THREE THINGS TO KNOW ABOUT DIGITAL HEALTH REGULATION IN HAINAN

PURPOSE

In February 2022, the APACMed China team hosted a multi-stakeholder webinar to discuss the latest advances in Digital Health Regulation (DHR) policy, particularly pertaining to SaMD. This file, therefore, is meant to serve as a write-up of the webinar content covered.

The write-up serves to appeal to a variety of healthcare ecosystem stakeholders (in China and beyond) who may not have been able to join the webinar, and therefore aspire to receive the highlights of the discussions.

Hainan, regarded as China's pilot province for the early adoption of new medical innovations, released its 14th Five-Year Plan for Digital Health Development on January 30, 2022. Hainan is the first province in China to incorporate Digital Health into such plans, thereby playing a leading role for the country and serving as a steward for other provinces to follow suit.

Subsequently in February 2022, the Asia Pacific Medical Technology Association (APACMed) hosted a Digital Health webinar to introduce the Hainan plan as well as to present findings from APACMed's recent whitepaper, covering regulatory trends for Software as a Medical Device (SaMD) in China and beyond. The webinar was attended by leading industry companies and graced with insights by Dr. Zhang Yuhui, Deputy Director General of Hainan Health Commission. The following article summarizes the key takeaways from the discussion, and the path forward for Digital Health in China.

Takeaway #1: Understanding the Role of Hainan Province

Hainan is an island province of China and the country's southernmost point, with a population of nearly 10 million people. The province, keen to transform itself, stated an ambition to build out innovation hubs in targeted cities by 2025, including construction of the Nanfan Silicon Valley. As a means to cultivate scientific best practices, accordingly, Hainan intends to operate national laboratories, using inbound and outbound corridors, to scale the innovations by collaborating with international partners.

These collaborations will be channelled through "entrepreneurship pilot zones" across a range of technologies as well as people and knowledge development objectives.

The overarching goal is for Hainan's output value of strategic emerging industries to reach USD 100 billion by 2025, with a stretch goal of an additional USD 125 billion for the high-tech industries.

"The Chinese Central Government positions Hainan as a pilot zone to demonstrate determination of reform and further opening up as a free trade island," said Dr. Zhang. "Targets within the plan's period (2021-2025) include increasing people's average life expectancy by two years."

Takeaway #2: Recent Digital Health Regulation Efforts in Hainan

Underpinning these broad reforms in China are a productive population as well as the role of Digital Health in innovation creation. In order to fulfil the ambitions, stakeholders during the webinar agreed that Hainan must think creatively about leveraging the potential of new technologies. When applied to the medical field, four main settings emerge:

Treatment	Care Coordination	Rehabilitation	Prevention & Screening
Grappling with the changing disease patterns (including of the behavioural-cognitive variety), and challenging assumptions about traditional interventions	To demonstrate noticeable improvements, emphasizing patient experience, particularly for control of chronic diseases such as diabetes and hypertension	A small but growing segment of demand by the population, in need of reimaging to drive the community-based delivery model vision through the use of more digital tooling.	Placing continued multi-stakeholder pressure on the "prevention paradox" through more rigorous proactive screening, again including mental illness too.

As inferred above, webinar stakeholders discussed the important role of Digital Health across the spectrum of settings identified. Digital Health stands to enable the desired care models, from the hospital to the community to the home, positioning Hainan as a leader in designing China's health transformation vision and providing a guiding light to other provinces.

According to Dr. Zhang, the first step is a matchmaking process whereby selected institutions in Hainan (e.g. hospitals, treatment centers, laboratories) will partner with clinical experts and medical innovation companies to engage in joint research endeavors. Thereafter, the Hainan Health Commission will work with regulators to offer fast track approval of the Digital Health interventions, potentially even simultaneously with the filing process. These steps are considered to be in line with the best practices identified by the APACMed SaMD report.

Webinar stakeholders did caution that the policies are currently still quite abstract, and thus discussions are being actively held so as to arrive at the next layer of detail. An example lies in cyber security and privacy, with Hainan exploring how data can be safely and more orderly flowed for the benefit of the healthcare ecosystem.

Takeaway #3: How the Implementation of Plans are Going Thus Far

Hainan, in its role as a pilot province for China, enjoys a number of benefits which are driving Digital Health policies, such as regulatory frameworks, in the country. These clear policies are making it possible, according to webinar stakeholders, to initiate innovation projects and to receive fast track approvals. Riding on the trend of internet-based hospitals and medical services, Hainan is aligning infrastructure efforts such as 5G in order to enable the Digital Health vision. The province is moreover taking the data flow challenge head-on, building a platform that will support collaboration partners with sustainable innovation development.

	Qualification	Risk Classification	Software with Multiple Fuctions	Alternative Pathways for DH	Pre-Submission Consultation	Framework for AI/ML
Best Practices	Software must have an intended purpose that fulfils the definition of a medical device in order to qualify as a medical device.	IMDRF's N12 guidance describes that the two key factors that should be taken into account when assessing the risk categorization of a SaMD product are: 1. State of the healthcare situation or condition that the SaMD is intended for. 2. The significance of the information that is provided by the SaMD to the healthcare decision.	For software products with multiple functions, regulatory authorities exercise oversight only over those functions with an intended purpose that fulfils the medical device definition.	Approaches to regulatory review that are tailored to the unique needs of DH solutions.	Opportunity to en-gage with regulato-ry authorities prior to premarket sub-mission review.	Risk-based guidance and/or framework suited to the unique regulatory challenges posed by AI/ML technologies.
China (NMPA)						
Korea (MFDS)						

Table 2 - Comparing the APACMed DH regulation best practices with the current state in China and Korea[1]

The best practices are not currently adopted
Some guideline is currently available, however, further improvements are recommended
Current regulatory framework encompasses the recommended best practices

APACMed assessment of SaMD regulatory efforts in the region, based on whitepaper analysis. Additional assessments are available for Singapore, Japan, India, and Australia.

If nothing else, proof that the Digital Health policy design in Hainan is having positive outcomes is evidenced through the emerging use cases. Hainan Boao Hope City is aggressively adopting the early use and approval of Digital Health solutions, serving as the only location in China in which real-world data is being leveraged for the regulatory submission and approval process. Likewise, in March 2022 alone, two Digital Health products were already approved in Hainan, with another 26 filings in the queue. Indeed, Hainan is adamant about its ambition to be the optimal launchpad for innovation companies, domestic as well as international, as a verifiable world island of Digital Health transformation.

"Hainan will continue to promote the use of Digital Health solutions, approved at home and abroad, to eligible provincial institutions and populations in need," said Dr. Zhang. "Digital Health plays a major role in our provincial level reform, in line with the master plan of Healthy China 2030." Specialized funding buckets have been created, according to Dr. Zhang, to foster the initial stages of research and collaboration, with the idea being to slowly scale from a few cities to ultimately province- and country-wide adoption of Digital Health solutions.

Beyond regulation, of course, is the next major Digital Health adoption to tackle in China – reimbursement. Of high interest to webinar stakeholders, reimbursement conversations thus far are still underway on alignment areas such as evidence requirements and value assessment protocols. APACMed published a report in 2021 about Digital Health reimbursement strategies for the region, a topic for the next discussion forum to be hosted in China. Stay tuned!

SOURCES
-v1 of the write-up as provided by the APACMed China team
-Author's own sources/knowledge of this space
-Additional lite research on the topic