



SINGAPORE, 24 MAY 2024

## HSA UPDATES

***“HSA UPDATES” addresses topics of current public interest and is subject to change as more information becomes available.***  
**HSA UPDATES NO 1/2024**

### **HSA FURTHER AFFIRMED BY WORLD HEALTH ORGANIZATION FOR ITS MEDICINES REGULATORY SYSTEM**

The Health Sciences Authority (HSA) has received further recognition from the World Health Organization (WHO) in the area of market surveillance and control for its medicines regulatory system. The latest achievement acknowledges that HSA’s WHO-Listed Authority (WLA) status now covers all regulatory functions for all medicines, from generics to new chemical entities, biotherapeutics and similar biotherapeutic products.

2 This affirms 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. It also demonstrates that the Authority is committed to continuous improvement and excellence in regulatory oversight. HSA was one of the first three regulatory authorities to be designated as WLA in 2023<sup>1</sup>.

3 WHO’s comprehensive assessment for the market surveillance and control performance indicator involved evaluating HSA’s core functions and operations in this area, which included studying how HSA samples and tests medicines in the market to ensure they are safe and of high quality. The assessment took place from 20 January to 9 April 2024.

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<sup>1</sup> <https://www.hsa.gov.sg/announcements/news/hsa-whowla2023>

## **HSA's journey towards regulatory excellence**

4 “The WHO’s endorsement of HSA’s market control and surveillance function marks the culmination of the HSA’s multi-year initiative to strengthen our regulatory system and benchmark it against international best practices. My colleagues and I are proud to receive this recognition which affirms HSA’s status as a trusted WLA. This achievement further reinforces our commitment to ensuring the availability of safe, effective, and good quality medicines for the public in Singapore,” said Dr Choong May Ling, Mimi, Chief Executive Officer of HSA.

5 As the national medicines regulatory agency, HSA is committed to protecting the health and safety of Singaporeans and has been continually upholding high standards and advancing its performance in medicines regulation. In January 2022, HSA attained the WHO Maturity Level 4<sup>2</sup> based on operational efficiency. This laid the foundation for subsequent assessment for WLA<sup>3</sup>, which is an initiative 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 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.

**HEALTH SCIENCES AUTHORITY  
SINGAPORE  
24 MAY 2024**

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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

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<sup>2</sup> <https://www.hsa.gov.sg/announcements/press-release/who-ml4>

<sup>3</sup> 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.

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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