The wrong clock

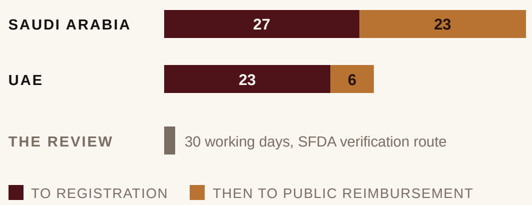
The Saudi FDA targets thirty working days on its fastest route. In oncology, the median wait from registration to public reimbursement has been twenty three months. Almost every Gulf launch plan is built around the first number.

WHO THIS IS FOR

Country and regional managers, market access and launch teams working in Saudi Arabia and the UAE. Most useful if you are setting a launch date, building a year one forecast, or being asked why revenue has not started.

The Saudi FDA has held **WHO Maturity Level 4** since October 2023. Three regulators in the world are at that level. Its published target is thirty working days on the verification route, sixty on the abridged one. No European regulator publishes anything like it. Worth saying plainly: these are targets, and SFDA does not publish what it actually achieves.

Two things about that. Both fast routes only work if the FDA or the EMA has already approved the product, so the speed is built to follow, not to lead. And registration was never what held anyone up. The part of the system that got faster is the part companies are already good at managing. The part that did not is the part they are not.



WHERE THE TIME GOES

Median months from first global launch, 183 oncology new active substances, 2014 to 2023. IQVIA Institute, August 2025. This is oncology, not launches in general, and it predates the 2023 maturity upgrade.

Registration is the cheap gate. Everything expensive happens after it.

FIVE QUESTIONS, IN THIS ORDER

1 **Which NUPCO tender window are you launching into, and what is its date?**

Not a quarter. A named tender with an opening date.

IF NOBODY CAN NAME IT

NUPCO's published plan for 2026 contains four pharmaceutical tenders for the entire year, and roughly four months run from opening to final award. The date in your launch plan is a registration date, not a revenue date.

2 **Who is your first customer: NUPCO, a cluster, or an insurer?**

Name the entity that signs.

IF THE PLAN SAYS THE MINISTRY OF HEALTH

It describes the system as it was. NUPCO holds the framework price, the twenty regional clusters increasingly decide volume, and their transfer to the Health Holding Company was still running through 2026.

3 **Where does your Gulf price land, and which markets inherit it?**

List the downstream markets by name.

IF THE LIST IS EMPTY

Saudi Arabia references sixteen countries, and the Gulf Committee for Pharmaceutical Pricing harmonises prices across the member states, so a Saudi price does not stay in Saudi Arabia. Morocco's decree references Saudi Arabia as one of only six countries and takes the lowest. Egypt was reported in September 2026 to have cut its basket to fifteen, added the UAE, and to take the lowest minus a further ten per cent.

4 **Is your economic evaluation built on Saudi data?**

Open it and look for local epidemiology.

IF IT IS A EUROPEAN DOSSIER IN ANOTHER CURRENCY

Economic evaluation became mandatory on 1 July 2025 for new registrations, price re-evaluations and renewals. This gate arrived as regulatory review got faster, which is why the front and the back of the system are moving in opposite directions.

5 **What is your localisation answer, and who signed it?**

Ask to see the document.

IF YOU ARE STILL EXPLORING OPTIONS

Since February 2025 an additional pharmaceutical price preference of up to twenty per cent stacks on the standard ten. You can be evaluated thirty per cent behind a local alternative, and secondary packaging alone does not count.

READING THE PATTERN

Fail on **1 and 2** and you have a calendar problem. The plan may be fine and the date wrong by a year. Fail on **3** and someone is making a pricing decision while believing they are making a timing decision. That one shows up last, in markets nobody on the launch team is measured on. Fail on **4 or 5** and you are competing on the terms of the old system. Worth correcting inside your own organisation: no European or United States basket appears to reference the Gulf. That is a negative finding rather than proof, but it points one way: the spillover runs into North Africa and the Levant, not into your American or European price.

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