EMA
EUROPEAN MEDICINES AGENCY

Using EMA assessments for Reliance in Post-Approval Changes

Insights from PAC Reliance pilots
15 June 2026

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EMA International affairs

Industry-EMA Reliance focus group

What is it?

Small sub-group from the industry stakeholder platform on the operation of the centralised procedure set up in November 2022

Members from different EU trade associations and EMA International Affairs/Human Medicines Division

Has regular meetings and broad and balance industry representation

What are the goals?

Discuss opportunities and challenges encountered by European industry when using EMA as Reference regulatory authority.

Identify priorities to normalize and facilitate reliance implementation in a sustainable way.

Discuss recommendations and actions to facilitate reliance in practice

Regulatory challenges of post approval changes

1. Increasing volume and complexity

2. Divergence in regulatory requirements and reporting categories

3. Duplication of assessments across NRAs

4. Unpredictable review and approval timelines

5. Delays can impact supply disruption and shortages

6. Need for practical models focusing on **efficiency, convergence, predictability**.

A practical model to implement reliance

Methodology of the Pilots

Convergence of requirements

Applicants submit same **Core data package** with aligned changes to eCTD,
(or clear notes on any dossier differences) and **EMA AR**

This enables NRAs to **test convergence of** requirements in real time and explore alignment or waivers where possible

Aligned timelines

Predictability is tested with **submission dates aligned** across all participating authorities

Pilots target a maximum of 6 months.

Collaborative approach

Opportunity for feedback on EMA Assessment Report.

Shared questions across NRAs allows **learning** and comparison of review approaches

Independent decision making

NRAs maintain **independence** in deciding whether and how to rely on EMA evaluation

Progress and early results

Pilot Status

44 pilots initiated to date with EMA as Reference Authority.

Findings based on the data available at the end of 2025 **collected by EFPIA**, including **9 completed and 8 ongoing pilots**, supported by an **NRA survey and two workshops.**

27 new pilots started/starting in **2026.**

Most pilots have focused on quality changes linked to supply, with a small number of clinical variations covering extension of indications or safety updates.

What the initial review shows

🌎 Broad international participation

📁 Convergence of submission and requirements was feasible

📉 Lower NRA workload + resource savings

🔎 High trust in EMA assessment reports

⚡ Faster approval

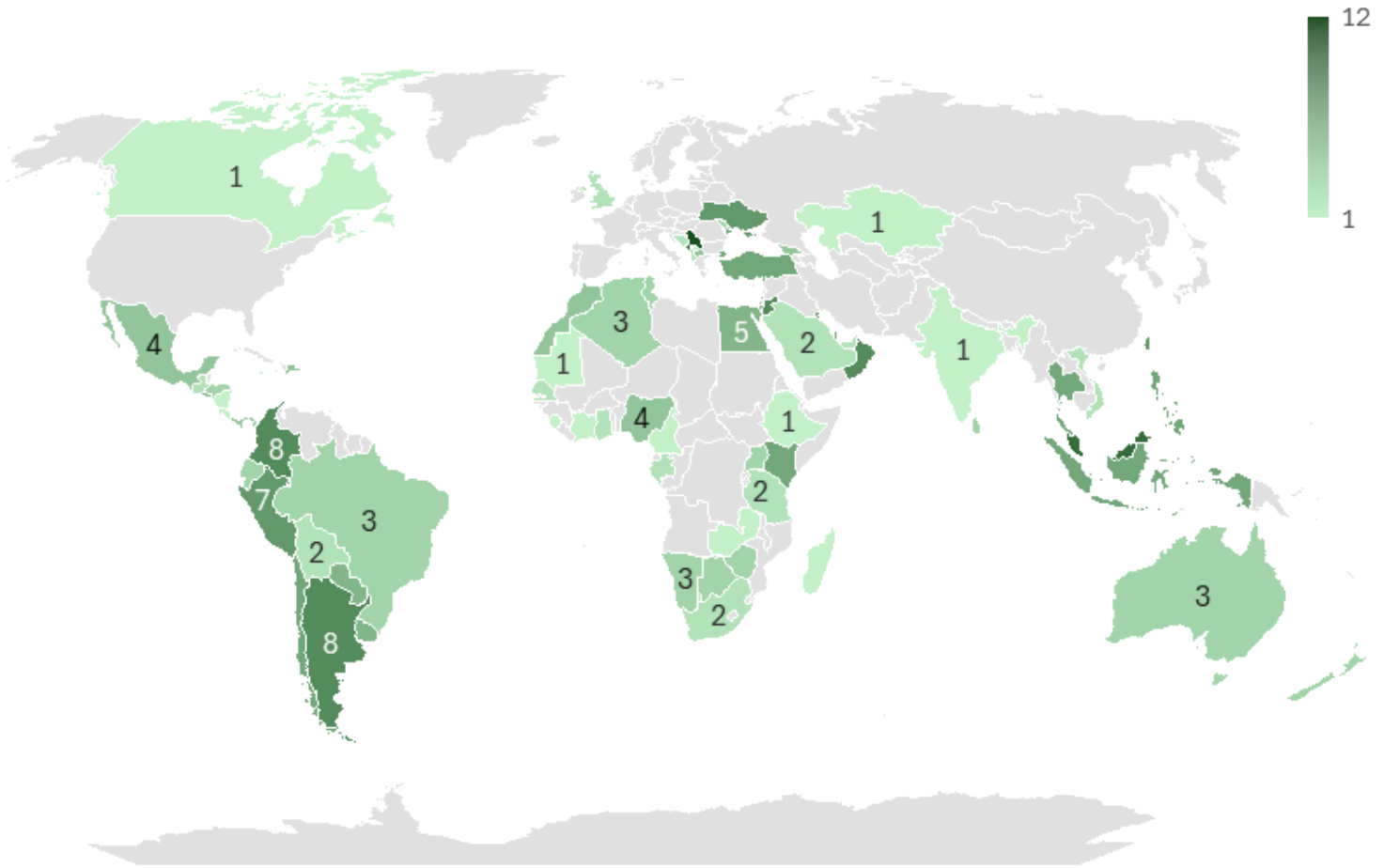
📊 Greater predictability, reducing shortage risks

High Global Engagement

Broad participation across regions and maturity levels.

Global feasibility and interest is clear, but participation was not consistent.

113	Regulatory Authorities invited
77	Participated in 1 or more pilots (24 accepted all invitations while 53 accepted only some)
36	Did not participate or respond to pilot invitations



Participation in finalised/ongoing pilots

Impact on timelines

Feedback from EFPIA survey

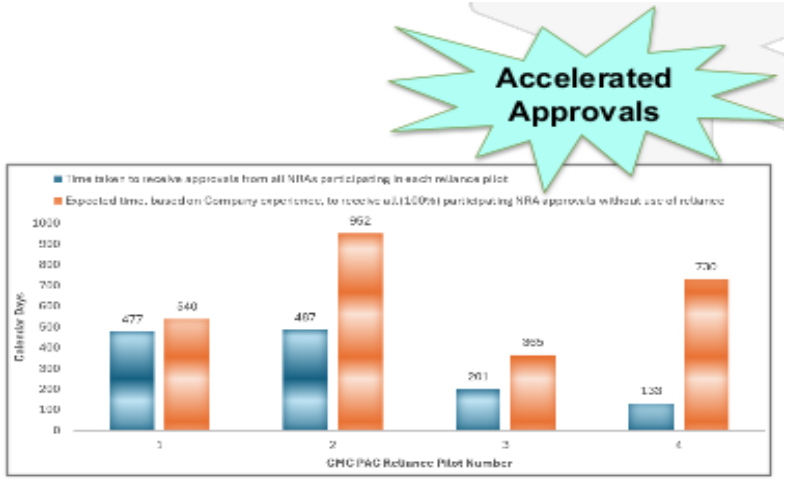
Approval Rates (as of Jan 2026)

7 pilots with an ~ **6-month** approval time

- % of NRA approvals received within proposed approval timeline ranged from **40-100% (average 74%).**
- **80% Relying NRAs approved in less than half the approval time that would usually be expected** (based on Applicant's experience of approvals without reliance).

1 pilot with a **3-month** approval time

- Only **17%** received approval within proposed approval time.



For the four pilots that have already received **all** approvals:

There is a **12-80% reduction in approval timeline** when using reliance than when compared to standard routes based on Applicant experience.

Feedback from NRA survey

Most NRAs reported faster review and approval timelines through the pilot.

Faster timelines were enabled by:

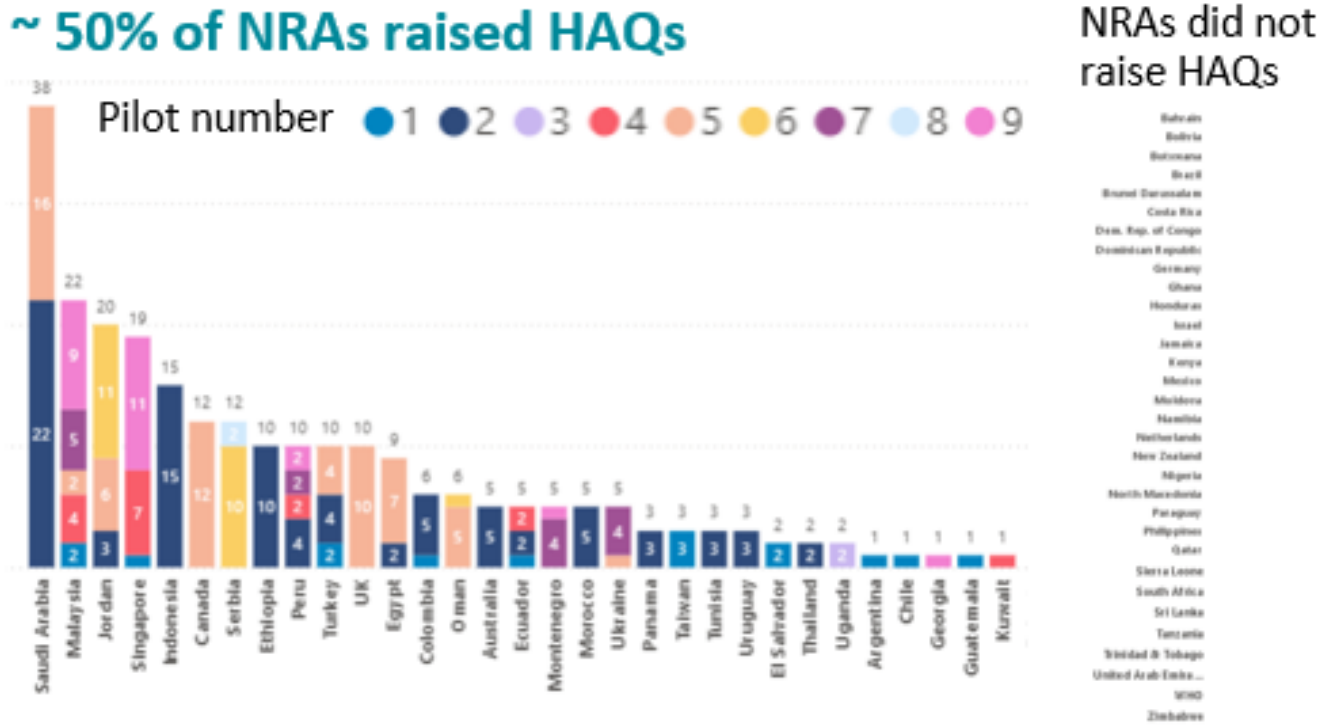
-Use of EMA assessment reports as the primary scientific basis

-Elimination of duplicate questions already resolved at EU level

Impact on resources

Feedback from EFPIA survey

Industry survey

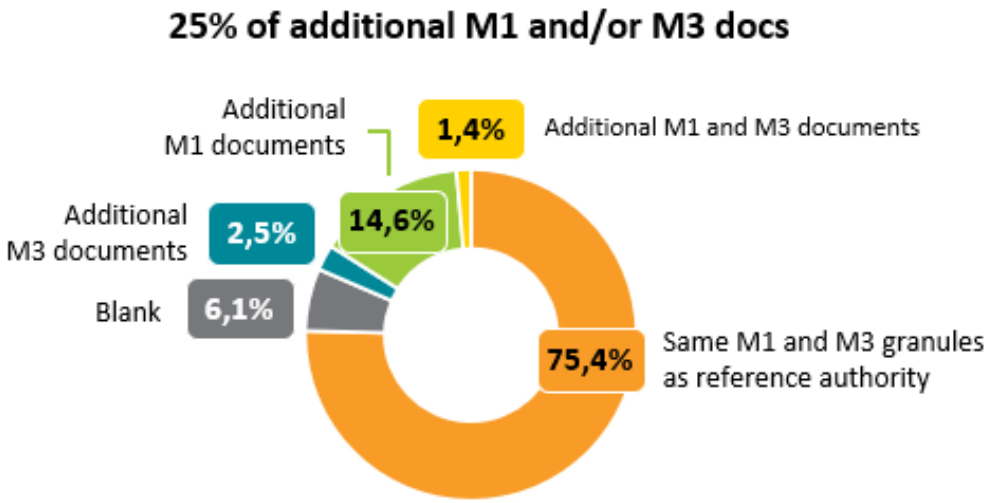


Feedback from NRA survey

- Reliance allowed NRAs to use resources more strategically while building capacity.
- **75% of NRAs reported resource savings** as EMA reports reduced duplication of work
- **~50% of NRAs raised no additional questions** and when they did, these were targeted (complex aspects, local requirements)
- Fewer questions not only reduced timelines but also freed up resources by limiting the need for follow-up review.

Impact on driving convergence

Feedback from EFPIA survey



While full harmonization is not realistic fragmentation can be reduced by aligning authorities around a shared assessment

Common data packages were used across NRAs
Alignment of requirements was achievable

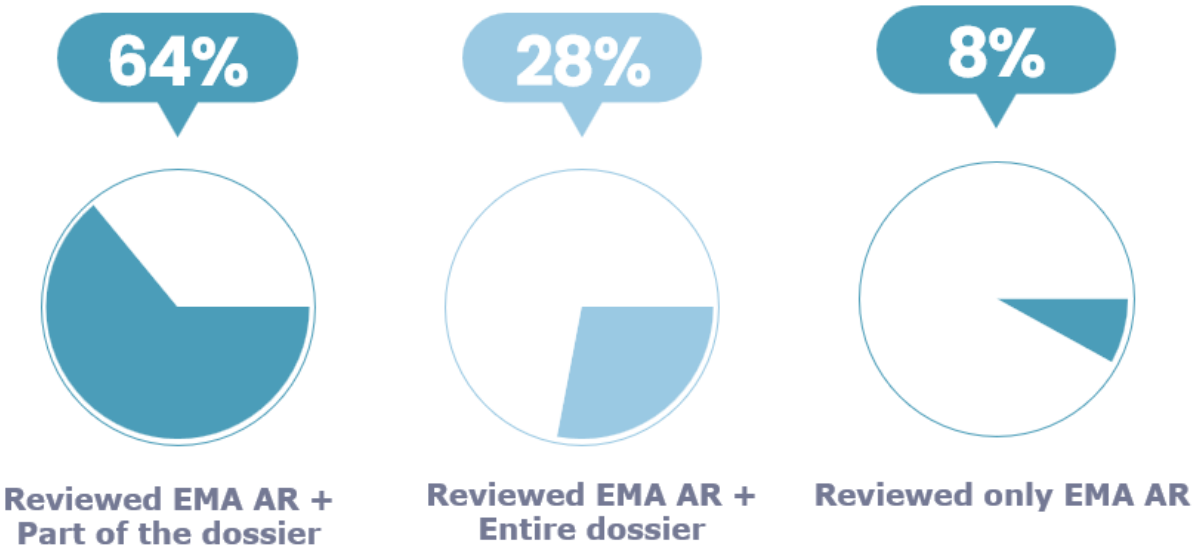
Reliance was applied despite different classification frameworks and used even when the initial MA was not approved via a reliance pathway

NRAs can apply flexibility based on risk and local context.

How reliance was applied across NRAs

- Access to EMA assessments, and when relevant inspection certificates or reports, was identified as key enabler of reliance.
- Aligned submission across NRAs, with transparency on dossier differences (if any) was critical to build trust.
- Most NRAs considered EMA assessment reports sufficiently detailed to support decision-making.
- In practice different approaches to reliance were observed depending on NRA context.

Feedback from NRA survey



Overall insights

- Close EMA–industry collaboration, steered by the focus group, was decisive in bringing the pilot to life.
- Workshop with regulators and industry identified reliance as a tool to manage post approval changes more effectively.
- Workload and backlog reduction is the strongest immediate value for NRAs, but there are broader benefits: capacity building, reduce duplication, improve convergence and supply resilience.
- Benefits are not automatic: impact depends on implementation, including clear workflows, access to assessment reports, triage, and how assessors apply reliance in practice.

Based on the pilot experience, several priorities emerge:

A

Strengthen Predictability and convergence

Formalise pathways or appoint focal points
Promote convergence of requirements, allowing flexibility
Streamline timelines and continue to explore digital tools

B

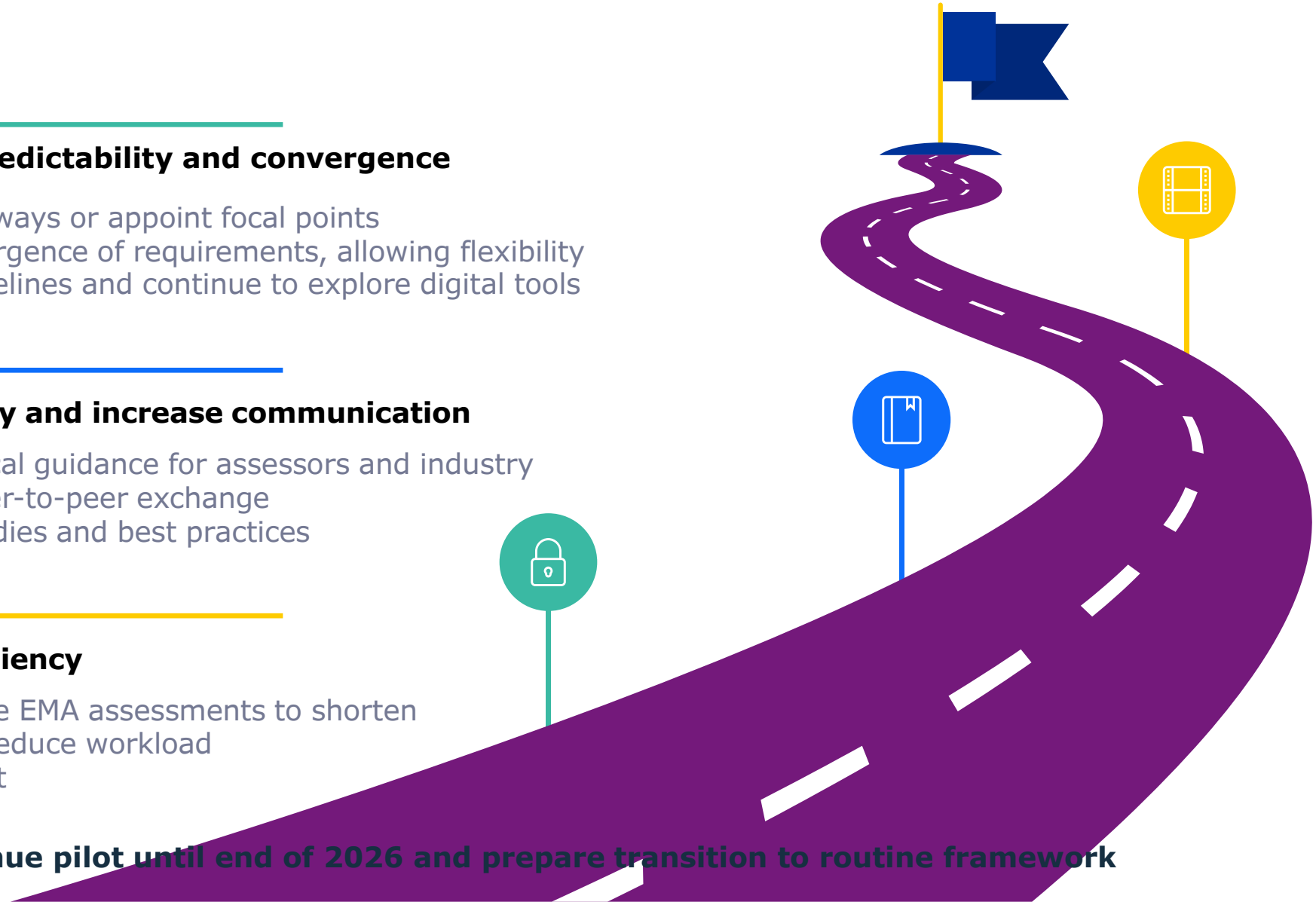
Build Capacity and increase communication

Develop practical guidance for assessors and industry
Strengthen peer-to-peer exchange
Share case studies and best practices

C

Focus on Efficiency

Make better use EMA assessments to shorten timelines and reduce workload
Measure impact



Continue pilot until end of 2026 and prepare transition to routine framework

Recognising the joint EMA–industry–WHO efforts to strengthen the Implementation of Reliance

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