

Regulatory reliance for convergence and harmonisation in the medical device space in Asia-Pacific

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ABSTRACT

While some sort of regulatory convergence and harmonisation are often needed for achieving regulatory reliance, in reality, regulatory reliance as a strategy towards convergence and harmonisation has never been more significant in Asia-Pacific (APAC). A sustained, rapid and large-scale provision of medical devices, including articles and apparatus used in diagnosis, care, treatment or prevention of disease and softwares, etc, across national boundaries, is the key to winning the fight against future pandemics and improving people's well-being in such a populous and geographically diverse region. The COVID-19 pandemic highlighted the value of regulatory reliance to enable easier access to medical devices that have gone through regulatory approvals in countries with mature regulatory systems based on the Quality Management System and product assessment guidelines of the International Medical Device Regulators Forum. This analysis focuses on why regulatory reliance is needed, how much has been achieved, its impact on the development of the medical device industry and challenges to be addressed in the region. By drawing on the experience from the Singapore Health Sciences Authority–Thai Food and Drug Administration regulatory reliance pilot and Vietnam's inclusion of Korea Ministry of Food and Drug Safety and China National Medical Products Administration as reference markets for fast review/approval, it aims to explore next viable steps and future trend of the APAC regional regulatory harmonisation mechanism through regulatory reliance in the post-COVID-19 era.

SUMMARY BOX

- ⇒ Regulatory convergence and harmonisation have become an imperative in achieving universal health coverage, and the need for regulatory reliance as a crucial strategy has never been more significant in the Asia-Pacific (APAC) region.
- ⇒ Since the outbreak of COVID-19, both regulators and the industry are more willing than ever to work together to explore expedited pathways to introduce and deploy sorely and urgently needed medical devices.
- ⇒ Our analysis summarises the background and current status of regulatory reliance schemes, deep dives into the Singapore Health Sciences Authority–Thai Food and Drug Administration regulatory reliance pilot and provides insights on the priority areas, drivers and manifestations of convergence and harmonisation in the next step.
- ⇒ We project the potential impact of regulatory reliance on the medical device industry and outline the challenges to be addressed in various aspects.
- ⇒ Given the magnitude of regional regulatory convergence and harmonisation in APAC, we strongly suggest and call for joint actions in the years to come.

INTRODUCTION

Strengthening the regulatory system is an integral part of the global efforts to improve health system performance and sustainability. According to WHO, regulatory reliance is the act whereby a regulatory authority in one jurisdiction may take into account/give significant weight to work performed by another regulator or other trusted institution in reaching its own decision.¹ WHO published new guidance to promote strong, efficient and sustainable regulatory systems in April 2021 featuring Good Regulatory Practices and Good Reliance Practices, which lists six overarching principles of regulatory

reliance in the field of regulation of medical products: universality, sovereignty of decision-making, transparency, respect of national and regional legal bases, consistency and competence.² WHO asserts that the purpose of the Good Reliance Practices is to promote a more efficient approach to regulation, thereby improving and expediting access to quality-assured, effective and safe medical products.³

As stated by WHO, regulatory harmonisation is defined as a process whereby the technical guidelines of participating authorities in several countries are made uniform. And regulatory convergence is defined as a voluntary process whereby the regulatory requirements in different countries or regions become more similar or 'aligned' over time.⁴ Convergence results from gradual adoption of internationally recognised technical guideline documents, standards and scientific



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principles, common or similar practices and procedures or the establishment of appropriate domestic regulatory mechanisms that align with shared principles to achieve a common public health goal. Convergence and harmonisation are always put together in the WHO context and are often referred to as ‘convergence/harmonisation’ in the US Food and Drug Administration (FDA) context. In spite of the differences in describing the process, the role of regulatory reliance remains the same. Regulatory reliance has been gaining popularity since it is regarded as a strategy for conserving resources by avoiding duplication and for improving allocation of resources where these are limited.⁵ In a globalised world, regulatory authorities need to act beyond borders to seek synergy and cooperation with their counterparts in exercising oversight over locally consumed medical products. While in the regulatory science, some sort of regulatory convergence and harmonisation are often needed for achieving regulatory reliance, in reality, regulatory reliance has been more widely considered a strategy that NRAs across the globe adopt to save resources and increase efficiency. Despite the benefits, it is no easy task to practice in regions with diversity and sharp differences in NRA competencies and level of maturity. This analysis focuses on Asia-Pacific (APAC)’s recent regulatory reliance actions in the field of medical devices, with an interesting case study between Singapore Health Sciences Authority (HSA) and Thai FDA and its follow-up impact, shedding light on the trend and next steps of regulatory convergence and harmonisation in the APAC region.

THE RATIONALES BEHIND REGULATORY RELIANCE IN ASIA-PACIFIC

While reliance has been practiced in various forms in other regions, it is of particular importance to APAC due to its vast population base, unbalanced economic growth and sharp differences in the competencies of NRAs.

The total population of the APAC region has reached 4.3 billion. The sustained, rapid and large-scale delivery of medical devices across national boundaries is the key to patient health in such a populous and geographically diverse region. The uneven economic growth and competencies of NRAs have made it very challenging to regulate essential medicines and health technologies across the region. There are more mature NRAs like Therapeutic Goods Administration (TGA) of Australia, HSA of Singapore, Pharmaceuticals and Medical Devices Agency (PMDA) of Japan and less mature ones in Low and Middle Income Countries (LMICs) of Association of Southeast Asian Nations (ASEAN). When a public health emergency occurs, a paucity of harmonised procedures for approval, differences in standards and inadequate information sharing among regulatory authorities would undoubtedly hinder access to essential and quality-assured medical devices and undermine the efforts to ensure patient health and safety, particularly in LMICs in the region.

Thus, as shown in the COVID-19 pandemic, regulatory authorities play a critical role and must be empowered by governments to engage in effective, agile regulation. Such agile approaches must be ‘interactive, flexible and fast—but contextually rigorous’ to ensure that reliable COVID-19 diagnostics and high-quality medical interventions are accessible in every country.⁶

Achieving regulatory agility through reliance is conducive to the trade development of medical products in APAC. The Regional Comprehensive Economic Partnership, a significant free trade agreement that came into force on 1 January 2022, represents one-third of the world’s Gross Domestic Product and most of the major countries in APAC. In addition, China and India are the powerhouses to supply medical devices at affordable prices and at scale. Therefore, regulatory reliance in the medical device sector would significantly improve people’s well-being and bring broader economic and social benefits.

The time is ripe for APAC to push forward regulatory reliance as a key strategy towards convergence and harmonisation, which will enable effective utilisation of resources by NRAs, and ensure speedy access to essential medical devices, particularly in LIMCs. Most importantly, enhanced collaboration and coordination would benefit patients by ensuring that the best possible science, standards and practice drive the regulatory process, resulting in improved safety, innovation and access.⁷

OBSERVATIONS ON REGULATORY RELIANCE IN ASIA-PACIFIC

Achieving regulatory reliance is a political commitment for the government that fully recognises the benefits and is willing to act proactively. On completion of legislation and settlement of resource insufficiency in the relying authority, concrete measures, including information sharing, regular communication and capacity building, are necessary for the relying authority to keep pace with the reference authority, which will lead up to a broader agreement and alignment. Depending on the trust and confidence built by NRAs, regulatory reliance may take various forms, including work sharing, abridged pathways, regional reliance mechanisms and unilateral or mutual recognition arrangements (MRAs).

In the medical device field, regulatory reliance regulations in ASEAN are entirely dependent on the Global Harmonisation Task Force (GHTF) model. The International Medical Device Regulators Forum (IMDRF) officially uses the GHTF acronym to benchmark countries for regulatory reliance protocols. These include the USA, European Union (EU), Canada, Japan and Australia. Most of the regulatory reliance in ASEAN is restricted to premarket compliance only. So here come two burning issues: What if ASEAN has its own regional regulatory reliance protocols? How likely is it for ASEAN to have mutual recognition regulatory model as in other regions?

In a broader context of the regulation of medicinal and health products, the EU is a typical example of MRAs

where members rely on each other for Good Manufacturing Practice inspection, information sharing and exemption of batch testing of products imported into the EU.⁸ The Mexico's regulatory authority Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS) is an example of unilateral recognition. It established unilateral agreements with European Medicines Agency, US FDA, Health Canada, TGA and Swissmedic to expedite the approval of new medicines into the Mexican market.⁹ NRAs across the globe also cooperate on international convergence and harmonisation arrangements like International Conference on Harmonisation, Pharmaceutical Inspection Cooperation Scheme, etc. In the case of medical devices, there are also a great number of international harmonisation/convergence arrangements, including IMDRF, Global Harmonisation Working Party (GHWP), Pan African Harmonisation Working Party and ASEAN Medical Device Directive.

It is worth noting that the APAC region is a hub where most of these international harmonisation initiatives converge (see figure 1). Most IMDRF, GHWP and ASEAN members are in the APAC region. Advanced NRAs have been taking the lead in forming such reliance mechanisms. The Australia–Canada–Singapore–Switzerland Consortium started in 2007 was a reliance pilot in medicines to respond to increasing workload and creating synergy. In October 2020, the UK MHRA joined and the group's name was changed into Access Consortium. The MHRA started work-sharing applications with Access partners from 1 January 2021.¹⁰ In 2021, TGA released the guidance for leveraging comparable overseas regulators/assessment bodies for medical devices, including in-vitro diagnostic (IVDs) to allow abridgement of TGA conformity assessments if the applicants provide evidence or documents issued by medical device regulators of EU members, US FDA, PMDA, Medical Device Single Audit

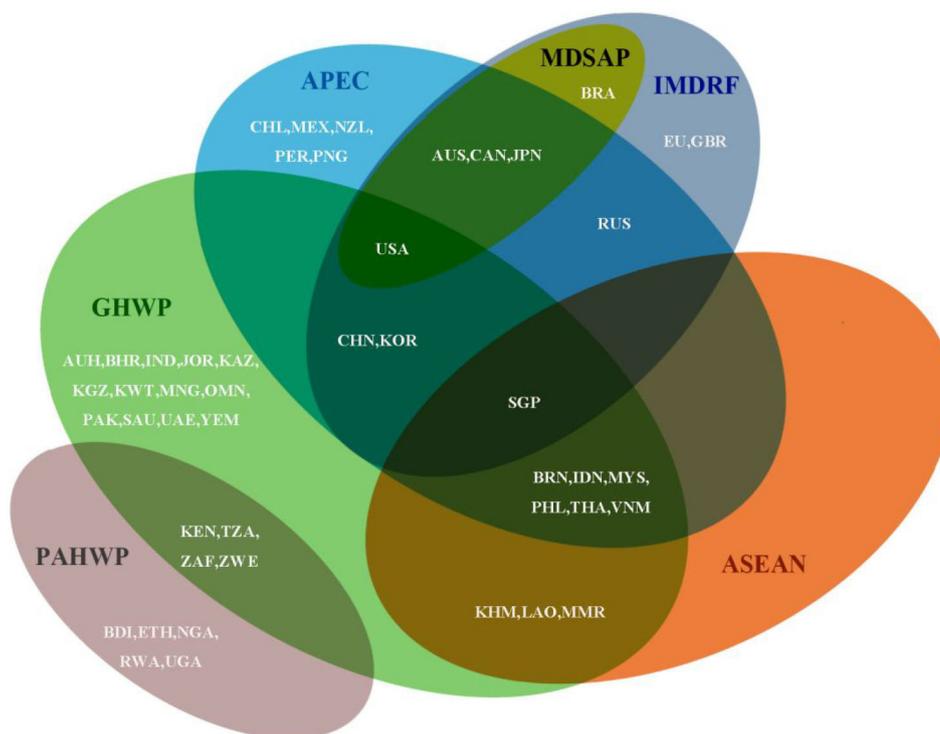


Figure 1 Global regulatory convergence/harmonisation initiatives in the medical device space. APEC, Asia-Pacific Economic Cooperation; ASEAN, Association of Southeast Asian Nations; AUH, Abu Dhabi, the UAE; AUS, the Commonwealth of Australia; BDI, the Republic of Burundi; BHR, the Kingdom of Bahrain; BRA, the Federative Republic of Brazil; BRN, Negara Brunei Darussalam; CAN, Canada; CHL, the Republic of Chile; CHN, the People's Republic of China; ETH, the Federal Democratic Republic of Ethiopia; EU, the European Union; GBR, the UK of Great Britain and Northern Ireland; GHWP, Global Harmonisation Working Party; IDN, the Republic of Indonesia; IMDRF, International Medical Device Regulators Forum; IND, the Republic of India; JOR, the Hashemite Kingdom of Jordan; JPN, Japan; KAZ, the Republic of Kazakhstan; KEN, the Republic of Kenya; KGZ, the Kyrgyz Republic; KHM, the Kingdom of Cambodia; KOR, the Republic of Korea; KWT, the State of Kuwait; LAO, the Lao People's Democratic Republic; MDSAP, Medical Device Single Audit Programme; MEX, the United Mexican States; MMR, the Republic of the Union of Myanmar; MNG, the State of Mongolia; MYS, Malaysia; NGA, the Federal Republic of Nigeria; NZL, New Zealand; OMN, the Sultanate of Oman; PAHWP, Pan African Harmonisation Working Party; PAK, the Islamic Republic of Pakistan; PER, the Republic of Peru; PHL, the Republic of the Philippines; PNG, the Independent State of Papua New Guinea; RUS, the Russian Federation; RWA, the Republic of Rwanda; SAU, the Kingdom of Saudi Arabia; SGP, the Republic of Singapore; THA, the Kingdom of Thailand; TZA, the United Republic of Tanzania; UGA, the Republic of Uganda; VNM, the Socialist Republic of Vietnam; YEM, the Republic of Yemen; ZAF, the Republic of South Africa; ZWE, the Republic of Zimbabwe.

Programme, etc.¹¹ East Asian NRAs, US FDA and HSA of Singapore are gaining more weight in the region as members of multiple international convergence and harmonisation initiatives.

The COVID-19 pandemic has put regulatory collaboration in the limelight in ASEAN due to the growing necessity and increased confidence and sympathy among stakeholders during the crisis. Prior to the pandemic, with the support of the Asia-Pacific Medical Technology Association (APACMed), the Thai FDA managed to send three evaluators to spend 2 weeks with HSA in Singapore to be familiarised with HSA's assessment approaches. The pandemic highlighted the urgency of collaboration between HSA and the Thai FDA, which resulted in a regulatory reliance pilot to include 12 medical devices in 2020. The pilot developed into phase II in 2021 to cover classes B, C and D medical devices and IVDs.¹² The formalisation of the Singapore HSA–Thai FDA Regulatory reliance pilot could not be separated from the trust between regulators, alignment of technical documentation, cultural proximity and facilitation of industry associations. On the pilot's success, it was transformed into a formal reliance pathway between Singapore and Thailand, the first of its kind in APAC. The phase I pilot resulted in eight products approved, and average approval time shortened by 5–8 months. The phase II pilot resulted in seven products approved and 16 products in progress now, with an average approval time shortened by 7–10 months. The expedited approval time was the result of the confidence of the relying authority in both the pilot and their own decisions.¹³ In medicines and vaccines (non-producing), HSA was listed as level 4 NRA by its level of maturity according to the WHO Global Benchmarking Tool (GBT) benchmarking tool in 2022.¹⁴ The GBT is designed by WHO as the first truly 'global' tool to evaluate the overarching regulatory framework and the component regulatory functions and also incorporates the concept of 'maturity level' (adapted from ISO 9004), allowing WHO and regulatory authorities to assess the overall 'maturity' of the regulatory system on a scale of 1–4.¹⁵ Now with regulatory reliance on medical devices, Singapore is emerging as a 'reference country' for other ASEAN members. The pilot has also sparked a mindset change as Thailand has decided to expand the pilot and more ASEAN countries are expected to join in the ASEAN reliance initiative by leveraging Singapore as the reference market.¹⁶

At the same time, other mature NRAs in the region are likely to jointly shape a diversified pattern of reliance arrangements. The GHWP, which was rebranded from Asia Harmonisation Working Party (AHWP) in 2021, advocates regulatory reliance among all its 32 members across the product life cycles as a smart strategy towards harmonisation.¹⁷ With US FDA joining GHWP in December 2021 and more to come in the future, one will surely expect more frequent regulatory collaboration in the APAC region. Furthermore, NRAs of East Asia are being considered new reference markets. PMDA of Japan

has already been considered a reference market and will continue to play an essential role in the post-COVID-19 period. In November 2021, Vietnam expanded its 'abridged pathway via reliance' in its new Decree 98, which added Ministry of Food and Drug Safety of Korea and National Medical Products Administration (NMPA) of China to be the reference markets for fast review and approval.¹⁸

While different countries would play different roles in regional harmonisation, actions taken by the NMPA of China to align with international regulatory practices are rather noticeable. Evidence can be found in both drugs and medical devices. In terms of drug regulation, it became a member of International Conference on Harmonisation (ICH) in 2017 and a member of the ICH management committee in 2018, which expedited the translation of ICH guidelines to the Chinese drug legislative system. In the medical device space, NMPA joined IMDRF in 2013 and served as the rotating president in 2018. In 2019, NMPA officially joined IMDRF National Competent Authority report Exchange Programme to ensure timely access and information sharing on medical device adverse events and better control of risks.¹⁹ The Postmarket Clinical Follow-Up Studies, a technical document driven by NMPA under the IMDRF was released in May 2021 as China's contribution to global medical device regulation.²⁰ NMPA joined AHWP in 2020, and as it is expected to play a bigger role in the rebranded GHWP, the Chinese regulator is highly likely to be a potential propeller of regional regulatory reliance in APAC.

POTENTIAL IMPACT OF REGULATORY RELIANCE ON THE DEVELOPMENT OF THE MEDICAL DEVICE INDUSTRY IN ASIA-PACIFIC

The size of the medical device industry in the APAC region is expected to reach US\$157 billion by 2022, with a compound annual growth rate of 8.8%. Companies in China, India, Japan and South Korea and other emerging markets are the main drivers of the rapid growth of the medical device market. Against such a diverse and fragmented regulatory landscape, it is so compelling to witness that a growing number of regulatory authorities have sped up the process of convergence and harmonisation and tried to make their regulatory systems more adaptable to the demand from the industry, which has been seen as a positive attempt to create benefits to companies in the global supply chain.

The potential impact of regulatory reliance in the region on the development of the medical device industry can be briefly summarised as follows: first, a more robust and shorter approval procedure will quicken market entry and reduce the lead time for companies in the absence of duplicated regulatory measures. Second, regulatory reliance will make it possible for companies to divert more financial resources to innovation. Third, due to a streamlined and synchronised regulatory arrangement, a more rational division of labour and cooperation

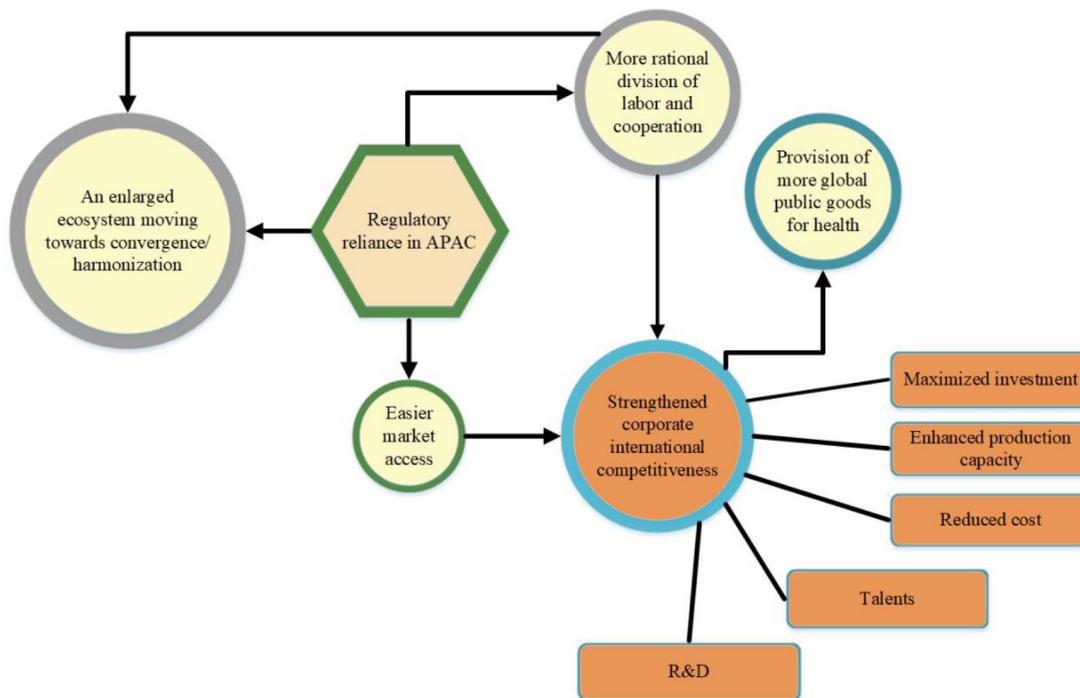


Figure 2 Potential impact of the regulatory reliance on the development of the medical device industry in APAC. APAC, Asia-Pacific.

can be achieved regionally to maximise the value of individual investments. Fourth, a well-connected, mutually trusted and ever-evolving regulatory network will facilitate market-shaping, unleash untapped value and create an enabling environment for companies with regional presence to enhance their international competitiveness through various alliances and cross-border cooperation. Fifth, regulatory reliance will galvanise companies into furnishing more affordable global public goods for health in case of health emergencies when the total cost of ownership is reduced, and production capacities are improved in a wide range of regulatory settings. Sixth, an enlarged ecosystem with diminishing demarcation lines in regulation will expedite the flow of information, capital, talent, health commodities and technologies, which are central to the sustained development of the medical device industry in the long run, as seen in figure 2.

CHALLENGES TO ACHIEVING REGULATORY RELIANCE IN ASIA-PACIFIC

Given the wide discrepancies in rules, laws, cultures and levels of competence in varying regulatory systems, challenges exist in achieving regulatory reliance. First and foremost, a lack of legal framework for regulatory reliance could lead to confusion, delay and redundancy in approval by the relying authority, but it is complex and time-consuming to be legally ready. Obstruction may also lie with the discordance of product risk classifications and sameness of products to verify that the version of a product being considered by the relying authority is identical to that assessed by the reference authority. Overly

redacted documents make reliance-based pathways particularly challenging, as it is difficult to ‘rely’ on an inspection report or scientific assessment report if significant parts are redacted.²¹ What may hinder the ongoing process include lack of political will, social and economic concerns, technology and resource inadequacy, language barrier and information asymmetry between the reference and the relying authority, for example, little understanding of the reference authority, non-disclosure of confidential regulatory information and internal considerations. Moreover, holdouts or resistance may originate from other stakeholders ranging from law enforcement, the industry, the social security administration to patient groups, etc. As regulatory reliance progresses, transparency, trust and consistency remain critical to navigating in the right direction.

NEXT AND BEYOND: CONSIDERATIONS, OPPORTUNITIES AND APPROACHES

There are considerations on flexibility in approach, reliance to be embedded in a national regulatory strategy, adequate investment of resources and time and cultural change. Notably, the role of reliance in public health emergencies needs to be clearly defined, and the involvement of the medical device industry also needs to be underscored.

As the regulatory reliance moves towards a regional reliance mechanism in APAC, the following areas are considered not-to-be-missed opportunities: (1) Information and data sharing among NRAs on emergency use review/approval for pandemic preparedness, including critical medical products and health technologies against

the pandemic. (2) Trust and confidence strengthening among NRAs via capacity building under the international convergence initiatives like WHO, ICH, IMDRF, GHWP, etc. (3) Collaborations on novel technologies, for example, artificial intelligence, next-generation sequencing, 3D printing and cybersecurity. (4) MDSAP expansion to overcome barriers in onsite inspection during a pandemic. (5) Global alignment of clinical trial requirements to increase the pace of development of vaccines, medicines and diagnostics. As Julie O'Brien *et al* pointed out, although this is a long-term journey and initially will be pioneered by more well-resourced regulators, the hope is that such a system can be designed to be scalable for use by all regulators and so the anticipated benefits of streamlined processes, reduced redundancy and rework and enriched regulatory decision-making will ultimately benefit all patients globally.²²

There will be no one-size-fits-all methodology for countries to join in. Instead, a fit-for-purpose approach tailored to specific concerns and needs of the national health and regulatory system is entailed to clear away hurdles and embrace the reliance initiative. More pilots are expected in regional regulatory reliance towards a higher level of harmonisation. At the same time, individual ASEAN countries might consider East Asian NRAs like Korea and China as new reference markets. There might also be more MRAs gradually leading to regional recognition arrangements. In order to enhance trust and transparency, widespread advocacy and education targeting a good variety of stakeholders should be carried out as soon as possible. While NRAs always need a little nudge to move, the industry shall play a more active role in facilitating such dialogues.

As a region with the largest trade agreement bloc, APAC is likely to benefit from quicker access to what is sorely and urgently needed should regulatory reliance be practiced and adopted more widely. Regulatory reliance will undoubtedly contribute to the development, production and supply of medical devices for APAC with LMICs as the bulk of beneficiaries.

CONCLUSION

Regulatory reliance has gained traction in most countries and paces of reliance in APAC in the post-COVID-19 era are being accelerated. It is certain to bring about transformative changes to the public health landscape in the region with a vast population base, diversity in NRA competencies and huge unmet needs for essential medical devices. Achieving reliance will bring about tangible benefits to patient access to health products and generate significant social and economic outcomes in the long run. Regulatory reliance is an effective and crucial strategy to achieve convergence and eventually full harmonisation. As more countries join in the APAC regional reliance initiatives, NRAs will need flexibility in the reliance approach and more room to form synergy and alignment. Furthermore, capacity building

of potential Reference Authority is needed. To support regulators in their decisions of choosing the most appropriate model of reliance, academia should work closely with the industry to fill the gap in understanding and develop fit-for-purpose reliance pathways for NRAs, particularly those in LMICs. For the purpose of increasing access to medical products, as all reliance arrangements are in the end 'trade agreements that aim to facilitate market access',²³ countries might need to integrate reliance arrangements under trade negotiations at an early stage so as not to impose trade bottlenecks. Finally, a harmonised regulatory ecosystem will only be established through a deeper level of trust and confidence, particularly among the major countries in APAC. In the years to come, APAC will embark on a bumpy but rewarding journey.

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