OFFICIAL OPENING OF HEALTHTECH X ASIA 2025 BY

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Distinguished guests, innovators, clinicians, entrepreneurs and partners in the HealthTech ecosystem,

Good morning

Introduction: A Vision for HealthTech Innovation

1 It is an honor to address you at the HealthTechX Asia 2025, an event that stands at the intersection of policy, innovation and patient care. Today, we stand at the cusp of a transformative era in healthcare, where technology—from AI to Brain-Computer interface implant to Digital Health—is reshaping lives and healthcare. And that's why this platform also brings together the various platforms of healthcare transformation: start-ups and tech leaders who drive innovation, providers who deliver care, academicians and researchers who look into the data and amplify the innovation, and of course government sectors who shape and govern healthcare systems.

2 As the CEO of Health Sciences Authority (HSA) and one whom has previously worked in the industry before a decade ago, I am inspired by the potential of these innovations to improve patient outcomes and enhance global health. But with great innovation comes great responsibility. Our role at HSA is to ensure that these technologies are safe, effective, and accessible, and yet fostering an environment where we do not stifle new innovative products and care models. It is indeed a very challenging balancing act to do, but I would

like to share with you how our regulatory evolution, driven by collaboration and a forward-thinking mindset, is enabling the future of HealthTech.

Reflecting on Our Journey: From Challenge to Opportunity

3 Let me first bring you down a memory lane to examine our regulatory journey thus far, particularly the watershed moment following the implementation of the Health Products Act of 2007 for medical devices during the period of 2010-2012. This period highlighted crucial challenges in our regulatory framework, notably prolonged processing times for device registration and limited market access. Industry feedback, particularly from smaller enterprises, highlighted the urgent need for a more agile and efficient system. HSA embraced this challenge as an opportunity, launching a comprehensive review that sparked transformative reforms.

4 By adopting a regulatory reliance approach, we leveraged approvals from trusted agencies, which include US FDA, Australia's TGA, Japan's Ministry of Health, Labour and Welfare, EU, and Health Canada, significantly streamlining registration processes, reducing delays, and enhancing market access while upholding rigorous safety standards.

5 A notable outcome was the introduction of the Class B Immediate Registration Route, which has demonstrably enhanced market access for low-to medium risk devices while maintaining stringent safety standards. This initiative has significantly reduced registration timelines without compromising our commitment to public health protection.

Listening and Collaborating: A Partnership Approach

6 Our regulatory philosophy has also evolved to emphasise partnership and consultation. At HSA, we believe that regulation is not about imposing rules but about co-creating solutions. Over the years, we've deepened our engagement with industry through active listening and consultation. A prime example is our Change Management Program, launched recently to address the rapid, iterative nature of Software as a Medical Device (SaMD). Through two rounds of focus group discussions and extensive industry consultations, we incorporated valuable feedback, including requests to extend the program to all registered medical devices and to allow post-approval inclusion of new changes. The result? A flexible, streamlined and agile model that allows manufacturers to implement software updates efficiently while maintaining safety and efficacy. Because innovation cannot wait. This program is just the beginning—we plan to extend it to other device types, ensuring our regulations keep pace with innovation.

7 Our commitment to collaboration doesn't stop there. Through our Medical Device Innovation Office established in 2017, we provide early-stage consultation to startups and innovators, helping them navigate regulatory pathways. In total, we have conducted 148 such consultations. This office acts as a bridge, fostering dialogue and ensuring that novel technologies, from AI diagnostics to wearable sensors, reach the market swiftly and safely. By listening and partnering, we're not just regulators—we're enablers of progress.

AI and Cybersecurity: Need for Regulations at the Speed of Thought

8 Nowhere is innovation moving faster than in AI. For those of you who watched the latest Mission Impossible movie, they paralleled it

to containing AI in the “blink of an eye” – too fast it will slip, take over and destroy the world and too slow we will not see its power. Well, I won’t provide more spoilers here for those who haven’t watched the movie, but for those who watched it, you know what I mean.

9 So in the realm of AI, HSA was among the first regulatory bodies globally in 2019 to establish tailored regulatory guidelines for AI regulated as medical devices (or AIMDs), setting a global benchmark for clarity and rigor. As AIMD technologies continue to advance, we remain agile, continuously refining our guidelines to keep pace with innovation while safeguarding trust.

10 As AI are also used in clinical services and store clinical information, HSA is collaborating with MOH to update the Artificial Intelligence in Healthcare Guidelines (AIHGle) which was first launched in 2021. This revision seeks to bolster patient safety and foster trust in AI adoption by promoting best practices for developers and healthcare providers. It will also provide targeted guidance for healthcare professionals, a critical third-party stakeholder, and address cutting-edge technologies, such as generative AI and continuously learning machine learning systems, ensuring our regulatory framework remains robust and forward-thinking in this rapidly evolving landscape.

11 We are also taking on the digital threat heads-on. The HealthTech landscape has grown exponentially complex. Today, we’re not just regulating traditional devices, but digital health solutions, AI-driven diagnostics, and technologies intertwined with cybersecurity concerns. With the emergence of fields like Generative and Agentic AI,

the challenge becomes clear: our regulations must evolve to match this dynamic landscape.

12 Through our partnership with the Cyber Security Agency of Singapore (CSA) and Synapxe, we launched the Cybersecurity Labelling Scheme for Medical Devices (CLS(MD)), a global first initiative demonstrating our commitment to promote trust and transparency in addressing emerging technological risks. This ensures that connected devices are secure against cyber threats, protecting patients in an increasingly digital world. These adaptations reflect our commitment to staying ahead of the curve, ensuring regulations enable rather than hinder innovation.

Global and Cross-Sector Collaboration: Building a Connected Ecosystem

13 Innovation knows no borders, and neither does regulation. At HSA, we recognise that collaboration extends beyond industry to global partners and other sectors. We work closely with the International Medical Device Regulators Forum (IMDRF) to harmonize standards, ensuring our regulations align with global best practices. Alongside the US FDA, HSA co-chairs the Good Regulatory Review Practices working group, driving global regulatory harmonization. Together, we developed a playbook for medical device regulatory reliance, providing strategies, practical examples, and flexible models to support diverse jurisdictions. This initiative represents a significant step toward regulatory convergence while respecting individual frameworks.

14 Our reliance model is not one-way and we are now working towards HSA's regulatory approvals opening doors to facilitate market

access in some countries, such as Australia, Thailand, Philippines and Hong Kong. This progressive regulatory reliance approach reduces duplication, accelerates global access to HealthTech, and positions Singapore as a trusted regulatory hub for innovation and investment.

Future-Proofing Our Regulations: A Progressive Vision

15 Looking ahead, HSA remains committed to being progressive and forward-thinking. We're not just reacting to change but anticipating it for tomorrow's breakthroughs. Our goal is to future-proof our regulations, ensuring they remain relevant amidst rapid technological advancements. This means investing in regulatory science, leveraging real-world evidence, and exploring sandbox approaches to test novel regulatory models. We are also deepening public-private engagements, fostering trust, and co-creating next-gen solutions that empower innovators while safeguarding public health.

Closing: A Call to Action

16 To the innovators in this room: you are at the forefront of transforming healthcare. We are here not to slow you down, but to see how to help you scale up – safely and successfully.

17 To the industry leaders and members, the future of HealthTech cannot be built alone. We see you as partners in this journey. We need to share the latest science and insights and co-create solutions.

18 To the clinicians in the room: your voices do matter too. You are not just the users of technologies but also the co-designers of care

models, so we also need to work together to see how to facilitate and enable the safe adoption and use of tech in clinical care for patients.

19 The future of healthcare technology demands a delicate balance between innovation and safety. At MOH and HSA, we stand ready to collaborate with all stakeholders in advancing this critical mission because we're not just regulating the present—we're enabling the future. So I encourage your continued engagement and partnership as we work to create a regulatory environment that promotes innovation while safeguarding public health. Together, we can ensure that technological advances in healthcare reach their full potential in service of global health outcomes. So let's work together to shape a future where technology delivers hope, opportunities, and better health outcomes to millions.

20 I wish all of you a productive and insightful 2 days ahead in the conference.