Effective mechanisms for regulatory reliance systems

An Industry perspective

Nevena Miletic
(Global Regulatory Policy, F. Hoffmann-La Roche)
on behalf of IFPMA Africa Regulatory Network

A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?
With over **7000** medicines in development, the exciting new wave of medical innovation will play a key role in addressing the challenges faced by patients and healthcare systems.

Source: Health Advances analysis; Adis R&D Insight Database. March 2015, compiled by PhRMA
How all stakeholders can work together towards this goal?
Industry contribution | IFPMA

- **AMRH partner** - supporting national, regional and continental harmonization efforts
- Active **user** and **promoter** of regional collaborative / joint assessment / work-sharing procedures (pilot and established ones)

**Survey on industry experience** conducted in Q2 2019

*Objective:* to collect Industry knowledges in order to support improvements and give appropriate recommendations
- 78 responders, covering 39 countries
- Topics:
  1. Policy/Legal and Regulatory Reforms/ Regulatory System
  2. Registration and Market Authorization
  3. Reliance and Collaboration – general, and region-specific
Regulatory Systems | what is in place?

1- Most African countries have a **NRA in place** covering a large scope of activities

2- **Most product categories** are included

3- **Resource capacity** largely **varies** between NRAs

How to fulfill all assigned tasks, while maintaining efficiency and quality of work?
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.

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.

How to implement it?
Best practices?

https://www.ifpma.org/resource-centre/ifpma-position-paper-on-regulatory-reliance/
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 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.

And spans the product lifecycle

Some global examples:

Inspections:
MRA for GMP Inspections - EU & USA

Regulatory review:
ZAZIBONA work-sharing - Regional Africa
Abridged or Verification Reviews - Mexico, Saudi Arabia

Post-Approval Changes:
Verification - Singapore

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Implementing regulatory reliance provides stakeholders with opportunities that go beyond regulatory processes.

Harmonization will foster regulatory reliance. Implementing WHO and ICH guidance can facilitate the implementation of regulatory reliance mechanisms.

Changes to regulatory and legal frameworks should aim to leverage the benefits of regulatory reliance.

Regulatory reliance supports capability building. The learning and experience-sharing aspect of regulatory reliance will allow NRAs to address potential capability gaps in the longer term.

Strengthening trust between stakeholders. Collaboration and dialogue will help to create and build trust, which is the foundation of regulatory reliance.

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Harmonization and Regulatory Convergence | Prerequisites for establishing reliance models

- National guidelines are aligned with International Standards (WHO, ICH etc.)

Continue and promote work on harmonization and regulatory convergence
Regional Procedures | Industry experience

- Strong interest from companies

- Yet, some obstacles/barriers to overcome
  - Lack of sufficient information/ awareness/ transparency
  - Anticipated challenges in the management of PAC
  - Product portfolio mismatch
  - ...

Continue promoting work on collaboration and understanding of the different reliance pathways in place - bringing awareness amongst industry and beyond is needed to improve and fully benefit from regulatory reliance mechanisms
Regulatory Reliance | Practical Considerations

Key elements for NRAs to consider when establishing and implementing effective regulatory reliance mechanisms

**Guidance on Documentation**
- What documents are required;
- How these documents will be used;
- Who should be providing which documents

**Clear Procedural Guidance**
- Predictable and transparent timelines;
- Simple, straightforward and pragmatic procedures;
- Publicly available list of accepted reference NRAs.

**Reduction in Regulatory Burden**
- Faster approvals;
- Reduced workload for NRAs and industry;
- Possibility of reliance through the entire product lifecycle.

Effective mechanisms benefit patients, NRAs and Industry!

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Challenges are what makes life interesting, and overcoming them is what makes life meaningful.

Let us make a difference for patients in Africa – together!
Back up
Regulatory Reliance | Examples

When can reliance be used?

- Dossier submission/registration/public assessment reports
- GMP, GCP, GLP
- Lifecycle management, e.g. post approval changes
- Import Testing/Lot Release
- WHO Prequalification Program, e.g. vaccines
- Others...

Depending upon the public health priorities and regulatory capability and capacity of NRAs

https://www.ifpma.org/resource-centre/ifpma-position-paper-on-regulatory-reliance/
Regulatory Reliance | Challenges

National Regulatory Agencies (NRAs)

- Administrative requirements for existing reliance schemes, e.g. CPP.
- When information to be relied upon is not agreed in advance between NRAs.
- Misalignment over source and volume of information: NRA or Manufacturer?
- No safeguards exist for confidentiality, i.e. IP and sharing of data.
- Need to map out implications of increasing reliance globally within existing regulatory networks/schemes.
- Post approval changes to be discussed in the following slides.

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As regulatory systems develop and evolve worldwide, the (divergent) requirements to submit and review PACs are increasing.

Example of change to pharmacopoeial method & specifications
In addition to varying classification categories for PACs and different country requirements, variable approval timelines were experienced leading to implementation delays.

Major challenge:
- Variable or unpredictable timelines across NRAs for change, review, and approval

Opportunities:
- Leverage regulatory mechanisms and tools 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