbook: how GCC hospitals legally access drugs before ministry approval.

A working guide for hospital pharmacists in the UAE, Saudi Arabia, Kuwait and Qatar, the named-patient, compassionate-use and special-access pathways that turn a bedside emergency into a cleared shipment, and the documentation that actually moves through customs.

Every GCC hospital pharmacist has had the same conversation. A consultant signs a prescription for a medicine the local pharmacy can't dispense. Procurement tells them the molecule isn't registered. The pharmacist emails around and finds out, eventually, that it *can* be imported, but nobody on the desk has ever done it. The patient is on a ward. The clock is running.

This is the post we wish someone had put on the internet five years ago. It is a practical playbook for the three legal routes that every GCC health authority operates for unlicensed or unregistered medicines, written in the order a working hospital pharmacist actually hits the questions.

What “unlicensed” actually means (and what it doesn't)

In the GCC, an **unlicensed medicine** is any pharmaceutical that does not currently hold a Marketing Authorisation in the destination country. That covers three separate situations,

and conflating them is where most procurement conversations go wrong on day one:

- 1. Never registered locally.** The molecule or brand has never been submitted to the national authority. Common for orphan drugs, rare-disease therapies, niche oncology lines, and recently approved US/EU innovations.
- 2. Registered elsewhere, not here.** The product has an EMA or FDA authorisation, and possibly a Saudi or UAE file in progress, but no current local licence. Common when a hospital is used to sourcing from a European formulary.
- 3. De-listed or temporarily withdrawn.** The product *was* registered locally but the manufacturer let the registration lapse or paused supply. Common for older essential medicines where the commercial case for renewal is weak.

None of these mean “illegal.” All three are addressable through the regulated pathways below. They just require different cover letters.

The three legal pathways every GCC authority runs

Every GCC health authority operates some version of the same three-route framework, the names and acronyms change, the logic does not:

1. Named-patient import (the default)

A treating physician identifies a specific patient, by name or unique hospital identifier, and issues a prescription for a medicine not currently registered locally. The hospital pharmacy, or a licensed importer acting on its instructions, applies for an import permit on a per-patient, per-quantity basis. The permit is bounded to the treatment course.

This is the workhorse. It is the pathway most hospital pharmacists will use for the majority of unlicensed requests, and the one that every supplier worth the name has a documented process for.

2. Compassionate use / early access

Used for medicines still in clinical development, or recently approved abroad but not yet commercially launched. The patient has a serious or life-threatening condition with no satisfactory authorised alternative. The manufacturer supplies the product through a formal

compassionate-use programme, with the destination authority's permission, usually free of charge or at cost.

Slower and more paperwork-heavy than named-patient import, because it requires the manufacturer's participation. But for the right case, it is the only route.

3. Special-access / specific-import authorisation (hospital-level)

Some authorities, SFDA in Saudi Arabia in particular, operate a hospital-level special-access register that allows designated tertiary hospitals to hold a rolling permission for a defined list of unlicensed specials, rather than apply per patient every time. The product list is reviewed periodically.

This route is where the big oncology centres and the military medical services sit. It is not a route most general hospitals will qualify for, but it is worth knowing it exists, because when you meet a hospital that runs on it, the conversation changes.

Country-by-country: how each GCC authority actually runs it

United Arab Emirates, MOHAP (federal) & DHA (Dubai) & DoH (Abu Dhabi)

The UAE runs a federated system: MOHAP issues the federal import permit, but within Dubai and Abu Dhabi the Dubai Health Authority and Abu Dhabi Department of Health add an emirate-level pharmacy licence layer on top. For a named-patient import into a Dubai hospital, you will touch all three in the paper trail.

Practical timing: 7–14 working days from complete file to cleared customs for a non-cold-chain line. Oncology and biologicals run longer. The permit is patient-specific and quantity-bounded, a three-month course is routine, a twelve-month supply requires justification.

Saudi Arabia, SFDA

The Saudi Food and Drug Authority runs the most mature unlicensed-medicines apparatus in the GCC. Every named-patient import goes through SFDA's e-permit portal, and hospitals that handle volume operate a standing relationship with a licensed local pharmaceutical establishment to process applications.

The SFDA special-access register is the route that MoD hospitals, KFSH and the Saudi-German chain use for recurring unlicensed lines. For a one-off named-patient request, realistic timing is 10–20 working days end to end.

Qatar, MoPH

The Ministry of Public Health runs a named-patient pathway through the Department of Pharmacy and Drug Control. Hamad Medical Corporation is the dominant user of the route, and its pharmacy has a streamlined internal workflow that external hospitals can follow. 7–14 working days for standard lines, assuming a complete file.

Kuwait, MoH

The Ministry of Health operates the Kuwait Drug & Food Control route, with named-patient imports going through the Registration Department. Turnarounds are variable, a clean file can clear in 10 working days; anything with queries can sit for three weeks.

Oman, Bahrain, MoH

Smaller volumes, less formal infrastructure, but the pathway exists. Oman's MoH and Bahrain's NHRA both operate named-patient imports on a case-by-case letter basis. Work with a supplier that has a Gulf-wide regulatory footprint rather than a single-country specialist.

The documentation pack that actually clears

The single biggest cause of delays on unlicensed imports is incomplete paperwork, not regulatory refusal. A proper named-patient file for any GCC authority should include:

- **Physician prescription**, on hospital letterhead, signed, identifying the named patient (or unique ID), diagnosis (ICD-10), dosing regimen, and duration of treatment.
- **Hospital pharmacy import letter**, confirming clinical justification, unavailability of a registered alternative, and the pharmacy's undertaking to dispense under controlled conditions.
- **Manufacturer's Certificate of Analysis (CoA)**, for the specific batch being supplied. Not a generic product CoA.
- **WHO-GMP certificate**, or EU-GMP / US-FDA equivalent, for the manufacturing site.

- **Certificate of Pharmaceutical Product (CoPP)**, WHO-format, issued by the exporting country's authority.
- **Certificate of Origin**, from an accredited chamber of commerce in the exporting country.
- **Destination-market pack insert**, original artwork, with Arabic translation where the authority requires it.
- **Cold-chain documentation**, for 2–8°C or –20°C lines, the validated packaging, shipper configuration, and logger data.
- **Invoice and packing list**, matched to the import permit quantity down to the last vial.

The pack is boring. The pack also decides whether the container sits at the airport for ten days or clears in two.

Realistic timelines

If you are scoping a named-patient import and need to tell a consultant what to expect, these are honest figures based on Gulf-wide hospital work over the last three years:

- **Standard solid-dose oral line, complete file, UAE or Qatar:** 7–10 working days.
- **Oncology or biological, cold-chain, UAE or KSA:** 14–21 working days.
- **Orphan drug, manufacturer-direct compassionate-use:** 4–8 weeks.
- **Special-access register addition (SFDA hospital):** variable, typically 6–10 weeks for a new molecule.

Four mistakes that cost you a week

1. **Generic CoA, not batch-specific.** Every GCC authority will bounce the file. Insist on a batch-matched CoA from the supplier before the permit application goes in.
2. **Prescription without ICD-10.** A clinical letter that says “for compassionate use” but doesn't state the diagnosis code will sit on a reviewer's desk.
3. **Pack insert in English only for an Arabic-required authority.** Translate before the shipment lands, not after.
4. **Cold-chain shipper without validated logger data.** No logger, no release. Every logger reading is part of the file.

M Care Exports supplies these consignments from India as the exporter of record, quoting against the hospital's import approval while the licensed importer in the destination market holds the permit.

FAQ

Is importing unlicensed medicines legal in the GCC?

Yes, under regulated pathways run by each national authority, named-patient import, compassionate use, and special-access programmes. The routes differ in detail across MOHAP, SFDA, DHA, MoPH and MoH Kuwait, but the underlying legal basis is the same: hospitals can access unlicensed medicines where there is a documented clinical need and the authority has issued a permit.

What's the difference between named-patient and compassionate use?

Named-patient import is physician-initiated, patient-specific, and quantity-bounded to a treatment course. Compassionate use is manufacturer-run, for products still in clinical development or pre-commercial launch, and requires the manufacturer's active participation and authority sign-off.

How fast can a hospital clear a named-patient request?

A complete documentation pack, a clean cold-chain file, and a GCC-experienced supplier can clear a standard named-patient import in 7–14 working days. Oncology and biological lines sit at the longer end.

Does M Care Exports handle named-patient and compassionate-use imports?

Yes. We run named-patient and compassionate-use shipments into UAE, Saudi Arabia, Kuwait, Qatar, Oman and Bahrain, with a Mumbai-based regulatory desk that handles the documentation end-to-end. Contact us with the molecule, the destination authority and the clinical justification, we'll come back within one working day.

