

# ARC 2020

ASIA REGULATORY CONFERENCE

## SUMMARY REPORT

Webinar Series  
3 – 6 November  
2020

10<sup>th</sup> Asia Regulatory Conference

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BUILDING TRUST & PARTNERSHIP  
TO DELIVER UHC IN ASIA



**IFPMA**

Partnered by

Pharmaceutical Association of Malaysia - PhAMA

## **10th Asia Regulatory Conference**

*The virtual conference 10<sup>th</sup> [Asia Regulatory Conference \(ARC\)](#), was hosted by the International Federation of Pharmaceutical Manufacturers & Associations ([IFPMA](#)) as a key Asian regulatory platform to exchange opinions and seek recommendations on the regulatory environment in Asia. The central theme revolved around regulatory reliance and building trust & partnership to deliver [Universal Health Coverage \(UHC\)](#) in Asia, and stimulated debates on capacity building and recent advancements in the region. The short webinars took place over four days and were held in collaboration with Pharmaceutical Association of Malaysia ([PhAMA](#)) as a co-host with engagement from the Malaysian regulatory agency, [NPRA](#). We were delighted to host speakers and participants from National Regulatory Authorities (NRAs), international organizations and the pharmaceutical industry not only from Asia, but also from other parts of the world.*

### **Executive summary**

Patients worldwide have a fundamental right to access medical care and life-saving medicines without compromising global standards of safety, quality, and efficacy. Development and implementation of globally aligned and harmonized regulatory frameworks is paramount to achieve this goal.

There are varying levels of maturity and regulatory capacity of National Regulatory Authorities (NRAs) across Asia, which results in regulatory hurdles at different levels. Yet, there are ample opportunities for strengthening regulatory systems in the region. These include promoting and implementing regulatory reliance and committing to building capacity to enhance competence and skills for effective regulatory oversight.

[Regulatory reliance](#) represents a more efficient way of regulating medicinal and healthcare products, augmented by regulatory cooperation, convergence, capacity building, strengthening systems, and advancing regulatory science. Patients and healthcare providers benefit from effective implementation of regulatory reliance, improving timely access to safe, effective, and quality medicinal products.

Efficient use of resources by regulators avoids duplication of work. It provides opportunities to strengthen the regulatory system through collaboration while maintaining sovereignty over national decision-making. Regulatory reliance is a useful tool in preparedness and response for public health emergencies such as seen during the COVID-19 pandemic.

Regulatory reliance is built with an underlying trust and confidence in cooperation. Building trust requires an open dialog with the public, patients, and healthcare professionals for more efficient and effective regulatory oversight and faster access to medicinal products. The outcome is based on robust regulatory processes and standards.<sup>1</sup>

Collaboration and work-sharing have come into the spotlight as the world navigates the challenges posed by the COVID-19. Today's reality and demands mean that regulatory agencies will continue to generate quality national decisions and increase their collaboration with each other to avoid duplication of effort. Limiting cooperation may result in increased regulatory burden and inefficient use of resources, which will impact the timely access to life-saving medicines. Regulatory reliance is now recognized as an integral part of the universal healthcare ecosystem and becoming a part of the present-day lexicon's regulatory parlance.

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<sup>1</sup> For more information on the topic, the DUKE-NUS Centre of Regulatory Excellence ([CoRE](#)) launched an [e-brochure](#) on Regulatory Systems Strengthening (RSS) for health products in the Asia Pacific region. It explains the importance of regulatory agility, convergence, reliance and capacity building as the key building blocks to strengthen regulatory systems ultimately benefiting the population across the region.



## **Day 1 – Regulatory Reliance**

[Faridah Aryani, Malaysia MoH](#), started the day by highlighting that regulatory reliance should be implemented with clear public health priorities based on medical needs and regulatory capacity assessments of National Regulatory Authorities (NRAs). Regulatory reliance can help NRAs use their resources more efficiently, build capacity, reduce duplication of effort, and ultimately promote timely access to safe and quality-assured medicines. She continued to argue that NRAs maintain independence, sovereignty, and accountability in regulatory decision-making by applying reliance in their daily practice.

A similar message was also highlighted by [Samvel Azatyan, WHO](#), that inadequate regulatory capacity and lack of collaboration and work sharing between some countries contribute to an estimated two billion people having no access to essential medicines worldwide. He continued to point out that NRAs worldwide can benefit from already conducted scientific assessments and inspections to support the national registration through 'facilitated' registration. He stated that reliance should be one of the hallmarks of a modern and efficient regulatory authority.

Professor [John Skerrett TGA & ICMRA](#) Vice Chair shared his insights into work-sharing on medicines evaluation and the ACSS experience (Australia, Canada, Singapore, and Switzerland) and how continuous collaboration and knowledge sharing within NRAs could improve public health and safety and regulation of medicinal products. Pilot programs for reliance-based regulatory procedures provide initial practical experience for NRAs, industry, and patients. Robust evaluation of results from collaborative programs (such as ACSS) and dialogue between stakeholders lead to increased trust and acceptability. Alignment of submission times, especially in secondary markets, and sharing redacted reports or limited redaction reports will be a good step. Streamlined management of regulatory

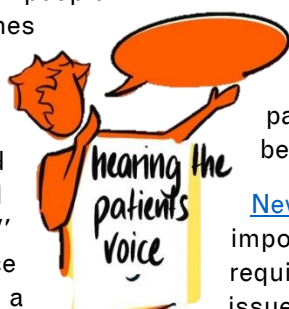
submissions combined with global supply systems and predictable timely approvals lead to timely access of medicinal products by patients.

With initiatives such as "[Access Consortium](#)", the regulators will continue working together to take on a more significant number of work-shared applications, including possible COVID- 19 treatments.

[Greg Perry](#), IFPMA moderated a panel session with patient organization representatives, [Ratna Devi, IAPO](#) and [Ranjit Kaur, BCWA](#). The importance of patient involvement in regulatory decision-making was one of the main topics discussed. Moreover, a patient-led partnership concept was raised to enhance patient engagement through national platforms (e.g. "ASIA-PATI", similar to 'EUPATI' which includes Europe and Japan). Having access to digital information for patients in Asian local languages would be useful.

[Nevena Miletic](#), IFPMA, pointed out the importance of clear guidance for requirements and procedures as critical issues that need to be adequately addressed regarding regulatory reliance. The key to effective implementation of regulatory reliance includes an accessible list of reference countries, guidance on required documentation, transparent assessment procedures, and uniform application of Good Reliance Practices (GRP) defined by the WHO.

Initiatives that foster trust among regulatory authorities are essential to promoting reliance. Trust comes from increasing familiarity and understanding of what stands behind regulatory outputs. By sharing information and working together, NRAs can build confidence leading to effective use of regulatory reliance. In practical terms, trust can be built in phases, starting with reliance using the exchange of reports and moving to work-sharing or joint assessments



## Day 2 – Regulatory Reliance in Asia

The opening keynote presentation from [Yasuhiro Fujiwara](#), [PMDA](#), ICMRA Vice-Chair, highlighted the importance of putting patients first. It promoted the need to have early access to medicinal products while ensuring safety, further strengthening Pharmacovigilance, and increasing collaboration in Asia and beyond. The role of the PMDA-Asia Training Centre (ATC) and its contribution to Universal Health Coverage Asia were presented as enablers for regulatory harmonization in the Asian region. Moreover, Dr. Fujiwara highlighted the importance of implementing global technical guidance and regulatory reliance to promote regulatory convergence and improve regulatory systems throughout his presentation.

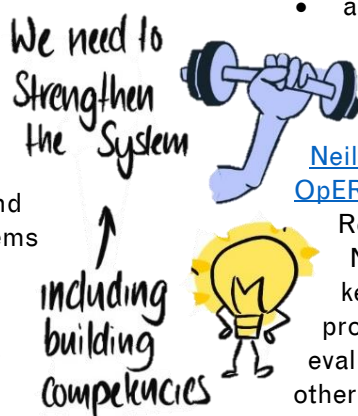
[Hasenah Ali](#), NPRA, explained the pandemic has acutely focussed all the stakeholders on seizing the opportunities through working collaboratively in a fast-changing regulatory landscape. Efficient scientific assessment pathways supported by ongoing dialogue and collaboration between stakeholders such as manufacturers, NRAs, and academic institutions are vital in bringing innovative products to market, especially in the pandemic era. As NRAs continue to facilitate learnings and share best practices, this will help address capacity gaps in the longer term and foster increased capability in the region.

[John Lim](#), [Duke-NUS-CoRE](#), discussed the importance of trust, partnership, and collaboration in building and strengthening healthcare and regulatory systems. COVID-19 highlighted the necessity for Regulatory Systems Strengthening (RSS), including the need to implement regulatory agility in systems to approve new diagnostics,

therapeutics, and vaccines. The broader context of the overall healthcare ecosystem needs to be considered and factored into regulatory frameworks and decision-making.

Prof. Lim pointed out that three key focus areas to strengthen regulatory systems for the future should include:

- preparing for digital health;
- enhancing supply chain integrity and quality of medicines;
- and commitment by wider stakeholders, including Governments.



[Neil McAuslane](#), [CIRS](#), spoke on [OpERA](#) (Optimising Efficiencies in Regulatory Agencies), which provides NRAs a simple structure to assess key granular milestones and agency processes. NRAs can use OpERA to evaluate their review process, learn from other agencies to strengthen their capacity, and better convey their needs to policymakers. He continued by pointing out that RSS and convergence are imperative for all NRAs, irrespective of maturity. Hence, NRAs in Asia are proactively evaluating and strengthening the review process through several approaches, including implementing reliance pathways.

[Dora Lau](#), IFPMA, presented best practices and how the pharmaceutical industry engages with various coalitions and collaborations. She stated that dialogue through collaboration and partnership helps building, convergence, reliance, and ultimately trust. Communication between regulators and the industry is vital to build trust and understand each party's expectations, concerns, priorities, and needs. Industry participation in pilots requires effective communication with regulatory agencies regarding timelines and new processes for improvement.

### Day 3 – ICH in Asia

Keynote speaker [Junko Sato](#), PMDA, talked about the 30 years since establishing the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and implementing reform to build the future of the organization.

ICH reform that came into force in 2015 allowed for an increase in international outreach and, by that, the involvement of new NRAs, industry, and relevant organizations in addition to the Founding Members. ICH was thus set up as a legal entity to enable ongoing activities with more members joining. Junko Sato also mentioned the importance of ICH's transparency and openness and its processes by publicly providing targeted information. Lastly, identifying an alternative funding model that would make ICH less dependent on the current form of industry funding.

There have been more than 60 finalized guidelines from ICH to date, with another 20 in development. Some topics, such as cell and gene therapies, need guidance. Still, supposed issues for delays are lack of scientific evidence for evaluation and rapid technology advancements raising the question of when is the best time for the ICH guideline development.

During the panel discussion that was led by, Angelika Joos, IFPMA; [David Jefferys](#), IFPMA, spoke of the mechanism by which non-aligned trade associations from new member countries can be engaged in ICH, which has evolved significantly over 5 years. Addressing agility issues, ICH now moves increasingly in step with regulatory science.

[Hironobu Hiyoshi](#), JPMA, explained ICH had held 65 face-to-face meetings, out of which 21 meetings have taken place in Japan. Approximately 1,324 participants from JPMA have attended the ICH meetings showing the level of support and commitment.

[Pär Tellner](#), EFPIA, highlighted three milestones for ICH: CTD success; MedDRA,

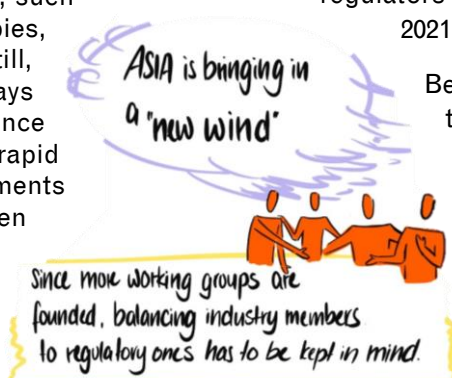
which has been pivotal for exchanging adverse drug reactions between authorities and industry; and ethnic factors in clinical trials agreement of bridging studies.

[Nihan Burul Bozkurt](#), TITCK, said ICH sets the highest standard internationally for safety, quality and efficacy. TITCK has recently joined ICH and stands ready to nominate experts to the working group, participate in harmonization activities, and improve bilateral cooperation to promote reliance practices. For example, licensing, Pharmacovigilance, and Clinical trial activities are conducted to international standards in Turkey. Tier One guidelines are being implemented.

[Junko Sato](#), PMDA, explained diversity of input by Asian regulatory authorities has been beneficial for all. There is a growing importance of further engaging Asian regulators with an expected meeting in June 2021, South Korea.

Because more NRAs are joining ICH, there is a need to maximize working groups' efficiency, which will have a knock-on effect on the decreased number of experts from the industry; thus, a balance must be kept operationally; this could become a challenge. Simultaneous ACSS review and harmonization of standards is a prerequisite for a collaborative effort. PMDA ATC seminar and joint symposia with other countries' global standards address the benefits of implementing ICH guidelines.

Areas for future focus include digital health, training (inc. non-ICH members), prospective guidelines at pace, speed up processes through electronic ways of working, and more patient engagement in guideline development 'cloud-based' 'real-time' regulatory submissions, fast concept papers, and keeping up with the pace of emerging regulatory science



## Day 4 – Agile Regulation for Supply Chain Management

[Barbara Allen](#), IFPMA, started with an overview of the impacts COVID-19 restrictions had on industry and regulators, from early R&D to product delivery. For R&D activities, these had to do with an increase in requests for initiating multiple clinical trials for COVID-19 therapeutics, disruption to regular conduct of ongoing clinical trials (including difficulties in supplying materials for clinical trials). Simultaneously, both Industry and NRAs saw high levels of absenteeism, further slowing down procedures. Other difficulties faced during this period include the ability to carry-out GxP-related activities in person with some NRAs adopting alternative approaches to ensure continuity – more information on this topic can be seen on the IFPMA points to consider on Virtual GMP Inspections. Finally, Barbara presented the recently issued IFPMA position on the importance of agile in-country quality controls<sup>2</sup>

[Anthony McDonnell](#), [Center for Global Development](#),

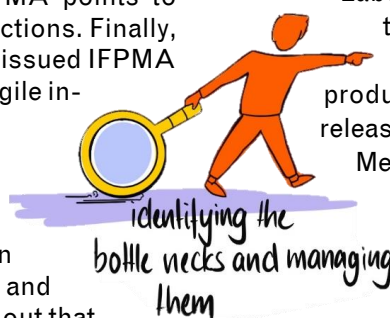
spoke about supply chain management during COVID and disruption triggers. He pointed out that they assessed answers to a survey done to private wholesalers and central medical stores and supply chain disruption data, and proposed mitigation measures.

[Samir Desai](#), [DCVMN](#), presented on vaccine registration harmonization initiatives supported by DCVMNs that improve vaccine coverage in developing countries and preparedness to outbreaks. The objectives include building technical capabilities and strengthening capacity to produce and deliver quality vaccines across the long-term; proactively shape the broader landscape and establish on-going dialogue with international bodies. Across four working groups, six initiatives looking at expanding training programs, sharing best practices, regulatory convergence, collaboration, technology adoption, and pharmacovigilance strengthening. Regulatory convergence and impact in Asian countries were reported as several fold: Collaboration Registration

Procedure (CRP) adoption; flexibility in accepting an ICH dossier format in vaccine producing countries to facilitate alignment in CTD format globally; development by ASEAN of a standardised Part I format.

[Ute Anna Roskopf](#), [WHO](#), spoke on the topic of COVID-19 vaccines & batch release and building on existing platforms to facilitate reliance during a pandemic. Harmonization of test methodologies change in Pre-Qualification procedure including optimized logistics, introduction of direct shipments of vaccines to WHO test laboratories and use of National Control Laboratory (NCL) of producing country (testing). National Control Laboratory Network for Biologicals aims to facilitate access to prequalified vaccines (or other biological products) through reliance on the batch release testing of the respective Network Members. Main objective of the network is to share quality information in order to facilitate access to prequalified vaccines through recognition by recipient countries of the lot release decisions of the responsible NRA. Intention is to build mutual confidence amongst members, reduce redundant testing, promote the development of common standards and facilitate the sharing of best practices.

[Greg Perry](#), IFPMA led a panel discussion, starting with the impact of advancing Digital health on the regulatory space. Digital and supply chain depend on the availability of type of data and information on manufacture, testing and distribution and better risk detection and is greatly facilitated. Optimizing procurement systems for continued supply leading to timely access and applying digital technologies could anticipate challenges and better modelling to avoid disruption to supply. Flexibility around multiple manufacturing sites is important for supply chain resilience in terms of contingency planning.



<sup>22</sup> The [IFPMA Position Paper](#) on Best Practices for In-Country Testing and Sample Management presents potential solutions to issues that can add additional layers of complexity to the supply chain.

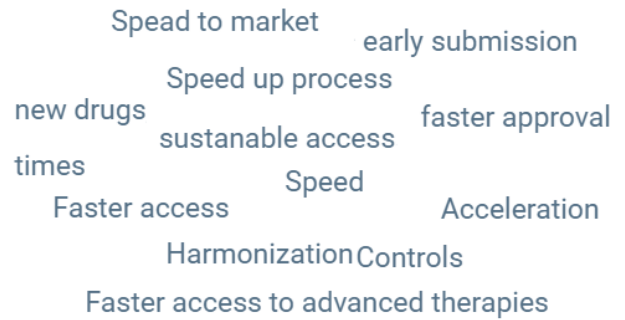
## Annex: Participant poll results

### **Results for Day 1- Regulatory Reliance**

What is the role of industry in pilot programs targeting regulatory reliance? What kind of feedback can the industry provide?



How could the reliance concept support innovation?

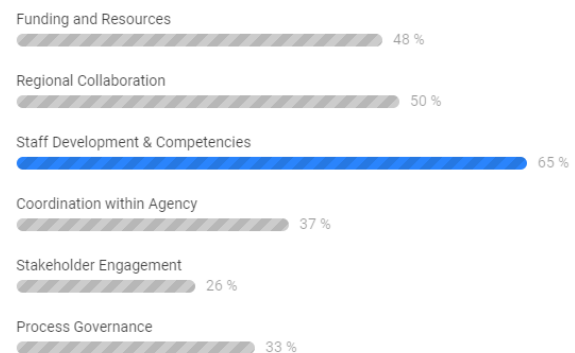


### **Results for Day 2- Regulatory Reliance in Asia**

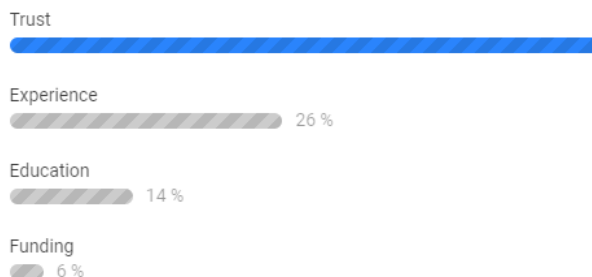
What do you think are the key barriers hindering the full use, adoption of regulatory reliance in Asia?



What do you think are the most important gaps in Regulatory Systems face in Asia?



Where do you see the main influence of initiatives such as ACSS in regards to regulatory reliance in Asia?





***Results for Day 3 - Participant poll results during Day 3- ICH in Asia***

What should ICH focus on in the next few years?



What are the biggest priorities for training on ICH guidelines?



### ***Results for Day 4- Agile Regulation for Supply Chain Management***

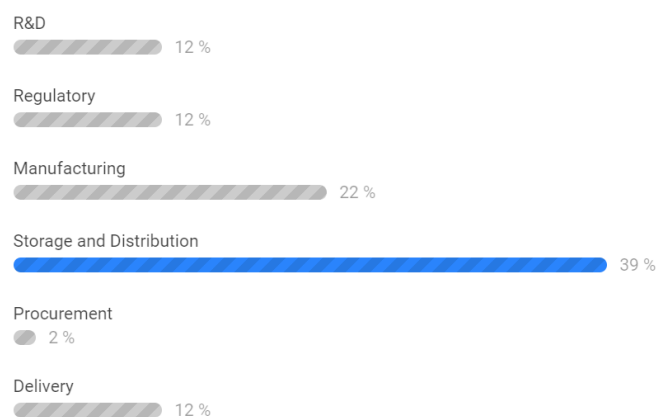
What is the main strength of a WHO-led network of laboratories for vaccine batch/lot release?



### What are the biggest challenges in registration and post-approval changes of vaccines?



What key process(es) in the supply chain of medicines would benefit the most from innovative technological solutions?



What is the single biggest challenge that supply chain actors need to tackle to ensure preparedness for future health crisis?

