Webinar - Fit-For-Purpose Regulatory Frameworks for Digital Health Post Covid-19: Opportunities for ASEAN

In contrast to traditional medical devices like therapeutic products and in vitro diagnostic medical devices, digital health solutions use platforms like mobile and computing devices that are more universal and affordable. This creates tremendous opportunities for access to healthcare. Yet current regulations that ensure the safety of traditional medical devices do not fit the rapid pace of innovation, iterative nature, and cross-border accessibility that characterise software and digital health. Hence, questions have been raised on how regulatory frameworks for digital health can be redesigned to accommodate its unique characteristics.

On 11 May 2021, the EU-ASEAN Business Council (EU-ABC) hosted a webinar titled: *Fit-For-Purpose Regulatory Frameworks for Digital Health Post Covid-19: Opportunities for ASEAN*. The panel comprised of Dr. Ferdinal M. Fernando, Assistant Director at the ASEAN Secretariat Health Division; Low Lai Peng, Deputy Director of Medical Devices Branch at Singapore Health Sciences Authority (HSA); Varun Veigas, Regional Regulatory Affairs and Policy Lead of the Asia Pacific at Roche Diagnostics and Regulatory Working Group Chair Representative at APACMed; Dr. John Richard Thornback, Chief Operating Officer at Diagnostics Development Hub; and Suntaraa Murthi Anamalai, Assistant Director at Medical Device Authority (MDA) under the Ministry Of Health Malaysia. The webinar was moderated by Chris L. Hardesty, Director of Healthcare & Life Sciences Practice at KPMG.

Digital Health Boom and Regulatory Initiatives that are Underway in ASEAN

Covid-19 has accelerated the speed of digital innovation and adoption in ASEAN, which has in turn initiated the removal of some regulatory and psychosocial barriers to digital health solutions. Dr. Fernando shared that there are various ASEAN initiatives that are underway which aim to help ASEAN transition into a digital society and increase ASEAN's capacity to detect, respond and manage health threats – both of which naturally support the development and uptake of digital health solutions. Specifically, he highlighted the role of the ASEAN Post-2015 Health Development Agenda (2016-2020), the ASEAN Economic Community Blueprint 2025, the ASEAN Socio-Cultural Community Blueprint 2025, and the ASEAN Digital Masterplan 2025 in driving the development and uptake of digital technology in both health and non-health sectors. He added that the mandate for digital health has its basis in existing and emerging cross-border threats like Covid-19 which has prodded policymakers, regulators, and private sector stakeholders to speed up the building of ASEAN's capacity to manage big data analytics and visualisation, provide timely assessments of the pandemic situation.

Dr. Fernando disclosed that the pandemic experience has initiated the removal of regulatory barriers to the uptake of digital services in various sectors. This includes the relaxation of regulations and systematic reviews to remove some regulations more widely. However, the development of regulatory frameworks specifically befitting digital health solutions is still in its infancy in ASEAN. For Singapore, Lai Peng revealed that a document of regulatory guidelines for software medical devices has been released and the HSA is working with stakeholders to firm up its contents. The document is intended to provide clarity, rather than prescription, on the regulatory requirements for software medical devices throughout their entire lifecycle – from development to post-market. In Malaysia, Suntaraa contended that specific regulatory guidelines for digital health devices have yet to be drafted, but the MDA is currently engaged in conducting relevant studies in hopes of developing them.

Regulatory Gaps & Challenges

Although digital health solutions present opportunities for the healthcare landscape, there remain regulatory gaps and challenges in developing and deploying them in ASEAN. The consensus amongst the panellists is that digital health solutions are different from traditional medical devices and drug

therapeutics and require fit-for-purpose regulatory policies. For instance, Varun pointed out that the iterative nature of digital health solutions necessitates regulatory frameworks that can account for the pace of modifications. He acknowledged that many agencies, like the HSA and the USFDA, are already engaging in pioneering work in this direction.

However, Dr. Thornback reiterated that the path to success is complicated by the lack of regulatory clarity and consensus on what constitutes a digital health device that needs to be regulated. He highlighted the differences between various methods of assessment, including HSA's risk classification based on intended use of device; the IMDRF's risk categorization approach; and the USFDA's pre-certification pathway. Any effort at harmonising vocabulary has stopped short of establishing a common understanding of regulatory classification schemes or requirements. Dr. Fernando pointed out that the variability in the uptake and deployment of digital health solutions across ASEAN countries because of their divergent healthcare provision capacities and regulatory expertise poses a challenge to ensuring consistency and predictability of regulatory review processes at the regional level. As a result, enabling safe, effective, and innovative digital health solutions to reach stakeholders across state borders in an expeditious manner remains an ongoing challenge for ASEAN.

The Strategic Role of Converging & Harmonizing Digital Health Regulations across ASEAN

Given the rapid pace of innovation, and iterative and cross-border nature that characterise digital health, the panellists highlighted the importance of collaborative spaces. Suntharaa shared that Malaysia has set out to close this gap through a collaborative and consultative platform between MDA and representatives from the medical device industry – the MDA-Industry Communicative Committee (MICC). It aims to foster greater collaboration and ensure intersectoral engagement and support from the product innovation phase to the product commissioning phase. Lai Peng agreed that it is of paramount importance that various stakeholders work in tandem from the early phases of product development, through an iterative process of gathering and incorporating user feedback, to clinical adoption. She added that the same should apply for the development of fit-for-purpose regulatory frameworks.

Dr. Fernando added that ASEAN-wide collaboration is also necessary to address the varying levels of uptake of digital health solutions and regulations. He shared that Covid-19 has initiated the development of a regional electronic health portal – the ASEAN Portal for Public Health Emergencies, which improves access to data and information pertaining to public health emergencies through cooperation with non-health sectors and enabling interactions between technical experts and the public. Dr. Thornback believes that the digital health space can take advantage of such collaborative spaces to ensure greater consistency and predictability in the region. In his closing remarks, Chris reaffirmed the tremendous potential in the digital health landscape and the strategic role of intersectoral collaborations and of coalescing regulations across ASEAN.