FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY
PRESS RELEASE
30 NOVEMBER 2017

HSA GAINS INTERNATIONAL ACCEPTANCE AS A MEMBER OF THE INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE (ICH)

The Health Sciences Authority (HSA) has been internationally accepted as a Regulatory Member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This marks a significant milestone for HSA as it joins the ranks of big regulators, including the US Food and Drug Administration, the European Commission and Japan's Pharmaceutical & Medical Devices Agency, to influence decision-making in pharmaceutical product development and registration. HSA's membership was announced at the recent meeting held in Geneva on 16-17 November 2017.

2 As a Regulatory Member of ICH, HSA has earned international recognition as a country with an advanced regulatory system for pharmaceutical products. HSA will have first rights, together with other ICH members, to participate in ICH expert working groups, and to vote on all matters raised at ICH meetings. This assures that Singapore's views are represented when developing the various ICH guidelines relevant to Singapore, for example the guidelines determining product registration, manufacturing and safety monitoring. More information on the ICH guidelines is available at www.ich.org.

Benefits to Local Pharmaceutical and Biotechnology Industries

3 HSA's membership will also facilitate the entry of local pharmaceutical and biotechnology industries into other markets. For example, Singapore's pharmaceutical exports will now enjoy priority status in public drug tenders and procurement in markets such as Vietnam and Hong Kong. It will also be easier for a company to launch a new drug in many countries at the same time if regulatory requirements for drugs are aligned, enabling faster global access to a new drug.

4 "The ICH membership signals HSA's commitment to align our regulatory requirements and keep pace with international standards. This will facilitate the entry of our local pharmaceutical industry into other markets and bring benefits to patients in Singapore with the faster development of drugs and quicker access to new therapies," said Dr Lam Pin Min, Senior Minister of State for Health and Transport, Singapore.

Background on the ICH

5 Regulators and industry associations from the United States, Europe and Japan established the ICH in 1990, with the mission of achieving greater harmonisation worldwide to ensure that safe, effective and high quality medicines are developed and registered in the most resource-efficient manner. Singapore first joined the ICH in 2008 with HSA as an observer. It is now the 9th Regulatory Member, after Canada, Switzerland, the Republic of Korea, China and Brazil.

HEALTH SCIENCES AUTHORITY
SINGAPORE
30 NOVEMBER 2017

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 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/.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

About HSA's Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.