Reliance for post-approval changes: an industry perspective

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Reliance is a reality in Latin America

In the past 3 years and beyond many regulators in Latin America have used reliance mechanisms to accelerate regulatory approvals, for COVID-19 related products and others, showing the value of this regulatory tool

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Reliance Concept

Slide adapted from WHO: Annex 10 Good regulatory practices Page 3

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Considerations for the use of reliance

- Have access to regulatory expertise from trusted party
- Have the same product
- Have the same essential technical data
- Understand validity for Benefit/Risk for local environment
- National legislation and sovereignty are maintained
- Confidentiality of commercially sensitive information is respected

World Health Organization

Slide adapted from WHO: Annex 10 Good Reliance Practices Page 4

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Sameness of product for reliance purposes

*Reliance can only be practiced if "the medical product being assessed is **essentially the same** as the one submitted to the reference NRA".*

But what can be considered "essentially the same"?

Sameness of product does not mean identical manufacturing sites or suppliers

Sameness of product does not mean identical dossiers or documentation

Sameness of product does not mean identical indications or conditions of use globally

Multinational companies must have a process in place under their Pharmaceutical Quality System (PQS).

Principles described in **ICH guidance (Q8-10)** can ensure that any changes are evaluated scientifically in a manner appropriate to the product type. The quality assurance department(s) of the company ensures there has been an appropriate assessment of the impact of potential differences on the product quality, safety and efficacy.

Reference: IFPMA Points to consider on the importance of product sameness in the context of regulatory reliance

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Benefits of the use of Regulatory Reliance

Patients and Health care providers

Have more timely access to safe, effective and quality medical products

National Regulatory Authorities

Use resources more efficiently by avoiding duplicating work and providing opportunities to strengthen the regulatory system while maintaining sovereignty over decision making

Pharmaceutical Industry

Benefits from streamlined management of regulatory submissions and global supply systems and predictable, timely approvals

Reference: IFPMA-Collaboration, Convergence and Reliance

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Our position

- FIFARMA supports and promotes the adoption of reliance by all regulatory authorities of the region
- Health authorities and industry shall work continuously in partnership to improve and maintain regulatory convergence
- All relevant stakeholders shall be engaged to increase their understanding and applicability of reliance
- The use of reliance shall be accepted during the entire lifecycle of the products

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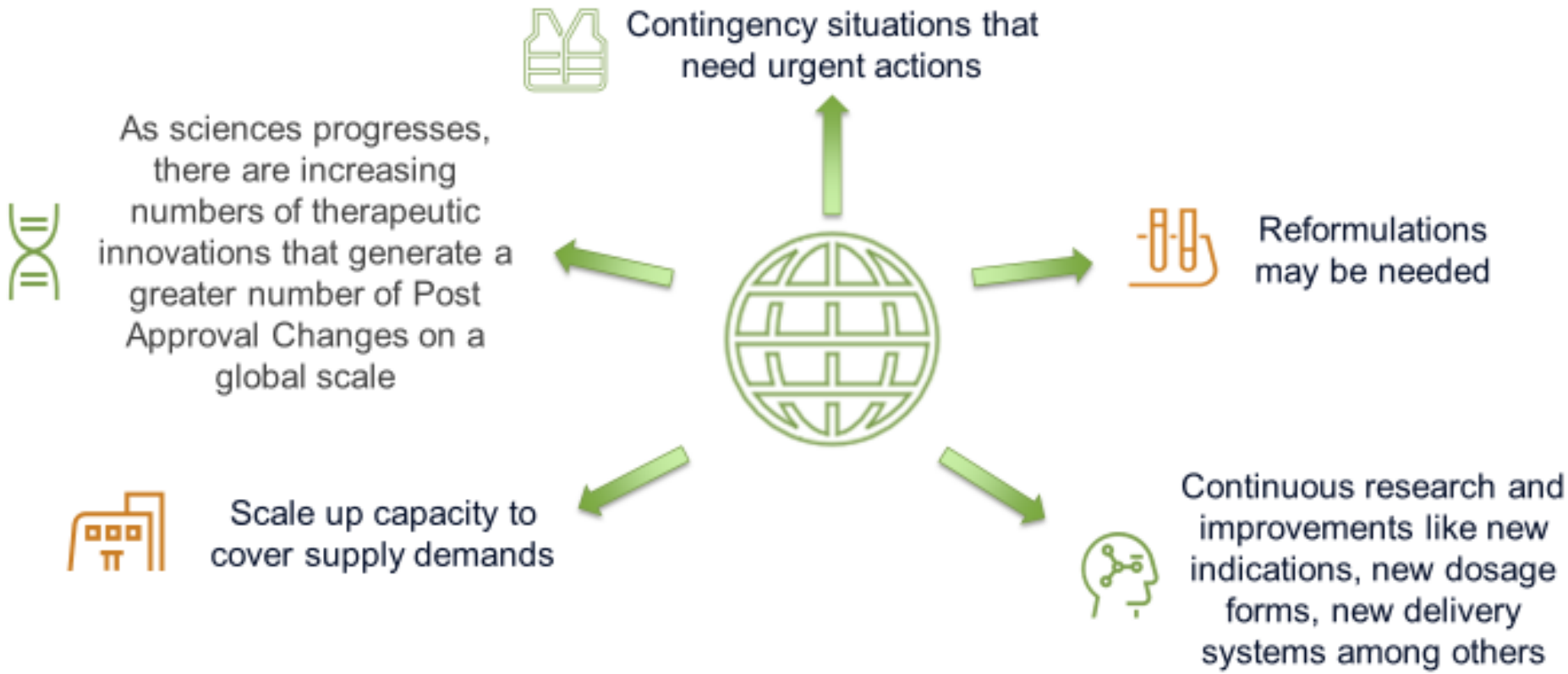
Reliance for post-approval changes (PAC)
Why is needed?



Reference: FIFARMA- Recommendations to apply regulatory reliance for the evaluation of post-approval changes

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Challenges of managing PAC in Latin America and the Caribbean

Reference: FIFARMA- Recommendations to apply regulatory reliance for the evaluation of post-approval changes

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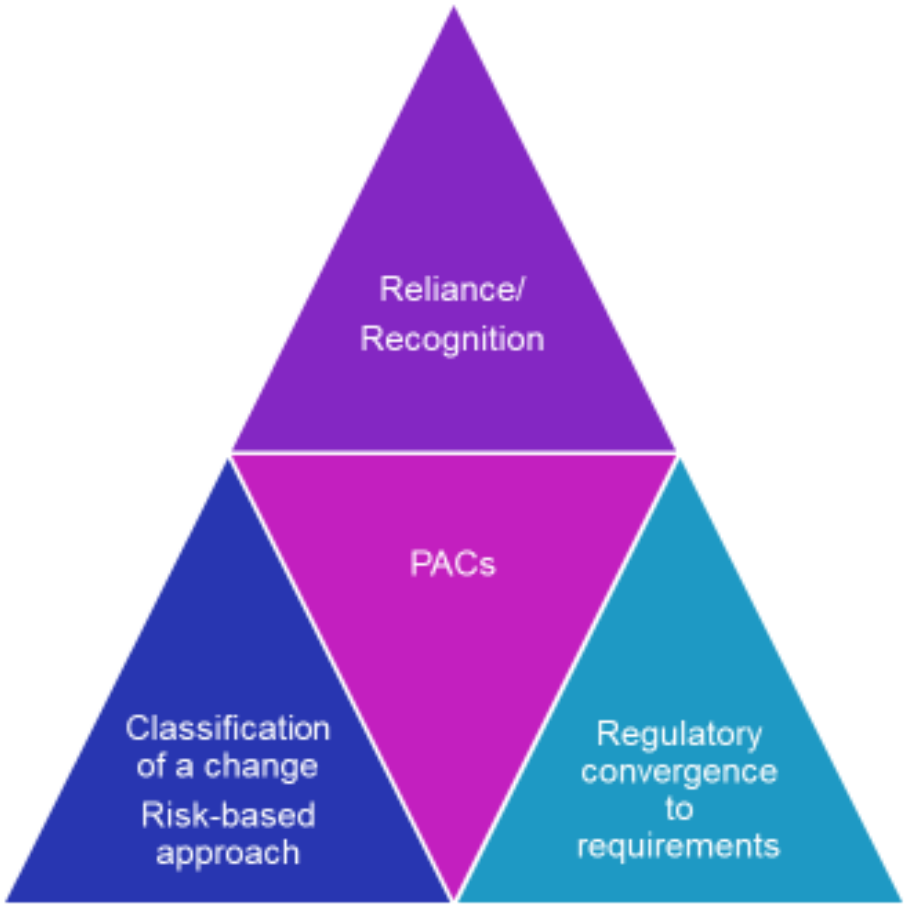
How to incorporate Reliance to PAC?



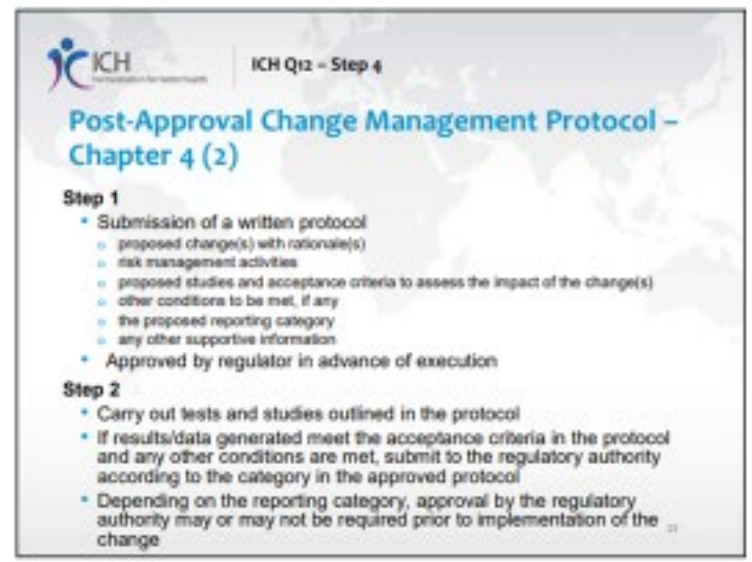
- Align approval times to WHO recommendation – maximum 6 months for major changes.
- Changes with no impact to quality, safety or efficacy should be managed internally, without any reporting to NRAs as per ICH Q12.
- The authority has the sovereignty to decide which PAC processes will apply through the reliance mechanism.
- The reference agencies and criteria for applying reliance must be clearly defined

Reference: EIFARMA- Recommendations to apply regulatory reliance for the evaluation of post-approval changes

Documentation to support Reliance in PAC

- **Proposed documents to enable reliance**
  - Approval- letter or equivalent from reference authority
  - Dossier with the affected sections according with local regulations
  - Cover letter (type of procedure)
  - Justification of sameness and classification of change
  - Local specific requirements are discouraged

- **The submission of a PACMP (Post Approval Change Management Protocol) can support an optimized analysis procedure for PAC**


ICH Q12 – Step 4

Post-Approval Change Management Protocol – Chapter 4 (2)

Step 1

- Submission of a written protocol
  - proposed change(s) with rationale(s)
  - risk management activities
  - proposed studies and acceptance criteria to assess the impact of the change(s)
  - other conditions to be met, if any
  - the proposed reporting category
  - any other supportive information
- Approved by regulator in advance of execution

Step 2

- Carry out tests and studies outlined in the protocol
- If results/data generated meet the acceptance criteria in the protocol and any other conditions are met, submit to the regulatory authority according to the category in the approved protocol
- Depending on the reporting category, approval by the regulatory authority may or may not be required prior to implementation of the change

Reference: EFARMA- Recommendations to apply regulatory reliance for the evaluation of post-approval changes

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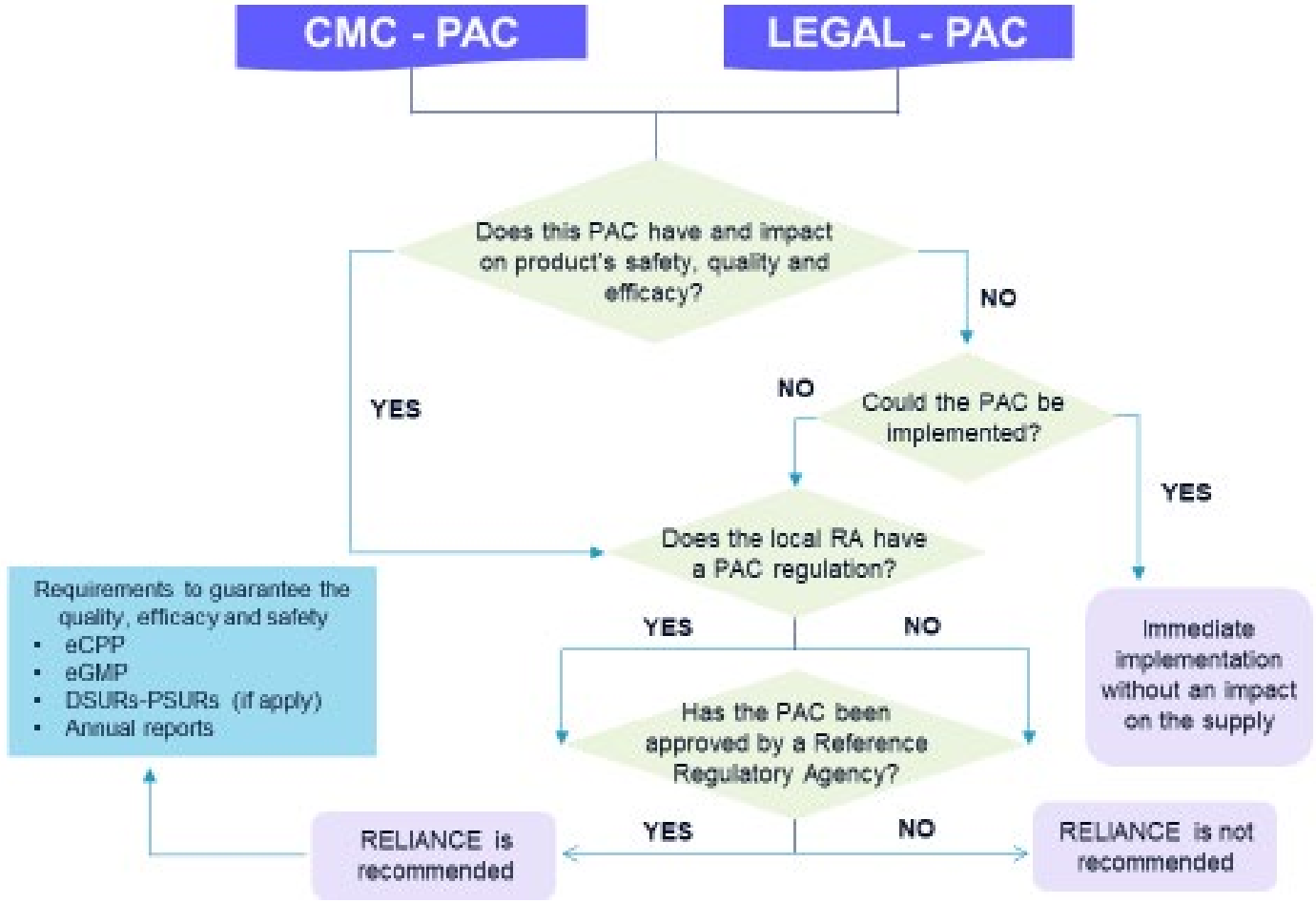
Flowchart: Post – Approval Changes (PAC) Reliance Implementation



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FIFARMA Position

- Reliance is an effective tool that can support National Regulatory Authorities achieve efficiencies
- The management of PAC in Latin America and the Caribbean faces various challenges, particularly for agencies with limited resources, **the lack of harmonization and the lack of specific regulations among others.**
- The adoption of reliance or unilateral recognition is recommended for a Post Approval Change strategy to achieve efficiencies, reduce backlog and allow product availability in the region

Reference: FIFARMA- Recommendations to apply regulatory reliance for the evaluation of post-approval changes

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Thank you

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