HEALTH SCIENCES AUTHORITY
PRESS RELEASE
12 MARCH 2026

HSA DEEPENS INTERNATIONAL PARTNERSHIPS AND REGULATORY RELIANCES TO GROW BIOMEDICAL SECTOR

The Health Sciences Authority (HSA) has deepened its collaborations with its regulatory counterparts in Malaysia and Uzbekistan that would pave the way for patients, healthcare and industry practitioners in the respective markets to enjoy greater access to medicines, medical devices and other healthcare innovations. The collaborations were pledged on the sidelines of the ongoing International Medical Device Regulators Forum (IMDRF), hosted by HSA, the current chair. This will contribute to the development and growth of the local biomedical sector, and is part of the expanded economic role for HSA as announced by Mr Ong Ye Kung, Minister for Health and Coordinating Minister for Social Policies at the opening of the IMDRF on 10 March 2026.

HSA Formalises Medical Device Regulatory Reliance Programme with Malaysia

2 Following a successful six-month pilot phase that ran from 1 September 2025 to 28 February 2026, HSA and Malaysia's Medical Device Authority (MDA) have announced on 11 March 2026 the full implementation of the Medical Device Regulatory Reliance Programme between the two authorities. From 1 March 2026, medical devices registered with HSA may undergo faster review for access to the Malaysian market, while medical devices registered with MDA can benefit from a shortened review pathway with HSA for access to the Singapore market. This bilateral arrangement allows for more efficient processes and eventually benefits patients as they can gain faster access to safe and high-quality medical devices. The six-month pilot has also been successful, with at least 15 HSA-registered products approved by the MDA to date, since the launch of the pilot.

Memorandum of Understanding with Uzbekistan's Ministry of Health Centre for Pharmaceutical Products Safety

3 On 9 March 2026, HSA signed a Memorandum of Understanding (MOU) with Uzbekistan's Ministry of Health Centre for Pharmaceutical Products Safety on the sidelines of IMDRF**.** The MOU establishes cooperation across pharmaceuticals, medical devices, and advanced therapeutics through key areas such as regulatory science and technical cooperation, knowledge sharing on digitalisation and innovation, laboratory practices and testing cooperation; post-market surveillance; and exploring regulatory reliance mechanisms. This partnership will strengthen regulatory cooperation between the two agencies in the fields of health products and facilitate the safe and efficient access of these products to their populations. Currently, Uzbekistan recognises regulatory authorities that have achieved World Health Organization (WHO) Maturity Level 4 (ML4) status for medicines, which enables reliance on HSA's

approvals given its ML4 achievement in 2022. Following the recent announcement of HSA achieving the highest WHO ML4 status for medical devices regulatory systems, both agencies will be exploring similar reliance mechanisms for medical devices under this partnership.

Participation in Medical Device Single Audit Program for Enhanced Regulatory Efficiency

4 Singapore will also be applying for full membership in the Medical Device Single Audit Program (MDSAP), in the second half of 2026. If successful, this advances HSA from its current official observer status. MDSAP is jointly managed by five leading regulatory authorities including Australia's Therapeutic Goods Administration, Brazil's ANVISA (Brazilian Health Regulatory Agency), Canada's Health Canada, Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA), and the United States Food and Drug Administration (FDA). The program allows a recognised auditing organisation to conduct a single audit of a medical device manufacturer that satisfies the regulatory requirements of participating regulatory authorities, thus replacing multiple manufacturing audits and reducing duplication. This membership will enhance HSA's regulatory oversight of manufacturers whilst accelerating patients' access to safer, more effective medical devices across participating jurisdictions.

5 "The collaborations pledged with Malaysia and Uzbekistan at the sidelines of the IMDRF will allow us to reduce duplications, enhance regulatory efficiencies, and expedite access of effective and safe health products to our populations. We welcome further input and engagement with other regulatory authorities and industry members to review how HSA could establish ourselves as a global reference point for regulatory reliance," said Adjunct Professor (Dr) Raymond Chua, Chief Executive Officer, HSA.

6 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.

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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.

ANNEX

HSA DEEPENS INTERNATIONAL PARTNERSHIPS AND REGULATORY RELIANCES TO GROW BIOMEDICAL SECTOR

Medical Device Regulatory Reliance Programme with Malaysia

Photo 1
From left: Adjunct Professor (Dr) Raymond Chua, Chief Executive Officer, HSA, Singapore and Dr Muralitharan Paramasua, Chief Executive, MDA, Malaysia

Photo 2
Adjunct Professor (Dr) Raymond Chua, Chief Executive Officer, HSA, Singapore, third from left and Dr Muralitharan Paramasua, Chief Executive, MDA, Malaysia, fourth from left, with delegates from HSA Singapore and MDA Malaysia

Singapore's Health Sciences Authority and Uzbekistan's Ministry of Health Centre for Pharmaceutical Products Safety (CPPS) Memorandum of Understanding Signing

Photo 3
From left: Mr Alisher Temirov, Director, CPPS, Uzbekistan and Adjunct Professor (Dr) Raymond Chua, Chief Executive Officer, HSA, Singapore

Photo 4
Mr Alisher Temirov, Director, CPPS, Uzbekistan, third from left and Adjunct Professor (Dr) Raymond Chua, Chief Executive Officer, HSA, Singapore, fourth from left with delegates from CPPS and HSA

All photos are to be credited to the Health Sciences Authority, Singapore.