

IFPMA Recommendations:

Regulatory agilities applied to regulatory processes¹

¹Processes for submission, review and approval of applications for marketing authorization and post-approval changes.

Introduction

The use of regulatory agilities during the COVID-19 pandemic allowed the development and approval of safe COVID-19 and non-COVID-19 related pharmaceutical products and facilitated the continuity of regulatory activities during the emergency. Agilities included increased digitalization of ways of working, increased collaboration and engagement among stakeholders and risk-based approaches to decision-making (accelerated reviews and approvals in absence of data provided in the future).

The experience of the pandemic offered unprecedented learnings on which the biopharmaceutical industry and NRAs (National Regulatory Authorities) can build on to improve the regulatory framework and the pharmaceutical industry is committed to playing a central role in this continuous effort.

For this reason, IFPMA is offering policy recommendations, for the attention of NRAs and the industry, to improve both the standard normative process and to enhance pandemic preparedness.

When considering recommendations on the use of agilities to improve standard normative processes, NRAs should consider local circumstances and needs.

Recommendations to improve pandemic preparedness focus on maximizing global coordination, collaboration, reliance and harmonization of regulatory requirements, procedures and guidelines to facilitate development, assessment and approval of products. Recommendations for the use of agilities should apply to all products.


The policy recommendations of this paper focus on maximizing efficiency, increasing collaboration, improving practicalities and supporting sustainability.



Efficiency



Collaboration




Practicalities



Sustainability



Digitalization



Early dialogue




Evidence




Environment



Ways of working



Transparency



PACs




Decision-making



Labeling & packaging



Reliance



Harmonization





Efficiency



Digitalization



<ul style="list-style-type: none"> • Improve technology facilities and all stakeholders to embrace virtual working and digital methods as much as possible to maximize efficiencies. • Institutionalize the use of electronic documents and methods, such as e-CPP (Certificate of Pharmaceutical Product) and e-records for GMP (Good Manufacturing Practice), e-signatures, e-submissions. • Accept digital tools for capturing endpoints to help advance clinical research. 	<p>Pandemic Preparedness</p> <ul style="list-style-type: none"> • Leverage virtual working and use of digital methods as much as possible. • Digitalization should be perceived as evolving with social and behavioural digital trends. <p>Standard Normative Process</p>
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- In **Africa**: Enhance digitalization, technology infrastructure and use of electronic tools to improve efficiency, avoid loss of documents, enable reliance and use of work from different jurisdictions.
- In **Asia**: Ensure trusted platforms for NRAs to access information/data and take decisions remotely (e.g. for accelerating processes).



Ways of working



Decision-making



Reliance

<ul style="list-style-type: none"> • Adopt risk-based approaches throughout the product lifecycle for all products, if needed, such as: rolling reviews, expedited approvals and approvals in absence of certain data provided at a later stage. • Promote joint regional initiatives and reliance and encourage NRAs to share Public Assessment Reports to enable reliance. • Reach international convergence on the minimum data package for applications. 	<p>Pandemic Preparedness</p> <ul style="list-style-type: none"> • Develop fit-for-purpose ‘ready-to-go’ frameworks with risk-based approaches for submission, review and approval, ideally including the implementation of a single dossier for global markets. • Be mindful of time and resources; temporarily suspend non urgent activities and restart them before creating a backlog; also attempt to leverage risk-based approaches to ensure continuity of activities. • Increase use of collaborative review, joint assessments, consortiums and work-sharing. <p>Standard Normative Process</p>
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<ul style="list-style-type: none"> • In Africa: Integrate reliance practices into the operations of the NRAs and increase work-sharing and joint assessment, also in light of the set up of the AMA (Africa Medicines Agency). • In Latin America & Caribbean: Improve publicly available information (marketing authorization, Public Assessment Reports and product information) to enable reliance, especially for regional reference agencies. 	<ul style="list-style-type: none"> • In Africa and Latin America & Caribbean: leverage reliance as much as possible as NRAs might have limited resources.
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Efficiency



Harmonization

- **Increase harmonization** across different jurisdictions, including for PACs, by the **adoption of international guidelines** such as from WHO and ICH (International Council for Harmonisation) to enable a more efficient global regulatory approach and to foster reliance.
- Integrate principles of **Good Regulatory Practices and Good Reliance Practices** and support WHO related activities.
- WHO to support **harmonization of product labeling** and information requirements, so that an aligned global technical standard can ensure information can easily be exchanged globally.

Pandemic Preparedness

- **Reach convergence in the emergency response** and **avoid multiple emergency plans** (via international cooperative schemes such as ICMRA).
- Reach international convergence on the **minimum data package for applications** (through ICMRA) and implement a **single dossier** for global markets.
- **Streamline and standardize regulatory requirements.**
- Ensure a **harmonized global framework for PACs** and guidelines, agree on one set of queries for each PAC and implement ICH principles.

Standard Normative Process



- In Africa: **Prioritize harmonized guidance** for NRAs across the continent.
- In Latin America & Caribbean: NRAs to consider **use of the WHO GBT (Global Benchmarking Tool) indicators** to develop regulations, policies, and procedures that facilitate strong regulatory emergency response.



Collaboration



Early dialogue



Transparency

- Encourage **NRAs to share appropriate data** such as public assessment reports (PAR). If more information is needed, share confidential review documents via secure platforms, safeguarding intellectual property and confidentiality, assuming memorandum of understanding (MOU) is in place.
- Promote **transparency, open communication, and collaboration** among all stakeholders.
- Increase **alignment** with other leading NRAs.

Pandemic Preparedness

- Ensure **early, frequent and transparent dialogue** between all stakeholders.
- **Maximize collaboration and data sharing** among all stakeholders.
- Share **experiences and knowledge** on effectiveness of regulatory agilities.
- Ensure **speed and clarity** when introducing agilities; provide clear **guidelines** to manufacturers and clear communication to the attention of the **public** and HCPs.
- **Support public confidence:** ensure clear communication on processes and safety of products. Consider **holding meetings open to the public** to promote transparency with independent scientific debates, for countries which do not do so already.
- Share experiences and knowledge gained on the effectiveness of regulatory agilities.

Standard Normative Process



- In Africa: **Increase transparency** and ensure **clear and understandable policies** for all stakeholders are in place. NRAs to also give **clear public information on product safety.**



Practicalities



Evidence



PACs



<ul style="list-style-type: none"> • Broaden the use of real-world data / real-world evidence and modernize regulatory evidence generation. • Further enable use of digital tools to capture endpoints. • Enhance evidence generation to inform on diverse populations 	<p>Pandemic Preparedness</p> <ul style="list-style-type: none"> • Weigh benefit/risk to guarantee quality, efficacy and safety of products, with ongoing generation of data. • Streamline evidence requirements when possible. • Support convergence of global data required. <p>Standard Normative Process</p>
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• In the **European Union**: Make EU Emergency use authorization pathway available.

<ul style="list-style-type: none"> • Enhance collaborative review and reliance practices, align on a unified set of queries for each PAC. • NRAs to fully implement and use ICH (International Council for Harmonisation) Q12. • Identify, maintain and adopt best practices (emphasis on submission process) and increase global harmonization. 	<p>Pandemic Preparedness</p> <ul style="list-style-type: none"> • Exercise risk-based regulatory agility for the data requirements (e.g. waiver of samples) • Make clear prioritization of changes based on public health and supply impact. • Maximize collaborative review and reliance, accelerate and simplify processes • Reach a global PACs framework and ensure broad adoption of international guidelines. <p>Standard Normative Process</p>
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• In the **European Union**: Revise European Union variations regulation to **enable PACs framework** and align it globally on joint scientific advice.



Practicalities



Labeling and packaging

- **Gradually implement e-labeling** and removal of requirement for printed product information, protect patient safety by increasing accessibility to up to date product information, promote treatment adherence and improve information sharing among all stakeholders.
- **Share labeling between countries** to improve supply chain resilience and efficiency.
- Integrate e-labeling **into the wider digital healthcare system** (link e-labeling with e-prescribing and e-health records to deliver integrated healthcare).

Pandemic Preparedness

- Implement an **electronic central platform** for sharing labeling.
- **Temporarily consider labeling agilities** such as allowing products to be distributed with English-only packaging and allow for English-only printed package leaflet (in geographies where it is possible such as in the EU).
- **Remove the requirement for printed product information** (once e-labeling is well established).

Standard Normative Process



Sustainability



Environment

- **Increased digitalization** to support environmental sustainability.
- **Adopt virtual meetings, e-documentation and centralized digital platforms.**

Pandemic Preparedness

- Leverage **virtual working and digital methods** as much as possible, including use of **e-labeling**.

Standard Normative Process

Background

IFPMA represent research-based biopharmaceutical companies, and regional and national associations across the world. Clarivate is a global leader in providing trusted insights and analytics to accelerate the pace of innovation. This document captures recommendations, derived from primary and secondary research and enriched by shared experience from the IFPMA Steering Group, to enhance the standard normative process and future pandemic preparedness. This document does not aim to provide an exhaustive list of global and regional recommendations.

Acronyms

AMA (Africa Medicines Agency)	ICH (International Council of Harmonization)
CPP (Certificate of pharmaceutical product)	NRA (National regulatory authority)
FDA (Food and Drug Administration)	PAC (Post-approval change)
GBT (Global Benchmarking Tool)	RWD (Real world data)
GMP (Good manufacturing practices)	RWE (Real world evidence)
HCP (Healthcare professional)	WHO (World Health Organization)

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