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ASIA EDITION

Made-In-Singapore Active Pharmaceutical Ingredients get easier access to EU

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Made-in-Singapore APIs for use in human medicines can now be exported to the EU



Singapore, through the Health Sciences Authority (HSA), has been recognised by the European Commission for its regulatory framework for active pharmaceutical ingredients (APIs), affirming that its quality oversight of APIs produced in Singapore provides public health protection equivalent to that required in the European Union (EU).

The Commission has adopted a decision that Singapore's standards and controls on Good Manufacturing Practice (GMP) in Singapore for APIs, which are the active substances responsible for the intended therapeutic effects of medicines, is equivalent to that in the EU.

With this recognition, made-in-Singapore APIs for use in human medicines can now be exported to the EU through simpler and faster procedures, without the usual written confirmation from HSA on GMP standards and manufacturing site oversight. API manufacturers can expect simpler processes, while patients can be assured of continued stringent quality standards from Singapore.

Singapore joins a select group of countries including the United States, Japan, Australia, Switzerland, South Korea, Canada, Brazil and Israel that have achieved this recognition. The Commission's decision follows HSA's implementation of a strengthened regulatory framework for APIs in December 2023 and the Commission's assessment of HSA's framework, including an on-site review in March 2026.

HSA has also signed a Working Arrangement with the Commission's Directorate-General Health and Food Safety (DG SANTE) and European Medicines Agency (EMA) to strengthen scientific and regulatory cooperation on medicines and medical devices. The Arrangement provides a structured framework for information sharing, scientific and expert exchanges, and opportunities to explore collaborative regulatory reviews. This Arrangement also envisages possible observer or expert participation in scientific committees and initiatives such as through EMA's Opening Procedures to Non-EU Authorities (OPEN) framework.

This closer cooperation will enable regulators to share expertise and leverage one another's scientific assessments, supporting more informed and timely regulatory decisions. It aims to enhance regulatory efficiency thereby facilitating patients' access to safe, effective and quality medicines and medical devices.