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Regulatory Reliance in the GCC

Using FDA/EMA Approvals to Accelerate Registration

HERMS Consultancy DMCC

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Using FDA/EMA Approvals to Accelerate Registration

Every GCC state now offers some form of faster route for medicines already approved by the US FDA or the European Medicines Agency. This paper sets out what each route requires, where companies lose eligibility, and how to sequence filings so that a reference approval becomes a regional launch.

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Executive Summary

Regulatory reliance allows a GCC authority to give significant weight to the assessment already completed by a trusted regulator, while keeping full responsibility for its own decision.1 Saudi Arabia, Kuwait, Bahrain and Oman have published reliance or fast-track routes linked to FDA and EMA approvals, the UAE has adopted reliance in law, and the Gulf Health Council offers a regional route.2,8,10,11,12

30 / 60 working-day SFDA targets for verification and abridged review2	**2 years** window after FDA/EMA approval to file in Saudi Arabia and Oman2,12	**10 days** Bahrain fast-track registration target for reference-approved products11	**47.92%** of 2019 FDA novel drugs never submitted to SFDA by mid-20245

The main barrier is no longer the regulator. It is the company: late filing, missing unredacted assessment reports, products that differ from the reference version, and no plan for which reference agency to use across the product lifecycle.

Six principles

File early. Saudi Arabia and Oman require filing within two years of the reference approval.2,12 Missing the window means a full review.

Choose the reference agency deliberately. In Saudi Arabia the chosen agency must be used for every later variation.2

Secure assessment reports at source. SFDA requires complete, unredacted reports and does not accept reports taken from the public domain.2

Protect sameness. Formulation, sites, specifications, API sources and packaging must match the reference approval.2

Use one approval to unlock the next. Bahrain accepts SFDA and Gulf central approvals, and Oman lists SFDA, UAE and Kuwait approvals among its reliance criteria.11,13

Plan beyond approval. Faster registration only helps patients if pricing, listing and procurement follow.10

HERMS view

A reference approval is a time-limited asset. Its value in the GCC depends on how quickly and how cleanly it is used across six markets.

1. What Regulatory Reliance Means

The World Health Organization defines reliance as the act whereby a regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution in reaching its own decision.1 The relying authority remains independent, responsible and accountable for that decision.1

WHO frames reliance as a way to avoid duplication and focus national effort on activities that only the national authority can perform, such as vigilance, market surveillance and oversight of local manufacturing and distribution.1

Forms of reliance used in the GCC

Form	How it works	GCC example
Verification	Light review confirming the product is the same as one approved by two reference agencies	SFDA verification (FDA and EMA)2; Oman verification12
Abridged review	Reduced review using one reference agency's assessment reports, focused on local requirements	SFDA abridged (FDA or EMA)2; Oman abridged12
Fast-track based on reference approval	National fast route with a short target for products approved by listed authorities	Bahrain 10-day route11; Kuwait 30/60-day targets10
Regional work-sharing	One scientific assessment recognised across several states	Gulf Health Council central registration10,14

Reliance is not automatic approval

SFDA states it is not obliged to approve a product because a reference agency has, and may move an application to the regular pathway if concerns arise.2 Oman's draft guideline says the same.12

2. Why Reliance Matters in the GCC

The access gap

Of 460 new medicines launched globally in 2012–2021, 38% were available in Saudi Arabia, 33% in the UAE and 14% in Kuwait, with average delays of 27–32 months after first global launch.17

A study of 48 novel drugs approved by the FDA in 2019 found that 21 (43.75%) had been approved by SFDA by mid-2024, while 23 (47.92%) had not been submitted at all.5 The median SFDA approval time of 248 days was close to the FDA's 243 days.5 The larger gap was submission, not review.

What reliance has already achieved

Saudi Arabia: in the first seven quarters after reliance was introduced, observed average reviews were six to seven months, against an earlier estimate of 16 to 18 months, although the 30/60-day targets had not yet been met.4

Gulf centralised procedure: median review times fell from 838 days in 2015 to 321 days in 2019.16

UAE: EDE approved orforglipron as the second country in the world to register it.18 Accelerated review has positioned the UAE among the earliest approving countries for some rare disease products.19

Targets versus reality

Published timelines are performance targets. They usually start only after the pathway is confirmed and pause during clarification requests.3 Plan on targets, budget for longer.

3. GCC Reliance Pathways at a Glance

The table summarises published national routes. Requirements change frequently; confirm the current version with each authority before filing.

Market	Route	Reference basis	Target timeline	Key conditions
Saudi Arabia (SFDA)	Verification; abridged	Verification: FDA and EMA. Abridged: FDA or EMA2	30 / 60 working days from pathway acceptance2	File within 2 years; product sameness; NCEs and biologics only; ATMPs and blood products excluded2
UAE (EDE)	Reliance in law; fast-track for innovative and orphan products	Approvals in reference jurisdictions taken into account8	Standard marketing authorisation service: 45 working days9	Fast-track terms to be set in executive regulations8
Kuwait (MOH)	Fast-track registration	Both EMA and FDA, one of them, or no prior approval10	30 / 60 / 90 days10	Sponsor requests fast-track designation; innovative, orphan or unmet-need products10
Bahrain (NHRA)	Fast-track; conditional fast-track	GCC central, SFDA, FDA, EMA, Swissmedic, MHRA11	10 days; 20 days conditional11	Full eCTD as approved, complete assessment report, batch-release site registered with same authority11

Market	Route	Reference basis	Target timeline	Key conditions
Oman (MOH)	Verification; abridged (draft); fast track	Verification: FDA and EMA. Abridged: FDA or EMA12	90 / 180 working days12	Approval within last 2 years; full assessment reports; sameness declaration12
Qatar (MOPH)	No published national reliance guideline identified	Regional routes via Gulf Health Council10	Not published	Rolling submissions accepted during the pandemic10
Gulf Health Council	Central registration; centralised fast track	Approval in at least two GCC states10	60 calendar days after receipt of scientific reports10	National steps and pricing still required in each state10,14

4. Saudi Arabia: Verification and Abridged

SFDA operates the most structured reliance framework in the region and is often the first GCC filing for innovative products.10

Eligibility

Product type: marketing authorisation for new chemical entities and biologics; abridged also covers type II variations.2 Generics are not eligible.2

Exclusions: blood products, advanced therapy medicinal products and veterinary vaccines.2

Timing: the application must reach SFDA within two years of the reference approval.2

Safety history: the product and intended use must not have been rejected, withdrawn or suspended for safety or efficacy reasons by any regulator.2

Manufacturing location: the manufacturer must be in one of 20 listed countries, including the USA, UK, Canada, Japan, Switzerland, Singapore and major EU states.2

Reference agencies: only FDA, EMA and USDA (veterinary biologics) qualify; Health Canada, PMDA, Swissmedic and TGA do not.2

The sameness test

The product must share the essential characteristics of the reference product: composition, strength, form, intended use, manufacturing process, API suppliers and excipient quality.2 A different container-closure system may be proposed to meet stability needs.2

Dossier requirements

eCTD in which Modules 2–5 are the same as the reference submission.2

Complete clinical and quality assessment reports from both agencies (verification) or one (abridged), including Q&A documents and annexes; reports from the public domain are not accepted.2

Stability data to SFDA guidelines, or a commitment and out-of-specification notification letter.2

Price certificate (Form 16) and evidence of added value from an economic perspective.2

Process and lifecycle lock-in

SFDA confirms the pathway within 10 working days; the 30- or 60-day target starts only after that confirmation.2 The applicant must keep the same reference agency for all later variations: an EMA-based registration cannot be varied on FDA documents.2

Decision point

Choose the reference agency whose approval package, labelling and post-approval change plan best match the product you intend to supply to Saudi Arabia, not simply the agency that approved first.

5. UAE, Kuwait, Bahrain, Oman and Qatar

United Arab Emirates

The UAE has adopted regulatory reliance and takes into account marketing approvals granted in reference jurisdictions.8 Federal Decree-Law No. 38 of 2024 provides a fast-track marketing authorisation for innovative products of therapeutic significance, with detailed terms to follow in executive regulations.8 EDE lists 45 working days for its marketing authorisation service.9

An earlier Ministerial Decree (No. 28 of 2018) set a route for innovative and rare medicines approved by accredited international authorities, with committee evaluation within 15 working days and a decision within 10 further working days.7 EDE has since taken over registration; confirm whether these timelines still apply.

Kuwait

Kuwait's fast-track process covers innovative medicines, orphan drugs and products for unmet needs. Targets are 30 days with EMA and FDA approvals and assessment reports, 60 days with one of them, and 90 days without prior reference approval.10

Bahrain

NHRA targets 10-day registration for products approved by GCC central registration, SFDA, FDA, EMA, Swissmedic or MHRA, provided the batch-release site is registered with the same authority and the full eCTD and assessment report are submitted.11 A 20-day conditional route allows a one-year licence while requirements are completed.11

Oman

Oman's draft verification and abridged guideline (August 2025) uses FDA and EMA approvals within the last two years, with anticipated timelines of 90 and 180 working days.12 Oman's framework guideline also lists fast-track tracks for SRA-approved new chemical entities, biologicals, biosimilars and vaccines, and for products registered through the Gulf Health Council.13

Qatar

No published national reliance guideline for Qatar was identified in this review. Products can use regional Gulf Health Council routes, and Qatar accepted rolling submissions during the pandemic.10

6. The Gulf Centralised Route

The Gulf Health Council's central registration provides one assessment for member states, followed by national administrative steps.14 By 2025 it had registered 2,021 pharmaceutical products.15

Centralised fast track: introduced in 2020; where a product is approved in at least two GCC states, the committee may issue central approval within 60 calendar days of receiving the scientific reports.10

GMP inspection: the bylaws provide for manufacturing site inspection, with 90 days to respond to an inspection report.14

National completion: companies have six months after central approval to complete national steps.14 Pricing and certificate issuance remain national.10

Reliance chain effect

National and regional routes can be linked. Bahrain accepts GCC central and SFDA approvals as reference.11 Oman lists SFDA, UAE and Kuwait approvals within two years among its reliance criteria and places Gulf Health Council-registered products on its fast track.13 Two early national approvals can also open the centralised fast track.10

7. Building a Reliance-Ready Dossier

Element	What authorities expect	Common gap
Assessment reports	Complete, unredacted clinical and quality reports with Q&A and annexes2,11,12	Public assessment reports only; reports for one agency missing
Sameness declaration	Formulation, sites, specifications, API sources and packaging identical to reference2,12	Different site or supplier for GCC supply
Approval evidence	Approval letters with dates inside the 2-year window2,12	Filing planned after the window closes
Site status	Batch-release site registered with the reference authority; GMP certificates and inspection reports2,11	Release site not covered by the reference approval
Stability	Data to local stability guidelines, or a formal commitment2,12	No data for hot and humid climatic conditions
Module 1	Local labelling, pricing certificate, value evidence2	Arabic labelling and price documents late

Securing assessment reports

FDA and EMA assessment reports usually sit with the global regulatory team or the licensor. Distributors and licensees should make access to unredacted reports, Q&A correspondence and variation assessments a contractual obligation before the reference approval is granted.

8. Advanced Therapies: the Reliance Gap

SFDA's current guidance excludes advanced therapy medicinal products from verification and abridged review.2 Earlier gene therapies such as KYMRIAH (abridged) and LUXTURNA (verification) were registered in Saudi Arabia through these routes in 2020, but current guidance no longer allows this.6

Gene therapies were also absent from SFDA approvals among 2019 FDA novel drugs, mainly because they were not submitted.5 For cell and gene therapies, companies should plan for full or priority review, early scientific advice and site readiness, rather than assume a reliance timeline.

Implication for sponsors

For advanced therapies, the reference approval remains valuable evidence, but it does not unlock the Saudi 30/60-day route. Early engagement and treatment-centre readiness matter more than the filing route.

9. The HERMS Reliance Sequencing Model

The model below is a HERMS planning framework. It should be adapted to each product's approvals, supply chain and commercial priorities.

Phase	Timing	Actions
Prepare	12–6 months before FDA/EMA decision	Map eligibility in each GCC state; secure report access in contracts; align GCC supply to reference sites and specifications; draft Arabic labelling
Choose	At first reference approval	Select the primary reference agency for each market; confirm lifecycle variation plan
Wave 1	Months 0–3	File SFDA verification or abridged; file Kuwait fast track; file UAE with reference approval evidence
Wave 2	Months 2–6	File Bahrain fast track using reference or SFDA approval; file Oman verification or abridged
Regional	After two GCC approvals	Consider the Gulf centralised fast track and Qatar route; complete national steps
Convert	From first approval	Run pricing, value dossiers and tender qualification in parallel (see WP2)

Why this order

It uses the two-year Saudi and Oman windows while the reference approval is fresh.2,12

It creates SFDA and Kuwait approvals that later markets accept as reference.11,13

It avoids launching first in a low-price market whose price may be referenced across the region.

10. Pitfalls and Readiness Checklist

Ten pitfalls

Filing after the two-year window.2,12

Using public assessment reports instead of complete, unredacted reports.2

Supplying the GCC from a site or API source not in the reference approval.2

Switching reference agency for variations in Saudi Arabia.2

Assuming advanced therapies qualify for SFDA reliance.2

Batch-release site not registered with the reference authority used in Bahrain.11

Treating published targets as end-to-end timelines.3

No stability data for local climatic conditions.2

Approval without a pricing and tender plan.10

Ignoring a safety-related rejection or withdrawal elsewhere.2,12

Readiness checklist

Area	Ready when
Eligibility	Reference approvals, dates and windows mapped for each GCC state
Documents	Unredacted assessment reports, Q&A and variation reports in hand
Sameness	GCC product matches reference formulation, sites, specifications and API sources
Lifecycle	Primary reference agency chosen per market; variation plan agreed
Local	Arabic labelling, stability, price certificates and local agent in place
Downstream	Pricing, value evidence and tender plan running in parallel

11. How HERMS Helps

HERMS Consultancy DMCC helps pharmaceutical and biotechnology companies turn FDA and EMA approvals into GCC registrations.

Reliance strategy: eligibility mapping, reference agency selection and filing sequence across six markets.

Dossier readiness: sameness gap analysis, assessment report packages, Module 1 and Arabic labelling.

Submission management: SFDA, EDE, Kuwait, NHRA, Oman and Gulf Health Council filings, queries and variations.

Advanced therapies: pathway planning, scientific advice and site readiness where reliance does not apply.

Access continuity: pricing, value evidence and tender preparation aligned with registration.

Request a GCC reliance eligibility review

HERMS will assess your product against every GCC reliance route and deliver a filing sequence within your approval windows.

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Disclaimer: This white paper is for information only and does not constitute legal or regulatory advice. It reflects public sources available on 5 November 2026. Some sources are drafts or secondary reviews, and timelines are published targets rather than guaranteed durations. Confirm current requirements with each

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Related HERMS resources

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Drug registration timelines by country

UAE pharmaceutical product registration

Cell and gene therapy readiness in the GCC

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