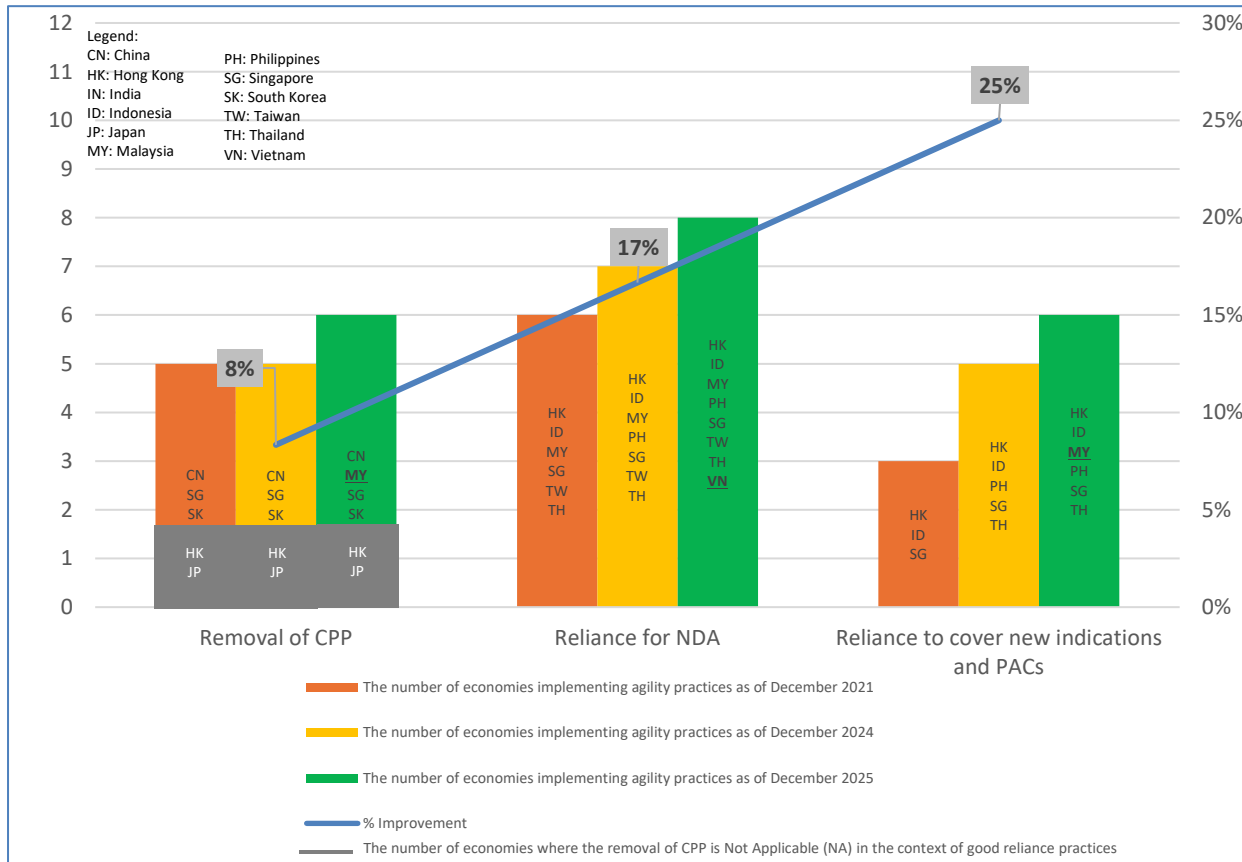


Reliance Pathways in APAC: Current Adoption, Challenges, and Opportunities for Optimization

Findings from APAC industry members across 12 economies
(manuscript under peer review)

Sannie Chong (Ph.D.), Asia Pacific Lead, Merck Sharp & Dohme
On behalf of APAC RA-EWG

Progress in CPP removal and Reliance expansion



- Malaysia removed CPP from verification route in 2025
- Malaysia expanded reliance to New Indications (NIs) and Post Approval Changes (PACs) in 2025
- Vietnam introduced NDA reliance pathway in 2025

Figure 1: Improvement in expanding reliance practices in Asia

Industry Workload Impact

Up to 30% additional workload

- Reliance pathways require substantial additional effort
- Driven by stringent or local-specific requirements
- Additional 30% workload compared to standard pathways

Most Frequently Used Reference Agency

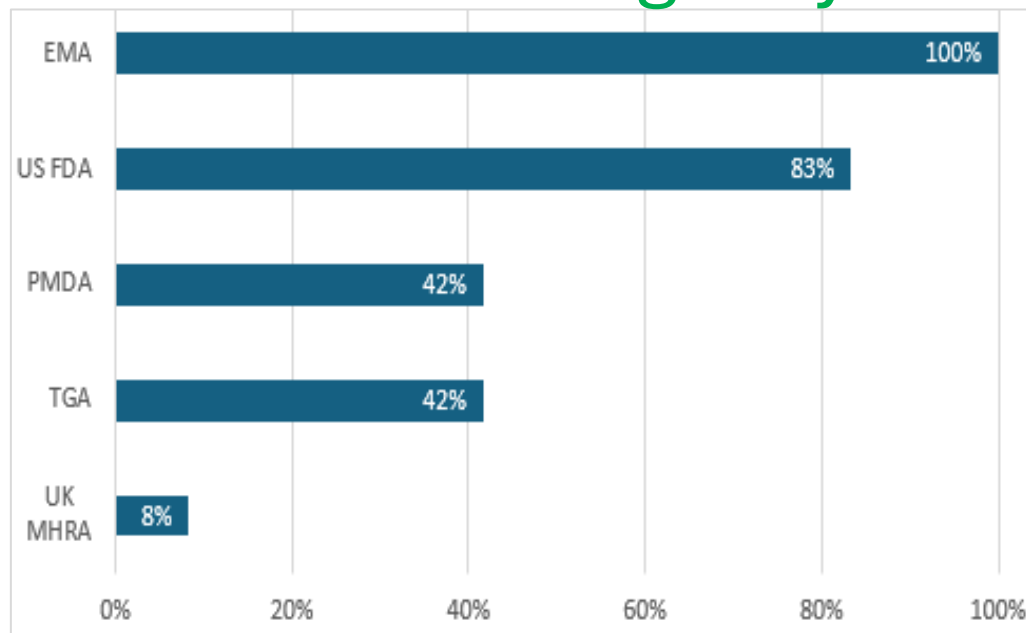


Figure 2: Preferred reference agencies are (100%) EMA, (83%) US FDA, (42%) TGA, (42%) PMDA and UK MHRA (8%)

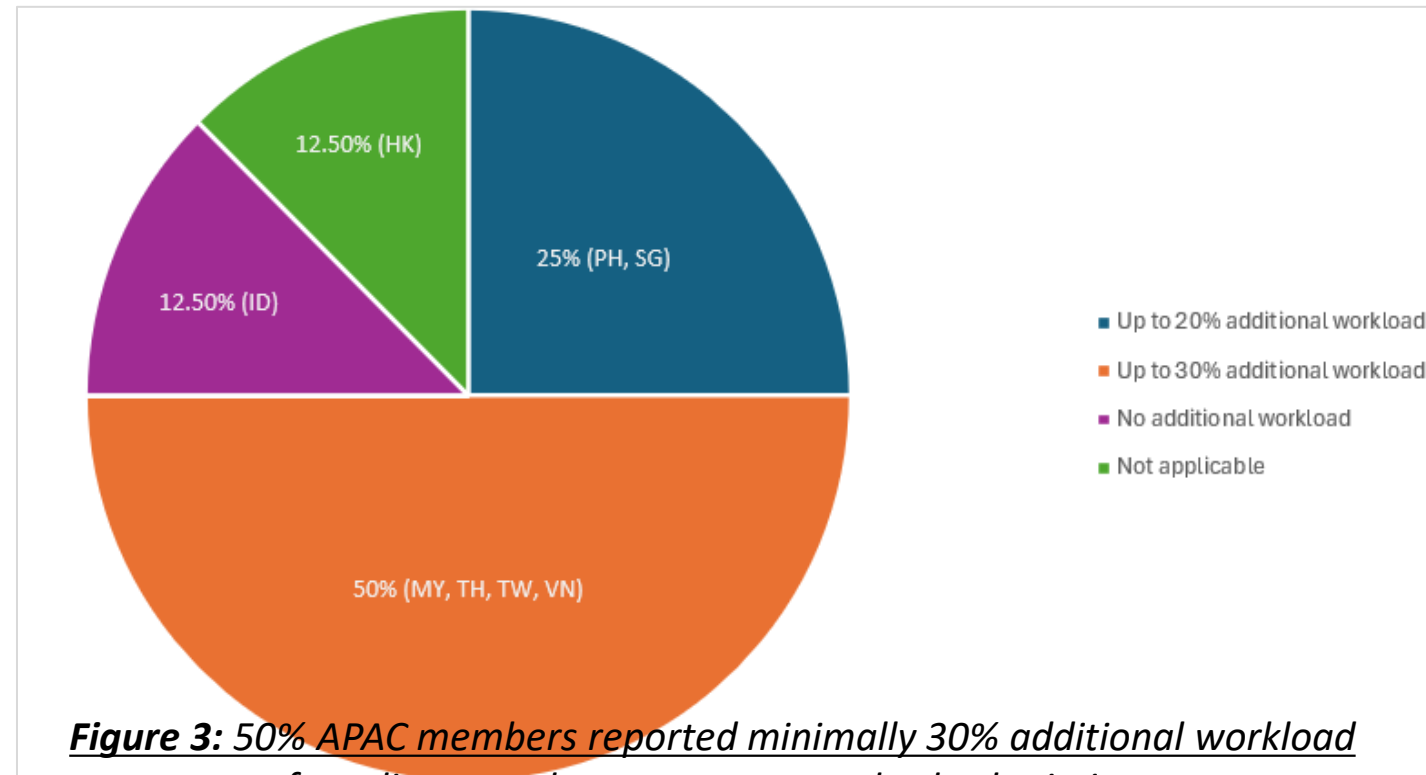


Figure 3: 50% APAC members reported minimally 30% additional workload for reliance pathways versus standard submission

NDA Reliance Barriers

- Local requirements not reduced
- Abbreviated pathway: Frequent request for unredacted non-public Assessment Report
- Requests go beyond eligibility criteria, including interim reports



Figure 4a: Top 3 barriers to use reliance pathway for NDA among participating APAC member associations

PAC Reliance Barriers

- Requests interim reports, Q&As, & dataset outside of guidelines
- Difficulty accessing unredacted non-PARs
- Complicated by variation classification inconsistencies

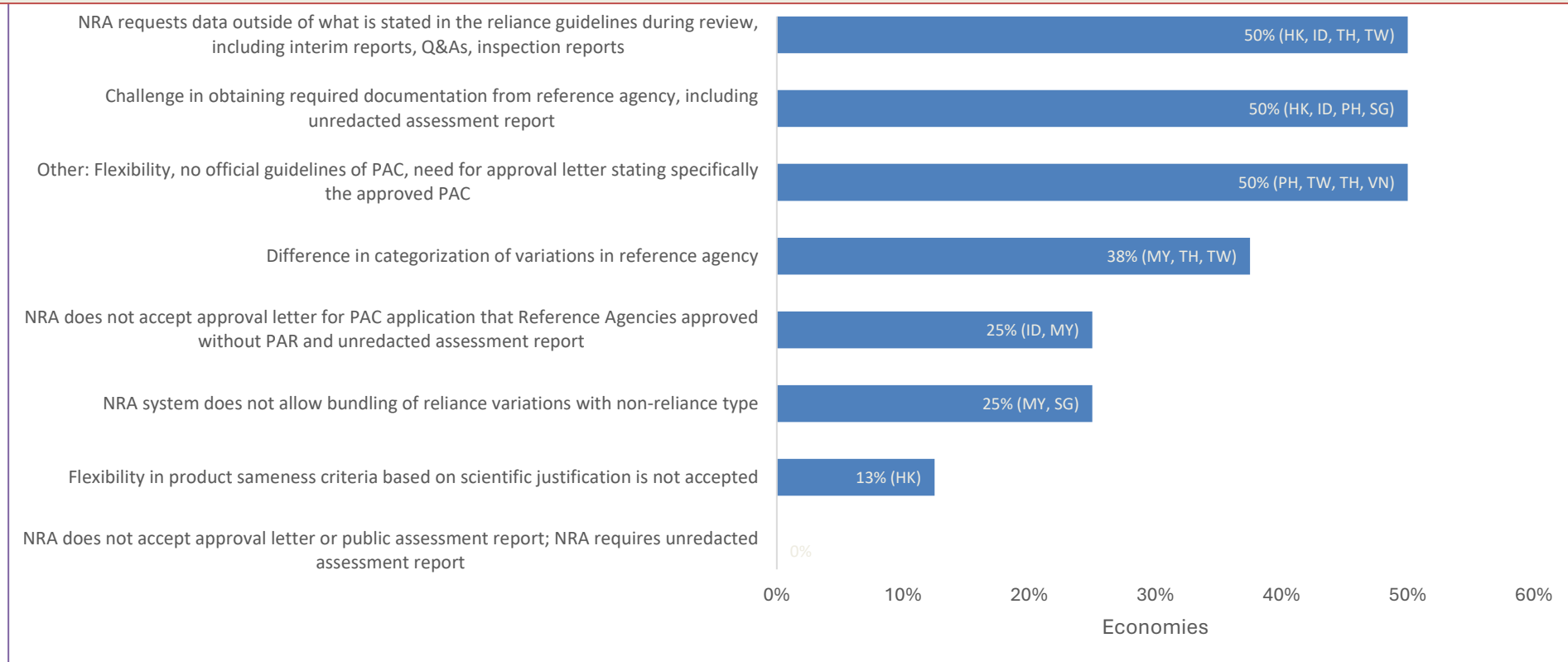
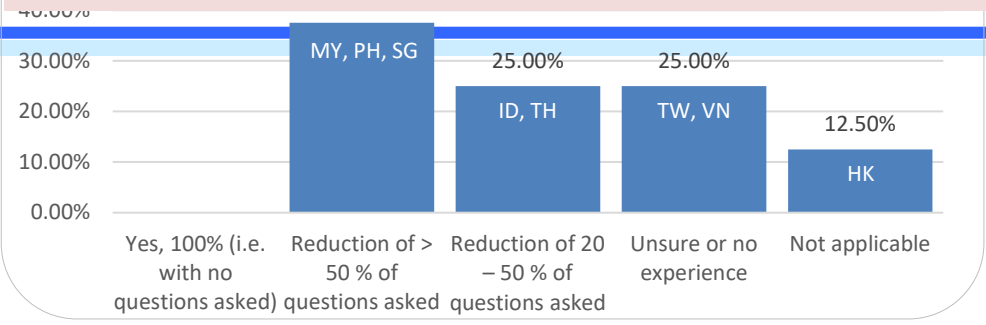


Figure 5: 50% of the APAC member associations perceived additional requests outside of reliance guidelines and requirements for unredacted non-PARs as key implementation challenges for reliance for PAC

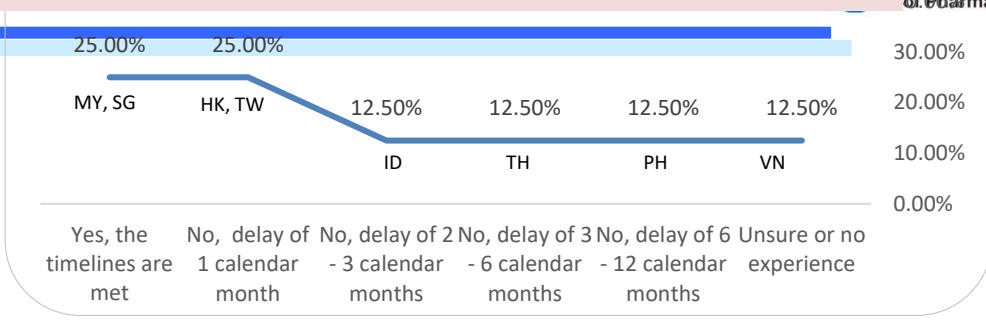
Reduction in questions observed in several economies

Timeline performance remains inconsistent. Malaysia and Singapore most consistent

NDA (n = 8)

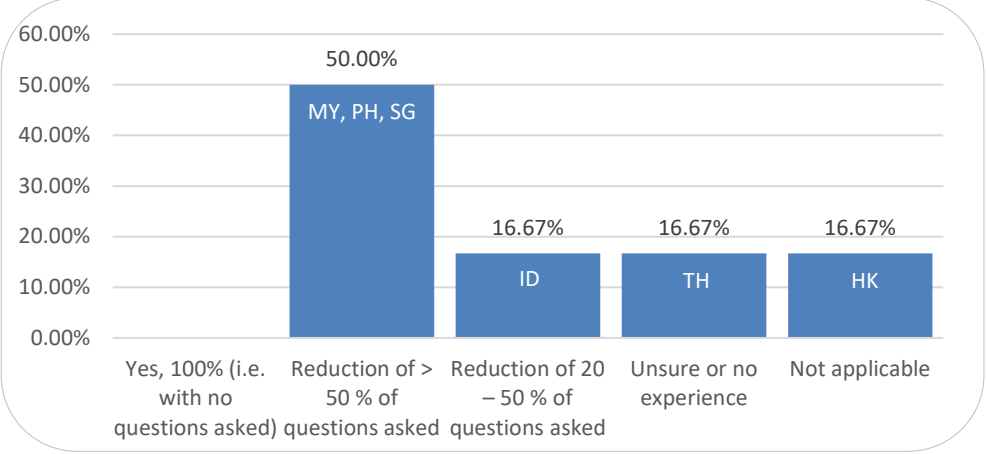


Reduction in number of

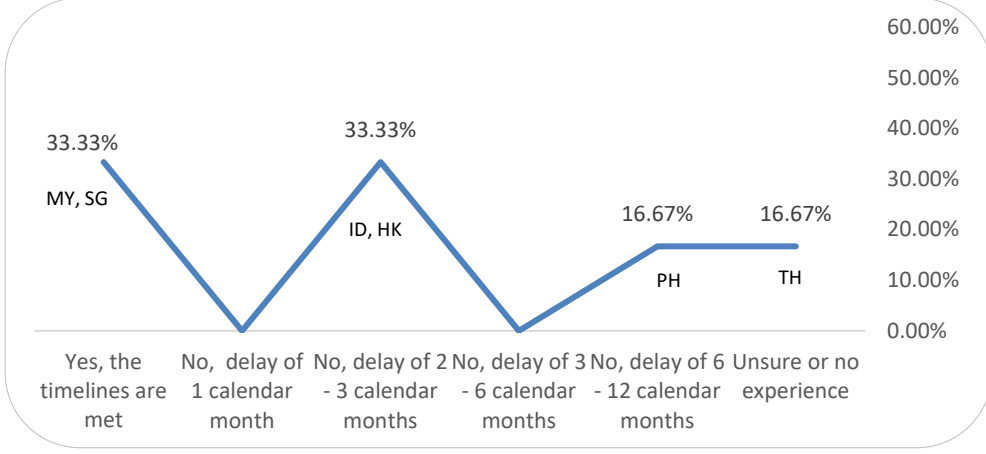


Published timelines met

New Indication (n = 6)

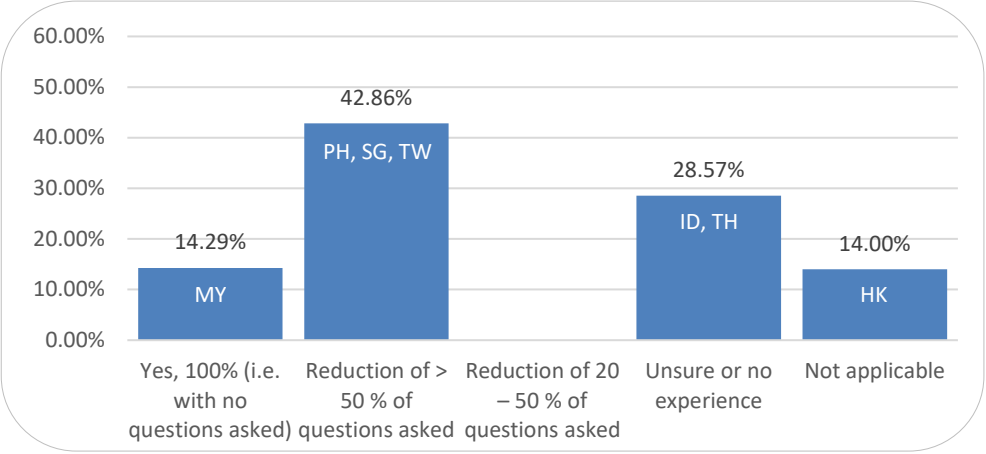


Reduction in number of questions

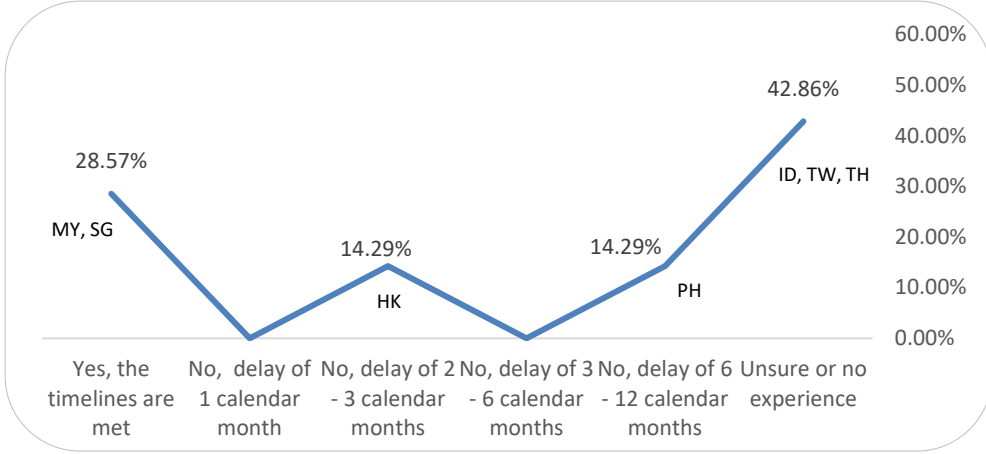


Published timelines met

PAC (n = 7)



Reduction in number of questions



Published timelines met

Optimizing Reliance Pathways in APAC to Support Harmonized and Efficient Regulatory Practices



APAC economies with local reliance pathway as of March 2026	New Drug Applications (NDAs)						Post Approval Changes (PACs)			New indications (NIs)
	Reliance Pathway		Adherence to timeline	Relying on approval letter &/or public AR		Reduction in queries	Guideline issuance	Adherence to timeline	Relying on approval letter	Guideline issuance
	Abbreviated	Verification		Abbreviated	Verification					
Hong Kong	A single pathway without dividing into abbreviated and verification pathways		No	Unredacted non-PAR required yet guideline states 2 CPPs only		NA	Yes	No	CPPs	Yes
Indonesia			No	Unredacted non-PAR instead		Y (20-50%)	Yes	No experience	No	Yes
Malaysia	Yes	Yes	Yes	Unredacted non-PAR instead	Unredacted non-PAR instead	Y (>50%)	Yes	Yes	PAR and/or approval letter	Yes
Philippines	Yes	Yes	No	Unredacted non-PAR instead	Unredacted non-PAR instead	Y (>50%)	Yes	No	Yes	Yes
Taiwan	Yes	No	No experience	Unspecified**		No experience	No			No
Thailand	Yes	No	No	Unredacted non-PAR instead		Y (20-50%)	No*			No
Singapore	Yes	Yes	Yes	Yes, with approval letter	Unredacted non-PAR instead	Y (>50%)	Yes	Yes	Yes	Yes
Vietnam	Yes	Yes	No experience	Unspecified	Unredacted non-PAR instead	No experience	No			No
APAC economies without local reliance pathway										
India	No						No			No
China	No						No			No
South Korea	In 2020, EMA launched the OPEN (“Opening our Procedures at EMA to non-EU authorities”) framework, enabling parallel and independent evaluations of new marketing applications by EMA and participating non-EU agencies—including South Korea’s MFDS and Japan’s MHLW/PMDA—supported by scientific exchange and broadly aligned timelines. The framework has recently expanded to include both new indications and PACs.									
Japan										
* Though there is no PAC guideline, the Thai FDA can accept an approval letter and assessment report from a reference country (no written guideline) to facilitate the acceleration of PAC										
** While official guidelines do not explicitly require an unredacted non-PAR, the Taiwan FDA has informally indicated that, in principle, and unredacted revision is expected for a successful submission.										

- Public ARs or approval letter as primary evidence and focus reviews on unresolved/local issues
- Meeting timeline: Identify bottlenecks and use tracking systems to monitor progress
- India: Harmonize practices by expanding reliance rule 101 across all drug categories

Best Practices

Call to Action: Optimize reliance execution is crucial to realize patient access benefits

Remove interim reports, non-value adding requirements

India to formalize reliance pathway for NDA

Harmonize practices by **expanding reliance rule 101 across all drug categories**

Greater use of publicly available PARs, particularly for Abbreviated

Leverage PARs as primary evidence and focus reviews on **unresolved/local issues**

Pragmatic acceptance of scientifically appropriate evidence, particularly for Verification

Expand reliance footprint to PACs and NIs

Improve adherence to timeline

Reliance preserves regulatory sovereignty, retaining independent decision-making while leveraging reference agency assessments to focus resources on local priorities—to ultimately benefit patients.

