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HSA in Singapore receives recognition as WHO stringent regulatory authority for IVDs

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HSA will continue to work closely with WHO in advancing regulatory efficiency

Health Sciences Authority (HSA) in Singapore has been recognised by the World Health Organisation (WHO) as a WHO stringent regulatory authority (SRA) for high-risk (Class C and D) in vitro diagnostic medical devices (IVDs), making it one of six regulatory authorities to receive the recognition.

This achievement validates HSA's stringent standards for quality, safety and efficacy. With the SRA status, IVDs that have been evaluated and approved by HSA can obtain faster evaluation for WHO prequalification. This in turn reduces the time required for companies to register their products in other countries, enabling IVD manufacturers accelerated access to global markets.

IVDs are regulated as medical devices under HSA, and are subject to evaluation and registration by HSA prior to supply and use in Singapore. This ensures that the tests meet appropriate standards of quality, safety, accuracy and performance when used in Singapore's healthcare system.

WHO performs a similar evaluation of IVDs and prequalifies them on a global basis, especially for priority diseases (e.g. human immunodeficiency virus, Ebola, human papillomavirus). WHO prequalification is meant to promote and facilitate access to safe, appropriate and affordable IVDs of good quality in an equitable manner. For instance, in countries which have little or no domestic regulatory frameworks, WHO prequalification provides complementary regulatory support.

HSA is one of the six SRAs for IVDs, the first authority outside the five founding members (European Union, United States, Canada, Australia and Japan) of the Global Harmonisation Task Force (GHTF) to receive the recognition.