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WHO awards HSA Singapore the 'Regulatory Excellence Award' for advanced medicines regulatory system

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Singapore is the first World Health Organization (WHO) member state to receive this highest recognition to become the first National Regulatory Authority (NRA) to achieve Maturity Level (ML) 4 status



Singapore's Health Sciences Authority (HSA) becomes the first National Regulatory Authority (NRA) to achieve Maturity Level (ML) 4 for its advanced medicines regulatory system. Singapore is also the first World Health Organization (WHO) member state to reach this milestone.

After a rigorous and comprehensive assessment by a team of 15 international assessors and 4 WHO officials using the WHO's Global Benchmarking Tool, Singapore is proven to have achieved the highest quality standards stipulated by WHO for regulatory excellence.

The ML4 status identifies HSA as an NRA that validates the high standards, quality, rigour of HSA's regulatory work, and audit capabilities in ensuring that medicines approved for use in Singapore are safe, of good quality and are effective for our population. The validation ensures that Singapore manufacturers conform to stringent international standards in the manufacturing of quality medicines. This will further enhance the transparency of HSA's regulatory decisions.

ML4 is the highest level of attainment for a regulatory system classification system conferred to an NRA. 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 functions. 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.

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.

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.