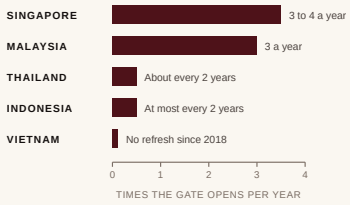
The door opens twice a year

Southeast Asia now registers on reliance, in ninety working days or less in several markets. Then the product waits for a committee that meets three times a year, or twice, or which in Vietnam's case has not substantively met since 2018.

WHO THIS IS FOR **Country and regional managers, market access and launch teams working across Southeast Asia.** Most useful if you are setting a launch date, building a year one forecast, or planning entry into Indonesia or Vietnam.

Part one said the Gulf got fast at registration and stayed slow at buying. Southeast Asia is the same shape with different machinery, which is why a team that has learned one region walks into the other and gets it wrong.

The regulatory side is quick. Singapore sits at **WHO Maturity Level 4**, same tier as Saudi Arabia. Indonesia's fast route runs ninety working days, Vietnam's nine months, and Malaysia opened a sixty-day pilot in May 2026. Every one of them needs an approval someone else granted first. And in none of these markets is the regulator the thing holding you up.



THE CALENDAR IS THE CONSTRAINT

Derived from published committee calendars, formulary cycles and regulations. Not measured outcomes.

Registration is measured in working days. The gate is measured in years.

FIVE QUESTIONS, IN THIS ORDER

1 **Which committee meeting are you aiming at, and when does it sit?**

A date, not a half-year.

IF THE ANSWER IS A HALF-YEAR

Singapore publishes its calendar far enough ahead that the date is calculable: for the March 2027 committee, intent was due in March 2026 and evidence in September 2026. Malaysia's panel has historically sat three times a year, though the current schedule is worth confirming. Missing a meeting does not cost weeks.

2 **Is your reliance window still open?**

Check the reference approval date, not your filing date.

IF NOBODY HAS CHECKED

Malaysia's recognition pilot requires submission within three months of FDA or EMA approval. Singapore's verification route needs two reference approvals with the primary inside three years. Indonesia's needs approval inside five. These clocks start on someone else's decision.

3 **In Indonesia and Vietnam, what is the second gate?**

Listing is not buying. Name the procurement step.

IF THE PLAN STOPS AT THE FORMULARY

Indonesia lists on the national formulary, then still has to reach the health ministry's electronic catalogue, which has been mid-migration between platforms. Vietnam sorts generics into five technical tiers that set both achievable price and who you bid against. The second gate is where volume and price are decided.

4 **What is your Vietnam reimbursement assumption?**

Ask what year the list was last substantively refreshed.

IF NOBODY KNOWS, IT IS 2018

A draft adding 84 medicines, 30 of them in oncology, went out for comment in November 2025 and was still unissued in March 2026. For a product registered after 2018 and not on the list, reimbursement is not a near-term event whatever the nine-month registration route suggests.

5 **Where does each market sit on the localisation ladder?**

Preference, requirement and exclusion are three different things.

IF THEY ARE BEING TREATED AS ONE

Indonesia requires imported medicines to be produced domestically within five years, and weights the active ingredient at half the local content score. Vietnam went furthest: an April 2024 circular named 93 medicines for which an imported product may not be offered at all, and a replacement has been in draft, so assume it has grown. The Philippines' 2024 act obliges public buyers to award to domestic bidders for ten years, though whether medicines are inside its covered list is worth checking.

WHAT THE TWO REGIONS SHARE

Both got faster at registration, and in both the speed depends on an **FDA or EMA approval that came first**. Neither region has moved ahead of the United States. Neither is built to. In both, the binding constraint moved to the back end, and the back end did not get faster. What differs is what it is made of: in the Gulf a tender calendar you can read and a price preference you can put a number on, in Southeast Asia a committee calendar, a second procurement gate in two markets, and a localisation regime that in places is no longer a preference. **Preference, requirement, exclusion.** The ladder has moved a rung in two years.

Anita Menon. Eighteen years across Abbott, Amgen, Mundipharma, Novartis and Cipla, including regional commercial excellence across six Southeast Asian markets. Based in Dubai. Engagements contracted through Muziris Ventures, Ajman, UAE. Sources: HSA and ACE Singapore, NPRA Malaysia, Thai FDA, BPOM and Kemenkes Indonesia, Vietnam MOH circulars, Philippine FDA and HTAC, WHO. Figures derived from published calendars, not measured outcomes. Open questions and source limits are set out in full on the site.

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