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INTRODUCTION

The Need for Efficient and Effective Regulation

- Good Regulation Facilitates Access to Medicines and Health Products
- Timely Response to a Rapidly Changing Landscape
- Celebrating the Efforts for Building Regulatory Capabilities

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The regulation of medicines represents a vital and unique component of any health system that truly cares for health. Delaying plans for an efficient and effective regulatory system would be detrimental to healthcare delivery. As such, regulatory systems strengthening is no longer an option to consider for the future, but requires the immediate commitment of all stakeholders to journey together for the interests of patients.

Dr Margaret Hamburg
Foreign Secretary
National Academy of Medicine
Former Commissioner
U.S. Food And Drug Administration
Chair, Advisory Board
Duke-NUS Centre of Regulatory Excellence

”
The Need for Efficient and Effective Regulation

Good Regulation Facilitates Access to Medicines and Health Products

* A robust health products regulatory system strikes a critical balance between facilitating timely access to good quality, safe, and efficacious health products and supporting the biomedical research and drug development ecosystem.

One of the objectives under the United Nations Sustainable Development Goal 3 for Health and Well-Being\(^1\) is to increase access to safe, quality and affordable essential medicines. The regulatory system for health products forms a critical part of the wider healthcare system and plays an important role in a country’s ability to effectively meet its local healthcare needs.

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Timely Response to a Rapidly Changing Landscape

Innovations challenge the existing and traditional regulatory frameworks, at times rendering certain processes and approaches obsolete or forcing urgent need for revision to accommodate new modalities of therapies and medical technology.

We are now experiencing a new wave of innovation in health and biomedical science that has great potential to meet these rising demands. Several significant developments promise to transform healthcare and deliver better health outcomes for patients, including targeted cell and gene therapies, the adoption of digital health technologies, and the focus on harnessing the wealth of health data and real-world evidence. Likewise, the regulatory environment must respond to these developments in ensuring the continuous progress of healthcare through efficient and effective systems.
Current status of the Regulatory Environment in Asia-Pacific

Celebrating the Efforts for Building Regulatory Capabilities

Leveraging on these efforts, stakeholders can expect progress in regulatory convergence, reliance and partnerships, and consequently, an efficient and effective regulatory environment in the Asia-Pacific.

PIC/S: PIC/S Increase in Regulatory Cooperation

10 countries in Asia-Pacific are PIC/s members, with 7 achieving accession recently in the last decade.

ICH: Pursuit of Regulatory Convergence and Harmonisation

Including Japan which is a founding member, 4 more countries have achieved member status, reflecting the implementation of common guidances and practices.

APEC RHSC: Commitment to regulatory training

10 Formal CoE Institutions

Out of the 10 formal COE Institutions, 6 are based in Asia-Pacific. Seven more institutions in this region are conducting pilot workshops.
Initiatives to enhance regulatory capabilities have been the key agenda for many regulatory and health organisations, some of whom have been committing to these efforts for more than 3 decades. Over the years, these activities have paved the way for regulatory systems strengthening, and created a strong momentum to improve regulatory frameworks, processes, competencies and collaboration.
CURRENT STATUS

Current Status of the Regulatory Environment in Asia-Pacific

- Opportunities for Improving Regulatory Capabilities
- Approaches to Regulatory Systems Strengthening
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To effectively address the evolving healthcare needs, an efficient regulatory system remains a key component to improve access to medicines. While the commitment from regulatory authorities is pivotal to the successes of such interventions, a collaborative effort among stakeholders including the industry and academia will be significant in progressing these initiatives further and reaching our goals earlier.

Mr Samvel Azatyan
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Regulation and Prequalification (RPQ)
Access to Medicines and Health Products (MHP)
World Health Organization
Current status of the Regulatory Environment in Asia-Pacific

Opportunities for Improving Regulatory Capabilities

Looking at the regulatory landscape across the countries in Asia-Pacific, there are varying levels of maturity and regulatory capacity of National Regulatory Authorities (NRAs). NRAs in lower income countries possess inadequately structured and under-resourced regulatory frameworks to promote optimal access to health products. Fragmented national regulatory requirements across the region, insufficient regulatory knowledge, and the lack of capacity to employ regulatory science and policy innovation are the major challenges to address.

Regulatory gaps and needs across the Asia-Pacific countries exist at all levels – from systems-level challenges, to organisational issues as well as gaps in specific regulatory functions. In a project to understand the regulatory systems in five countries of the Greater Mekong Subregion (GMS), gaps in regulatory capabilities, and other factors like political instability and poor governance contributed to a weaker regulatory environment. In line with World Health Organisation (WHO) findings in the western pacific region and other studies done, there are several opportunities for strengthening existing regulatory systems in Asia-Pacific.

**Potential Areas for Improving Regulatory Capabilities in Asia Pacific**

1. Increase Stakeholder Engagement
2. Improve Coordination within Agencies
3. Strengthen Process Governance
4. Commit Funding and Resources
5. Commit to Staff Development & Competencies
6. Explore Regulation of Full Range of Health Products
7. Enhance Statutes, Regulatory Frameworks and Processes
8. Facilitate Regional Regulatory Co-operation
9. Strengthen Post-Market Surveillance, Controls and Inspections

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3. Findings from a project supported by the Asian Development Bank and CoRE, Duke-NUS Medical School. 2017
5. The figures are briefly summarised findings from a project supported by the Asian Development Bank and conducted by CoRE, Duke-NUS Medical School. Common challenges and gaps across the medicines and medical devices regulatory systems were identified through assessments conducted in five countries in the Greater Mekong Subregion.
Current status of the Regulatory Environment in Asia-Pacific

Approaches to Regulatory Systems Strengthening

The concept of regulatory systems strengthening should encompass both technical and systems issues, engagement in relevant networks, and may also require intervention at a broader health system and policy level. A number of global and regional bodies have identified the need to strengthen regulatory systems to drive health\textsuperscript{6,7}.

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Strengthen National Regulatory Authorities
- Increase regulatory technical competencies
- Share and adopt good regulatory practices
- Enhance local regulatory duties e.g. post-market surveillance
- Increase financing and political commitment

Engage in networks of National Regulatory Authorities
- Increase communication and cooperation among NRAs
- Promote and implement regulatory convergence, cooperation and reliance
- Strive for regulatory efficiency and effectiveness

Develop systems for managing regulatory data
- Enhance transparency of decision-making, accountability and performance of regulatory systems

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Three key principles for regulatory systems strengthening as identified by international regulatory and industry organisations and associations

Regulatory Convergence
Promote regulatory convergence through implementing global technical guidance and sharing similar requirements

Regulatory Reliance
Implement regulatory reliance to promote regulatory efficiency and effectiveness

Capacity Building
Commit to relevant capacity building to enhance competence and skills for effective regulatory oversight

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Regulatory convergence as defined by the Asia-Pacific Economic Cooperation (APEC) Life Sciences Innovation Forum (LSIF) Regulatory Harmonization Steering Committee (RHSC), is a voluntary process whereby the regulatory requirements across economies become more similar or “aligned” over time as a result of the gradual adoption of internationally recognised technical guidance documents, standards and scientific principles (harmonisation) and common or similar practices and procedures. At the same time, the distinctive national legislative, demographic and risk-tolerance factors are being taken into account.

"We have seen significant progress in the regulatory capabilities of the economies in APEC, and more importantly, moved closer to the goals of regulatory convergence to facilitate the timely entry of medicines. The partnership among industry, regulators and academia has been effective in achieving this, and I believe this partnership should continue to provide the relevant platform to enrich the regulatory systems."
In all forms of regulatory cooperation, the sovereign responsibility of the regulators to protect the public remains with the jurisdiction. By leveraging on the works of trusted partner regulators, regulatory processes and decision-making can be streamlined and the overall efficiency can be increased. Resources can then be diverted to the NRAs’ regulatory duties that only local authorities can appropriately account for, and increase the regulatory oversight and effectiveness.

These duties include:
- Pharmacovigilance and investigation of adverse event reports
- Post-market surveillance including quality assurance
- Inspections of local manufacturers and distribution chain integrity
- Assessment of clinical trials involving human subjects

The WHO’s Good Regulatory Practices (GRP) guideline illustrates the concept of regulatory cooperation to improve efficiency. The activities can range from simple exchanges of information among NRAs, initiatives for work-sharing or joint assessments, to formal full recognition of another NRA’s decision. Reliance is one of the key components of regulatory cooperation, “the act whereby the NRA in one jurisdiction may take into account and give significant weight to – i.e., totally or partially rely upon – evaluations performed by another NRA or trusted institution in reaching its own decision.”

The common goals help to initiate a momentum in regulatory systems strengthening, and indicative of the benefits of regulatory cooperation and partnerships among stakeholders.

Given the many opportunities to impact this environment, many organisations have set into their agendas the provision of training, guidances and platforms to facilitate the journey of regulators in improving the efficiency and effectiveness of their roles.
Various initiatives in different parts of the world are undertaken to promote and develop regulatory cooperation. Three successful examples are highlighted here for their pragmatic outcomes, cohesive collaboration and progressive outlook in this field.

The WHO-ASEAN Joint Assessment project to Strengthen Implementation of ASEAN Harmonised Requirements for Drug Registration (SIAHR)

ACSS Consortium
Collaboration of regulators in Australia (Therapeutic Goods Administration), Canada (Health Canada), Switzerland (SwissMedic) and Singapore (Health Sciences Authority)

APEC LSIF Regulatory Harmonization Steering Committee
Provide a coordinated approach among 21 economies to achieve regulatory convergence and cooperation
**Current status of the Regulatory Environment in Asia-Pacific**

**Regulatory Cooperation**

- Facilitates convergence among the regulators in South East Asia, through identifying country specific requirements and gaps in implementing the ASEAN Common Technical Dossier and technical guidelines
- Leverages on the trust and existing relationships among the ASEAN members
- Coordinated by WHO and the ASEAN Pharmaceutical Products Working Group
- With inputs from industry, the project is progressing to further build confidence in regulatory cooperation mechanisms

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The WHO-ASEAN Joint Assessment project to Strengthen Implementation of ASEAN Harmonised Requirements for Drug Registration (SIAHR)\(^\text{10}\)

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Recognises that regulatory convergence is required for improving public health in the 21 economies under APEC

Promotes the use of regulatory reliance, of which convergence is the foundation

Using existing platforms of regulatory cooperation, Key Performance Indicators (KPIs) were developed to measure regulatory convergence in APEC:

- The appropriate use of the Certificate of Pharmaceutical Product
- The appropriate use of PIC/S membership
- The appropriate management of multiple sites
- The appropriate use of risk-based evaluation and information sharing

Advocates capacity building as an enabler for regulatory convergence and cooperation

APEC LSIF Regulatory Harmonization Steering Committee
Provide a coordinated approach among 21 economies to achieve regulatory convergence and cooperation

Coordinating regional capacity building

Monitoring progress of regulatory convergence

Regulatory Cooperation

- Four similarly-sized and like-minded NRAs acknowledged the utility and value of regulatory cooperation
- Initiated work-sharing as a trust-building exercise to facilitate deeper levels of regulatory cooperation
- Agreed upon the need to
  - Communicate frequently on issues to address
  - Align regulatory systems and utilize common assessment standards as a baseline for good regulatory decision-making
  - Explore similar report format to facilitate exchange and communication
- Commendable progress achieved through the Generic Medicines Working Group

ACSS Consortium
Collaboration of regulators in Australia (Therapeutic Goods Administration), Canada (Health Canada), Switzerland (SwissMedic) and Singapore (Health Sciences Authority)\(^\text{11}\)

Piloting concepts in regulatory work-sharing
Developing tools for regulatory cooperation

Overcoming Resource Limitations faced by Regulators

Strengthening regulatory systems is a resource-intensive effort. It is not feasible for any single agency or authority to tackle this alone, given the limited resources, expertise and infrastructure available to NRAs. Even when efforts to enhance regulatory capabilities are well implemented, long-term sustainability of these activities to reap the benefits of such interventions can be extremely challenging. The lack of or decreasing commitment by sponsors, unwillingness to commit to long-term strategies, lack of clarity and understanding, and inadequate capability and capacity for consistent implementation are issues that can hamper sustainability of these efforts.

With strengthening of regulatory capabilities as a common goal, regional collaboration among NRAs and like-minded partners at a local, regional and global level helps to consolidate and coordinate initiatives, optimise resources, and create opportunities for wider and more impactful regional outcomes.

Leveraging on the momentum generated over the years for building regulatory capabilities, there are now practical opportunities for stakeholders to participate and contribute to regulatory systems strengthening.

Positive outcomes of alleviating resources constraints of National Regulatory Authorities

- Facilitates effective implementation of regulatory guidelines and good practices
- Increases participation in global and regional networks for regulatory collaboration and work sharing
- Supports efforts to determine scope and approach for regulatory innovation
- Facilitates effective stakeholder collaboration with government, industry, academia, patient advocacy groups and other non-governmental organisations

Future of Regulatory Systems Strengthening in Asia-Pacific

- Important Considerations for Regulatory Systems Strengthening
- Focus Areas
  - Enhancing Supply Chain Integrity and Quality of Medicines
  - Committing to Regulatory Systems Strengthening
  - Preparing for Digital Health
- A New Paradigm in Health Products Regulation

"There should be no ambiguity about the focus of regulatory systems strengthening – it is for the patients. There are valuable opportunities to enhance processes, share technical expertise and optimise efficiency through regulatory reliance. In the near future, engagements among industry, regulators, academia and healthcare stakeholders will be greatly enhanced through collaborative platforms that are built on trust and a single goal to improve patient access to appropriate medicines."
The initiatives in different regions and globally over the past decade have significantly advanced regulatory systems strengthening and supported the key approaches of convergence and reliance. While efforts have intensified in the past few years, it is nonetheless important for all stakeholders to align goals and strategies for system strengthening so that going forward, efforts become increasingly complementary and optimized to effectively enhance the overall healthcare environment.

A recent paper\textsuperscript{13}, collectively representing the main stakeholders in the regulatory environment, summarized the factors to consider in progressing efforts for regulatory systems strengthening.
Future of Regulatory Systems Strengthening in Asia-Pacific

Now that a firm foundation of capability-building activities has been built over the past decade by committed regulatory organisations, and with various opportunities identified, it is important to forge a coordinated effort to optimise the impact of activities moving forward. Three areas are highlighted here, in view of their potential to fulfil the needs of the regulatory environment and healthcare of the future.

**Focus Areas**

- **Enhancing Supply Chain Integrity and Quality of Medicines**
- **Committing to Regulatory Systems Strengthening**
- **Preparing for Digital Health**
Future of Regulatory Systems Strengthening in Asia-Pacific

Focus Area: Committing to Regulatory Systems Strengthening

Regulatory Systems Strengthening (RSS) is an ongoing journey by the NRAs to accommodate the changing needs, evolving sciences and pursuit of an efficient and effective regulatory environment. Using a systems approach, the scope of enhancements should cover the regulatory framework, processes and personnel. Training and professional development remains pivotal in strategies for regulatory systems strengthening. Plans for RSS should identify and address the gaps in the regulatory capabilities through

- Leveraging on trusted partners for regulatory cooperation
- Diverting resources for supporting local regulatory roles
- Building competency to fulfil local regulatory roles

The recent COVID-19 pandemic highlighted the increasingly uncertain environment where public health needs and sciences rapidly evolve. NRAs should strive to acquire regulatory agility, which is the ability to make timely adjustments to the regulatory framework for facilitating access to medicines in exceptional situations like pandemics. More efforts should be invested in RSS to reap initial outputs to justify this continual process of regulatory improvements, as well as to sustain the momentum of activities to reach to the milestones.

<table>
<thead>
<tr>
<th>Priority Actions</th>
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| **Optimise regulatory convergence**
  - Identify and rectify country-specific requirements through adoption and accurate application of harmonised technical guidelines |
| **Implement a risk-based approach**
  - Review of regulatory framework and processes to increase efficiency and effectiveness
  - Requisite for regulatory cooperation and reliance |
| **Participate in regulatory cooperation**
  - Contribute to existing platforms for work-sharing, joint assessments and reliance processes
  - Trust-building exercise for NRAs to pave for deeper levels of regulatory cooperation
  - Industry to consider a regional submission strategy to support regulatory cooperation |
Focus Area

Enhancing Supply Chain Integrity and Quality of Medicines

The supply chain of medicines is increasingly global as manufacturing and production sites are diversified geographically, increasing the chances of non-compliance to quality standards. Product owners and NRAs are increasingly challenged to maintain effective oversight of the multiple sites and parties involved in the complex supply and distribution chains. In addition to potential lapses in quality assurance, the public health impact of counterfeits and falsified medicines is well established, noting that:

- Countries with weak regulatory systems and controls are more susceptible
- Limited legal empowerment hampers the enforcement capabilities
- Multi-sectoral cooperation is currently inadequate

The rise of online platforms further compromises the ability of NRAs to ensure quality, safe and efficacious medicines. The public has now easier and greater access to medicines that are potentially substandard, adulterated, counterfeits or falsified, and bypasses the regulatory controls. Substandard and Falsified (SF) medicines continues to be a threat to healthcare systems in all parts of the world. This is an opportunity for regulatory stakeholders across various countries to coordinate a united agenda to address this public health threat.

**Priority Actions**

**Fortify surveillance activities and post-market controls**
- Divert sufficient resources to maintain adequate operations for inspections of facilities and sampling of products for quality deviations
- Leverage on regulatory cooperation
  - WHO Global Surveillance and Monitoring System
  - Platforms for coordinated surveillance of online SF dealers e.g., Operation Pangea by Interpol
- Industry to proactively discuss plans with NRAs to optimise supply chain integrity through new technologies and tools

**Increase awareness of the impact of SF on public health**
- Educate the consumers on the dangers of SF and means of reporting to authorities
- Emphasis on need for inter-agency and stakeholders cooperation and communications

**Foster dialogue among countries to address SF issues**
- Reach consensus on effective tools to be implemented by partner countries
- Consistent communications and commitment for progress
- Leverage on existing regional regulatory platforms to fulfil a common agenda
  - ASEAN
  - APEC RHSC
Novel modalities in medical science now challenge traditional boundaries of health products regulation. Digital therapeutics linking prescribing and consumption of pharmaceuticals, the use of medical devices for diagnosis and monitoring, and software for deciding the best suited clinical intervention.

WHO, in recognition of the impact of digital technologies on universal health coverage and access to healthcare services and products, recommended health ministries to prioritise the greater use of these digital technologies. The guidance also emphasised the importance of evidence-based digital health interventions. With the advent of digital technology in health, the role and contributions of regulatory science will now have to consider the wider healthcare system as decisions will impact patient care management and data governance.

**Priority Actions**

**Prepare Infrastructure for Digital Health**
- Review regulatory framework and processes to accommodate efficient management of products that combines both pharmaceuticals and medical technologies
- Adopt standards that support interoperability
- Address technical competencies and incorporate use of regulatory reliance through RSS, particularly for medical devices and technology
- Understand the limitations of the local IT infrastructure

**Use digital technologies for post-market activities, surveillance and enforcement**
- Utilise Real World Evidence collected from studies and digital means to support regulatory decision-making and pharmacovigilance
- Strengthen supply chain integrity with increased traceability and real-time information afforded by digital technology
- Assist in reducing counterfeits by using digital means to validate product authenticity
- Manage real-time stock levels to optimise product inventory

**Promote Regulatory Partnerships**
- Initiate communications among healthcare stakeholders to create awareness of the impact of digital health interventions
- Expand and engage stakeholders (healthcare professionals, patients) to increase relevance and robustness of regulatory decisions
- Share state-of-art technology between industry and NRAs to facilitate implementation and utility

With the advent of patient-centricity and connectivity in healthcare delivery, regulatory systems must progress in tandem with technology and the changing expectations of the stakeholders. New or modified frameworks will be needed to accommodate these rapid changes in less familiar domains of therapeutics and care delivery.

Regulatory agility is now an expected characteristic of a developed NRA system, helping NRAs to respond to healthcare needs in a timely manner, while upholding their pivotal role in ensuring quality, efficacious and safe medicines for the public. It will be a key enabler in the pursuit of smart regulation, providing the necessary balance in reducing barriers to access of quality and safe medicines while facilitating industry innovation. Pandemics in the last decade, like the H1N1, Ebola and especially the latest COVID-19, have affirmed the utility and need to increase regulatory agility.
Future of Regulatory Systems Strengthening in Asia-Pacific

A New Paradigm in Health Products Regulation

As leading regulatory organisations advance the agenda for regulatory systems strengthening, it is vital to review these efforts as part of the wider context of strengthening overall health systems and policies. This is a logical extension since health products regulation cannot exist in isolation from the wider health and socio-economic ecosystems of countries and regions. Outcomes for regulatory systems strengthening should directly or indirectly contribute to an improvement in the care management of patients, be it the assurance of safety, quality and efficacy of health products, timely access, or optimizing the value of these in healthcare.

The regulatory environment is a fundamental component of the wider healthcare system and the synergistic partnership among the key stakeholders will be required in regulatory systems strengthening efforts.
Beyond innovations, the use of health products and the way in which care is delivered are increasingly intertwined. To enhance the success of regulatory systems strengthening for health products, the wider context of the overall healthcare ecosystem needs to be considered and factored into regulatory frameworks and decision-making. Boundaries need to be increasingly broken down so that the various stakeholders who contribute to high quality regulation and delivery of healthcare can more effectively collaborate and cooperate for the ultimate benefit of patients and populations.

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Enhancing the Success of Regulatory Systems Strengthening

Expand goals of regulatory systems strengthening to health systems

- Reinforce the significance of health products regulation to the wider healthcare system
- Communicate to stakeholders in healthcare on their roles in health products regulations

Develop frameworks for novel health products and regulatory science

- Clarify and refine the decision-making process to accommodate inputs from various stakeholders
- Incorporate use of Real World Evidence

Incorporate multiple stakeholder perspectives into decision-making

- Refine the decision-making process to accommodate inputs from various stakeholders, including patients
- Accommodate considerations for value-based healthcare and Health Technology Assessments
We would like to thank the contribution of the Steering Committee in developing this brochure:

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**About CoRE**

The Centre of Regulatory Excellence (CoRE) is the first dedicated Asian Centre targeted at the needs of the national health regulators, the biomedical industry and pharmaceutical and medical device companies. Formally inaugurated in November 2014, CoRE offers itself as a neutral platform in the academic setting of Duke-NUS Medical School.

The Centre’s mission is to help establish regional platforms and networks, to build competencies, enhance collaboration and promote thought leadership in innovative regulatory science and policy within national regulatory agencies, industry and academia. Since its inception, CoRE has organised and hosted key events advancing regulatory excellence and promoting regulatory innovation in ASEAN and Asia-Pacific.

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