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GCC Market Access Playbook

Registration, Pricing and Tender Sequencing

HERMS Consultancy DMCC

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Registration, Pricing and Tender Sequencing

In the GCC, a registration certificate is only the first of four gates. This playbook shows how to sequence registration, pricing, reimbursement and tenders across six markets so that a new medicine reaches patients faster and at a sustainable price.

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Executive Summary

The six GCC states share a Gulf Health Council framework but run their own regulators, pricing committees, formularies and purchasing bodies. Most delays and value losses happen when companies treat these as separate projects run one after another. Market access in the GCC is a sequencing problem: the order and timing of decisions across registration, pricing, reimbursement and tenders determine both speed and price.

30 / 60 working-day SFDA targets for verification and abridged reliance review1	**2 years** window after reference approval to use SFDA reliance pathways1	**July 2025** economic evaluation dossiers mandatory for key product types in Saudi Arabia9	**SAR 2.4bn+** Gulf joint procurement tenders conducted in 20254

Five principles of the playbook

Plan all four gates from day one. Registration, pricing, reimbursement and tender readiness should be prepared in parallel, not in sequence.

Protect the price corridor. Several GCC states reference each other's prices, often taking the lowest.6 The first GCC price set can cap prices across the region.

Use reliance early. SFDA reliance pathways must be used within two years of reference-agency approval.1 Late filers lose the fastest route.

Build value evidence before launch. Saudi Arabia now requires economic evaluation for new, high-cost and first-in-class products, and Abu Dhabi has published HTA guidelines.9,13

Work back from the tender calendar. Registration, pricing, listing and supplier qualification must all be complete before the bid deadline.16

HERMS view

The fastest GCC launches are not those with the fastest single approval. They are those in which every gate is ready when the previous one opens.

1. Why Sequencing Decides Success

A new medicine passes through four gates before it reaches patients through the public sector in the GCC:

Gate	Decision	Main decision-makers
1. Registration	Is the product safe, effective and of good quality?	SFDA, EDE, national authorities, Gulf Health Council
2. Pricing	What is the maximum price?	National pricing committees
3. Reimbursement and formulary	Will payers and hospitals use and pay for it?	Ministries of health, insurers, hospital P&T committees
4. Tender and procurement	Who supplies what volume, at what price?	NUPCO, Gulf Health Council, national and emirate buyers

How sequencing errors cost time and value

Lost reliance window: filing in Saudi Arabia more than two years after FDA or EMA approval removes eligibility for verification and abridged review.1

Price cascade: a low price agreed in one GCC state can be referenced by others using lowest-price rules.6

Missed tender: a product registered but not priced, listed or supplier-qualified at the bid deadline waits for the next cycle.16

Evidence gap: a missing economic evaluation dossier can stall pricing or listing in Saudi Arabia.9

The result is visible in availability data: of 460 new medicines launched globally in 2012–2021, 38% reached Saudi Arabia, 33% the UAE and 14% Kuwait, with average delays of 27–32 months after first global launch.21

2. The GCC Access Landscape

The table summarises the main bodies and pricing approaches. Pricing methods are drawn from published rules and a 2018 regional mapping and should be confirmed with each authority before use.

Market	Regulator	Pricing approach	HTA and value evidence	Main public purchasing
Saudi Arabia	SFDA	Pricing Rules weigh added therapeutic value, alternatives, economic studies and prices in a 16-country reference list5	Economic evaluation mandatory for key product types since July 2025; SFDA and CCHI9	NUPCO unified procurement17
UAE	EDE (federal); DoH Abu Dhabi and DHA at emirate level	External reference pricing using Gulf and European prices7; 2018 mapping: median of 18 countries6	DoH Abu Dhabi HTA guidelines published 2025; Dubai HTA pilot 2025–2713	Federal and emirate-level purchasing, including Abu Dhabi Unified Purchasing Program14
Kuwait	Ministry of Health	2018 mapping: lowest GCC price and an average across a wider basket6	No national HTA body identified in sources reviewed	MOH procurement; GHC joint procurement
Qatar	Ministry of Public Health	2018 mapping: lowest price; country of origin and GCC basket6	National HTA unit project launched January 202515	National purchasing; GHC joint procurement
Bahrain	NHRA	2018 mapping: lowest price; GCC states and country of origin6	No national HTA body identified in sources reviewed	National purchasing; GHC joint procurement
Oman	Ministry of Health	2018 mapping: lowest price; GCC states and country of origin6	No national HTA body identified in sources reviewed	National purchasing; GHC joint procurement

The regional layer

Gulf Health Council central registration offers consolidated registration across member states. Its programme had reached 2,021 registered pharmaceutical products by 2025.4

Gulf Joint Procurement Program runs scheduled tenders for member states and conducted tenders exceeding SAR 2.4 billion in 2025.4,18

3. Gate 1: Registration

Choose the route

Route	Best suited to	Key requirements
SFDA verification	Products approved by both FDA and EMA	Filed within two years of reference approval; manufacturer in an eligible country; 30 working-day target1
SFDA abridged	Products approved by one reference authority	Same eligibility conditions; 60 working-day target1
UAE marketing authorisation (EDE)	UAE entry	45 working-day stated service duration2
Gulf Health Council central registration	Multi-country portfolios from manufacturers with GHC-registered companies and sites	Company registration with GMP inspection; response to inspection report within 90 days; national administrative completion within six months3
National standard review	Products without eligible reference approvals	Full assessment; longest timelines

Registration readiness

Legalised certificates (CPP, GMP, manufacturing licence) ready before submission.

Dossier aligned to the reference-agency approved version for reliance routes.1

Arabic labelling and patient leaflet prepared in parallel.

Lifecycle plan: SFDA requires the same reference agency to be used for variations.1

Pricing documents prepared for submission alongside registration (see Gate 2).

4. Gate 2: Pricing

Saudi Arabia

The SFDA Pricing Rules state that a product is priced taking into account its added therapeutic value, the prices of registered therapeutic alternatives, economic evaluation studies, ex-factory and wholesale prices in the country of origin, export prices to markets where it is sold, and prices in approved reference sources. The price certificate must not be more than six months old at the time of pricing.5

The approved price is a maximum; the company may sell lower.5

Generic ceilings: first generic 70%, second 65%, third and later 60% of the originator price before generic entry.5

The price certificate lists 16 reference countries, including Australia, Canada, France, Germany, Japan, South Korea and the UK.5

United Arab Emirates

EDE pricing certificate applications require the proposed UAE price and CIF prices in reference countries where the product is marketed.7

Re-pricing applications require reference prices from Gulf and European countries.8

Price referencing across the GCC

A 2018 regional mapping found that Bahrain, Oman and Qatar applied lowest-price rules with GCC states in their baskets, while the UAE used a median price across 18 countries.6 Kuwait's Ministry of Health has reduced prices for hundreds of products to be the lowest in the GCC.20 Because states reference each other, the first GCC price is a regional decision.

Price corridor rules

1. Agree a single GCC target price corridor before the first submission.
2. Do not accept a price in one state that falls below the corridor floor without modelling the regional impact.
3. Submit pricing applications in an order that sets reference prices in the most-referenced markets first.
4. Keep confidential discounts, rebates and managed entry agreements separate from list prices where permitted.

5. Gate 3: Reimbursement and Formulary

Saudi Arabia

From July 2025, economic evaluation dossiers are mandatory for new drugs and biologics, orphan drugs, high-cost or re-priced drugs, and first-in-class drugs or biosimilars for high-impact diseases.9

SFDA conducts the assessment and its findings, including cost-effectiveness and budget impact, inform pricing. CCHI determines insurance coverage and MOH lists products for public use.9

SFDA has published Economic Evaluation Studies Guidelines that apply to registration, price re-evaluation and renewal.10

MOH formulary additions must be requested by a consultant or senior registrar and approved through hospital and regional committees.12

The MOH Managed Entry Agreement Policy covers financial agreements (discounts, price-volume, paybacks, free doses, dose caps) and value-based agreements linked to outcomes, involving MOH, NUPCO, manufacturers and providers.11

United Arab Emirates

DoH Abu Dhabi launched an HTA unit in 2018 and published HTA guidelines for high-cost therapies and devices in 2025.13

DoH Abu Dhabi has added coverage indicators, including a definition for performance-based managed entry agreements, to its drug coding list.14

Outside Abu Dhabi, HTA activity remains limited; Dubai is piloting a technology-driven HTA system in 2025–27.13

Value dossier essentials

Component	Content
Clinical value	Comparative efficacy and safety against local standard of care
Economic evaluation	Cost-effectiveness model adapted to local costs and practice, following SFDA guidelines where applicable10
Budget impact	Eligible population, uptake and net budget effect over three to five years
Local epidemiology	Prevalence and disease burden in the target market
Managed entry proposal	Financial or outcomes-based agreement options11

6. Gate 4: Tenders and Procurement

Saudi Arabia: NUPCO

NUPCO runs unified procurement for government health sectors.17

Suppliers must be registered and qualified with NUPCO before buying the tender booklet through SADAD.16

Initial results usually follow technical and financial evaluation within 4–8 weeks, and objections are answered within a further 4–8 weeks.16

Some published NUPCO tender announcements specify three-year contract periods.22

Saudi Arabia has applied an additional price preference for national products in pharmaceutical and medical sectors since 2020.19

Regional: Gulf Joint Procurement

The Gulf Health Council publishes an annual tender schedule and procures medicines, vaccines, supplies and devices for member states through joint committees.18,4

Tender readiness timeline

Months before bid deadline	Requirement
12+	Registration submitted in target markets; tender calendar mapped
9	Pricing application submitted; supplier registration and qualification started
6	Price approved; formulary or catalogue listing requested
3	Technical documents, certificates and samples prepared; tender price modelled
1	Bid bond, compliance check item by item, final pricing approval

7. Launch Sequencing Strategies

There is no single correct sequence. The right choice depends on product type, evidence, price position and supply capacity.

Strategy	When to use it	Advantages	Watch-outs
Saudi-first	Products eligible for SFDA reliance with strong value evidence	Largest market; NUPCO volume; reliance targets of 30–60 working days1	Mandatory economic evaluation for key product types9; price becomes a regional reference
UAE-first	Products seeking early private-market access and visibility	45 working-day stated EDE service duration2; private insurance channel	Emirate-level formulary and HTA steps; median-based referencing6
Parallel Saudi and UAE	Innovative products with complete dossiers and a set price corridor	Shortest overall time to patient	Requires strong local teams and coordinated pricing
GHC central route	Portfolios from manufacturers with GHC-registered companies and sites	One process for several states; access to joint procurement3,4	Company and GMP registration first; national administrative steps still needed

Typical HERMS recommendation for an innovative medicine

File Saudi Arabia and the UAE in parallel within months of the first reference approval, set a GCC price corridor before either pricing decision, prepare a Saudi economic evaluation and an Abu Dhabi value dossier during registration, and follow with Kuwait, Qatar, Bahrain and Oman once reference prices are established.

8. The HERMS 24-Month Access Roadmap

Month 0 is the first FDA or EMA approval. Activities in the same column run in parallel.

Workstream	Months −6 to 0	Months 0 to 6	Months 6 to 12	Months 12 to 24
Registration	Dossier, legalisation, Arabic labelling, route selection	Saudi and UAE submissions under reliance where eligible	Approvals; Kuwait, Qatar, Bahrain, Oman submissions	Remaining approvals; variations
Pricing	GCC price corridor and referencing model	Saudi and UAE pricing applications	Saudi and UAE prices approved	Other GCC prices within corridor
Value and reimbursement	Local economic model and budget impact	Saudi economic evaluation dossier; Abu Dhabi value dossier	Formulary and coverage decisions; managed entry agreement negotiation	Formulary listings across GCC
Tenders	Tender calendar map; supplier qualification	NUPCO and GHC qualification complete	First tender submissions	Awards; supply contracts
Launch operations	Local agent, distributor and pharmacovigilance set-up	Import permits, stock planning	First supply	Market expansion

Timelines are indicative and depend on product type, authority workload and evidence requirements.

9. Pitfalls and Readiness Checklist

Ten common pitfalls

Filing in Saudi Arabia after the two-year reliance window has closed.1

Accepting a low price in a small market that is referenced by others.6

Price certificates more than six months old at the time of Saudi pricing.5

No economic evaluation dossier for a product type that requires one in Saudi Arabia.9

Registering a product but not qualifying as a supplier before the tender opens.16

Tender item descriptions that do not match the buyer's catalogue.

Arabic labelling finalised after registration approval.

Treating each emirate in the UAE as identical for formulary and coverage.

No managed entry proposal for a high-cost product.11

Separate country teams with no single owner of the GCC timeline.

Readiness checklist

Area	Ready when
Registration	Route chosen, dossier aligned, certificates legalised, Arabic labelling approved internally
Pricing	GCC price corridor approved, reference prices documented, certificates current
Value evidence	Local cost-effectiveness and budget-impact models complete
Reimbursement	Formulary sponsors identified; managed entry options defined
Tenders	Supplier qualification complete; tender calendar mapped; catalogue items matched
Operations	Local agent, distributor, QPPV and supply plan in place

10. How HERMS Helps

HERMS Consultancy DMCC supports pharmaceutical, biotechnology and medical device companies across every gate of GCC market access.

Access strategy: market prioritisation, launch sequencing and GCC price corridor modelling.

Registration: route selection, dossier preparation, submission management, renewals and variations.

Pricing and value: pricing applications, economic evaluation dossiers, budget-impact models and managed entry proposals.

Tenders: supplier qualification, tender calendar planning, technical compliance and bid preparation.

Launch operations: pharmacovigilance, Arabic labelling and promotional compliance.

Request a GCC access sequencing review

HERMS will map your product against all four gates in each GCC market and deliver a 24-month access roadmap.

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Related HERMS resources

GCC pharmaceutical pricing and market access strategy

UAE pharmaceutical product registration

GCC central registration through the Gulf Health Council

Drug registration timelines by country

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