HEALTH SCIENCES AUTHORITY
PRESS RELEASE
10 MARCH 2026

HSA Achieves Highest Level Recognition from WHO for Medical Devices Regulatory Systems; Launches Expanded Economic Development Role for Biomedical Sector

The Health Sciences Authority (HSA) has become the **first national regulatory authority in the world to attain the highest World Health Organization (WHO) Maturity Level (ML4) for medical devices regulatory systems**. This was announced by Mr Ong Ye Kung, Minister for Health and Coordinating Minister for Social Policies in his opening speech at the International Medical Device Regulators Forum (IMDRF) 29th Session in Singapore on 10 March 2026. This recognition from WHO reflects HSA's capabilities and high level of excellence and credibility for its medical device pre- and post-market regulatory functions. This enables HSA to serve as a global reference authority that other regulators worldwide can confidently rely upon, to protect public health and safety.

2 Over the years, HSA's regulatory system has been recognised worldwide as operating at an advanced level of performance, including:

- **WHO Stringent Regulatory Authority –** Since 2023, WHO recognised HSA as a Stringent Regulatory Authority for high-risk in-vitro diagnostics (IVDs). This means that high-risk in-vitro diagnostics devices registered by HSA qualify for expedited assessment pathway under WHO's prequalification programme, which facilitates faster access to global markets.
- **Medicines Regulatory Systems** – In 2022, HSA was the first regulator in the world to achieve WHO Maturity Level 4 (the highest level) and was among the first three regulators recognised as a WHO-Listed Authority. This means that HSA is recognised globally as operating at an advanced level of regulatory performance, ensuring that medicines in Singapore meet high safety, efficacy and quality standards.

3 Minister Ong also shared about HSA's expanded economic role, and how this will enable economic value for Singapore's biomedical ecosystem.

Expanded HSA's Economic Role and Holistic Value Proposition for Industry

4 HSA's internationally recognised regulatory excellence anchors clinical developments and product regulations, defining Singapore as a key gateway to market access for health products and healthcare innovation both locally and globally. This in turn bolsters support for the growth and development of the biomedical industry, a key contributor to Singapore's economy.

5 This comes amid futureproofing a rapidly evolving health and medical technology sector prompted by developments in artificial intelligence (AI), precision

medicine, and next-generation diagnostics. To expand HSA's economic role, HSA will set up an industry development function to offer a holistic value proposition to the industry, and evolve its regulatory framework:

(i) The Research, Innovation and Enterprise (RIE) Plan comprises a series of rolling five-year investments, with S$37 billion (approximately US$29 billion) allocated to the latest plan, RIE2030, for the next five years. One of the key domains of investments is Human Health and Potential. Through sustained investment, Singapore has built strong biomedical and biomanufacturing capabilities. HSA will work alongside universities, academic medical centres, hospitals and the Agency for Science, Technology and Research (A*STAR) to strengthen the biomedical innovation pipeline, which could potentially result in impactful clinical applications.

(ii) HSA will work closely with A*STAR, the Economic Development Board (EDB) and Enterprise Singapore (EnterpriseSG) to offer a more holistic value proposition for global and local biomedical companies. For international biomedical companies establishing a presence in Singapore, they can look forward to HSA's rigorous yet expedient registration process. HSA will work with A*STAR to anchor translational research and industry-relevant innovation, and support EDB in attracting manufacturing, R&D and regional headquarter investments for Singapore. This will contribute to Singapore's biopharmaceutical manufacturing output, which has doubled over the past two decades, to S$13.9 billion in 2023. Similarly, the MedTech industry manufacturing output grew about tenfold over the same period from S$1.8 billion in 2003 to S$18.9 billion in 2023. For homegrown companies, partnership with EnterpriseSG will help to facilitate access to regional and global markets, and deepen collaborations with biomedical multinationals in Singapore.

(iii) In drug development, Singapore actively supports clinical trials. As a reputable and well-trusted regulatory and clinical ecosystem, we are able to be part of multi-centre clinical trial networks, for companies seeking to validate their innovations. About 100 industry-sponsored clinical trials are started every year in Singapore. HSA will continue to partner with other public sector agencies like the Consortium for Clinical Research and Innovation, Singapore (CRIS) to enhance our clinical trial capabilities and grow this number.

(iv) Within the family of agencies under the Ministry of Health (MOH), HSA will work with the Agency for Care Effectiveness and public healthcare clusters to explore aligned pathways that simultaneously facilitate regulatory approval, health technology assessment, and clinical development for products addressing Singapore's disease priority areas including cardiovascular diseases, diabetes, and metabolic disorders.

Advancing Regulatory Frameworks to Support Emerging Technologies

6 HSA will continue to advance its regulatory capabilities to embrace emerging technologies, positioning Singapore at the forefront of innovation whilst maintaining

the highest safety standards. This approach creates competitive advantages for companies choosing Singapore as their base.

7 **MOH and HSA co-developed and launched the revised AI in Healthcare Guidelines (AIHGle 2.0) on 10 March 2026**. Building on the 2021 framework, AIHGle 2.0 addresses developments in AI, such as Generative AI, and clarifies that AI should augment and empower our healthcare professionals in enhancing patient care. The updated guidelines will enable healthcare institutions to build and implement clinically safe and effective AI solutions, with patient safety at the core of it. Key updates to AIHGle 2.0 include: (a) strengthening accountability through clarity of responsibilities for key stakeholders; (b) improving trust via guidance on transparency to facilitate informed decision-making; and (c) updated guidance on AI deployment, such as assessing and mitigating risks. AIHGle will be periodically updated to provide appropriate guidance, considering developments and new technologies.

8 Besides regulating AI, HSA will also be progressively adopting AI technologies that create value for industry partners. From today, HSA has launched its AI-enabled Medical Device Risk Classification Tool (https://mdrc.hsa.gov.sg/) for industry partners to trial and provide feedback. This beta tool provides automated guidance on preliminary risk classification estimates during product development.

Bridging Healthcare, Regulatory Systems and Industry

9 The IMDRF 29th Session, is being held from 9 to 13 March 2026 in Singapore. It brings together over 400 attendees including global regulators and industry experts to discuss critical advancements in medical device regulation and technology. The Forum is organised by HSA, which is also the current chair of the IMDRF. As the chair of IMDRF, HSA continues building meaningful bridges between regulatory systems and industry, fostering innovation whilst ensuring patient safety remains paramount.

10 Adj Prof (Dr) Raymond Chua, Chief Executive Officer, HSA, and Deputy Director-General of Health (Health Regulation), MOH, said: “We are deeply honoured that HSA has been conferred the highest Maturity Level (ML4) for medical devices regulatory systems by the WHO, and the first country in the world to achieve this recognition. This achievement comes as HSA is expanding our economic role to benefit the biomedical industry, and at future-proofing our regulations to support the rollout of more healthcare innovations, such as AI, in the healthcare sector. HSA will continue to engage and partner the industry and their associations in this expanded economic agenda and our regulatory work. We hope to use this Forum for the regulators and industry to work together towards ensuring that patients around the world are best served by the latest and safest medical devices available for the treatment of various health conditions.”

HEALTH SCIENCES AUTHORITY
SINGAPORE
10 MARCH 2026

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 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 the International Medical Device Regulators Forum

IMDRF is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonisation Task Force on Medical Devices and aims to accelerate international medical device regulatory harmonisation and convergence. HSA is the current Chair of the IMDRF in 2026.