Responding to the Changing Regulatory Landscape in Asia – HSA's perspective

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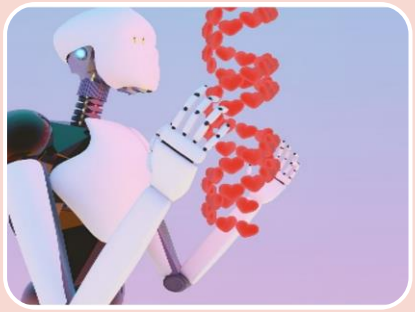
Overview

- Evolving Healthcare Landscape and Regulatory Challenges
- Lessons from COVID-19 Pandemic
- Principles to address Regulatory Challenges:
  - Balancing innovation and safety
  - Leveraging technology
  - Enhancing supply chain resilience
  - Engagement and collaboration with stakeholders

Evolving Healthcare Landscape and Regulatory Challenges



Digitalisation in Health

- AI integration in drug research and product development
- AI transforming healthcare services and delivery
- Digital health

Personalised healthcare

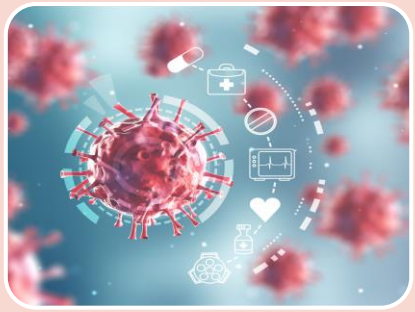
- Precision Medicines – revolutionising healthcare
- Devices for individual patient needs, e.g., 3D-printed implants and prosthetics

Use of RWD/RWE

- Increasing use of real-world evidence/data
- New data sources e.g., e-health records, wearables, apps
- New analytics methods using AI

Demand for cost effective medicines

- Timely access to generics and biosimilars – can lead to significant cost savings^



Emerging Health Threats

- Living in the age of calamity with polycrisis, increased spillover events in 2050 compared to 2020*

^*Tan, S.H., Goh, L.G.H., Ong, B.S.K. et al. https://doi.org/10.1007/s41669-024-00491-w*

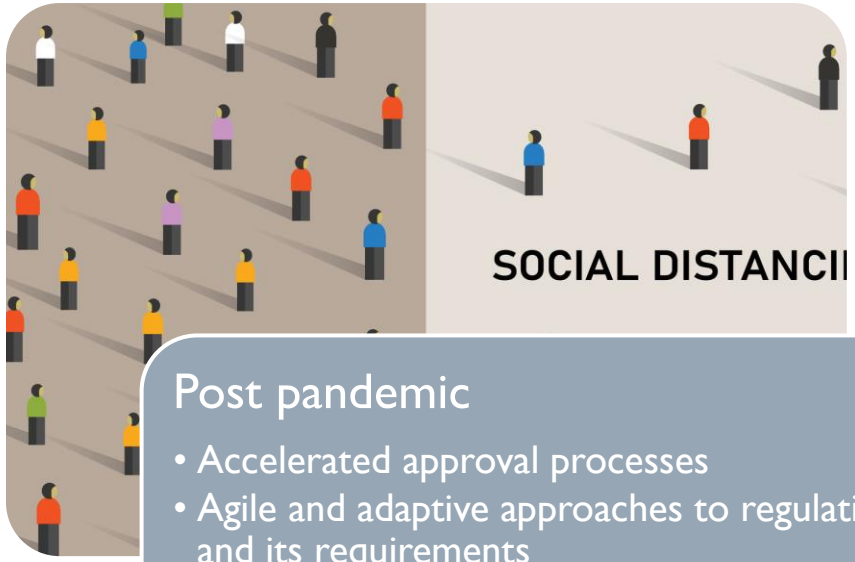
**Williams, B.A., Jones, C.H., Welch, V. et al. https://doi.org/10.1038/s41541-023-00773-0*

Regulatory Challenges: Gatekeeper and Enabler Roles, Gaps in Knowledge and Capacity, Increasing Product and Supply Chain Complexity

Lessons from COVID-19 Pandemic

Pre pandemic

- Traditional approval pathways
- Less flexibility in regulatory approaches
- Relatively slow trial recruitment in Asia
- Regulations governing telemedicine and digital health solutions were relatively limited



Post pandemic

- Accelerated approval processes
- Agile and adaptive approaches to regulation and its requirements
- Enhanced regional/international trial networking
- Enhanced focus on Digital platforms and services
- Strengthen supply chain resilience
- Expanded collaboration

Principles to address Regulatory Challenges

Fundamental of health products regulation remains unchanged –
benefits of health product must outweigh expected harms, based on sound scientific principles

Balancing **innovation** and **safety**

- Establish **future proof, risk-based, fit for purpose** regulatory framework to facilitate innovation, such as for Cell, Tissue and Gene Therapy Products
- Incorporate **real-world data and evidence** as part of benefit-risk assessment for regulatory approvals
- **Robust post market surveillance**
- **Patient centricity** – e.g. a focus on aging populations
- **Collaborate** regionally/globally including convergence, reliance and worksharing in view of limited regulatory & industry resources

Principles to address Regulatory Challenges

Use **technology** to facilitate regulation

- Use of large data sets such as electronic health records, national immunisation registry to enable faster and better regulatory decision making
- Leveraging technologies such as Blockchain to streamline workflow while assuring authenticity & verification
- Automation of processes e.g., use of Robotic process automation (RPA), AI and machine learning

Resilience in Health Products Supply

- National preparedness for new emerging infectious health threats:
  - National coordinating body
  - Assure access to critical vaccines e.g. through end-to-end manufacturing capabilities and capacity
  - Vaccine lot release and biologics testing
- Partnering WHO in enabling reliance and capability building e.g. WHO Listed Authority Framework, South-East Asia's mRNA Consortia for mRNA Technology Transfer Programme

Boosting MRCTs in Asia

Establishment of Japan-led network

ARISE's strategic framework for partnership and collaboration

- ***Value of clinical trials in developing novel therapeutics and healthcare benefits***
- ***ASEAN, with its diverse and sizeable population, is an important region to conduct clinical trials***

HSA Health Sciences Authority

- Potential to better integrate ASEAN as a key CT region to foster impactful collaborations in innovative therapeutics and significant diseases in Asia
- Facilitates understanding of local context and addressing respective countries interests with better engagement and learning from each other

ARO Alliance for ASEAN & East Asia (ARISE)

Accelerate in Asia

- Investigator-initiated Trials
- Research Strategy
- Capacity Development
- PAPPs
- Regulatory Consultation
- Quality Management
- Health Diplomacy

Research collaboration with Asian countries

Establishment of NCGM offices in Asia

Indonesia office, University of Indonesia

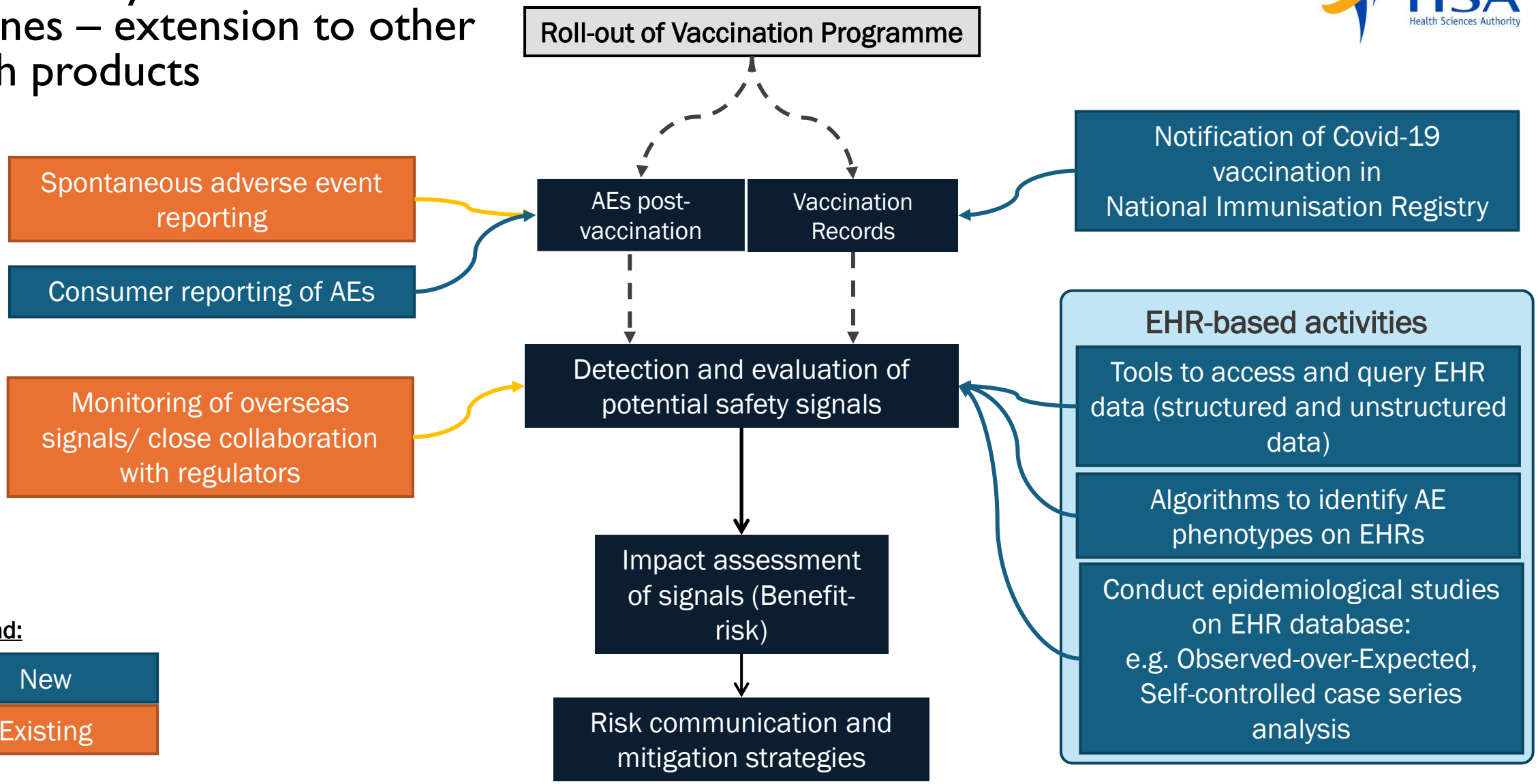
Vietnam office, Bach Mai Hospital

Philippine office, University of Philippines Manila

Thai office, Faculty of Medicine Siriraj Hospital, Mahidol University

ARISE Members
(Kick off mtg 9th Dec, 2021)

Digitalisation to Enhance Active Safety Surveillance of Vaccines – extension to other health products



Forging Ahead in Harnessing Collaboration

- Fostering open dialogues and collaboration among Asian regulators on regulatory science, capacity building, facilitated pathways etc. e.g., Asian Network Meeting platform
- Promoting regulatory convergence and reliance among Asian regulators e.g. regional harmonisation platforms such as ASEAN- Japan Comprehensive Strategic Partnership, APEC RHSC
- Leveraging existing platforms and frameworks such as ASEAN Pharmaceutical Regulatory Policy and ASEAN Pharmaceutical Regulatory Framework for furtherance of work


Thank you