

The National Academies of Sciences, Engineering & Medicines

**Mutual Recognition Agreements and Reliance in the
Regulation of Medicines – 10 July 2019**

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Regulatory Reliance | Multiple advantages

All stakeholders impacted by regulatory systems have the potential of benefiting from Regulatory Reliance



Patients & Healthcare Providers

Timely access to safe, effective and quality medical products.



National Regulatory Agencies

Efficient utilization of resources by avoiding duplication of work and providing opportunities to strengthen the regulatory system, while maintaining sovereignty over decision-making.



Manufacturers

Streamlined management of regulatory submissions and global supply systems as well as predictable, timely approvals.

Regulatory Reliance | Current landscape

“The act whereby the regulatory authority in one jurisdiction may take into account and give significant weight to – i.e. totally or partially rely upon – evaluations performed by another regulatory authority or trusted institution in reaching its own decision. The relying authority remains responsible and accountable for decisions taken, even when it relies on the decisions and information of others.”

Definition taken from WHO's Good Regulatory Practices, 2016

Regulatory Reliance is already a reality

*Regulatory reliance is being practiced by some NRAs of different resource and capacity levels and independent of their maturity. In fact, streamlined processes for handling regulatory reliance can be seen as **an exemplar of maturity**.*

ZAZIBONA
Regional Africa

Verification Route
HSA

MRA for GMP
Inspections
EMA & US FDA



Regulatory Reliance | Opportunities



National Regulatory Agencies (NRAs)

- Should be simple, straightforward and pragmatic
- Reliance-based regulatory procedures can be implemented at many stages in the product life-cycle
- For example:
 - Registration of new products
 - GMP, GCP, GLP inspections
 - Lifecycle management, e.g. post approval changes
 - Import Testing/Lot Release
 - WHO Prequalification Program, e.g. vaccines
- Depends on public health priorities; regulatory capability & NRA capacity

Regulatory Reliance | Challenges



National Regulatory Agencies (NRAs)

- Lack of regulatory convergence and varying implementation of WHO & ICH guidance.
- Additional, e.g. administrative requirements, for existing reliance schemes such as CPP.
- When information to be relied upon is not agreed in advance between NRAs.
- Lack of clarity over type and source of information: NRA or Manufacturer?
- When no safeguards exist for confidentiality, i.e. IP and sharing of data

Regulatory Reliance | Post-approval Changes (PACs)

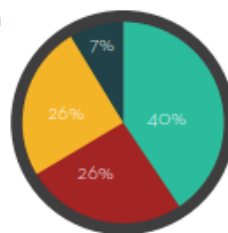


Variable Approval Timelines

In addition to varying classification categories for PACs and different country requirements, variable approval timelines were experienced leading to implementation delays.

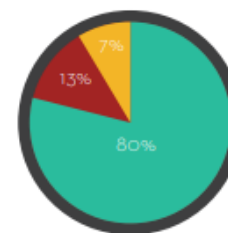
Asia Pacific Region

- 0-2 weeks
- 1-6 months
- 6-12 months
- >12 months



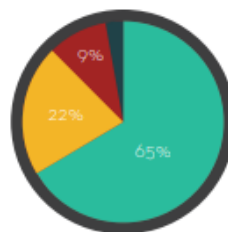
Latin America

- 0-2 weeks
- 1-6 months
- 6-12 months
- >12 months



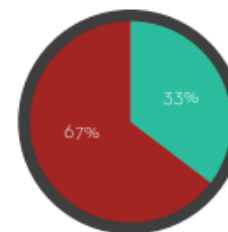
Rest of the World

- 0-2 weeks
- 1-6 months
- 6-12 months
- >12 months



EU/CH/AUS/NZ CAN/USA

- 0-2 weeks
- 1-6 months
- 6-12 months
- >12 months



Example of
change to
pharmacopoeial
method &
specifications

Regulatory Reliance | Post-approval Changes (PACs)



Manufacturers

- Growing divergence of PAC regulations, causing increased complexity across countries
- Major challenges are posed notably by variable or unpredictable timelines across NRAs for change, review, and approval

Opportunity:

- Leverage regulatory mechanisms, tools and guidance to streamline PAC review
- Enhanced use of electronic means for timely access to updated product safety information
- Enhanced communication and collaboration between NRAs, leading to reliance and mutual recognition

Regulatory Reliance | Practical Considerations



Guidance on Documentation

What documents are required?
How will these documents be used?
Who should be providing which documents?



Clear Procedural Guidance

Predictable and timely approvals;
Implementation of a risk-based approach;
Reduction in administrative requirements;
Publicly available list of accepted reference NRAs.



Implementing Regulatory Reliance

Regulatory convergence across different jurisdictions will foster regulatory reliance;
Regulatory reliance supports capability, collaboration & strengthens trust between Stakeholders.

Thank you!