



**HEALTH SCIENCES AUTHORITY
PRESS RELEASE
28 FEBRUARY 2022**

**HSA SINGAPORE THE FIRST NATIONAL REGULATORY
AUTHORITY AWARDED THE HIGHEST RECOGNITION
FOR AN ADVANCED MEDICINES REGULATORY SYSTEM
BY THE WORLD HEALTH ORGANIZATION**

The Health Sciences Authority (HSA) is the first National Regulatory Authority (NRA) and Singapore is the first World Health Organization (WHO) member state to achieve Maturity Level (ML) 4 for its advanced medicines regulatory system. This achievement came after a rigorous and comprehensive assessment by a team of 15 international assessors and 4 WHO officials using the WHO's Global Benchmarking Tool. The assessment took place from 25 October to 5 November 2021.

2 ML4 is the highest level of attainment for a regulatory system classification system conferred to an NRA that has met the highest quality standards stipulated by WHO for regulatory excellence. WHO objectively evaluates the overall maturity of a country's medicines regulatory system from a scale of one (existence of some elements of a regulatory system) to four (operating at an advanced level of performance and continuous improvement). The quality standards employ a Global Benchmarking Tool that comprises a comprehensive set of 251 indicators to monitor and validate the performance of a regulatory system spanning across 8 core regulatory functions¹. They cover the entire regulatory lifecycle for medicines from clinical trials, marketing authorisation to post-market safety monitoring, audit and licensing of manufacturers and dealers, and laboratory testing of medicines.

ENHANCING PUBLIC CONFIDENCE AND TRUST

3 The ML4 status identifies HSA as an NRA that is operating at an advanced level of performance and continuous improvement. It validates the high standards, quality and rigour of HSA's regulatory work in ensuring that medicines approved for use in Singapore are safe, of good quality and are effective for our population.

¹ The 8 core regulatory functions are the National Regulatory System, Registration and Marketing Authorisation, Vigilance, Market Surveillance and Control, Licensing Establishments, Regulatory Inspection, Laboratory Testing and Clinical Trials Oversight.

4 It also validates the rigour of HSA's audit capabilities in ensuring that our manufacturers conform to stringent international standards in the manufacturing of quality medicines.

5 Attaining ML4 requires HSA to publish its assessment reports detailing the safety, efficacy and quality of registered medicines and vaccines and their benefit risk analysis. This will further enhance the transparency of HSA's regulatory decisions. Other international regulatory agencies can leverage HSA's reports, which are made publicly available on HSA's website, to facilitate their review of these products.

6 WHO has also validated HSA's innovative post-market monitoring system that uses data analytics, and that leverages the nation's electronic medical health records and the extensive network of healthcare professionals, to monitor the adverse drug reactions associated with medicines and vaccines. This system enables HSA to take swift actions to protect public health and safety. A key example is its quick and close monitoring of the safety of COVID-19 vaccines and monthly release of safety reports.

7 This external validation by WHO will enhance the Singapore public's confidence and trust in HSA as an innovative and effective medicines regulator working to protect and advance their health and safety.

8 Throughout HSA's 3-year benchmarking journey, the WHO gave valuable feedback, coordinated the entire benchmarking process, and engaged a strong and experienced team of international assessors to undertake an extensive review of HSA's regulatory processes and documentation. The WHO's support and guidance were instrumental in HSA's journey to achieve the ML4 status.

9 "This is a great achievement for Singapore," said Dr Mariângela Simão, WHO Assistant Director General for Access to Medicines and Other Health Products. "The core of WHO's work is to empower countries through support and knowledge transfer so that they can expand access to health services for their populations. If countries want to improve health outcomes, if they want to expand local production, they first need to be able to ensure access to safe and quality medical products that actually work and benefit patients."

10 "This is a remarkable achievement for HSA. It is the highest standard promulgated by the WHO, and HSA is the first to achieve it. It means that HSA is recognised internationally as one of the most trusted and advanced regulators for medicines, contributing to public health outcomes in Singapore, the region and beyond. The Singapore public will now have even greater confidence in HSA's assessments, and that they have access to high quality, safe and effective medicines," said Mr Ong Ye Kung, Minister for Health, Singapore.

BACKGROUND ON THE WHO GLOBAL BENCHMARKING TOOL

11 The WHO Global Benchmarking Tool is a standardised tool which enables WHO to benchmark regulatory systems for the regulation of medical products to determine the overall maturity in terms of the level of performance and continuous improvement. The benchmarking is part of the WHO programme for regulatory system strengthening. For more information on WHO GBT, please refer to <https://www.who.int/tools/global-benchmarking-tools>.

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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 details, visit <http://www.hsa.gov.sg/>.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

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.