

CoRE Regulatory Perspective

Regulating Digital Health to Promote Public Health and Innovation in Asia-Pacific

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The COVID-19 pandemic has boosted the development and implementation of digital health solutions worldwide (1). Digital health has shown the potential to be applied across the spectrum of healthcare, from speeding up diagnostic services, continuous monitoring, personalized treatment and drug discovery processes to patient engagement and health promotion. Digital health encompasses diverse categories such as mobile health (mHealth), health information technology, wearable devices, telehealth and telemedicine, and personalized medicine (2).

With such diverse categories in an evolving global environment, a range of tools has been deployed to regulate digital health, including new legislation, regulatory sandboxes to test innovations, and evolving guidance and standards. But conventional frameworks might not be well suited for regulating such fast-developing technologies like artificial intelligence (AI) in healthcare. Governments are faced with the challenges of digital technologies such as the short technology life cycle, and how to apply regulatory enforcement with regard to the geographic scope of the market (3). Different regions of the world are also adopting different approaches. The Council of the European Union recently approved a version of the first proposal of an Artificial Intelligence Regulation Act. Digital health solutions undergo frequent updates and have unique cybersecurity considerations for connected devices and cloud transmitted data. It is also challenging to distinguish the regulatory categories and clinical validity of digital health services as some of their requirements overlap and products with similar functions may qualify for different regulatory frameworks (4).

New regulatory initiatives have moved in tandem with the growth of the digital health market, often with diverse priorities and focus areas. Most of the current regulatory measures for digital health focus on medical devices, digital therapeutics, AI and telemedicine. As an example, during the pandemic, the demand for telemedicine surged and telemedicine services emerged as an essential healthcare service for triage, diagnosis, treatment, monitoring and surveillance in public health. A review of telemedicine guidelines in South East Asia (SEA) found that regional countries have guidelines on telemedicine with varying degrees of breadth and depth (5). In several countries in the broader region, the pandemic provided the impetus for clarifying or implementing appropriate regulatory frameworks to support this. For example, in Japan, telemedicine can now be used for first visits and the range of diseases managed over telemedicine has also been extended during the pandemic (6). The regulation for Software as Medical Device (SaMD) follows the same trend and new countries are adopting specific regulatory frameworks for SaMD (7).

In 2018, Singapore launched the Licensing Experimentation and Adaptation Programme (LEAP), with a focus on telemedicine services. The regulatory sandbox aimed to better understand the risks and challenges of telemedicine services and develop risk-mitigation measures. This was followed by a licensing measure under the Healthcare Services Act (HCSA). In addition, many guidance mechanisms and guidelines are being developed by the Singapore Ministry of Health and other health authorities to meet the needs and specifications of the digital health field (8).

This myriad of diverse tools and approaches can be confusing to innovators, healthcare institutions and professionals, service providers, manufacturers and the public. Key enablers

to effectively define and deploy digital health regulation are international collaboration towards harmonization and convergence initiatives. This is a critical juncture to promote greater regional collaboration to co-create, coordinate and clarify digital health regulation when the technologies, applications and guidelines are still at a nascent stage. Given digital health's huge transformative potential, the digital health environment must be strengthened through capacity building, product and service innovation support, and innovative measures to evaluate, scale up and improve products and services. In order to harness the full potential of digital health, the regulatory frameworks around the world and across Asia-Pacific need to evolve and harmonize to encourage innovation and allow for regulatory flexibility, while ensuring core principles of quality, performance characteristics, safety and effectiveness.

Drawing on the experiences during the pandemic and to accommodate rapidly evolving technologies and associated issues, CoRE urges regulators to adopt appropriate flexible frameworks that are calibrated to the level of assessed risk of the digital health solution to public well-being. This needs to be done in a way that supports innovation while safeguarding public health. We encourage regulators to partner innovators, healthcare professionals, academia and the public at this nascent stage of digital health to discuss and address key concerns and challenges; these include data security, interoperability, quality of apps, societal trust, digital divide issues, and AI "black boxes" and lack of sufficient data to develop trusted deep learning algorithms.

CoRE is dedicated to providing a neutral platform to engage stakeholders, stimulate discussions, and provide support to define appropriate regulatory approaches that are needed to facilitate adoption of digital health solutions in the region. Now is the time for regional governments to harness industry and academic support to establish a collaborative platform to develop innovative, appropriate and harmonised regulation to unlock the immense potential of digital health for enhancing population health across Asia-Pacific.

This Perspective is based on a keynote address by Professor John Lim on "Digital Health Regulation in ASEAN: Context, Challenges & Opportunities" at the 2nd ASEAN Digital Public Health Conference, Brunei Darussalam on 23rd November 2022.

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