

Singapore and Japan Strengthen Regulatory Cooperation in Health Products

Asia – Pharma

Singapore's Health Sciences Authority (HSA) and Japan's Ministry of Health, Labour and Welfare (MHLW) signed a Memorandum of Cooperation (MoC) to strengthen regulatory collaboration on health products. The agreement expands the use of regulatory reliance mechanisms, allowing both authorities to leverage each other's assessments, inspections, and regulatory decisions to improve efficiency while maintaining high standards of safety, quality, and efficacy. A key element is mutual reliance on Good Manufacturing Practice (GMP) inspections and certificates, reducing duplicative oversight and administrative burdens for manufacturers. The MoC also promotes cooperation across the full product lifecycle—from clinical trials and product evaluation to manufacturing and post-market surveillance—and supports information sharing on advanced therapies and emerging health technologies, with the goal of accelerating patient access to innovative medical products.

In April 2026, **Singapore's Health Sciences Authority (HSA)** and **Japan's Ministry of Health, Labour and Welfare (MHLW)** entered into a **Memorandum of Cooperation (MoC)** aimed at **enhancing bilateral collaboration in the regulation of health products**. The agreement reflects the growing emphasis among regulatory authorities on international cooperation, regulatory reliance, and the development of more efficient approval pathways for medical products. By strengthening existing ties between the two agencies, the MoC seeks to **improve regulatory efficiency, support innovation, and facilitate earlier patient access to safe, effective, and high-quality health products**.

The agreement builds upon a longstanding regulatory relationship between **Singapore** and **Japan**. Bilateral cooperation in this area has evolved over several decades, supported by broader economic and regulatory partnerships between the two countries. The MoC therefore represents not the beginning of a new relationship, but rather the continuation and formalization of an existing collaboration that has progressively expanded in scope and depth.

A central feature of the MoC is the commitment to **expand the use of regulatory reliance mechanisms**. Regulatory reliance allows one authority to take into account the assessments, inspections, or decisions of a trusted foreign regulator when carrying out its own regulatory functions. In this context, HSA and MHLW have agreed to deepen cooperation in areas such as product evaluation, manufacturing oversight, and information exchange. Such reliance-based approaches are increasingly viewed as an effective means of reducing unnecessary duplication of regulatory activities while maintaining robust standards for quality, safety, and efficacy.

Particular emphasis has been placed on **cooperation in relation to Good Manufacturing Practice (GMP)** inspections. The MoC provides a framework for the mutual reliance of GMP certificates and inspection outcomes relating to pharmaceutical manufacturers operating in either jurisdiction. This initiative is expected to **reduce the need for duplicative inspections by both regulators**, thereby **lowering the administrative burden** on manufacturers and **allowing regulatory resources to be deployed more efficiently**. Importantly, the parties have emphasized that such efficiencies will not come at the expense of regulatory rigor, as both authorities will continue to apply stringent standards to ensure the safety and quality of medicinal products.

Beyond manufacturing oversight, the MoC establishes a formal basis for **cooperation throughout the entire lifecycle of health products**. The collaboration extends from the review of clinical trials and product assessments to registration processes, manufacturing controls, and post-market surveillance activities. This lifecycle approach reflects the increasing complexity of modern healthcare products and the need for regulators to work collaboratively in addressing emerging scientific and technological developments.

The scope of the cooperation also includes the **exchange of information and expertise relating to advanced and innovative technologies**. This is particularly significant in light of the rapid growth of novel therapeutic modalities, including cell therapies, tissue-engineered products, gene therapies, and other advanced medicinal products. Such technologies often present unique regulatory challenges due to their scientific complexity and evolving risk profiles.



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