JOINT PRESS RELEASE BY THE HEALTH SCIENCES AUTHORITY AND THE SINGAPORE MANUFACTURING FEDERATION

HSA-SMF PARTNERSHIP PIONEERS INTEGRATED REGULATORY SUPPORT FOR MEDTECH INDUSTRY TO PROMOTE ACCESS INTO SINGAPORE AND OTHER MARKETS

From 2 Oct 2025, the Health Sciences Authority (HSA) and the Singapore Manufacturing Federation Medical Technology Industry Group (SMF MTIG) are pioneering a comprehensive support ecosystem for Singapore's MedTech industry through their strategic partnership, combining the SME Centre@SMF's services with HSA's Health Products Regulation Group (HPRG) Innovation Office's technical regulatory expertise.

2 This dual-pronged approach transforms the regulatory journey from reactive compliance to proactive guidance, offering early consultations during product development or registration. It also promotes awareness to HSA's agile frameworks and new initiatives such as the mutual reliance pilot between Medical Device Authority (MDA) of Malaysia and HSA. Signed on 22 August 2025, the Medical Device Regulatory Reliance Programme with Malaysia runs from 1 September 2025 to 28 February 2026, facilitating faster registration processes for Class B, C and D medical devices.

3 HSA has established reliance programmes with Australia, Hong Kong, Philippines, Thailand, and Sri Lanka, which companies can tap on to reduce time-to-market. As of September 2025, more than 500 applications of medical devices have been processed through Thailand and Australia's reliance on HSA's approval. The strategic alignment between regulatory excellence **(See Annex A for details)** and industry support infrastructure positions companies to capitalise on Singapore's growing international regulatory influence while receiving the guidance needed to navigate these accelerated approval processes effectively

4 "Close partnership between regulator and industry association is essential to ensure regulations remain relevant and responsive to the dynamic needs of this rapidly evolving transformative industry. This enables us to co-create forward-looking regulatory frameworks that accelerate breakthrough technologies to market whilst upholding our unwavering commitment to patient safety. This collaborative approach positions Singapore at the forefront of global regulatory excellence and reinforces our role as a trusted gateway for MedTech innovation both in Asia and globally," said Adjunct Professor (Dr) Raymond Chua, CEO of HSA.

Enhanced Support through SME Centre@SMF

5 SMF is happy to partner with HSA's HPRG Innovation to utilise business advisory services from SME Centre@SMF to provide early regulatory consultation.

This enables MedTech companies to receive expert guidance during the critical early stages of product development and regulatory planning, potentially streamlining and expediting their path to market. Specialised professional development programmes **(See Annex A for details)** will also be rolled out to help MedTech companies navigate the regulatory landscape more effectively and efficiently. HSA experts will serve as speakers and advisors for these programmes, sharing insights on regulatory requirements and best practices to build industry capability and understanding.

6 “We’re excited for this collaboration with HSA to unite Singapore’s MedTech ecosystem. This collaboration provides our companies with a clear pathway to success. We've built an integrated foundation where streamlined regulatory processes, a robust framework for intellectual property protection, and essential trade facilitation services like the Certificate of Origin are all seamlessly linked. This enables firms in Singapore to innovate, scale manufacturing, and secure their assets, giving them a strong launchpad to access global markets.” said Eugene Yoo, Chairman, SMF-MTIG, “We encourage all MedTech companies to join the MTIG industry group to reinforce Singapore’s position as a thriving MedTech hub and leader in the region.”

7 “While clinicians and researchers develop innovative concepts, it is the manufacturing sector that turns these ideas into tangible, life-changing products. Singapore's MedTech success is built on an ecosystem defined by an agile and responsive regulatory framework and strong Intellectual Property (IP) protection. We hope more industry players will work with us in managing the complex regulatory environment for Software as a Medical Device (SaMD) and AI-powered devices, and by creating new approval schemes to boost innovation,” said Dennis Mark, CEO of the Singapore Manufacturing Federation,” said Dennis Mark, CEO of the Singapore Manufacturing Federation.

HSA's HPRG Innovation Office: Driving Regulatory Innovation

8 HSA has established the Health Products Regulation Group (HPRG) Innovation Office bringing together all agile regulatory frameworks and sandbox initiatives under one roof. The office pioneers responsive regulatory approaches that adapt to rapidly evolving technologies whilst maintaining rigorous safety and efficacy standards. Examples of agile frameworks for the MedTech industry includes the Software as a Medical Device (SaMD) Change Management Programme, the Singapore Health Product Access and Regulatory E-System (SHARE), the Cybersecurity Labelling Scheme for Medical Devices (CLS(MD)) and the Centre for Advancing Regulatory Science Research in Next-Generation Therapeutics (ASCENT) **(See Annex A for details)**.

HEALTH SCIENCES AUTHORITY SINGAPORE
SINGAPORE MANUFACTURING FEDERATION
2 OCTOBER 2025

About the Health Sciences Authority (HSA)
The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit http://www.hsa.gov.sg/.

For more updates on public health and safety matters, follow us on social media: LinkedIn, Instagram, X and YouTube.

About HSA's Health Products Regulation Group
The Health Products Regulation Group (HPRG) of HSA ensures that medicines, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.

About Singapore Manufacturing Federation
Established since 1932, the SMF represents the interest of the manufacturing community in Singapore, driving its competitiveness and sustainable growth through serving industry-specific needs. Supported by 10 industry groups and its Associated Services, the SMF enhances the competitiveness of the industry by encouraging capacity development and capability building, innovation and productivity. The SMF provides opportunities for companies to collaborate, network, and to grow and expand both locally and internationally. Current membership stands at about 5,000 members comprising SMEs, MNCs and Affiliate members. For more information, please visit www.smfederation.org.sg.

Annex A

Recognition of HSA's Regulatory Standards

The World Health Organization's (WHO) recognition of HSA's Stringent Regulatory Authority status for high-risk in vitro diagnostic (IVD) medical devices (Class C and D) has enhanced its credibility of approvals by multiple jurisdictions, positioning Singapore as a trusted regulatory standard that opens doors to global markets.

HSA's regulatory agility has also been well recognised by industry, as demonstrated in a survey conducted by the Asia Partnership Conference of Pharmaceutical Associations (APAC), where Singapore was ranked first among 12 economies in Asia, particularly so in the comprehensive adoption of good reliance practices for market authorisations.

Enhanced Offering by SME Centre@SMF

SME Centre@SMF will deliver timely updates, offer guidance on available programmes, and facilitate strategic connections with HSA and key stakeholders to enhance support for Singapore's growing MedTech sector. This would include horizon scanning workshops to determine any new and upcoming health technologies for the regulators to be aware of, as well as developing whitepapers to outline strategies for the local MedTech sector to enhance regulatory alignment or strengthen local capacity for global growth.

Agile Frameworks for Medtech Industry

I. SaMD Change Management Programme

Launched in December 2024, this programme enables manufacturers of SaMD to implement rapid software updates with reduced regulatory burden through pre-specified changes. The programme addresses growing market demand - SaMD applications more than doubled from 33 in 2023 to 67 in 2024, with an additional 47 applications in early 2025. To date, HSA has received one application under this new framework.

II. SHARE System

Launched in July 2025 and has transformed how companies submit applications and manage their products throughout the lifecycle. The platform replaces hundreds of pages of guidance documents with contextualised, bite-sized guidance tailored to specific user needs. It also supports single ZIP file upload with background processing, eliminating the need for multiple individual file uploads resulting in significant time saving. Within two months of operation, SHARE processed over 8,100 applications and received positive user feedback. HSA continues to enhance the platform based on user suggestions and ongoing stakeholder engagement.

III. CLS(MD)

Launched in October 2024 in collaboration with the Ministry of Health and Cyber Security Agency of Singapore, CLS(MD) addresses critical security risks in connected medical devices. Since its launch, the scheme has received 60 applications.

IV. Centre for Advancing Regulatory Science Research in Next-Generation Therapeutics (ASCENT)

Launched in August 2025 in collaboration with A*STAR - Agency for Science, Technology and Research, ASCENT strengthens Singapore's position as a global thought leader in evaluating and approving novel biotherapeutics and digital technologies, enabling patient access to safe, high-quality, and cost-effective therapies. Through ASCENT, HSA will be leveraging A*STAR's multi-disciplinary expertise to develop advanced regulatory science capabilities in three critical areas: mRNA therapeutics, digital technologies, and biologics.