Regulatory Agilities and Lessons Learned from Covid-19

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Why Regulatory Agilities?

Strengthen standard normative process

GOAL: Strengthen regulatory systems by simplifying, harmonizing and using reliance mechanisms to increase efficiency and accelerate patient access to all medicinal products.

Next pandemic preparedness

GOAL: Maximize to the highest degree possible global coordination, collaboration, reliance and harmonization of regulatory requirements, procedures and guidelines to facilitate rapid development, approval and distribution of products aimed at fighting the global health emergency, while securing patient access to other medicinal products.

Regulatory Agilities - Project Objectives

- During the COVID-19 pandemic, many examples have emerged of regulatory agility in relation to pharmaceuticals
- Several national and regional trade organizations of IFPMA gathered information around this trend
- Consolidating & exploring recommendations to address the following:
  - **How should the industry and national regulatory authorities prepare for future pandemics?**
  - **Which of the regulatory agilities could/should be integrated into standard normative processes?**

Topics applicable to all regulatory agilities

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Global Findings & Recommendations

STANDARD NORMATIVE PROCESS

- **Increase digitalization**, embrace virtual working, use of e-documents and digital methods.
- **Risk-based approaches** to improve efficiency (e.g. rolling review).
- Promote **transparency and reliance** to maximize efficiencies.
- Strive for broader **adoption and implementation of WHO and International guidelines.**
- Feed recommendations into the NRA's work on the **future vision for the NRAs.**

PANDEMIC PREPAREDNESS

- Leverage **virtual working and digital methods** as much as possible.
- **Temporarily delay/health non-urgent activities**
- Ensure **speed and clarity** when introducing agilities.
- **Increase collaboration and data sharing among all stakeholders.**
- **Provide guidelines** to sponsors.
- Ensure **early and continuous dialogue between sponsors and NRAs.**
- Share experiences and knowledge on **effectiveness of regulatory agilities.**
- **Reduce burden** on Healthcare Professionals.

Regional Overview: Asia

Quality | Regulatory | Clinical trials

Trends

- **Integrate global approach**
- **Consider governments' political will**
- Improve **digitalization** & use of **E-documents**
- In pandemic situation use **accelerated processes** and **reliance mechanisms**

- **Expedited review** to approve COVID-19 vaccines.
- **Remote inspections**
- **'Grace periods' for PACs implementation**.
- **Alternative measure** for sponsor/clinical trial site.

Recommendations

Opportunities

Challenges

- Clinical trials databases only in **local languages**
- **Complex addition of multiple sites**
- **Different knowledge / experience among governments**
- Burden from pandemic on NRAs led to **delayed approval of other products**

- **Enablers for agilities in pandemic times**
- **NRAs** to make **content easier to understand**
- **Advocacy** from local trade associations to help adopt flexibilities in standard normative process.
- **Virtual inspections** allow for resource efficiency.

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GMP: Good Manufacturing Practice. NRA: National Regulatory Authority. PAC: Post Approval Change.

How could Asia prepare for the future?

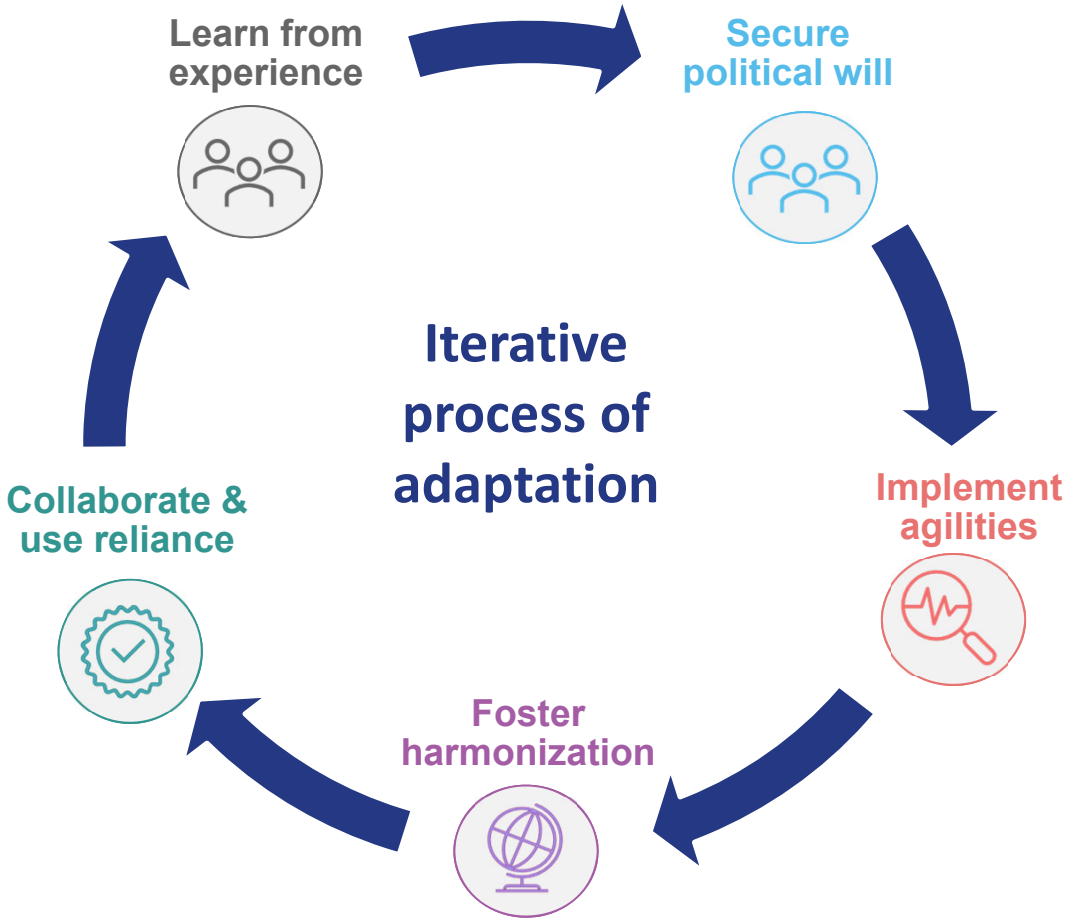
STANDARD NORMATIVE PROCESS

- Consider different **governments' political will** when implementing flexibilities.
- Adopt a **pragmatic approach.**
- **Optimize good reliance practices** in medicines regulations in line with WHO recommendations.
- **Improve digitalization** (trusted platforms for NRAs to access information/data and take decisions remotely, for remote inspections, for accelerating processes).
- **Increase communication** among stakeholders to **maintain trust.**

PANDEMIC PREPAREDNESS

- **Prioritize agilities** for treatments/ vaccines development and approval and simplify administrative process.
- **Ensure clear criteria for prioritization** of products to benefit from flexibilities and publish **clear procedures.**
- NRAs to make communications to the public **easier to understand**.

How can we fit it all together?



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Thank you!