PROJECT HIGHLIGHTS AND RECOMMENDATIONS

ADB-CoRE VACCINE REGULATION FIRM

Collaboration between

Asian Development Bank (ADB)

and

Centre of Regulatory Excellence (CoRE)

Duke-NUS Medical School, Singapore

ADB

DukeNUS Medical School | Centre of Regulatory Excellence

Table of Contents

1 Executive Summary

In 2023, the Centre of Regulatory Excellence (CoRE) continued its collaboration with the Asian Development Bank (ADB) on regulatory systems strengthening in developing member countries to promote equitable access to innovative health products. The current project, Vaccine Regulation Firm, is supported under ADB's Support to Enhance COVID-19 Vaccine Access by Developing Member Countries (APVAX) program, with the overarching goal of strengthening the regulatory resilience for public health emergencies. This project aims to inform the Health Sector Group of ADB on the regulatory landscape in Asia and the Pacific, focusing on a review of regulatory systems strengthening in Bangladesh, India, Indonesia, Singapore, and Korea with a deep-dive review of Bangladesh and Indonesia.

In this project, the team conducted a series of educational, think tank and advisory activities on regulatory systems strengthening work and established a network of vaccine developers, manufacturers and regulators among the Asian Development Bank developing member countries (DMCs). These activities include an inaugural ADB-CoRE Vaccine Seminar, a regional landscape analysis, two country-specific landscape analyses (Indonesia and Bangladesh) and two workshops for the regulators in the Indonesian Food and Drug Authority (FDA). This impactful project has garnered extensive media attention and has been covered in regional media. Details are listed in Annex.

This collaborative partnership between ADB and CoRE highlights the amplifying effect of partnerships in regulatory systems strengthening. Continual and sustained regulatory capacity building through education, think tank and advisory activities will advance regulatory excellence among developing member countries of the ADB, support local and regional production, and facilitate access to essential medicines, medical devices and vaccines, high quality health services and a health promoting environment. This report summarises the project highlights and recommendations for next steps in regulatory systems strengthening among ADB DMCs.

2 Project Highlights

2.1 ADB-CoRE Vaccine Seminar

The ADB-CoRE Vaccine Seminar on "Fit-for-Purpose Vaccine Technologies: The Amalgamation of Science, Policy and Practice" was conducted from 5 to 7 October 2023 at Duke-NUS Medical School in Singapore. This by-invitation seminar gathered more than a

hundred senior leaders from multiple sectors, active in vaccine development, financing, manufacturing and regulation to discuss scientific, technical and regulatory issues in this interpandemic phase. Public sector representatives from Bangladesh, India, Pakistan, Cambodia, Lao PDR, Viet Nam, Thailand, Malaysia, Philippines, Indonesia, Kazakhstan, Mongolia, Australia, Singapore and Korea attended. The seminar comprised four themes: (a) Science of Vaccine Technologies, (b) Manufacturing and Other Considerations of Vaccine Technologies in Low-Resourced Settings, (c) Regulation of the Vaccine Life Cycle, and (d) Sustainability in Resource Constraint Settings. Throughout the two days, the diverse stakeholders discussed common ground and solutions for issues supporting equitable vaccine access and regulatory system strengthening.

This seminar exemplified the approach and commitment of CoRE to advance regulatory excellence. Through multi-sectoral partnerships, a fit-for purpose collaborative vaccine strategy with consideration of scientific, technical and regulatory issues will ultimately advance sustainable vaccine manufacturing and regulatory agility in the Asia Pacific and strengthen the region's resilience to manage future pandemics and other public health emergencies.

Figure 1: Inaugural Asian Development Bank-Centre of Regulatory Excellence Vaccine Seminar attended by over 100 thought leaders in vaccine research & development, manufacturing and regulatory science.

2.2 Regional Landscape Analysis

The regional landscape analysis provided an assessment of the vaccine ecosystem and regulatory frameworks of five countries, namely Bangladesh, India, Indonesia, Republic of Korea and Singapore. Findings were based on systematic literature review, semi-structured interviews with key stakeholders and insights garnered from the regional multi-stakeholder ADB-CoRE Vaccine Seminar titled “Fit-for-Purpose Vaccine Technologies: The Amalgamation of Science, Policy and Practice”, held from 5-7 October 2023.

2.3 Country-specific Landscape Analysis

The country-specific report on Bangladesh and Indonesia aimed to share expert insights on the vaccine regulatory frameworks and propose practical recommendations on regulatory systems strengthening and capacity building efforts for Bangladesh and Indonesia. These reports provide country-specific strategic roadmaps for regulatory systems strengthening towards World Health Organization Listed Authority (WLA). In discussing country-specific requirements and roadmaps, strategic engagements with vaccine stakeholders, ministries of health and NRAs were conducted. One example was the Indonesian Stakeholders Meeting involving the Indonesian Ministry of Health, Indonesian FDA, ADB, CoRE and vaccine manufacturers at the launch of Indonesia’s VOLARE initiative.

Figure 2: Prof John Lim, Executive Director of the Duke-NUS Centre of Regulatory Excellence (CoRE) engaging with Mr Budi Gunadi Sadikin, Health Minister of Indonesia at the Indonesian Vaccine Manufacturing Stakeholders Meeting with Duke-NUS CoRE and the Asian Development Bank. January 2024, Jakarta

Figure 3: Indonesian Vaccine Manufacturing Stakeholders Meeting with Duke-NUS Centre of Regulatory Excellence (CoRE), and the Asian Development Bank, attended by Professor John Lim, Executive Director of CoRE, Mr Budi Gunadi Sadikin, Health Minister of Indonesia, Dr Lucia Rizka Andalucia, Director General for Pharmaceutical and Medical Devices, Ministry of Health, Indonesia and Dr Patrick Osewe, former Director, Human and Social Development Sector Office, Sectors Group, ADB. January 2024, Jakarta

2.4 Capacity Building Workshops

Additional capacity workshops were initiated based on expert insights which highlighted regulatory capacity building as one of the key recommendations to support the Indonesian FDA in its regulatory systems strengthening aim of attaining WHO Listed Authority status. The additional capacity building activities completed were:

• 1st Workshop: Fundamentals of Health Products Regulation, in Singapore

• 2nd Workshop: Regulatory Oversight for Advanced Therapy Medicinal Products (ATMP), in Indonesia

1st Workshop: Fundamentals of Health Products Regulation

The first ADB-CoRE Capacity Building Programme: Fundamentals of Health Products Regulation leveraged on the ongoing CoRE Graduate Certificate on Pharmaceutical Regulation, a National University of Singapore-accredited course (GMS5003). This fundamental course provided the understanding of the contribution of the various stakeholders, functions and guidelines that shape the regulatory environment and impact on the healthcare management environment. The concept of product life cycle was also explored among other contemporary regulatory approaches. Nine senior Indonesian FDA officers, chosen from various regulatory backgrounds, participated in both theoretical and practical training on the essentials and international best practices of regulatory principles throughout the entire product life cycle.

Figure 4: Regulators from the Indonesian Food and Drug Authority attending the Duke-NUS Centre of Regulatory Excellence's "Fundamental of Health Regulation" Workshop. 9 – 13 September 2024, Singapore

2nd Workshop: Regulatory Oversight for Advanced Therapy Medicinal Products (ATMP)

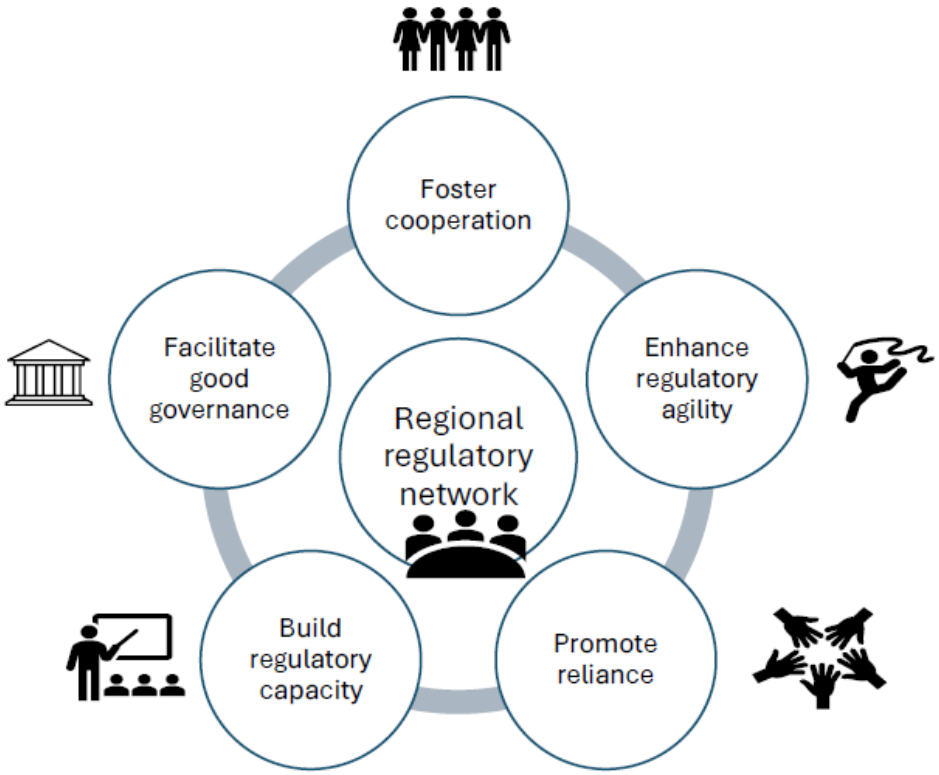
This course aimed to provide a better understanding of the different frameworks and practices regulating advanced therapies, including requirements for product evaluation and dossier submission for an effective product life cycle management. The course was useful for enabling Indonesian FDA regulators to understand global trends in regulatory approaches and strengthen the skillsets to accommodate innovation. There was also a focus on promoting convergence of regulatory approaches for advanced therapies. The CoRE team completed in-country ADB-CoRE Capacity Building workshop in Indonesia from 11 to 14 November 2024 with support from international speakers from the Australian Therapeutic Goods Administration (TGA), Japan's Pharmaceuticals and Medical Devices Agency (PMDA), and Chinese Taipei's Taiwan Food and Drug Authority. The workshop was well-attended by 42 Indonesian FDA regulators, 3 Indonesian Ministry of Health officers and 80 virtual participants. Mr Renadi Budiman, ADB's Deputy Country Director for Indonesia and Prof. Taruna Ikrar, Chairperson of the Indonesian FDA honored the workshop with their presence.

Figure 5: Asian Development Bank-Centre of Regulatory Excellence Training Workshop: Indonesian Food and Drug Authority. Regulatory Oversight for Advanced Therapy Medicinal Products (ATMP). 11 – 14 Nov 2024, Jakarta. Attended by Prof Taruna Ikrar, Chairperson of the Indonesian Food and Drug Authority, Mr Renadi Budiman, Deputy Country Director for Indonesia, Asia Development Bank as well as Asst. Prof James Leong, Head of Health Products & Regulatory Science and Asst. Prof Tan-Koi Wei Chuen, Lead of Regulatory Systems Strengthening at the Duke-NUS Medical School Centre of Regulatory Excellence.

3 Recommendations

The recommendations on regulatory systems strengthening from the regional landscape analysis and policy briefs will help to strengthen the foundations for building functional national regulatory systems and strengthen regulatory resilience for public health emergencies in Asia and the Pacific, particularly in low-resourced DMCs.

Figure 4: Key recommendations of the regional landscape analysis report



Recommendations on Regulatory Systems Strengthening

With an understanding of the key regulatory factors, coupled with a whole-of-region perspective in approaching the challenges associated with strengthening of regulatory systems for sustainable vaccine manufacturing, this section provides five key recommendations to strengthen regulatory systems at a regional level.

3.1 Foster Cooperation

Challenges: Participation in regulatory platforms has been shown to build trust and foster regulatory cooperation among the national regulatory agencies (NRAs), particularly in the

context of the regulatory systems in Asia and the Pacific. Existing regulatory platforms are often sub-regional in nature. There often exist overlaps in NRAs affiliated to various sub-regional groupings and in the scope of regulatory work covered.

Recommendation: Deepening cooperation among member states within existing sub-regional multi-stakeholder alliances would be an important first step. Nonetheless, regional models are not without challenges which would need sustained efforts to boost cooperation and consensus building, including on important areas around legislative frameworks of member states and data governance. Leveraging and building on existing political and economic frameworks such as the Association of Southeast Asian Nations (ASEAN) to foster multi-stakeholder regulatory cooperation could support consensus building in addressing these issues. The regulatory efficiencies and coordination of resources from adopting a whole-of-region approach has the potential to better support regulatory system strengthening in lower-resourced member states in Asia and the Pacific. While existing models in other parts of the world such as the European Union (EU) and Africa are based on legislative frameworks, the principles and structures could be useful references for a multi-stakeholder regional alliance. Adapting these models to the socioeconomic and political context of Asia and the Pacific would be crucial to facilitate strengthening regulatory frameworks to enable sustainable regional vaccine manufacturing.

In addition, public-private partnerships (PPP) can be further strengthened. Collaborating with the private sector can enhance regulatory efficiency and leverage external technical expertise and insights. There are many potential areas of collaborations including providing input via public consultation of the draft regulations, collaborating in research on innovative regulatory approaches, methodologies, and standards, developing medicines for neglected diseases while ensuring affordability. PPPs are powerful approaches in the pharmaceutical regulatory field, fostering innovation, improving regulatory efficiency, and enhancing global public health. However, careful governance and transparency are essential to maximise their benefits while minimising risks.

3.2 Enhance Regulatory Agility

Challenges: While NRAs globally demonstrated regulatory agility during the COVID-19 pandemic, more can be done to build trust, share best practices and equip NRAs with the necessary tools during peacetime to facilitate an effective and agile regulatory response during public health emergencies.

Recommendation: Existing regulatory networks such as the International Coalition of Medicines Regulatory Authorities (ICMRA) and South-East Asia Regulatory Network (SEARN) are important to not only provide a platform for regular exchanges among NRAs but also to build trust over time, which forms the basis for effective and agile regulatory response during emergencies. The regular exchanges during peacetime to enhance sharing of regulatory best practices and innovative regulatory approaches provide NRAs with the necessary tools to be nimble in response to a public health crisis.

In addition, it is important to periodically review the need to enhance legal and regulatory framework**.** Augmenting legal and regulatory frameworks is essential for fostering a transparent, efficient, resilient governance system. This can be achieved by regulatory harmonisation, modernisation of regulations, closing regulatory gaps, and ensuring alignment with international best practices. Along with enhancing legal and regulatory framework, strengthening independent regulatory bodies with adequate resources and skilled and trained professionals will support impartial enforcement which is free from political influence.

3.3 Promote Reliance

Challenges: Duplicative efforts among NRAs can contribute to regulatory burden, negatively impact the ability to respond with agility, and ultimately hinder the equitable, timely access to vaccines and other essential medical countermeasures across regional markets in a public health crisis.

Recommendation: Reliance is a pragmatic way for NRAs to augment their regulatory capacity, minimise regulatory burden and develop accelerated approval pathways while continuing to ensure quality of decision making. Regulatory networks are important platforms that support the building of trust among NRAs, encouraging increasing levels of reliance over time that can eventually pave the way for formal mutual recognition agreements. It can also facilitate broadening the list of legacy reference agencies to include other functional NRAs in the wider regional regulatory network. However, adopting reliance practices is not without challenges and does require significant investments. These include the need to invest in secure platforms such as cloud-based technologies to enable safe and timely sharing of confidential information within the regional regulatory network, guidance on data governance, and data transparency that could involve consensus building around the minimum information required in reference agencies' assessment reports to determine product sameness. More

emphasis is needed to support NRAs in adopting reliance mindset and practices while at the same time adopting WHO Global Benchmarking Tool to evaluate and work towards regulatory systems strengthening towards well-functioning maturity level 3, 4 and WHO listed authority (WLA) status.

3.4 Build Regulatory Capacity

***Challenges*:** Attaining and maintaining strong regulatory systems can be resource-intensive, particularly for NRAs that are maturing in their regulatory systems.

***Recommendation*:** Taking reference from the WHO Coalition of Interested Parties (CIP) model for capacity building, a coordinated approach among stakeholders can provide for a more resource-efficient model, although this can require some effort to coordinate resources and scope of work among stakeholders involved. A neutral, multi-stakeholder regional network could provide the practical means to facilitate coordination among stakeholders, with the opportunity to tap on the complementary scope of expertise of diverse stakeholder groups. Given the ever-evolving vaccine landscape and emerging platform technologies, industry and academic stakeholders who are at the frontier of these advancements are better poised as knowledge partners to help equip regulators with the regulatory capacity to be at the forefront of regulating latest vaccine developments.

A well-designed training programme for regulators is essential for building capacity, ensuring consistency, and improving the effectiveness of enforcement and compliance in regulatory systems. Given the diverse nature of the Asia-Pacific region, regulators must be equipped with the necessary skills, knowledge, and tools to address domestic and international challenges. For example, in the example of the reliance approach, WHO and APEC Regulatory Harmonization Steering Committee (RHSC) Centres of Excellence can lead in capacity-building initiatives. Other key areas of interest include the conduct of audits and inspections. Regulatory officials should be well-versed in the practices of conducting audits and inspections and have the necessary skills to identify violations, conduct investigations, and take enforcement action.

3.5 Facilitate Good Governance

Challenges: The diverse regulatory systems in the region can pose challenging barriers to vaccine firms seeking to access multiple regional markets in a timely manner.

Recommendation: Strong regulatory systems are a hallmark of good governance. Adoption

of internationally harmonised standards provide a common understanding around vaccine safety, efficacy and quality to support cooperation and strengthening of regulatory systems. This in turn can attract investments into the region. Advanced NRAs, such as the Republic of Korea's Ministry of Food and Drug Safety and Singapore's Health Sciences Authority, provide benchmarks and models of good governance for Asia and the Pacific, advance innovative regulatory policy, and can potentially provide leadership for coordinated regional regulatory responses during public health emergencies.

In addition, efficient enforcement mechanisms, including penalties for violations, must be backed by laws and regulations. While penalties can vary significantly from country to country, they should be sufficient to act as a deterrent against non-compliance. This may include financial fines, suspension of operations, or other administrative sanctions. Regular audits, real-time monitoring, and alternative dispute-resolution mechanisms help maintain regulatory effectiveness without overburdening legal systems.

4 ADB-CoRE Policy Briefs

A series of policy briefs have been prepared to highlight the importance of the interconnectivity between vaccine science, manufacturing and regulatory science, particularly in lower-resourced countries and in the context of the growing interest in local production. These policy briefs were published on Development Asia, the ADB's knowledge collaboration platform for sharing development experience and expertise, best practice and technology relevant to the Sustainable Development Goals. The topics are,

- Enhancing Vaccine Regulation for Pandemic
- Building Sustainable Vaccine Manufacturing Practices in Lower-Resourced Settings
- Ensuring Sustainable, Locally Relevant Vaccine R&D in Resource-Limited Settings

4.1 Enhancing Vaccine Regulation for Pandemic Preparedness

Link

- Enhancing Vaccine Regulation for Pandemic

Key Points

1. COVID-19 has highlighted the importance of good and agile regulation to enable timely access to safe, effective and quality vaccines. However, regulatory system strengthening remains a particular challenge for lower-resourced countries.
2. Regulatory system strengthening can be approached from different strategies such as systematic approach to address gaps in regulatory system and supporting education of regulatory professionals.
3. Regulatory convergence and cooperation, through confidence-based mechanisms and work sharing arrangements, is a key strategy for lower-resourced countries to leverage on regulatory capacities of other stable, well-functioning regulatory systems while facilitating mutual learning among regulators. Initiatives like the ASEAN Mutual Recognition Arrangement and Access Consortium have demonstrated the efficacy of shared reviews, expediting access to vaccines and increasing regulatory efficiency. Such collaboration allows for streamlined regulatory assessments, shortening the approval timelines while maintaining robust safety and efficacy checks.
4. A risk-based approach across the vaccine life cycle supported by a robust post-market monitoring framework forms the basis of regulatory agility.

5. Strengthening multisectoral collaboration promotes resilient health systems.

Recommendations

Paradigm shifts in recognising the enabling role of regulation in proactively guiding the development and application of scientific advancements and access to novel vaccines.

Regulatory systems strengthening and capacity building

1. A systematic approach to strengthening the regulatory system, using the World Health Organization Global Benchmarking Tool (WHO GBT)
2. Sustained capacity building and education of regulatory professionals

Regulatory convergence and cooperation

1. Leverage regulatory assessments made by reference agencies through formal recognition arrangements
2. Promote work sharing and joint assessments, with formalised processes and relationships
3. Indicators can be created to measure work sharing efficiency

Risk-based approach with robust post-market surveillance

1. Participate in surveillance networks
2. Upskill competencies in post-market surveillance and pharmacovigilance
3. Adopt post-market surveillance framework such as the proposed by WHO 3S (Smart Safety Surveillance) stepwise strategy

Enhance multisectoral collaboration

1. Offer early industry engagement during pre-submission regulatory consultations as a standard approach
2. Drive multisectoral collaboration
3. Partner the wider community of stakeholders

4.2 Building Sustainable Vaccine Manufacturing Practices in Lower-Resourced Settings

Link

- Building Sustainable Vaccine Manufacturing Practices in Lower-Resourced Settings

Key Points

1. Disparity of vaccination access between low and high-resourced countries leads to a higher burden of vaccine-preventable diseases in lower-resourced countries. Vaccine manufacturing capacity is restricted to a small number of manufacturers. Suboptimal investments in vaccine R&D and manufacturing in markets with lower commercial value further compound inequity.
2. In this interpandemic phase, independent vaccine manufacturing capacity and self-reliance are actively being explored as options to enhance equitable access to high-quality, safe, and effective vaccines.
3. Vaccine manufacturing is influenced by vaccine demand. There are significant financial investments required for product development, facilities, labour, licensing and regulatory processes.
4. Vaccine manufacturing, involving many upstream and downstream processes, demands a robust quality management system to ensure an uninterrupted supply of raw materials and consumables, current good manufacturing practice (cGMP) compliant facilities and state-of-the-art equipment.
5. Manufacturing collaborations heavily rely on technology transfer, extensive and transparent knowledge sharing from the innovators to ensure consistent vaccine production with acceptable variations.
6. Existing multinational, regional vaccine manufacturer platforms or hub-and-spoke networks could support vaccine manufacturers in their effort to work towards sustainable vaccine manufacturing.
7. Fragmented regulatory requirements increase barriers to sustainable manufacturing.
8. There is a delicate balance between incentivising innovation, advocating for equitable access, and protecting intellectual property (IP) law and rights. Vaccine manufacturing must consider the impact on the environment.

Recommendations

1. Conduct feasibility assessments and demand forecasting to understand vaccine demand and choose the appropriate technology platforms and vaccine candidates for sustainable vaccine manufacturing.
2. Direct public investments in manufacturing facilities, including funding in national budgets.
3. Employ a life-course approach to vaccination. This includes immunization schedules and access to vaccination for individuals of all ages with national disease burden consideration, individual phase of life, lifestyle preferences and risk factors for infectious disease.
4. Improve regulatory pathways and standards using regulatory reliance and strengthen regulatory capacity by training and upskilling the regulatory workforce.
5. Greater collaboration and cooperation among countries to address systemic issues around intellectual property rights, technology transfer and data sharing.
6. Implement optimising packaging materials and sustainable manufacturing practices to maintain ecological sustainability.

4.3 Ensuring Sustainable, Locally Relevant Vaccine R&D in Resource-Limited Settings

Link

- Ensuring Sustainable, Locally Relevant Vaccine R&D in Resource-Limited Settings

Key Points

1. The choice of vaccine platforms and development requires a comprehensive understanding of the pathogen family, sites of infection, immune correlates of protection, outbreak scenarios (pandemic versus endemic), and costs.
2. While mRNA may be the platform of choice for pandemic vaccines due to its ease of scalability, other considerations such as vaccine efficacy and long-term immunity may be prioritized when developing vaccines for endemic diseases.
3. Judicious research & development (R&D) investments in a variety of platforms, innovations in manufacturing, and assays may help to maximize the likelihood of finding successful vaccine candidates for infectious diseases.
4. Vaccine R&D funding decisions must be based on a rational investment framework to forecast the demand for vaccines and to determine their 'full' value, including the social, economic and population health benefits.
5. Regulatory agility principles, including rolling review of data and decisions based on anticipated benefit-risk profiles, have been key to facilitating timely access to safe and high-quality vaccines during the COVID-19 pandemic.
6. An entire ecosystem for vaccine development and deployment, including capacity building initiatives and support for technology transfer in lower-resourced countries, will help to improve vaccine affordability in these countries.

Recommendations

1. Prior to determining the path for vaccine design and development, a thorough understanding of the pathogen, vaccine technologies, immune correlates of protection, outbreak scenario, and the costs must be considered.
2. Invest in a diverse portfolio of vaccines.
3. Conduct a systematic gap analysis to identify areas of guidance and develop tailored programs to strengthen the ecosystem for resourced-limited countries.
4. Develop capacity to implement various strategies for accelerating clinical trials.
5. Create downstream collaborative multi-stakeholder networks to encourage transparent data-sharing on manufacturing processes, vaccine safety and efficacy data, to align regulatory requirements and resolve intellectual property issues.

5 The Way Forward

Despite the differences in national regulatory systems and a wide spectrum of maturity levels, Asia and the Pacific as a region has the tremendous potential and ability to strengthen its regulatory systems to support sustainable vaccine manufacturing in ensuring collective vaccine resilience. The establishment of a regional regulatory network could potentially be a way forward to securing this possible future.

To move forward with such a network, there is a need for proactive engagement of government leaders and policy makers from all relevant member states within the region, as well as with stakeholders including NRAs, industry, academia and across different government agencies beyond the health sector. Leveraging the existing political and economic frameworks of Asia-Pacific Economic Cooperation (APEC), ASEAN, SEARN and others will provide support to the establishment of this network and minimize duplicative initiatives. This proposed regional regulatory network underpinned by the principles of neutrality and inclusion can provide a platform for all relevant stakeholders within the vaccine ecosystem to openly engage in contributing to building regional regulatory capacity. There are also other sociopolitical and economic benefits of this network, and further engagements are needed with relevant experts and stakeholders to map its structure and ensure sustainability.

6 Annex: Media Coverage

Source: Asia Today

Indonesia Plays a Big Role in Realizing Vaccine Resilience in Asia Pacific

by Redaksi Asiatoday — January 27, 2024 in News Reading Time: 2 mins read

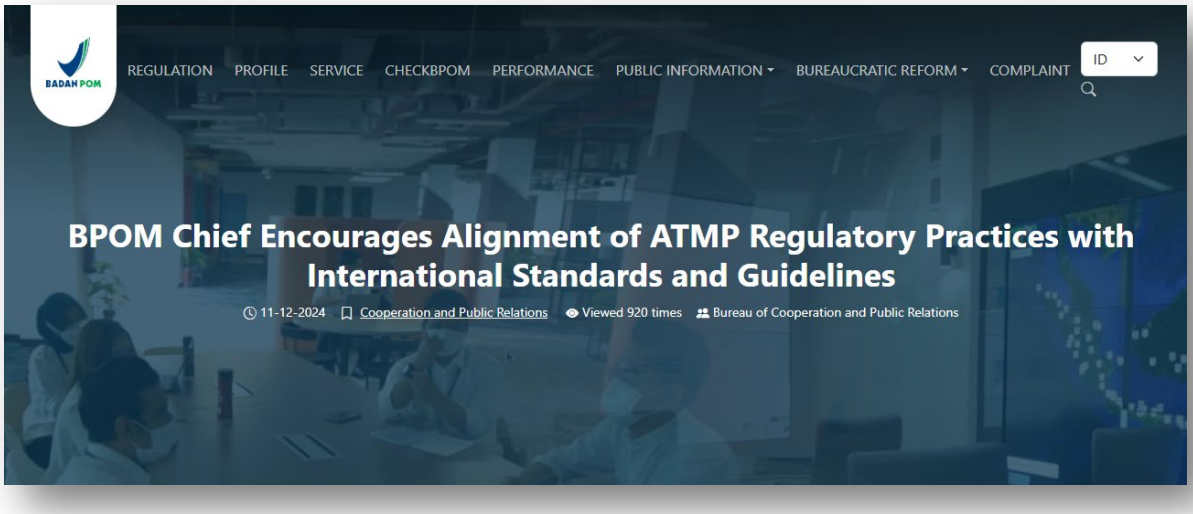
AA 0

Vaccine in Indonesia. Doc

ASIATODAY.ID, JAKARTA – Indonesia plays a major role in the Asian Development Bank (ADB) Vaccine Regulation Project program in the Asia Pacific Region.

Source: [Ministry of Health, Indonesia]

Source: [Kontan Press Release]



Source: https://www.antaranews.com/berita/4461949/bpom-selaraskan-praktik-regulasi-atmp-dengan-standar-internasional

ANTARA KANTOR BERITA INDONESIA

HOME POLITICAL LAW ECONOMY METRO FC

BETWEEN > Humanities > BPOM aligns ATMP regulatory practices with international standards

BPOM aligns ATMP regulatory practices with international standards

Tuesday, November 12, 2024 21:49 WIB

Head of the Food and Drug Supervisory Agency (BPOM) Taruna Ikrar gave a speech at the Workshop "Regulatory Oversight for Advanced Therapy Medicinal Products (ATMP)", Monday (11/11/2024).

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The views presented in this report are those of individual contributors and do not represent formal consensus positions of the authors' organisations or CoRE.

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