

SINGAPORE. 3 NOVEMBER 2023

HSA UPDATES

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HSA UPDATES NO 4/2023

HSA SINGAPORE DESIGNATED AS WHO-LISTED AUTHORITY FOR ITS MEDICINES REGULATORY SYSTEM

The Health Sciences Authority (HSA) has been designated by the World Health Organization (WHO) as a WHO-Listed Authority (WLA) on 26 October 2023 for its medicines regulatory system. This means that HSA is now recognised globally as operating at an advanced level of regulatory performance, ensuring that medicines in Singapore meet high safety, efficacy and quality standards.

- In January 2022, HSA had attained the WHO Maturity Level 4¹ based on our operational efficiency. The subsequent assessment for WLA included a thorough review of the quality of regulatory assessments, the scientific soundness of the decision-making and their consistent implementation. WHO's comprehensive assessment of HSA's core functions and operations, conducted by a team of 10 international assessors and WHO officials, took place from October 2022 to March 2023.
- The WLA² initiative was implemented by WHO to promote access and supply of safe, effective and quality medical products. It also provides for the optimal use of limited global regulatory resources by facilitating reliance on the decisions of trusted

¹ https://www.hsa.gov.sg/announcements/press-release/who-ml4

² A WLA has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking and performance evaluation process. Only regulatory authorities with ML3 and ML4 are eligible to become a WLA, following a further performance evaluation.

agencies in the decision-making of regulatory authorities. Having a list of trusted WLAs enables this through promoting confidence, trust and reliance on authorities that have attained this global recognition.

- In addition to contributing to global cooperation, Singapore's status as a WLA could encourage more pharmaceutical companies to choose Singapore as one of the first few markets to register their novel and innovative medicines. This would enable patients in Singapore to gain earlier access to novel lifesaving medicines and treatments. It could also potentially spur the health and biomedical sciences sector in Singapore.
- Says Dr Choong May Ling, Mimi, Chief Executive Officer of HSA, "I am very proud of HSA's achievement. I believe HSA's WLA status will serve to foster greater public confidence and trust in HSA and our work to safeguard public health. I look forward to continuing our strong collaboration with WHO in regulatory systems strengthening."

HEALTH SCIENCES AUTHORITY SINGAPORE 3 NOVEMBER 2023

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/.

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