HERMS WHITE PAPER | NOVEMBER 2026

The Cost of Delay

Quantifying Patient and Commercial Impact of Late Therapy Access in the GCC

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Innovative medicines reach GCC patients years after their first global launch. This paper measures that gap, translates it into patient and commercial terms, and sets out a practical framework to close it.

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Contents

Executive Summary

1. Defining the Cost of Delay

2. Measuring the GCC Access Gap

3. The Patient Cost of Delay

4. The Commercial Cost of Delay

5. Root Causes of Delay

6. Levers to Accelerate Access

7. The HERMS Time-to-Patient Framework

8. How HERMS Helps

References

Executive Summary

For a patient with a serious, progressive disease, the most important property of a new medicine is whether it is available today. In the Gulf Cooperation Council (GCC), many innovative medicines arrive years after their first global launch, and many never arrive at all. That gap carries a clinical cost for patients and a measurable commercial cost for the companies that develop them.

38% of new medicines launched 2012–2021 were available in Saudi Arabia1	**33%** were available in the UAE; 14% in Kuwait1	**27–32** months average delay after first global launch in UAE, Saudi Arabia and Kuwait1	**8%** higher risk of death per four-week delay in breast cancer surgery5

Key findings

The access gap is large. Of 460 new medicines launched worldwide between 2012 and 2021, 38% reached Saudi Arabia and 33% reached the UAE, with average delays of 31 and 27 months after first global launch.1

Review speed is no longer the main problem. The SFDA median approval time for novel drugs approved by the US FDA in 2019 was 248 days, comparable to the FDA's 243 days. Almost half of those drugs (47.92%) were never submitted in Saudi Arabia.3

Delay continues after approval. In oncology, the reported median time to public reimbursement was 6 months in the UAE and 23 months in Saudi Arabia.2

Time costs lives. Across seven cancers, each four-week delay in starting treatment was associated with a 6–13% increase in the risk of death for many indications.5

Time costs revenue. An average prescription medicine forgoes about USD 500,000 in sales for every day of delay in its main market.6 Lost GCC launch time also erodes the period of exclusivity in which value is recovered.

HERMS view

The largest delays are now created before submission and after approval, not during scientific review. They can be planned out. Treating registration, pricing, formulary listing and tender readiness as one sequence, rather than as separate projects, is the single most effective way to shorten time to patient.

1. Defining the Cost of Delay

A medicine is not available to a patient when a regulator approves it. It is available when it can be prescribed, dispensed and paid for in the patient's own health system. Between those two points sits an access chain with several steps, each of which can add months.

Step	What happens	Typical source of delay
1. Submission decision	Company decides whether and when to file in each GCC market	Market deprioritised; filing after US and EU launches
2. Registration	Authority reviews quality, safety and efficacy	Incomplete dossiers, legalisation, queries, pathway choice
3. Pricing	Price approved, often with reference to other countries	Price sequencing and referencing constraints
4. Reimbursement and formulary	Public payers and hospitals list the product	Value evidence gaps, committee cycles
5. Tender and procurement	Government buyers purchase volume	Missed tender windows, catalogue mismatch
6. Import and distribution	Product shipped, cleared and stocked	Labelling, permits, cold chain
7. Prescription	Clinician prescribes to an eligible patient	Awareness, guidelines, diagnosis and referral

Three dimensions of cost

Patient cost: health lost while an effective therapy is unavailable, including disease progression, irreversible damage and death.

Health system cost: avoidable hospitalisations, complications, long-term disability care and lost productivity.

Commercial cost: sales forgone during the delay and a shorter period of exclusivity in which to recover investment.

2. Measuring the GCC Access Gap

Availability and launch delay

PhRMA analysed 460 new medicines first launched worldwide between 2012 and 2021 across 72 markets. Saudi Arabia and the UAE lead the Middle East and Africa region, yet both still have access to only around one-third of new medicines.1

Market	Share of new medicines launched	Average delay after first global launch
Saudi Arabia	38%	31 months
United Arab Emirates	33%	27 months
Kuwait	14%	32 months
Middle East and Africa average	17%	42 months

Source: PhRMA Global Access to New Medicines Report, 2023.1

Oncology: registration and reimbursement

The IQVIA Institute assessed 183 novel oncology active substances launched globally between 2014 and 2023. Only 31% were registered in the UAE and Saudi Arabia, compared with 52% authorised in the EU.2

Market	Median time from global launch to registration	Median time to public reimbursement
United Arab Emirates	23 months	6 months
Saudi Arabia	27 months	23 months

Source: IQVIA Institute, August 2025.2 A separate study of 135 oncology targeted therapies approved between 1997 and 2022 found Saudi Arabia's drug lag significantly longer than in the US and EU.10

Review times have improved

For 48 novel drugs approved by the US FDA in 2019, the SFDA median approval time was 248 days, against 243 days for the FDA. By mid-2024, 43.75% had been approved in Saudi Arabia and 47.92% had never been submitted.3

The study concluded that non-submission, not review inefficiency, was the main reason for limited approval coverage.3

Average review times under the Gulf centralised procedure fell from 838 calendar days in 2015 to 321 days in 2019.4

What the data shows

The GCC access gap is driven less by how long regulators take to review and more by when, or whether, companies submit, and by how long pricing, reimbursement and procurement take after approval.

3. The Patient Cost of Delay

Direct evidence on the health effect of drug-launch delays in the GCC is limited. The strongest quantitative evidence comes from studies of delays in starting treatment. These provide a conservative analogue: when a therapy is unavailable, patients either wait or receive a less effective alternative.

Evidence from cancer treatment delay

A BMJ systematic review and meta-analysis of 34 studies across seven cancers found that a four-week delay in treatment was associated with increased mortality across surgical, systemic and radiotherapy indications.5

Treatment and indication	Hazard ratio for death per four-week delay
Breast cancer surgery	1.08 (95% CI 1.03–1.13)
Colectomy	1.06 (1.01–1.12)
Breast cancer adjuvant systemic therapy	1.09 (1.07–1.11)
Breast cancer neoadjuvant systemic therapy	1.28 (1.05–1.56)
Colorectal adjuvant chemotherapy	1.13 (1.09–1.17)
Bladder neoadjuvant systemic therapy	1.24 (1.03–1.50)
Head and neck radical radiotherapy	1.09 (1.05–1.14)

Source: Hanna et al., BMJ 2020.5

Risk compounds with time. For breast cancer surgery, the authors estimated a 17% increase in risk of death at eight weeks and 26% at twelve weeks.5 Average GCC launch delays are measured in years, not weeks.

Ten patient risks of delayed access

Risk	What it means for the patient
Disease progression	The condition advances while effective therapy is unavailable
Irreversible damage	Organ, neurological or tissue loss that cannot be recovered
Organ failure	Chronic disease progresses to dialysis, transplant or ventilation
Increased mortality	Higher risk of death, particularly in cancer, rare disease and infection
Treatment resistance	Less effective alternatives can drive resistance
Severe complications	Uncontrolled disease causes avoidable acute events
Emergency hospitalisation	Unplanned admissions replace planned care
Reduced survival	Later-line treatment often delivers less benefit
Permanent disability	Delayed intervention leads to lifelong impairment
Poorer prognosis	Outcomes worsen the later effective treatment begins

4. The Commercial Cost of Delay

The value of a day

The Tufts Center for the Study of Drug Development estimates that an average prescription drug or biologic forgoes approximately USD 500,000 in sales for each day of delay, with infectious, haematological, cardiovascular and gastrointestinal medicines among the highest.6 This figure reflects the US market, but the principle applies in every market: each day without access is a day of value that cannot be recovered.

How GCC delay erodes value

Lost sales: revenue forgone for every day a product is not available.

Shorter exclusivity: patent and data protection run from global dates, so a later GCC launch leaves less time to recover investment.

Missed tender cycles: much GCC volume flows through unified procurement, including NUPCO in Saudi Arabia and Gulf Health Council joint procurement.1112 A product not registered and qualified by the tender deadline can lose a full procurement cycle.

Price pressure: launching late, after reference prices are set elsewhere, can reduce pricing flexibility.

Competitive position: a later entrant may face established competitors and entrenched prescribing habits.

Estimating the commercial cost

HERMS uses a simple model to make delay visible in planning:

HERMS Cost-of-Delay formula

Daily value of access = expected annual GCC net sales at peak ÷ 365

Cost of delay = daily value × days of delay + value of any missed tender cycle + exclusivity erosion

Illustrative example (hypothetical): a product expected to reach USD 40 million in annual GCC net sales has a daily value of about USD 110,000. A six-month delay forgoes roughly USD 20 million in sales before tender or exclusivity effects are counted.

5. Root Causes of Delay

Root cause	Where it occurs	Effect
Late or no submission	Before registration	GCC filed after US and EU launches, or never filed3
Incomplete dossier	Registration	Queries, clock stops, resubmission
Legalisation and certificates	Registration	Weeks lost obtaining and authenticating documents
Pathway not optimised	Registration	Standard review used where reliance was available
Arabic labelling issues	Registration and import	Artwork rejection or shipment hold
Sequential planning	Pricing and reimbursement	Each step starts only after the previous one ends
Weak local value evidence	Reimbursement	Formulary committees defer decisions2
Tender timing	Procurement	Approval falls just after a tender closes
Supply and shortage risk	Distribution	Stock-outs interrupt treatment13

6. Levers to Accelerate Access

Use reliance pathways

GCC authorities have introduced pathways that take account of trusted reference-agency decisions.

Authority	Pathway	Target timeline
SFDA (Saudi Arabia)	Verification: approved by both FDA and EMA	30 working days7
SFDA (Saudi Arabia)	Abridged: approved by one reference authority	60 working days7
EDE (UAE)	Marketing authorisation service	45 working days stated service duration9
Kuwait	Fast track with FDA and EMA approval and assessment reports	30 days7
Kuwait	Fast track with one of FDA or EMA	60 days7

SFDA states that it is not obliged to approve an application simply because a reference agency has, and applicants must remain with their chosen reference agency for the product lifecycle.8

Plan in parallel, not in sequence

Include GCC markets in the global launch plan from the start.

Prepare GCC-ready dossiers, legalised documents and Arabic labelling before reference approval.

Build pricing strategy and value dossiers while registration is under review.

Map tender calendars against expected approval dates.

Qualify suppliers, catalogue items and distribution in advance.

7. The HERMS Time-to-Patient Framework

HERMS measures access as a single chain, with one owner for the whole timeline. Each milestone has a target, a responsible party and a tracked actual date.

Metric	Measured from	Measured to
Time to Submission	First reference approval (FDA or EMA)	GCC submission
Time to Approval	GCC submission	Marketing authorisation
Time to Price	Marketing authorisation	Approved price
Time to Formulary	Approved price	Formulary or reimbursement listing
Time to Tender	Listing	First tender award or purchase order
Time to Patient	First reference approval	First patient treated in the GCC

Patient-days lost

For each product and market, HERMS also estimates **patient-days lost** = eligible patients × days of delay. This makes the human cost of delay visible to decision-makers alongside the commercial cost.

Recommendations

For pharmaceutical companies	For authorities and payers
File in the GCC within months of first reference approval	Publish and report against review and pricing timelines
Use verification and abridged pathways where eligible	Extend reliance to pricing and reimbursement decisions
Run registration, pricing and tender readiness in parallel	Align formulary and tender cycles with approval dates
Prepare local value evidence before launch	Pilot outcomes-based agreements for high-cost therapies
Track Time to Patient as a leadership KPI	Measure and publish time from global approval to patient access

8. How HERMS Helps

HERMS Consultancy DMCC works with pharmaceutical, medical device and life-sciences companies to shorten the path from global approval to GCC patient access.

Access readiness review: a market-by-market assessment of dossier, labelling, pricing and tender readiness.

Regulatory strategy and submission: pathway selection, dossier preparation, submission management, renewals and variations.

Market access: pricing strategy, value dossiers, budget-impact models and formulary submissions.

Tender readiness: technical documentation, compliance checks and tender calendar planning.

Pharmacovigilance and compliance: local QPPV services, safety reporting and promotional review.

Request a Cost-of-Delay assessment

Contact HERMS to quantify the patient and commercial cost of delay for your portfolio.

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Subject index

Select a topic to go to its section in this white paper.

Access acceleration

Commercial impact

Cost of delayed therapy access

GCC access gap

Patient impact

Time to patient

Related HERMS resources

GCC pharmaceutical pricing and market access strategy

Drug registration timelines by country

UAE pharmaceutical product registration

GCC central registration through the Gulf Health Council

Contact HERMS

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