Reliance for post-approval changes: an industry perspective
FIFARMA
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.
Considerations for the use of reliance

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

Slide adapted from WHO, Annex 10, Good Reliance Practices, Page 4
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.
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
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
Reliance for post-approval changes (PAC) Why is needed?

As sciences progresses, there are increasing numbers of therapeutic innovations that generate a greater number of Post Approval Changes on a global scale.

Contingency situations that need urgent actions

Scale up capacity to cover supply demands

Reformulations may be needed

Continuous research and improvements like new indications, new dosage forms, new delivery systems among others

Reference: FIFARMA- Recommendations to apply regulatory reliance for the evaluation of post-approval changes
Challenges of managing PAC in Latin America and the Caribbean

Inconsistent classifications systems
Unpredictable and variable approval times
Different Regulatory Requirements
Post Approval Changes Challenges
Differences in implementation times
Lack of regulation/Limited resources
Divergent decisions based on the same product and information

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

Page 10
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
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 reciprocal reliance for the evaluation of post-approval changes.
Thank you