Achieving Vaccine Regulatory Convergence and Agility in ASEAN: *The Way Forward*

Asia Pacific Immunization Coalition

Photo: Nafise Motlaq / World Bank

Abstract

At present, member states in the Association of Southeast Asian Nations (ASEAN) region have to register a medical product separately subject to different national regulations, which results in varied approval times. **Regulatory harmonization** is a process where the technical requirements to develop and market pharmaceutical products become **more uniform** across different regulatory authorities. Regulatory harmonization has many advantages, such as promoting efficiency to support accelerated access to medicines and treatments, reducing unnecessary duplication and authorization of pre-marketing regulatory dossier and fostering best practice and resource sharing between regulatory bodies. While regulatory harmonization in the ASEAN region is an ideal yet to be achieved for vaccine development and its rollout, ensuring uniform regulatory process has potential disadvantages, such as the over-dependence of resources and decision making on larger regulatory bodies. Due to the differences in capabilities and healthcare priorities in the region, **regulatory convergence**, where requirements and processes become **more aligned** over time, may be a more realistic goal for the ASEAN region. There is an opportunity to strengthen regulatory convergence for vaccines in the region by convening national regulatory bodies and other stakeholders in governments, academia and industry to collectively address common technical and benefit-risk issues, developing guidance and training for regulators and building platforms to promote rapid data sharing.

Key takeaways

Informed by best practice from existing global and regional initiatives and interviews with key experts, regulatory convergence can be strengthened in the ASEAN region through the following four areas:

1. Advocate for regulatory convergence and agility to reduce dissimilarities between different regulatory bodies
2. Promote information sharing, as well as develop guidance and training for regulators
3. Promote sustained political will through regular capacity building and best practice sharing sessions
4. Build platforms to promote rapid data sharing throughout the vaccine development and rollout process

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Background

While the development and manufacturing of vaccines against COVID-19 in record speed was an unprecedented public health and scientific success, many countries continue to struggle with achieving widespread population immunization (Table 1). One of the challenges, especially faced by lower-resourced countries, is the lack of vaccine access and equity.

As there was no global or regional agreement on the equitable distribution of COVID-19 vaccines, their manufacturing, procurement and distribution resulted in divergent political and competitive market processes. Additionally, due to the different speeds at which COVID-19 vaccines were developed, governments in the Association of Southeast Asian Nations (ASEAN)* region have secured vaccines from different sources under different agreements, with no uniform processes and guidance.

Within ASEAN, some member states, like Singapore, acted quickly in securing agreements with manufacturers and procured large quantities of vaccines. In contrast, other countries were short of supplies and had to wait as they lack the capacity to plan, negotiate, or execute such agreements with vaccine manufacturers.[1]

Share of people fully vaccinated against COVID-19 (%)

High-income Countries		Upper middle-income countries		Low and middle-income coutnries	
Bruinei Darussalam	92	Malaysia	81	Philippines	61
Singapore	91	Thailand	73	Indonesia	59

Table 1: % of people vaccinated against COVID-19, as of 27 Apr 2022 [2]

Taking lessons from the COVID-19 pandemic, there is a need for greater regional cooperation and convergence in authorizing, procuring and distributing vaccines, so that the region can better prepare for future outbreaks and ensure equitable access to immunization, beyond COVID-19.

*The Member States of ASEAN refer to Brunei Darussalam, Cambodia, Indonesia, Lao People's Democratic Republic, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam.

What is regulatory harmonization, convergence and agility?

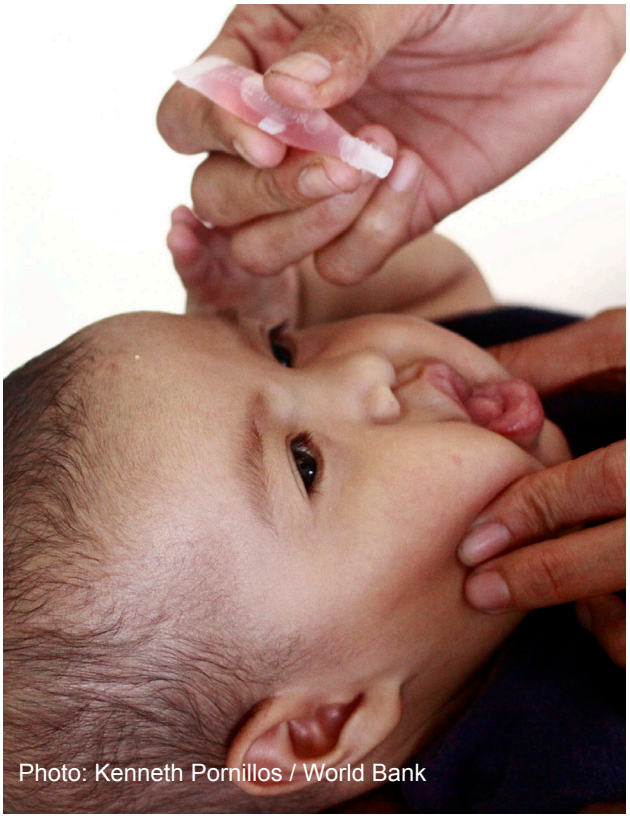

Photo: Kenneth Pornillos / World Bank

Regulatory harmonization is "the process of aligning regulatory requirements across economies or regions over time through the adoption of internationally recognized standards and practices."[3] It accelerates processes across regulatory authorities and vaccine producers, through **uniform guidelines and standards**, to ensure that patients can rapidly access effective medicines.

Regulatory convergence is the "*voluntary process* whereby regulatory requirements across economies become *more similar or aligned* over time through gradual adoption of internationally recognized technical guidance documents, standards and scientific principles and **common or similar practices and procedures**."[4]

Regulatory agility is the "adoption of risk-based, context-driven approaches and regulatory cooperation based on sound scientific evidence and information."[5] to expedite regulatory decisions without necessarily depending on established decision processes. As regulatory systems become more converged over time, national regulatory systems can become more agile in processing applications of new medicines by referencing decisions of trusted benchmark authorities and adopting risk-based approaches to national contexts. These are further informed by shared information and resources.

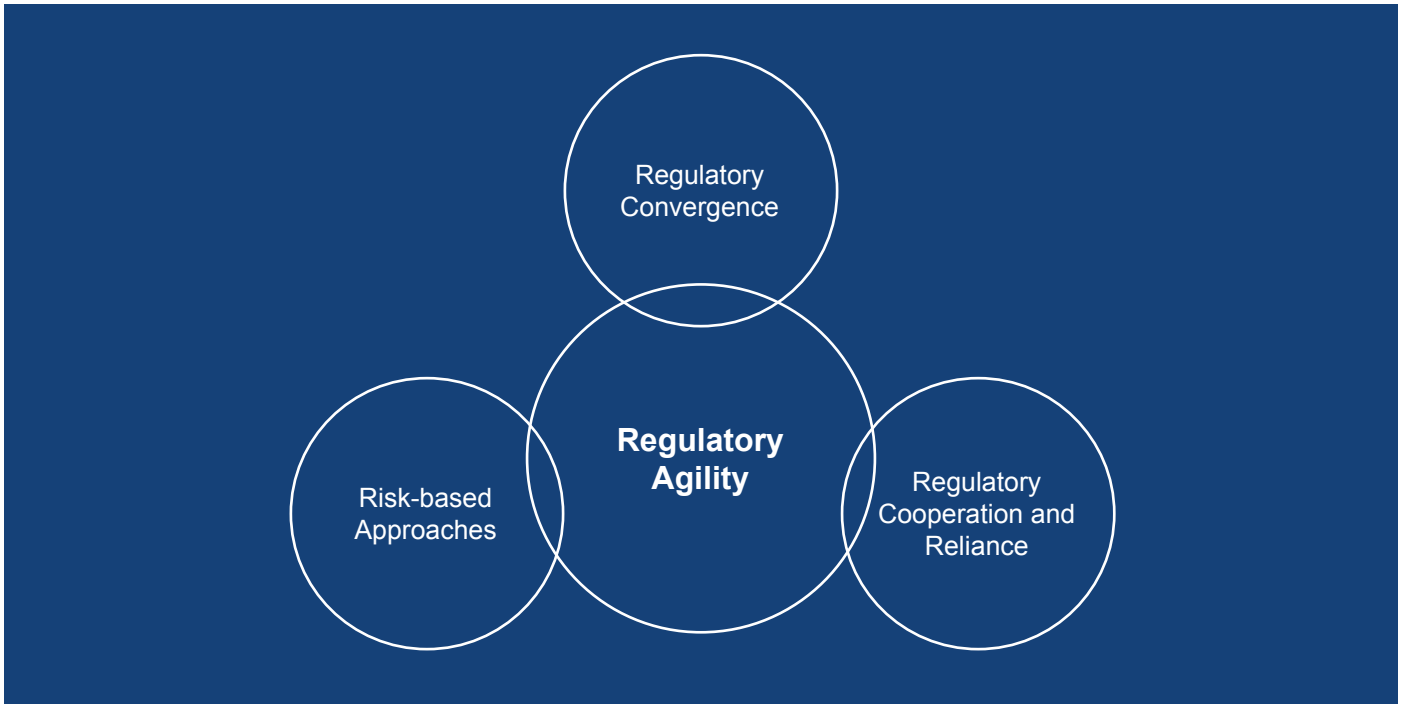

Figure 1: Elements to promote regulatory agility.[6]

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Advantages of regulatory harmonization

Better health outcomes

When reviews are harmonized, helps to ensure that approved products are effective, safe and quality assured to the highest standard of care for patients.

Increase availability of products

Harmonization reduces duplication of approval processes, ensuring that medicines and drugs are more readily available on the markets (Refer to Figure 2 for current regulatory approval timelines for clinical trials globally). Consequently, more populations across the region are able to access the needed medicines to stay healthy and curb outbreaks.

Maximize public resources

Tapping into the resources of other countries or high-performing regulators avoids unnecessary duplication and wasteful spending to approve a vaccine.

Better economic outcomes by attracting investment

Streamlined processes attract both local and international companies to conduct clinical trials and operations in the region. Companies may not need to conduct clinical trials in various countries or submit multiple applications for the same product. Quicker approvals of application allows for earlier access and improved patient and economic outcomes.

Potential disadvantages of regulatory harmonization

Over-dependence of resources and decision making on larger regulatory bodies

Without concurrent capacity building for less-resourced regulatory authorities, they may be heavily dependent on the capabilities of better-resourced countries over time. The latter in turn face greater accountability and burden.

Political inertia

Every country has its own regulatory and legal framework, as well as diversity in their healthcare landscapes and medical priorities, which makes the political case for regulatory harmonization difficult to achieve and advocate for – as no country is the same. In addition, reliance on other countries may be seen to threaten political self-sufficiency and a country's independence to formulate its own standards and guidelines.

Lack of practical feasibility

Many regulatory bodies in the region face human, financial and infrastructure resource constraints to implement and develop optimal regulatory processes that are aligned with regional and international standards. The setup of new systems and practices is time intensive and resource consuming, which may hinder the political will to advocate for regulatory harmonization.

Differences in priorities

While better-resourced countries with better developed regulatory systems will strive towards innovation, countries with less developed regulatory systems need to build their foundations and fill the gaps in capacity. The difference in priorities makes it challenging to harmonize between countries.

Table 2: Advantages and potential disadvantages of regulatory harmonization

Photo: Markus Kostner / World Bank

The current landscape of regulatory harmonization in ASEAN

Regulatory capacity across ASEAN varies widely with countries operating across a wide spectrum of financial, human resource and technical capacities. The COVID-19 pandemic has paved the way for innovations in the regional regulatory environment, with high-income countries in the region developing alternative authorization pathways to expedite special use authorization for vaccines during the pandemic.

Low-and-middle income countries, however, generally have weaker regulatory capabilities, which puts them at a disadvantage in conducting robust, timely reviews and safety assessments to make informed decisions about vaccines. The need for regulatory science proficiency, especially in smaller regulatory agencies, is a major constraint that must be resolved.

ASEAN, under The Pharmaceutical Product Working Group (PPWG) has convened national regulatory authorities since 1999.[7] It has introduced common technical requirements and dossiers for the region. However, member states in ASEAN have diverse regulatory requirements for registering drug products and may decide to adopt the standards differently, as they are not legally bound to them.

The regulatory process for obtaining market authorizations for drugs in the ASEAN region is highly country-specific, despite regional harmonization efforts (Refer to Table 3 for the number of COVID-19 vaccines approved in ASEAN member states). Thus, a product approved to be marketed in one member-state still needs to be registered separately in other member states, which is subjected to different national regulations. Other initiatives to further harmonize the pharmaceutical regulatory landscape in the Asia Pacific include the South-East Asia Regulatory Network (SEARN) established by the World Health Organization (WHO)[8] and the ASEAN Joint Assessment Procedure.[9]

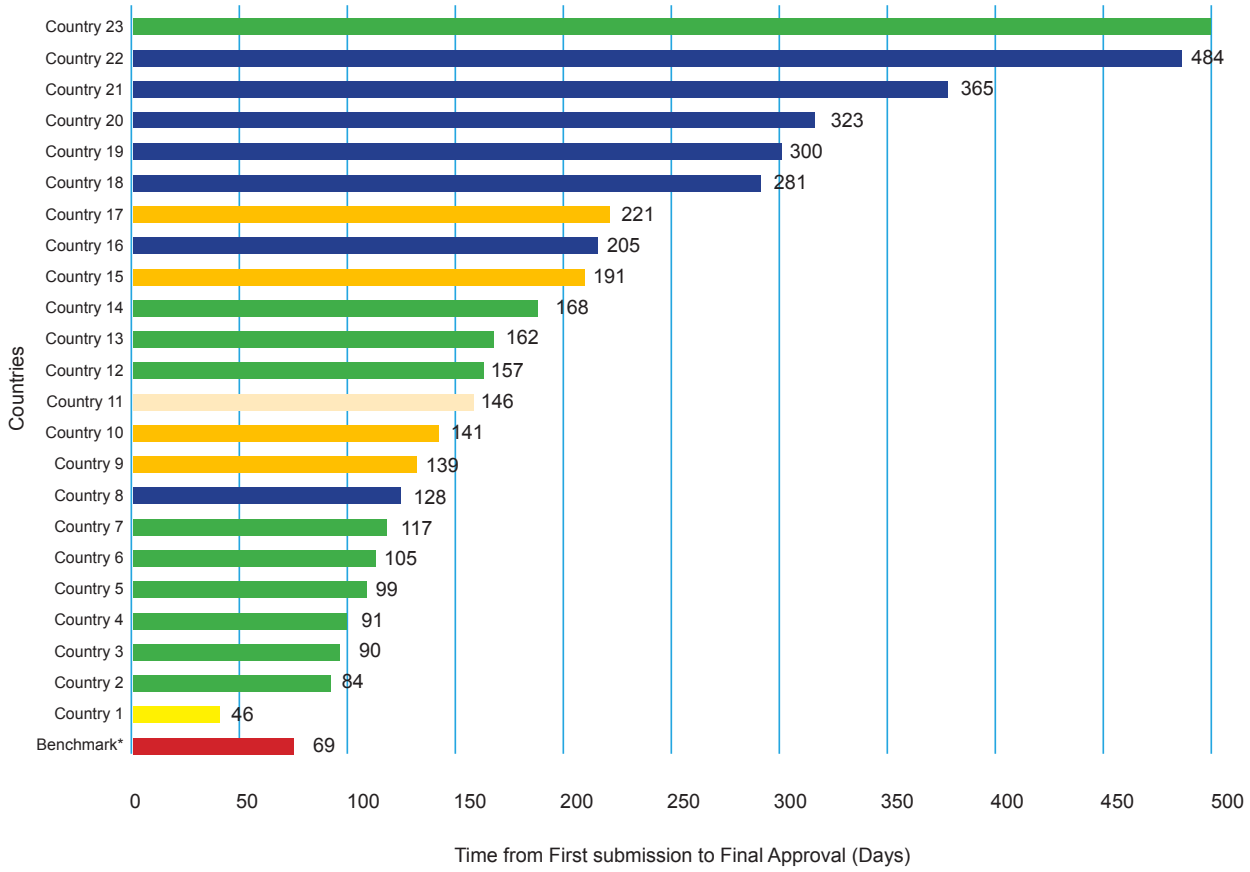

Figure 2: Regulatory approval timelines for clinical trials globally. Names of countries have been anonymized.[10]

Country	No. of COVID-19 vaccine clinical trials	No. of COVID-19 vaccines approved†
Brunei Darussalam	0	4
Cambodia	0	8
Indonesia	18	11
Lao People's Democratic Republic	2	6
Malaysia	3	8
Myanmar	0	3
Philippines	15	11
Singapore	7	4
Thailand	21	7
Vietnam	12	8

Table 3: Number of approved COVID-19 vaccines in ASEAN member states, as of 27 Apr 2022.[11]

† Vaccine approvals include vaccines that have been approved, authorized, licensed, given emergency use status, or made available for use outside of clinical trials via any pathway.

The Asian Development Bank's (ADB) Health Sector Group has also created the Regional Vaccine Advisory Group to facilitate regional partnerships and information sharing regarding COVID-19 vaccine regulatory practices in the Asia Pacific region.[12] This includes giving regulatory and technical advice on the quality, safety and efficacy of vaccines to developing member states.

Several developing countries in Asia follow the WHO Emergency Use Listing or the approval of regulatory bodies in developed countries, such as the European Medicines Agency (EMA)◊ or the US Food and Drug Administration (FDA)‡. However, this still requires that national regulatory agencies have strong post-marketing surveillance capacity to monitor vaccine effectiveness and possible adverse events following immunization.

Countries in the region, including Indonesia and Thailand, are making efforts to be a global hub for manufacturing vaccines to distribute vaccine production globally and ensure the region is resilient to meet evolving demands for vaccines.[13] Harmonized regulatory processes across the whole life cycle of a vaccine, from the development stage to post-marketing surveillance, is a crucial gap that must be addressed, as the region builds its capacity to respond to future pandemics.

Problem Statement

In ASEAN, different member states have their own procurement and authorization strategies for vaccines. Even though regulators in ASEAN have committed to harmonization since the 1990s,14 regulatory processes are still highly fragmented and country-specific, and many countries lack the capacity to ensure a robust regulatory system to license and monitor medicines.

While there are many advantages to regulatory harmonization, striving towards a uniform regulatory process in the ASEAN region is not realistic due to the differences in regulatory capabilities and capacity, as well as healthcare priorities among member states. As such, there is an urgent opportunity for countries to advocate for regulatory convergence and greater regional collaboration, coordination and agility as the first steps, while striving to achieve regulatory harmonization over time.

A more converged regulatory system in ASEAN has the potential to increase equity in vaccine manufacturing, rollout and delivery in the region, improve the agility and resilience of immunization in the region and ensure future pandemic preparedness.

This requires collaboration and commitment from various stakeholders – politicians, regulatory authorities, the pharmaceutical industry and academia – to advocate for regulatory convergence in the region, while tackling the potential challenges when designing a converged system.

Photo: Simone D. McCourtie / World Bank

◊ The EMA is a supranational and centralized organization that evaluates and monitors medicines within the European Union (EU) and the European Economic Area (EEA). Once a single marketing authorisation has been granted, the medicine can be marketed through the EU and the EEA.

‡ The FDA is a national food and drug regulatory body composed of seven centers. These centers ensure the safety, efficacy and security of the nation's human and veterinary drugs, tobacco products, biological products, medical devices, food, cosmetics and products that emit radiation.

Photo: Chhor Sokunthea / World Bank

Best practice examples from existing global and regional initiatives

1. Promote political will for convergence among policymakers

Communicate the importance of regulatory convergence at the highest political levels

- Organize policy dialogues to discuss regulatory convergence and support needed to establish or change legal frameworks, laws or regulations with ASEAN stakeholders, including regulatory policymakers, legislators and parliamentarians, patient organizations, and senior trade and health officials
- The National Vaccines Institute, Thailand and WHO have established the ASEAN Collaboration Initiatives for Regional Vaccine Security and Self-reliance (VSSR). This initiative facilitated cooperation on VSSR from a national to a regional level. In 2014 and 2015, it brought together policymakers, immunization programme managers, and experts from government and partner agencies to understand perspectives and identify the needs of ASEAN countries on vaccine safety. The recommendations included regional collaboration strengthening on system development for vaccine security, human resource development, price policy for vaccines, and pooled procurement. Since these recommendations are not binding on member countries, it requires strong policy commitment and sustained involvement of relevant partners.[15]

Share progress towards regulatory convergence amongst countries

- Share Good Manufacturing Practices (GMP) certification
  - From 2008 to 2020, there was a 14.3% increase in the number of APEC member economy regulatory authorities sharing Good Manufacturing Practices (GMP) Certificates and a 28% increase in the number of regulatory authorities accepting multi-site licenses.[16]
  - EU and Israel's Agreement on Conformity Assessment and Acceptance of Industrial Products mean that the GMP Certificates, manufacturing and import authorizations and certification of conformity of each batch, issued by either party, are mutually recognized. This means fewer "non-tariff barriers" to pharmaceutical trade, such as divergent standards and customs checks.[17]

2. Facilitate cooperation among regulatory authorities

Build platforms for regulatory information-sharing

- In June 2008, the EU and the US signed a Medicines Regulation Transatlantic Administrative Simplification Action Plan, which promoted cooperation in inspections, biomarkers, counterfeit medicines, risk management, scientific advice, biosimilars, pediatrics and advanced therapies. These initiatives have become standard practice for the EU and the US, with further collaboration on pharmacovigilance, orphan drug development and inspections.[17]
- Collaboration, joint dossier reviews and inspections of manufacturing sites, reliance and cooperation are key factors to build trust and capacity among NMRAs (national medicines regulatory authorities) in East Africa. All the NMRAs have functional registration and GMP inspection systems, supported by regional harmonized guidelines for registration, inspection, quality management and information management systems.[18]
- WHO has developed the Global Benchmarking Tool (GBT) as the global standard for objectively assessing regulatory capacity for medicines and vaccines to support low-income and middle-income countries in strengthening their capacity to effectively and efficiently regulate medical products.[19]
- The East African Community Medicines Regulatory Harmonization initiative reduced the amount of time it took to register medicines in individual countries by about half by instituting a suite of regulatory standards and processes aligned across the region, as well as by building the capacity of all its Partner States' NMRAs to engage in regulatory activities. Joint GMP inspections are now being conducted as well, further contributing to regulatory efficiency in the region. There is more trust among and between experts in the region.[20]
- The African Vaccine Regulatory Forum (AVAREF) overcame the lack of ethical and regulatory bodies in the region by leveraging on the resources of each body, while promoting communication and collaboration to minimize duplication of efforts. Key achievements include the establishment of innovative regulatory pathways for clinical trials, development of shared guidelines for clinical trial applications and joint reviews of multi-country applications and good clinical practice inspections.[21] This played a pivotal role in accelerating the clinical evaluation of Ebola vaccine candidates during its outbreak in the region.[22]

3. Build human capacity among medical product regulatory staff

Continued support of training centers for regulatory science

- The Centers of Excellence for Regulatory Science (CoEs) under the Asia-Pacific Economic Forum provides high quality training programs through partnerships with academia, regulators and industry.[23]

4. Continued and increased investment in regulatory system strengthening

Continued and increased investment in regulatory system strengthening (RSS) is needed in terms of:

1. Advancing and leveraging convergence and reliance initiatives;
2. Institutionalizing sustainability;
3. Utilizing risk-based approaches for resource allocation;
4. Strengthening registration efficiency and timeliness;
5. Strengthening inspection capacity and effectiveness;
6. Developing and implementing risk-based post-marketing quality surveillance systems;
7. Strengthening regulatory management of manufacturing variations.[24]

Photo: Chhor Sokunthea / World Bank

Policy and implementation recommendations

Challenge	Proposed Strategy	Recommendation
Over-dependence of resources and decision making on larger regulatory bodies **Political inertia** **Lack of practical feasibility** **Differences in priorities**	Advocate for **regulatory convergence and agility** to reduce dissimilarities between different regulatory bodies	"Different regulatory bodies will ultimately make an informed decision on the approval of a vaccine but convergence and reliance approaches will expedite the process and ensure that the medicine reaches communities quicker. From a population health perspective, promoting **regulatory agility**, especially during a dynamic and fast-moving outbreak, is worth pursuing. We should advocate for **regulatory convergence**, which aims to reduce dis-similarities and reference other countries, as it is more appropriate and feasible, compared to harmonization, which tends to assume absolute similarities and is difficult to achieve due to issues such as sovereignty concerns and different legal systems." **Prof John CW Lim**, *founding Executive Director, Center of Regulatory Excellence (CoRE), Duke-National University of Singapore Medical School (Duke-NUS)*.
	Promote **information sharing**, as well as develop **guidance** and **training** for regulators, so that national regulatory bodies can leverage on shared resources and adapt to respective national contexts and ensure pandemic preparedness	"The open sharing of information during the COVID-19 pandemic has facilitated a greater confidence in regulators to allow emergency use authorizations and conditional approvals of new vaccines. Ongoing sharing of information should be done early and regularly during an outbreak so that lower resourced countries can leverage on decisions and expertise of more developed regulatory systems, and adapt the information into a national context to expedite the approval process for vaccines." **Prof John CW Lim,** *founding Executive Director, Center of Regulatory Excellence (CoRE), Duke-National University of Singapore Medical School (Duke-NUS).*

Promote **sustained political will through capacity building** and regular best practice sharing sessions in each country and between different regulatory bodies, so there are multiple touchpoints with all relevant stakeholders to share progress and learnings	"Countries with stronger regulatory capabilities should spearhead the changes needed to support other countries in striving towards regulatory harmonization and convergence with the help of neutral third-party organizations, such as the World Health Organization." **Prof John CW Lim**, f*ounding Executive Director, Center of Regulatory Excellence (CoRE), Duke-National University of Singapore Medical School (Duke-NUS)*. "There has to be a top-down and bottom-up approach to achieve regulatory harmonization. We need to communicate the benefits of regulatory harmonization for the region with policymakers, while providing training and scholarships for junior regulators, so they are equipped with the skills needed to advocate for a converged and harmonized regulatory system in ASEAN." **Dr Kenneth Y. Hartigan-Go** (Philippines), *Senior Fellow, Ateneo Policy Center of Ateneo School of Government.*
Build platforms to promote **rapid data sharing** between countries. The end-to-end value chain, from the registration of clinical trials to the reporting of safety and efficacy in the post-market phase has to be considered.	"Public health and regulatory officials are very risk averse, therefore the status quo (of a lack of regulatory harmonization) is more attractive than innovation and advocating for harmonized and converged regulation. Therefore, we need to build a robust system of pharmacovigilance and risk-based management approaches to ensure that other countries' regulatory authorities whose decisions are adopted, are not held accountable for any adverse effects from a new product adopted in another country." **Dr Kenneth Y. Hartigan-Go** (Philippines), *Senior Fellow, Ateneo Policy Center of Ateneo School of Government.*

Table 4: A summary of proposed strategy and recommendations to improve regulatory harmonization in ASEAN

Conclusion

The COVID-19 pandemic has intensified discussions on the need for better regulatory workflows and convergence for vaccines and health products at large. While each country has the responsibility to make their own informed decisions on vaccines, a converged approach would be transformative for resource and information sharing and would accelerate processes to tackle current and future healthcare challenges.

"The time to advocate for regulatory convergence is now, as there are greater conversations stemming from the COVID-19 pandemic to ensure future pandemic preparedness. However, this requires stakeholders to focus on the common interests to public health and the system to which they are in. For example, the private sector aims for predictability, speed and agility. A converged regulatory system ensures these focus areas are met, so they can plan and allocate the needed resources and ensure timely access of new vaccines for populations. We need to focus on the benefits and maximum impact that regulatory convergence has, while working to minimize the potential pitfalls to build a fair and just system for countries with varying resources." **Dr Khor Swee Kheng**, *Senior Visiting Fellow, United Nations University, International Institute for Global Health.*

Photo: Markus Kostner / World Bank

Methodology

A literature review was conducted to determine the current regulatory landscape in ASEAN. The following questions were answered:

- Why is the regulatory landscape fragmented in the region and globally?
- What are the benefits and potential disadvantages of regulatory harmonization?
- What are the existing initiatives globally that can inform learnings for future initiatives in ASEAN?

Additionally, structured interviews were conducted with key stakeholders in the immunization and regulatory field to determine the opportunities and recommendations to promote a more harmonized and converged regulatory landscape in the region. The following experts were interviewed:

1. Prof John CW Lim, founding Executive Director, Center of Regulatory Excellence (CoRE), Duke-National University of Singapore Medical School (Duke-NUS).
2. Dr Kenneth Y. Hartigan-Go (Philippines), Senior Fellow, Ateneo Policy Center of Ateneo School of Government.
3. Dr Khor Swee Kheng, Senior Visiting Fellow, United Nations University, International Institute for Global Health.

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About APIC

The Asia-Pacific Immunization Coalition (APIC) was formed in 2021 to protect and sustain the hard-fought vaccination gains and build confidence in new vaccines resilient immunization systems that are well-resourced, sustainable, equitable, and integrated into the wider national healthcare system. The coalition aims to achieve this by using an evidence-informed approach to advocacy, activities and research to instill the value of vaccines among consumers, policymakers and other heath stakeholders.

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