



Accelerating Diagnostic Access in ASEAN

ASEAN Regional Consultation

16 February 2022
Via Zoom



ASEAN Dx Initiative (ASEAN Dxi)

The ASEAN Dxi was endorsed at the 76th ASEAN COSTI in 2018 to facilitate the co-development and adoption of healthcare diagnostics solutions for unmet clinical needs across ASEAN Member States (AMS). Co-chaired by the Philippine Council for Health Research and Development (PCHRD) and Singapore's Diagnostics Development Hub (DxD Hub), its objectives include addressing the rapidly growing healthcare demand driven by population growth and a rising middle class, as well as commercialising and making locally developed diagnostic products accessible in ASEAN.



ASEAN Network for Drugs, Diagnostics, Vaccines and Traditional Medicines Innovation (ASEAN-NDI)

The ASEAN-NDI is a regional innovation network composed of the ASEAN member states, namely: Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam. Its concept was proposed by the Philippines to ASEAN and was first discussed among the ASEAN member states during the 40th Meeting of the ASEAN Sub-Committee on Biotechnology (SCB) in Bali, Indonesia on 25–26 May 2009, and was later adopted by the ASEAN Committee on Science, Technology, and Innovation (COSTI) as its own initiative. ASEAN, through COSTI, approved the creation of the ASEAN-NDI in 2009. The Philippine Council for Health Research and Development (PCHRD) of the Department of Science and Technology (DOST) served as the secretariat of the ASEAN-NDI.



Diagnostics Development Hub (DxD Hub)

DxD Hub is Singapore's national platform for diagnostics development and is dedicated to leading MedTech innovation through partnerships and an undiminished passion for creating positive health outcomes. As well-recognised productisation experts, DxD Hub partners innovative companies to bring their products to market.



London School of Hygiene & Tropical Medicine (LSHTM)

LSHTM is renowned for its research, postgraduate studies and continuing education in public and global health. It has an annual research income of more than £180 million and is one of the highest-rated research institutions in the UK. With its collaborative ethos and an international presence in over 100 countries, LSHTM is uniquely placed to help shape health policy and translate research findings into tangible impact to improve health worldwide.



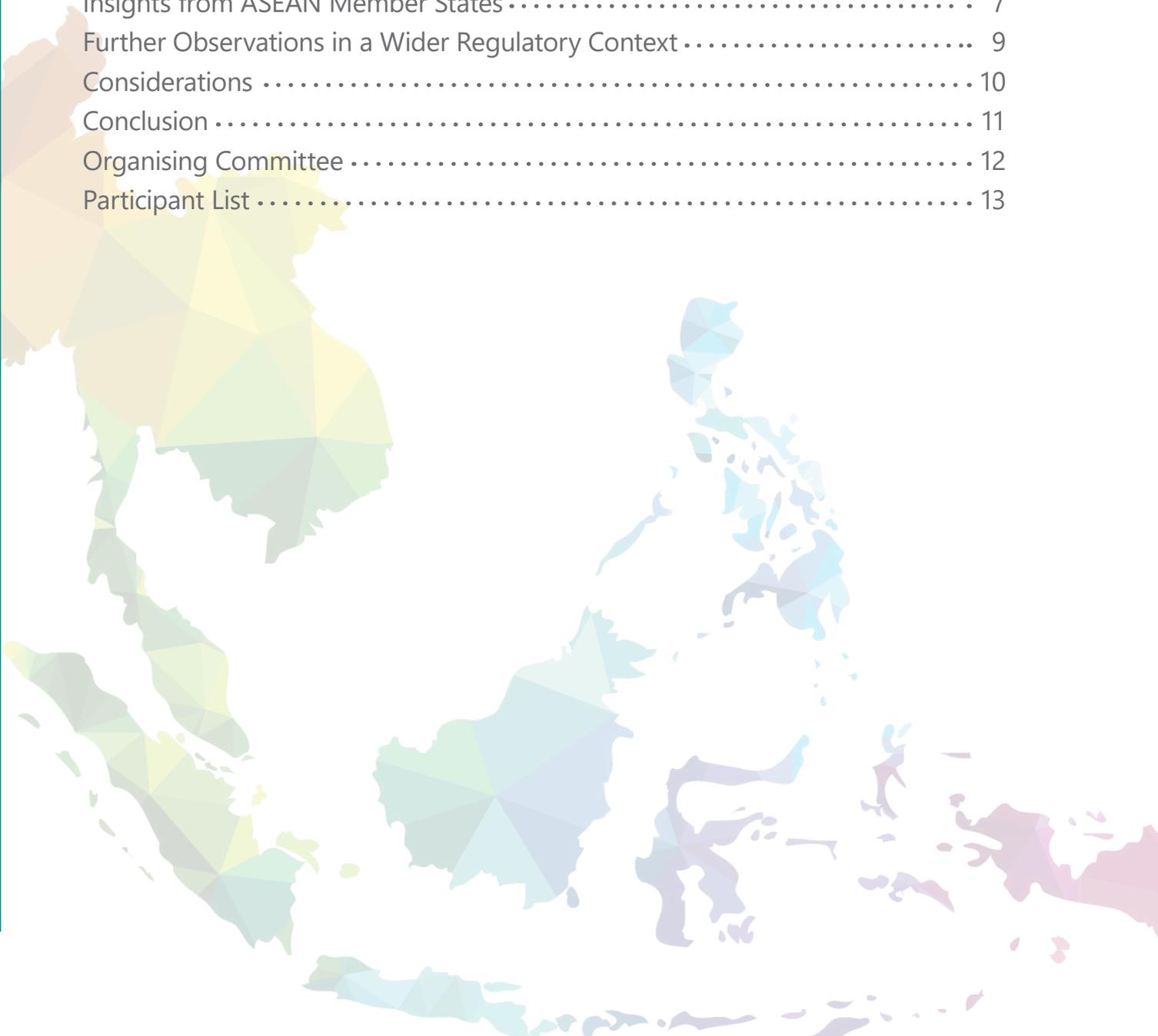
Philippine Council for Health Research and Development (PCHRD)

PCHRD is one of the three sectoral councils of the Department of Science and Technology (DOST). It is a forward-looking, partnership-based national body responsible for coordinating and monitoring research activities in the Philippines.

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Executive Summary

The ASEAN Regional Consultation, held on 16 February 2022, was organised by ASEAN Dxl and LSHTM as a proactive step to consolidate the learnings and recommendations from ASEAN countries for future pandemic preparedness. It sought to share key findings, experiences and best practices of member ASEAN countries and establish the follow-up measures needed in diagnostics capacity building based on the lessons learned over the last two years.

Common feedback across all member countries included a concern for quality of diagnostic results, given the speed at which diagnostic kits are produced, as well as a call for collaboration across all countries to share data, best practices and resources. The individual journeys of each country, with many processes duplicated at needless expense, highlighted the pressing need to come together to fight the pandemic by coordinating responsibilities through shared laboratories and involving more stakeholders, including key government and regulatory decision makers, in the diagnostics capacity building roadmap.

Moving forward, ASEAN Dxl is focused on a four-pronged approach: 1) regulatory measures to establish a regional platform for diagnostics approval for faster access to market as well as a pathway framework and centralised regional database to share diagnostics evaluation; 2) quality assurance of products developed with the establishment of a network of Product Quality Laboratories across ASEAN to share biological samples to develop ASEAN-relevant diagnostic kits; 3) diagnostics capacity building to ensure preparedness for future pandemics, learning from international partnerships; and 4) improved collaboration with public health and policy makers to establish a regional committee that would serve as a platform for global discussions on diagnostics and would require involvement of all sectors, disciplines, governments and policies to contribute to developing common statements on diagnostics.

Introduction

Since the COVID-19 pandemic emerged in late 2019 and spread rapidly across the globe, affecting in some way every person in every country in the world, the importance of timely, accurate diagnosis has become very clear. The pandemic also served to highlight the lack of capability and capacity to provide a timely and adequate diagnostic response.

Diagnostics takes its place

During the last two years of the COVID-19 pandemic, diagnostics has been recognised as an integral step in controlling COVID-19. The pandemic has shown that diagnostics has many uses beyond simply patient management. It is required for detection to provide early alerts of outbreaks. It is also needed to look at using case rates to inform control strategies, indicate where we should step up, where contact tracing is needed, etc.

In terms of epidemiologic research, diagnostics is used to help understand the pattern of spread, the transmission of disease and, during clinical trials, to define the patients for which drugs or vaccines may be useful. It also has a place outside of the health sector, for example, during a pandemic to enable mass gatherings and travel, etc.

The ASEAN Dx Initiative

The ASEAN Dx Initiative (DxI) was endorsed by the 76th ASEAN Committee of Science, Technology and Innovation (COSTI) in 2018 to facilitate the co-development and adoption of healthcare diagnostics solutions for unmet clinical needs across ASEAN member states. In October 2020, in response to the COVID-19 pandemic, the 78th COSTI approved the proposal to include diagnostics capacity building among the ASEAN member states as an area of focus for ASEAN DxI to strengthen our ability to respond to the current pandemic and those in the future.

Early feedback revealed three common observations

In January 2022, ASEAN DxI ran two sets of surveys to gather feedback within the ASEAN region. It sent out one survey to its ecosystem from 29 January 2022 to 7 February 2022 and received 12 responses from three countries. These responses revealed three common observations:

1. The expedited pathway played a very key role in the response to COVID-19.
2. There was a general concern about quality, given the speed of development and approval.
3. There was a resounding request for information sharing and capacity building with regards to diagnostics resources.

The observations were consistent with findings from the Africa Collaborative Initiative to Advance Diagnostics (AFCAD) and Pan American Health Organisation (PAHO). Emboldened by the feedback, ASEAN Dxl ran a webinar poll the following week and received more than 800 responses, half of which were from the public sector. The same three topics emerged as the top three responses once again.

The ASEAN Regional Consultation

The ASEAN Regional Consultation, held on 16 February 2022, was a roundtable discussion organised by ASEAN Dxl as a proactive step to consolidate the learnings and recommendations from ASEAN countries for future pandemic preparedness. The programme was split into two sessions. The first session included representatives from the public sector in the ASEAN region. Participants from the first session were also present in the second session, which was also attended by diagnostics industry observers.

The Regional Consultation aimed to:

- ◆ share key findings with ASEAN Dxl Strategic Planning Panel members of a recent survey on COVID-19 diagnostic accessibility conducted by the ASEAN Dx Initiative;
- ◆ exchange best practices and learnings with LSHTM's Accelerating Dx Access Project (ADAP); and
- ◆ develop follow-up actions in diagnostics capacity building for pandemic preparedness or disease outbreak management.

The various consultations that have taken place aim to shed light on the lessons that have been learned and how we can apply those learning now to prepare well for the next pandemic. The following pages summarise what was derived at the ASEAN regional consultation.

Insights from ASEAN Member States

On 16 February 2022, ASEAN DxI held an ASEAN Regional Consultation to gather further insights and share experiences and recommendations with its fellow regulatory counterparts in the ASEAN region. Eight of the ten countries participated and shared the following insights:

Cambodia

- ◆ Cambodia has a strong partnership with private companies in the pharmaceutical industry. The companies collaborate with the National Laboratory in the regulation and provision of rapid test kits and PCR tests in line with the country's Rapid Test Strategy.
- ◆ There was a call for the region to have stronger collaboration with the public and private sectors in diagnostics through better sharing of information and resources. This would help bridge knowledge gaps, mitigate the impact of diseases and foster collaboration for research.

Indonesia

- ◆ Given the logistical challenges presented by Indonesia's vast geography of islands, 977 laboratories were established. These are capable of running PCR and molecular tests across Indonesia's provinces. There is more than one laboratory present in each province.
- ◆ Indonesia has a close network of national research institutes able to perform research on serology tests to understand antibody response after vaccination or infection.
- ◆ Cost is a major challenge in diagnostics access in Indonesia. There is a need to share diagnostic standards, vaccines and treatments with the FDAs of other countries, which will help reduce costs significantly.
- ◆ Indonesia is also conducting genome sequencing to detect the variants of SARS-COV-2 and has mapped around 19,000 sequences of the virus. It is also working on diagnostic tests like rapid diagnostic tests for contact tracing and screening as well as research to understand antibody response after vaccination or infection.

Malaysia

- ◆ At the start of the pandemic, the National Laboratory had to take up the responsibility of procuring reagents and biological materials to validate diagnostics tests. It also relied on retained samples from past pandemics.
- ◆ There is a regulatory framework in place to monitor the quality of diagnostics entering the market.
- ◆ The cost of diagnostics is controlled by government policies to make it affordable.
- ◆ There is a need for an epidemiological approach to understand pandemic progression to allow for timely interventions for public health.
- ◆ Access to quality data is necessary for decision making.

Myanmar

- ◆ Myanmar had been able to acquire its COVID-19 diagnostic kits under a WHO pre-qualified diagnostics programme.
- ◆ Local government guidelines are in place to approve diagnostics for domestic use.
- ◆ Improvements to current product performance evaluation procedures for diagnostics are needed.
- ◆ Myanmar imports all its diagnostics from major manufacturers in China and America.
- ◆ Areas for improvement include a network to update on developments in diagnostics in ASEAN countries and more training programmes and resources for diagnostics.

Philippines

- ◆ The Philippine FDA approves all COVID-19 diagnostics used in the country. It has established requirements to ensure product performance prior to market entry.
- ◆ The Philippines has in place an Emergency Use Authorisation equivalent for COVID-19 test kits.
- ◆ For imported products, the Philippine FDA would consider performance evaluations from foreign mature regulatory bodies.
- ◆ The government has partnered with private companies to take up the manufacturing of diagnostic kits with government supervision and guidance.
- ◆ There is collaboration with national reference laboratories (e.g. Research Institute for Tropical Medicine) and private reference laboratories to validate the performance of diagnostics.
- ◆ Health technology assessment is conducted on all products that will be procured by the government.

Singapore

- ◆ Singapore uses a risk-calibrated approach towards evaluating and developing diagnostics for COVID-19.
- ◆ The public sector works with developers of the tests, researchers and experts to develop diagnostics, which enables it to leverage more resources such as in silico data and bioinformatics.
- ◆ Post market surveillance is in place for approved products. Products approved under provisional authorisation are required to transit into full registration within a given timeframe.
- ◆ Requirements for dataset guidelines for full registration (analytical performance and clinical validation) were made available online.
- ◆ In silico (bioinformatics) data is considered for diagnostics for new SARS-COV-2 variants.
- ◆ Improvements can be made in the following areas: testing standards, reference standards, reference materials.
- ◆ Having qualified testing facilities or clinical testing labs in the region would be helpful.

Thailand

- ◆ Thailand's Emergency Operations Centre oversees the country's COVID-19 response.
- ◆ Thailand was able to develop diagnostics to screen for COVID-19 relatively rapidly.
- ◆ Challenges were faced in the following areas: Capacity of regulatory agency, capacity of manufacturers to keep up with the demand for diagnostic kits and raw materials used in manufacturing these kits.
- ◆ Health Technology Assessment can be a tool for researchers and regulators to determine the effectiveness of diagnostic kits or products.

Vietnam

- ◆ Vietnam faced challenges in acquiring information and quality control samples.
- ◆ Establishing a regional network to share accurate information and control samples would be key to pandemic preparedness.
- ◆ A central raw materials-type production clearing house serving the region would also be useful.

Further Observations in the Wider Regulatory Context

Regulatory agility is a must

All countries recognised the need to be agile, a term that has been used often over the last two years by regulatory authorities and the governments, not only within the ASEAN region but across the world. That being said, the R&D communities, both public and private, faced great difficulty in getting products approved in a timely manner. Understandably, regulatory authorities need to ensure unsafe products don't reach the market. Regulators must also ensure that they work under strict laws and regulations that prevent them from being proactive in supporting new products.

The need to work together

Before the pandemic, there were already a lot of initiatives ongoing to promote convergence or harmonisation in regulatory systems and this applied both for diagnostics and therapeutics. However, at the start of the pandemic, there was understandably more divergence because every country had to respond quickly and independently within the limitation of resources available.

Considerations – 4 Focus Areas

The discussions during the regional consultation generated some common considerations that focused around 4 areas:

- 1) Regulatory,
- 2) Product development & quality assurance,
- 3) Diagnostics capacity building and
- 4) Collaboration with public health and policy makers.

Participants are confident that these measures would provide the necessary impact towards improving access to diagnostics across the ASEAN region.

Regulatory Focused

- ◆ Establish a regional platform for diagnostics approval to allow evaluation and approval of diagnostics to be sped up for faster access to the regional market.
- ◆ Develop and implement a set of diagnostics development standards and an ethical framework to guide diagnostics development in ASEAN to ensure appropriate evaluation of kits before entering the market.
- ◆ Establish a regional pre-market product validation and post market surveillance mechanism such as a Pathway Framework and a centralised regional database for data sharing to facilitate diagnostics evaluation.

Product Development & Quality Assurance

- ◆ Establish a network of Product Quality Laboratories across ASEAN as a regional platform to facilitate sharing of qualified biological samples and provide shared databases for diagnostics use cases and performance. This would facilitate the development of ASEAN-relevant diagnostics kits.
- ◆ Establish a regional manufacturing facility for reagents and materials for diagnostics production. This would strengthen the supply chain for these materials and facilitate the development and manufacturing of diagnostics in the region.

Diagnostics Capacity Building

- ◆ Ensure a level of pandemic preparedness by developing expedited regulatory pathways. This would accelerate diagnostics approval in times of pandemics and facilitate the supply of diagnostics to meet pandemic requirements.
- ◆ Advocate diagnostics to audiences in the medical device and public health industries through the use of webinars on key diagnostics issues and developments.
- ◆ Scale efforts globally in order to improve diagnostics access through international partnerships and collaborations such as with AFCAD and PAHO. This would allow sharing of best practices across regions that may develop innovative solutions to address diagnostics access across regions.

Collaboration with Public Health and Policy Makers

- ◆ Establish a regional committee on diagnostics. This would serve as a platform for regional discussions on diagnostics. It would require cooperation by scientific academies and ministries to initiate the process, which will promote partnerships and advocate for diagnostics in these sectors.
- ◆ Take a multisectoral approach towards the development of diagnostics. This would require involvement of all sectors, disciplines, governments and policies to contribute to developing common statements on diagnostics.

Conclusion

Diagnostic access plays an essential role in medical management and public health interventions across the ASEAN region and the world, yet huge challenges exist in providing access to those who need it. The Accelerating Diagnostic Access in ASEAN Regional Consultation was key to taking the first step in developing solutions to tackle this issue. Solutions that were derived from the discussions concentrated on the four focus areas of regulatory approval pathways, product development and quality assurance, diagnostics capability building and collaboration with public health and policy makers. Solutions developed from these would go towards regional efforts to enhance and accelerate access to diagnostics in the ASEAN region, which in turn will prepare and equip us to respond well to pandemics in the future.

“May we all heal as one.”

Dr. Oscar Gutierrez Jr., Director General
Food and Drug Administration, Philippines

Organising Committee

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ASEAN Dx Initiative

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Participant List

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