

## EXECUTIVE INSIGHTS

# Navigating Asia's Regulatory Mosaic: Achieving Excellence in Generative AI for Healthcare

Generative artificial intelligence (AI) is driving transformative processes across the medical technology landscape. As powerful as it is disruptive, it has already demonstrated substantial utility in healthcare, particularly in two broad categories: generating operating efficiencies and assisting with patient-facing tasks.

Operationally, generative AI accelerates research, identifies drug targets faster, drives sales and optimizes supply chains. When patient-facing, generative AI can help automate administration, generate patient data summaries, enhance diagnoses, suggest treatment options and more.

As the technology evolves, policymakers are working to determine how best to encourage innovation while minimizing risks. Keeping abreast of the disparate approaches regulators are taking is critical to understanding emerging challenges and opportunities in this space.

Key concerns revolve around regulation pertaining to privacy and intellectual property (IP) protection, with the risks most evident in applications around patient data management. Not only does this type of data have to be protected, the risk of running afoul of existing privacy laws is not insignificant. This challenge was brought into the spotlight this past spring when thousands of complaints of mistaken identity were lodged related to Japan's My Number system, launched in 2016 to assign a unique identifier number to every person in the country. According to one study, as many as 1 million people were affected by problems with the system between May 23 and June 19.<sup>1</sup>



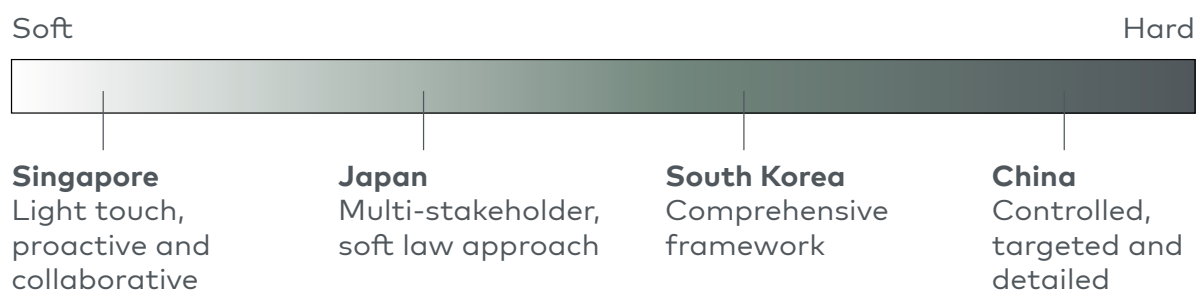
Regulatory approaches must also facilitate innovation while allaying concerns related to potential liability, a significant issue in healthcare because determining responsibility for errors or harm is not always straightforward.

Across Asia, there is a wide spectrum of approaches to regulating generative AI, from relatively passive, principles-based guidance (as in Japan) to detailed and explicit regulations (as in China). The nascency of this regulatory patchwork presents opportunities for the healthcare industry and governments to collaboratively frame policies that will shape the development and use of generative AI for the benefit of all stakeholders in the healthcare ecosystem.

### Four countries, four approaches

Even by modern standards of innovation, the speed at which generative AI emerged and spread has been unprecedented. Correspondingly, there has been a lack of agreement on how best to regulate the technology. Several multinational initiatives have emerged to create consensus on regulation, such as those led by the World Economic Forum and the G7 Hiroshima Summit, but countries in Asia are generally pursuing their own paths—although there are some similarities with approaches taken by countries in the EU, U.S. and U.K. The experiences of Singapore, Japan, South Korea and China are informative, as they represent a spectrum of approaches to the development of generative AI and, more specifically, its use in healthcare.

**Figure 1:**  
Generative AI regulatory gradient



Source: L.E.K. research and analysis.

### Singapore: Light, practical and gradual

The development and implementation of generative AI tools hold immense promise for addressing pressing challenges in Singapore’s healthcare sector, where government projections highlight an urgent need to expand the medical workforce by 40% by 2030 to support an aging population. Generative AI tools can attenuate the need for such a rapid surge in medical personnel.<sup>2</sup>

Singapore has taken a proactive approach to generative AI development. In June, the government published a discussion paper that presented an approach to regulation focused on the development of technical tools, standards and technology. Singapore's approach to regulating generative AI has been collaborative, with an emphasis on voluntary measures.

Central to this approach has been the development of a governance testing framework called "AI Verify" that draws from global standards and principles. This framework is designed to enable companies to voluntarily assess and validate their AI systems.<sup>3</sup> By bringing technology giants into this initiative, Singapore's government aims to harness the collective expertise of the industry to develop robust AI standards and practices that can guide the responsible use of AI. The dedicated IT system of the Ministry of Health of Singapore, which rebranded in July as Synapxe, is a case in point, as it plays an important role in catalyzing the development and implementation of generative AI tools by incorporating the technology into the National Electronic Health Record system, launched in 2011 to act as a centralized archive for health records and aggregated data from healthcare providers.

Synapxe is working with Microsoft<sup>4</sup> to enhance collaboration in generative AI and cloud innovation. A result of this collaboration is the Secure GPT for Healthcare Professionals system, based on the Azure OpenAI service. The system aims to put in place the infrastructure for the development of large language models and related healthcare applications,<sup>5</sup> the automation of tasks and the efficient gathering of information.<sup>6</sup> This partnership highlights the government's openness and its proactive stance on working closely with industry leaders to cultivate innovative use cases and establish best practices for generative AI in healthcare.

### **Japan: Multi-stakeholder framework and guidance**

Japan's government is taking a sector-specific and soft law-based approach that promotes AI governance through nonbinding guidance,<sup>7</sup> echoing strategies embraced by the U.K. and U.S.

In May, Japan established an AI strategy council of experts with a particular focus on generative AI, a major topic of discussion during the Japan-led G7 Hiroshima Summit and integral to the "G7 Hiroshima Process on Generative Artificial Intelligence" report. Despite the nonbinding nature of the country's guidance, Japan has not been passive in regulating AI, implementing both general and sector-specific rules in areas such as transportation and finance.<sup>8</sup>

In the healthcare sector, Japan's approach to generative AI is still taking shape. While specific regulations and guidance are yet to be unveiled, there has been notable mention of

support for AI applications in the space, including in areas such as drug discovery and the use of software as a medical device.

There have already been some noteworthy developments in generative AI tools in Japan, including:

- Multiple homegrown generative AI tools that are already coming onto the scene to support doctors with everyday tasks such as generating patient summaries, anticipating complications and tracking prescriptions.
- The development of AI Fast Doctor, which used ChatGPT to develop LHTM-2, a specialized language model tailored to Japanese medical practices that has successfully passed Japanese medical exams and is aimed at assisting doctors by providing answers to common inquiries and aiding in diagnoses.<sup>9</sup>
- CalqKarte, another tool powered by ChatGPT, that is instrumental in recording and formatting clinical consultation notes within electronic medical records (EMRs), further streamlining administrative processes.<sup>10</sup>

Ultimately, the demand for generative AI tools in healthcare in Japan is driven by the need to alleviate workloads for healthcare providers, an issue exacerbated by the relatively slow adoption of technology to streamline administrative tasks.

Impending workplace reforms that will cap overtime hours for doctors starting in 2024 are also expected to be a key demand driver for innovative technology solutions.

### **South Korea: Comprehensive regulatory framework**

South Korea has no regulations specific to generative AI, but the country's approach to AI regulation mirrors that of the European Union in proposing an "AI Act" master bill. This legislation would consolidate various AI-related laws into a unified framework to regulate AI and establish ethical guidelines and a strategic policy roadmap. Some aspects of this approach support the development of generative AI.

One distinctive facet is an emphasis on corporate self-regulation rather than government regulation. In this, the government's only role is to provide clear rules that ensure legal certainty and the protection of individuals.<sup>11</sup>

Within the proposed regulatory framework, there have been notable concerns around the vagueness of what constitutes "high-risk AI," a category that has been applied to both healthcare and medical technology applications. It remains unclear how this determination is made and what systems will fall under the label. Legislation is complicated by an absence of clearly defined penalties for violations and the uncertainty surrounding enforcement. Some commentators have floated concerns about South Korea's approach potentially hindering innovation and the country's competitiveness on the global AI stage.

Nevertheless, South Korea's thriving health data ecosystem is well positioned to provide a solid foundation for innovation and the development of generative AI tools. According to the Health Insurance Review and Assessment Service, South Korea boasts an impressive adoption rate of EMR systems, which are widely used as part of a near-universal digitization trend, encompassing the digital storage of clinical images and electronic hospital administration databases and the expanding use of remote sensor technology, making vast volumes of patient data readily accessible and analyzable.<sup>12</sup>

While South Korea enforces stringent legal protocols regarding patient data privacy and consent, updates to existing laws in 2020 allow for the sharing of de-identified or pseudonymized data, striking a delicate balance between fostering innovation and safeguarding patient privacy. With a strong data infrastructure, a focus on corporate self-regulation and generating legal certainty, South Korea has set the stage for innovation in AI to flourish while avoiding stifling any advantages domestic companies might have. Companies like Naver Health and Kakao Brain, for example, are actively partnering with clinical institutions and university hospitals to facilitate the integration of generative AI into medical practice:

- As of May, Naver Health has been collaborating with a large domestic ophthalmic clinic to develop a multimodal chatbot service that can review medical images for diagnostic support via an AI vision correction prediction tool. Moreover, the company aims to introduce a "vision chat" service that leverages AI to analyze patient data alongside EMRs, facilitating more effective patient communication and care.<sup>13</sup>
- In December 2022, Kakao Brain completed joint research agreements with nine university hospitals propelling advancements in medical imaging through the development of AI models, which allowed it to develop a research AI web service to interpret chest X-rays that it plans to release in 2024.

### **China: Controlled development and targeted regulation**

China is moving quickly to develop AI technologies and regulate their use. The country has rolled out a steady stream of regulations over the past two years, including the first set of rules specific to generative AI in July.

"We need to appreciate that China is ahead in regulating generative AI. China has taken the first and most ambitious steps at regulating AI in the world," says Rebecca Arcesati, lead analyst at the Mercator Institute for China Studies in Berlin.

China's interim measures on generative AI focus on services available to the public and showcase a deliberate effort to balance innovation with responsible usage.<sup>14</sup> Regulations issued in final form in July turned out to be far less restrictive than an initial draft first circulated in March, reflecting an emphasis on industry development. Key changes included

the removal of fines and an abandonment of real-name verification requirements. Instead, the regulations highlighted Beijing's penchant for using regulations as a tool to both control technological development and foster innovation. These regulations do not extend to the application, research, development or internal use of generative AI services within organizations.

While the sector-specific approach in China is different from that of the EU, which has sought to cover a broader spectrum of AI,<sup>15</sup> China's regulations generally align with global standards and emphasize critical aspects of the technology, such as the quality of training data, bias mitigation, IP protection and privacy safeguards. A key difference in China, however, is a requirement that generative AI systems reflect "core socialist values," which raises questions about the stability of the environment for foreign generative AI systems such as ChatGPT, which has been banned, and the potential censorship of AI systems, which could have implications for the global development of AI.

More practically, China has spread responsibility for the development of AI to different government departments, entrusting them to enhance rules within their respective industries. This industry-specific approach aims to give full play to specialized expertise and mirrors the approach being taken by the U.K.

However, while China's national approach to generative AI regulation emphasizes growth, municipal governments also play a pivotal role in shaping the regulatory landscape. Certain municipal governments have taken measures that could introduce complexities into the development of generative AI. For instance, the Beijing government has formulated regulations that impose limits on the use of generative AI in healthcare, notably prohibiting its use for the automatic generation of medical prescriptions.<sup>16</sup> As generative AI regulations evolve, companies must closely monitor not only national regulations in China but those at the provincial and city levels as well, as they could impact the feasibility and investment of generative AI applications in healthcare, influencing the development of the sector.

In healthcare specifically, China has aimed its regulatory focus at generative AI in applications available to the public. A logical next step would be for regulators to focus on non-patient-facing applications such as diagnosis chatbots or communication tools that aim to ease the burden on healthcare professionals. According to *BMJ Open*, a peer-reviewed, open-access medical journal, China faces a scarcity of doctors, ranking 77th globally in terms of doctors per capita, with pronounced rural-urban healthcare inequalities. Generative AI tools like Ping An Good Doctor, which aids doctors in handling patient inquiries,<sup>17</sup> and MedGPT, an advanced chatbot and medical document platform,<sup>18</sup> can play an important role in bridging this gap. These innovations alleviate the burden on healthcare professionals, who have long been strained due to rising patient numbers.

## Next steps for healthcare and generative AI

Regulators are playing catch-up with the rapid advancements in generative AI and frameworks remain a work in progress. However, for businesses in generative AI and healthcare, this presents an opportune moment to gain firsthand experience, define a vision for generative AI and positively inform regulators' perspectives on its use in healthcare.

To do this, companies must first develop an internal vision and governance structure for the use of generative AI, ensuring alignment with broader strategic goals. Additionally, the strategic implementation of smaller pilot-scale projects across various applications could provide invaluable insights into the benefits and risks associated with different use cases, mitigating regulatory risk. Furthermore, fostering partnerships and coalitions with industry players and associations is essential to building consensus and collectively influencing policy, thereby amplifying the impact of individual efforts in shaping regulation.

For more information, please contact [apac.healthcare@lek.com](mailto:apac.healthcare@lek.com).

## Endnotes

<sup>1</sup><https://apnews.com/article/japan-digitization-id-mynumber-8d8b7e968b9c1a3b7d19d8bd7738ce16>

<sup>2</sup>Tan K., Strait Times, 2023

<sup>3</sup>Chiang, S., CNBC, June 2023

<sup>4</sup>Frontier Enterprise, July 2023

<sup>5</sup><https://www.healthcareitnews.com/news/asia/singapores-ihis-develop-healthcare-gpt-microsoft>

<sup>6</sup>Abdullah, Strait Times, 2023

<sup>7</sup>Nussey, S., Kelly, T., Reuters, July 2023

<sup>8</sup>Habuka, H., CSIS, February 2023

<sup>9</sup>Fast Doctor Co. Ltd., PR Times, 2023

<sup>10</sup>KandaQuantum Inc., PR Times, 2023

<sup>11</sup>Yulchon LLC, March 2023

<sup>12</sup>Digital Health South Korea, Intralinks, 2019

<sup>13</sup>ETNews, May 2023

<sup>14</sup>Wu, Y., China Briefing, July 2023

<sup>15</sup>Wu, Y., China Briefing, October 2022

<sup>16</sup>South China Morning Post, August 2023

<sup>17</sup>Shenshen Z., Shine, 2023

<sup>18</sup>MedCloud.PH, MedGPT, 2023

## About the Authors

**Yuta Inokuchi**

PARTNER, TOKYO

Yuta Inokuchi is a Partner in L.E.K. Consulting's Tokyo office and a member of the firm's Life Sciences practice. He is a biopharmaceutical and healthcare specialist, and has led projects in biopharma and biotech, medical devices, contractor services, life sciences tools, and broader healthcare sectors on a range of topics relating to growth strategy, organizational strategy and transaction support.

**Arnaud Bauer**

PARTNER, SINGAPORE

Arnaud Bauer is Head of Healthcare Services and Healthcare M&A for Southeast Asia at L.E.K. Consulting. Arnaud's experience in the healthcare provider space spans the entire care continuum, including with government agencies for healthcare investment planning and promotion across the Middle East and APAC regions.

**Tingting Pi**

PARTNER, SHANGHAI

Tingting Pi is a Partner in L.E.K.'s Healthcare practice, based in Shanghai. She brings over 20 years of consulting experience, with 15 years dedicated to life sciences and healthcare. TingTing has worked extensively with multinational and local Chinese clients in the Pharmaceutical and MedTech sectors, advising them on strategic and operational issues. She has deep experience on preparing organizations to adopt new ways of work through innovation and technologies.

**Saleem Butt**

PRINCIPAL, SINGAPORE

Saleem Butt is a principal in L.E.K. Consulting's APAC Healthcare practice, where he specializes in advising Asian and multinational companies on opportunities across the APAC region.

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