

17-21 October 2022

**An overview of key concepts and
recommendations from ARC2022**

ASIA PAVING THE WAY IN A NEW REGULATORY WORLD — WHAT DOES THIS MEAN FOR PATIENTS, REGULATORS, AND INDUSTRY?

Organized by:



**In partnership
with:**



The virtual 11th Asia Regulatory Conference ([ARC](#)) was hosted by the International Federation of Pharmaceutical Manufacturers and Association ([IFPMA](#)), together with the Singapore Association of Pharmaceutical Industries ([SAPI](#)). For more than a decade, ARC has established itself as the premier forum for dialogue, recommendations and expertise-sharing on the regulatory environment in Asia. The conference attracts speakers and participants from National Regulatory Authorities (NRAs) and representatives from regulatory centers of excellence, international organizations, patient groups, and the pharmaceutical industry from across the world.

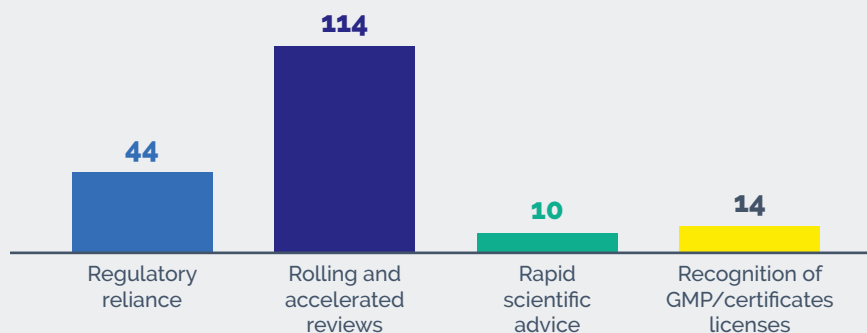
The conference stimulated discussions over four days (17-21 October 2022). Each day, it saw more than 350 stakeholders exchanging on advancing regulatory science, reliance, convergence and quality, safety, and efficacy of medicines and vaccines in Asia. This document outlines key concepts and recommendations from ARC2022.



Day 1: Regulatory agilities and further accelerating patient access to safe and effective medicines and vaccines

Regulatory agilities – The use and implementation of regulatory agilities, whether inside or outside a public health emergency context, should maintain trust and support public confidence in both national regulatory authorities (NRAs) and industry. Regulatory agilities include a broad range of both regulatory (e.g. rolling reviews, virtual inspections) and scientific (e.g. alternative process validation approaches, predicted shelf-life) tools. Much is being done to help improve coordination and collaboration in the use and implementation of these tools amongst all stakeholders.

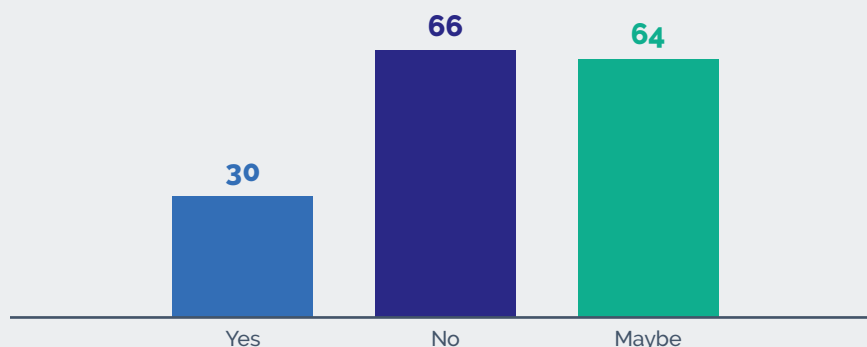
What do you think was the most important regulatory agility to be used during the Covid-19 pandemic?

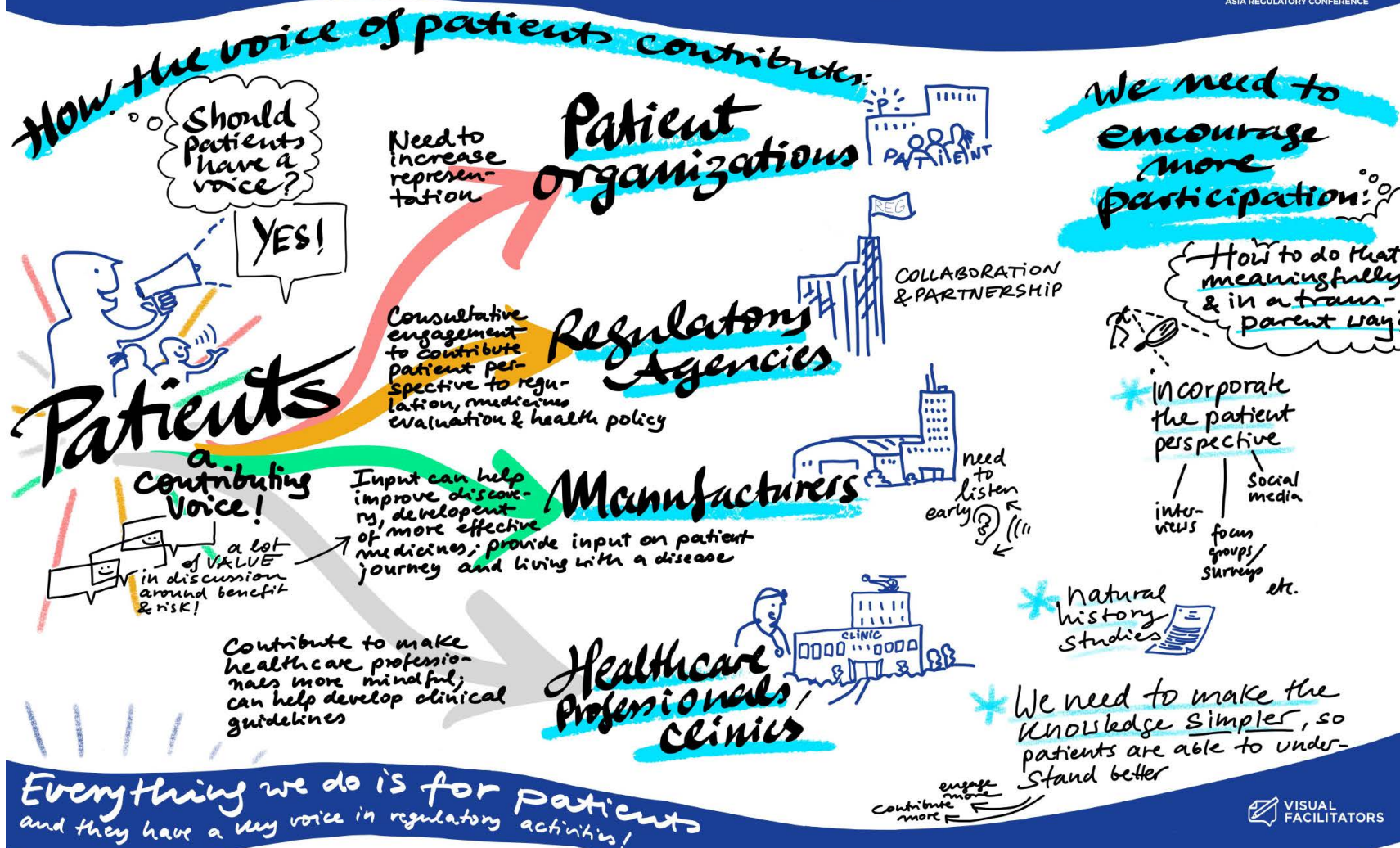


Best Practices – Use of reliance, digital platforms, acceptance of e-documentation, and process integration highlighted areas where learnings from their use and application could be further implemented in Asia. Presenters also identified the promotion of regulatory agilities, convergence and harmonization, coordination amongst NRAs, and use of mutual recognition agreements as additional elements for fostering pandemic preparedness in the region.

Patient engagement – Understanding the perspectives of patients is critical to the development of medicines and vaccines that are safe, effective, and meet patients' needs. Engaging patients in all aspects of pharmaceutical development and clinical management will help to facilitate adherence and uptake of medicines and vaccines as well as improving health literacy overall. The conversation with patients highlighted also the need for better understanding by NRAs and Industry of patient engagement processes at a national level in Asia.

Are you familiar with patient engagement in your country?





Learn more:

- [Presentations on regulatory agilities](#)
- [Video recording from Day 1](#)
- [Video presentation by Dr Mimi Choong](#), Chief Executive Officer, Health Sciences Authority, Singapore

Day 2: Reliance, Convergence/Harmonization and Risk Based Approaches to Post Approval Changes (PACs)

The post-approval changes (PACs) session brought together experts from industry, NRAs and WHO to discuss and present the challenges and opportunities of using principles of convergence & harmonization; reliance; and risk-based approaches to accelerate the submission, review and implementation of the necessary changes needed to ensure continued availability of quality efficacious and safe medicinal products.

Convergence & Harmonization - Understanding the global regulatory network and how individual countries can link into regional or international harmonization and convergence efforts can support timely access to innovative medicinal products and foster regulatory capacity building. Industry plays a role in these efforts by providing a global perspective and working with NRAs to highlight the value of applying these principles.

Reliance - Applying the WHO good reliance practices is a defined way of using global resources more efficiently but does require various enablers to be present and utilized. Most of these enablers are present to some extent or another in different countries and there is a willingness and ability from NRAs and companies to implement reliance principles to accelerate the approval of PACs.

Risk-based approach - Company's pharmaceutical quality systems (PQSs) effectiveness can be evaluated in relation to risk-based change management principles. Applying and demonstrating a clear and consistent risk-based classification enables the maximization of the benefits of innovation and continual improvement. A specific PAC may be categorized differently depending on the level of knowledge, risk controls, and PQS effectiveness. The outcomes of the risk assessment are derived on change planning, prioritization, implementation, and timelines. The accuracy of the risk assessment associated with a PAC should be in line with the complexity and/or criticality of the change.

All the principles outlined above are being used to accelerate and streamline the submission, assessment and approval of PACs across the world, enabling rapid access to quality, safe and efficacious innovative products.

Learn more:

- [Presentations on post-approval changes](#)
- [Video presentations on post-approval changes](#)

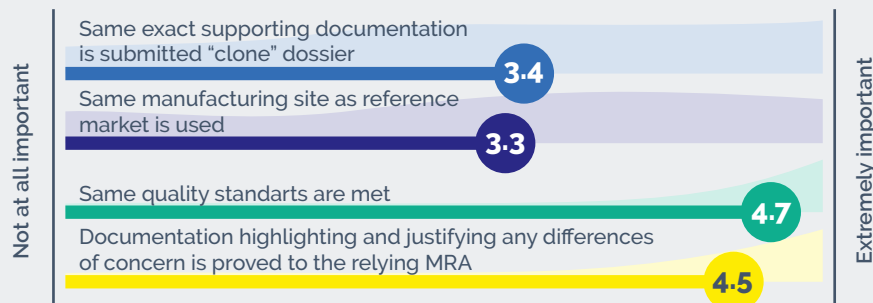
Day 3: Delivering products with the same quality standards to patients everywhere

This session provided an overview of different mechanisms in place to ensure that products provided by multinational pharmaceutical companies around the world adhere to the same high-level quality standards.

Supply chain integrity and resilience – These are important components of patient access to medicines and vaccines, and flexibility is needed in supply chain manufacturing and distribution in order to respond to dynamic supply needs. Optimizing regulatory frameworks through GMP convergence, aligned inspection processes and NRA cooperation inspection programs will avoid duplication and redundancy, facilitating reliable global supply chains.

Product sameness - Mutual trust between all parties is the foundation of reliance. When applying reliance, a mutual understanding of product sameness is critical. Nonetheless, regulatory reliance can always be used as long as the essential quality product characteristics are the same. Defining what different parties consider in their definition of "sameness" for pharmaceutical products is important to foster reliance. Though often time more than one manufacturing site is used to ensure uninterrupted supply of medicinal products, industry is ready have a preliminary discussion with NRAs to highlight any differences of concern and provide the evidence to NRAs decide if such differences have no impact on the quality, efficacy and safety of the physical product.

How important is for each of these conditions to be met when assessing "product sameness" in order to apply reliance?



In-country testing - Collaboration between NRAs and implementation of reliance on testing from networks of regional control testing laboratories can eliminate redundant testing and speed up supply to patients. Risk-based national strategies for quality control, increased transparency and international alignment will reduce effort duplication through, for example, the granting of waivers on in-country testing. This is specifically important in the context of public health emergencies or natural disasters to ensure uninterrupted supply of medicines. In conjunction with reliance, a robust post-marketing surveillance system is a key tool in strengthening national quality control strategies without increasing the risk of supply interruption/drug shortages that registration testing may cause.

Learn more:

- [Presentations on quality standards](#)
- [Video presentations on quality standards](#)

Expansion, Collaboration, Training - ICH continues to grow and expand its membership as well as the number of topics that it is addressing. The expansion of ICH is demonstrating a broader impact in building regulatory science expertise and networks globally. Factors to ensure the future success of ICH include efficient and effective training where there are many initiatives to strengthen this area e.g. new training associates, diversified training tools. Collaboration with new stakeholders, e.g. ICMRA, IPRP, PIC/S, patient organizations, academia is also important to build trust and confidence.

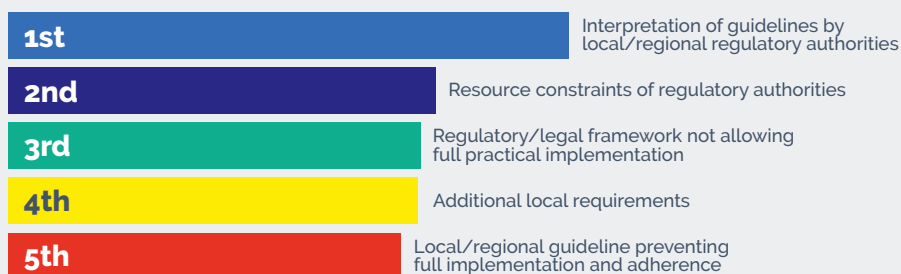
What are the key factors for ICH success moving forward (rating from 1 to 6)?



ICH Efficacy Guidelines - These guidelines should be considered and used in an integrated and holistic manner rather than focusing on only one guideline or subsection. Aligning expectations between industry and NRAs is key to successful application of the guidelines overall.

Guideline Implementation - Global implementation of ICH Guidelines is critical for regulatory harmonization and convergence, and good progress is being seen in the Asia region to implement ICH guidelines. However, additional tailored regional and local training activities may be needed to further facilitate implementation, and broader representation in the ICH EWGs will also help.

What do you consider as key factors impeding the full benefits of applying ICH guidelines in Asia (rating from 1 to 5)?



Learn more:

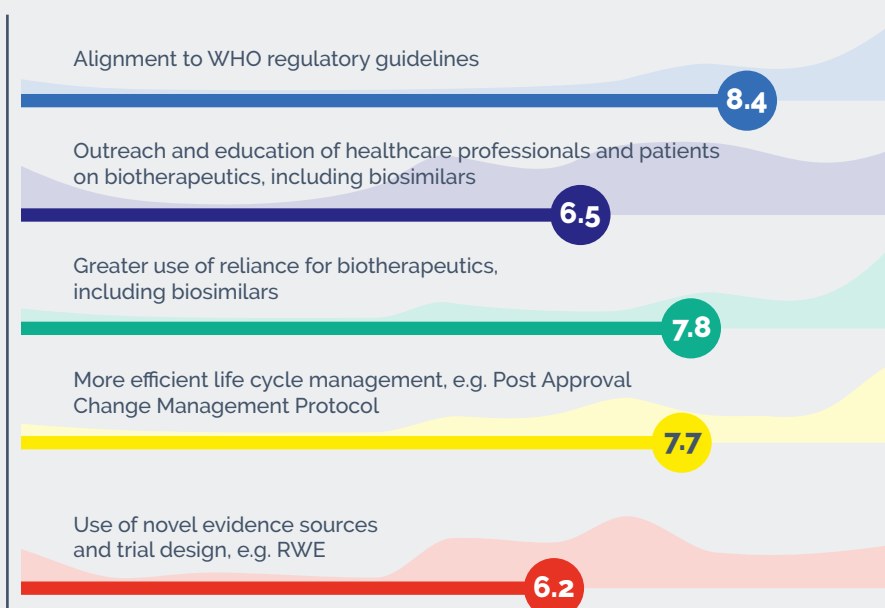
- [Presentations on ICH](#)
- [Video presentations on ICH](#)

Day 5: Changing regulatory landscape of Biotherapeutics and Advanced Therapy Medical Products (ATMPs)

Biotherapeutics: Biotherapeutic products, which are neither originator products nor biosimilars, are approved in several developing nations. In some countries, there is a need to foster a better understanding of what is meant by the term 'biosimilars'. The inappropriate labeling of products as biosimilars is a barrier to the uptake of biosimilars as it decreases confidence in biosimilar use. These products are referred by WHO as 'non-innovator products', and can make up a substantial proportion of products on the market. The practice of interchangeability and the naming of biosimilars which are related to the use of biosimilars are evident issues. Each NRA has their own approach on the designation of interchangeability, and there is still no consensus among countries on the naming and labelling of biosimilars. Some important framing changes in global policy recommendations in the biotherapeutic space include:

- Focus for evaluation centers on the totality of evidence, and no longer refers to an overall 'stepwise' development;
- Non-locally approved reference products can be used, but should be licensed in a "well-established regulatory framework" with experience in the evaluation of biological products and post-marketing surveillance activities;
- Relatively (even) greater emphasis on the quality and in vitro evidence as the foundation for biosimilarity;
- PK and PD studies may be sufficient for establishing confirmatory evidence of biosimilarity;
- Confirmatory efficacy trial may not be necessary if sufficient evidence for biosimilarity is established in other parts of comparability exercise;
- Experience as a prerequisite for NRAs which can be an opportunity for greater reliance in biosimilar approvals.

What should we prioritize for action to ensure greater access of biotherapeutics, including biosimilars, for patients in Asia? (rate from 1st to 5th)



ATMPs - As regulatory frameworks are rapidly evolving, continued analysis of national regulatory landscapes for ATMPs is necessary in order to identify differences and to share best practices. One of the challenges in regulating cell, tissue, and gene therapies is to establish a clear definition that determines product classification for ATMPs, and the applicability of the corresponding regulations. WHO's new CGTP document is viewed as a first step towards addressing five key priorities for WHO and Member States by ICDRA. It provides definitions for some key terms, a means for categorizing HCTs and ATMPs, key elements for establishing an effective regulatory framework, and provides an annotated bibliography of relevant references and resources. As newer therapies and technologies push the limits of regulatory and scientific expertise both within the agency and among other key stakeholders, a multiparty engagement and collaboration is essential to bring such novel and life-saving products to clinics as fast as possible yet protecting patient's health and safety.

Learn more:

- [Presentations on ATMPs](#)
- [Video presentations on ATMPs](#)



