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Regulators-Only Workshop on Reliance for Post-Approval Changes (PACs) | 18–19 May 2026

Meeting report

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1. Executive Summary

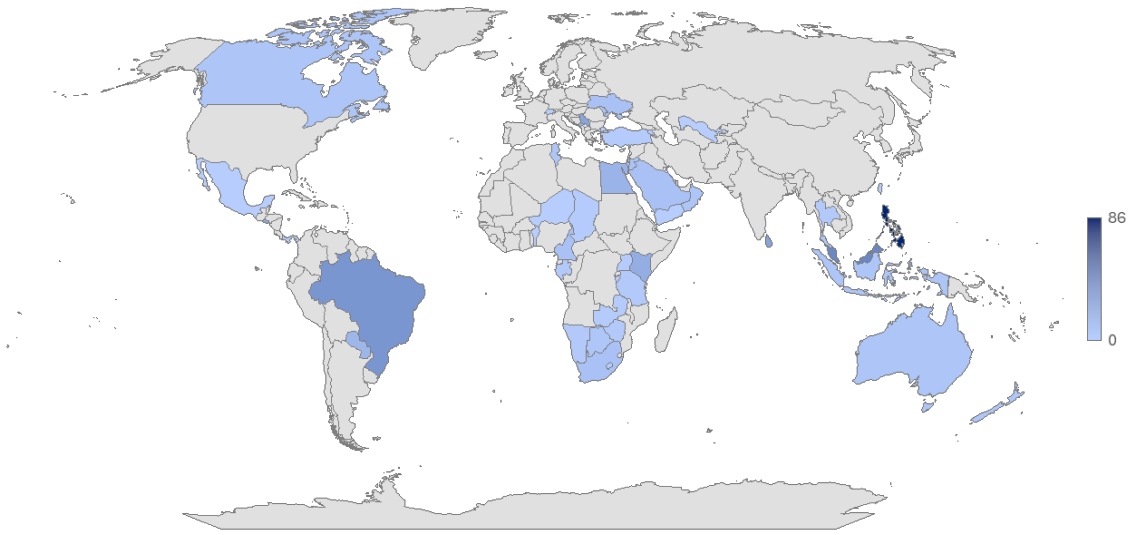
This regulators-only workshop focused on moving reliance for post-approval changes (PACs) from pilots to routine practice. It combined evidence from EMA-WHO PAC reliance pilots with practical implementation experience from Serbia (ALIMS), Egypt (EDA) and South Africa (SAHPRA), framed by WHO Good Reliance Practices.

Why this matters: PACs are becoming more frequent and complex, while divergent requirements and long, unpredictable timelines increase workload, delay implementation, and raise shortage risks.

As Emer Cooke, Executive Director of EMA, noted, the question is no longer whether reliance is needed, but how to implement it in a way that improves efficiency, convergence, and predictability in practice.

Key takeaways:

- Reliance for PACs is feasible in practice and can reduce timelines and workload while improving predictability and convergence.
- Benefits are not automatic: impact depends on implementation, including clear workflows, access to assessment reports, triage, and how assessors apply reliance in practice.
- Scaling reliance requires practical guidance, trained assessors, and simple systems to track impact and support continuous improvement.
- Workload and backlog reduction is the clearest near-term use case, but the value of reliance goes beyond efficiency: it can build capacity, avoid duplication, reduce divergence, and help maintain supply.



Global Engagement: 400+ regulators from 49 regulatory authorities joined the workshop.

2. Framing the challenge for PACs: Perspectives from EMA and WHO

2.1. EMA-WHO PAC reliance pilots: early evidence

EMA provided a Snapshot of the pilot program:

- 40 pilots initiated with EMA as reference authority as of May 2026
- Mid-pilot review based on 9 finalised and 8 ongoing pilots, supported by an NRA survey (by end-2025 cut-off)
- Broad global engagement: 77 regulatory authorities participated in at least one pilot.
- Timelines: most NRAs reported faster approvals; for completed CMC pilots, 80% were approved in less than half the expected time.
- Most NRAs reported resource savings; around half raised no additional questions.
- High trust in EMA assessment reports supported reliance in practice.
- Convergence of submission requirements was shown to be feasible in many cases.
- Greater predictability helped reduce the risk of supply shortages.
- The pilot is helping to normalize reliance as a smart way of working.

End-to-end efficiency gains were observed for regulators and industry—across submission (one core data package, aligned timelines), review (use of EMA assessment reports), and implementation (faster uptake of supply-critical changes). However, benefits depend on how reliance is applied in practice. Key priorities to maximise impact are: strengthening predictability and convergence, building capacity and practical guidance, and maintaining a clear focus on efficiency.

2.2. WHO perspective on scaling reliance in practice

WHO highlighted uneven global regulatory capacity and the need to use reliance, work-sharing and collaboration across the product lifecycle and for all regulatory functions for a more efficient global regulatory oversight and to reduce duplication.

For PACs, WHO emphasised the need to embrace pragmatic approaches: efficient tracking systems, separate queues/lines for reliance, promote convergence, ensuring product sameness, accommodate new concepts for product lifecycle management (e.g. ICH Q12), increasing transparency, and building trust between stakeholders.

Reliance is proposed as an efficient tool to manage the post-authorisation changes workload and facilitate access and supply to quality-assured products globally.

3. Practical Implementation: Recommendations from NRAs

The following recommendations synthesise some of the practical experience from ALIMS, EDA and SAHPRA, grouped to avoid duplication and framed as guidance for other regulators.

3.1. Establish a clear operational framework

- Engage policymakers to update legislative frameworks, if necessary.

- Publish guidance/SOPs covering eligibility, required documents, timelines, review model and contact point.
- Define internal workflow steps (validation criteria, roles, decision points) to make reliance predictable.
- Create a focal point/triage function to ensure applicants know where to request reliance.
- Clarify and publish the criteria used to select reference agencies and the list of authorities that NRAs may rely on.

3.2. Redesign assessment practice (avoid "full review, faster")

- Use verification as default for low-risk variations; apply abridged review only for critical/local elements.
- Train assessors on "how to rely" (what not to redo; how to use reference reports; targeted questioning).
- Remove low-value steps for low-risk changes where feasible.

3.3. Ensure access to assessment reports and complete reliance packages

- Require applicants to provide assessment reports approval/outcome evidence.
- Where needed, explore secure channels/platforms for confidential information exchange.
- Use checklists/templates at validation to reduce incomplete submissions and delays.

3.4. Promote convergence pragmatically through risk-based flexibility

- Align classification approaches with international standards where possible and apply risk-based flexibility to minimise local specifics.
- Consider accepting alternative documentation and waive non-critical national requirements when justified.
- Work towards reducing review-timelines and support consistency in implementation periods across jurisdictions, where feasible.
- Apply reliance for post-approval changes even where the initial marketing authorisation was not granted through a reliance pathway.

3.5. Standardise and operationalise "sameness"

- Adopt a standard declaration of sameness and require structured disclosure of dossier differences.
- Apply clear criteria for determining when differences require targeted review versus full review.

3.6. Use reliance strategically to reduce backlogs

- Quantify backlog and address root causes (process, capacity, and workload planning).
- Introduce coordination roles to reduce administrative burden on assessors and improve tracking.
- Simplify processing of high-volume minor variations (verification, templates, grouping where possible).

3.7. Invest in capability and culture shift

- Provide training and peer-to-peer exchange to build confidence and trust in reliance.
- Reinforce that reliance preserves sovereignty and should be understood as insourcing additional expertise, rather than outsourcing decision-making.

3.8. Digitise and automate to scale

- Invest in digitalisation and tracking dashboards to reduce manual work and sustain performance.
- Adopt structured templates for validation and abbreviated reports to reduce report-writing time.

3.9. Invest in International collaboration

- Invest in international collaboration to equip regulators and reviewers with best international regulatory practices shared across forums.
- Promote structured knowledge exchange through joint reviews, staff exchanges, and participation in international procedures to support consistent implementation.