



SINGAPORE ASSOCIATION OF PHARMACEUTICAL INDUSTRIES

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Agency for Care Effectiveness(ACE) - Singapore Association of Pharmaceutical Industries (SAPI) Consultation Concluded for the New Company-led HTA Submission Process

December 1, 2020, SINGAPORE — Since January 2019, Singapore Association of Pharmaceutical Industries (SAPI) has been involved in a consultation process with the Agency for Care Effectiveness (ACE) on their new procedural and methodological guidelines that have been developed for companies that wish to prepare an evidence submission to inform funding decisions for their medicines.

The aim of the new process is to enable medicines to be evaluated close to the anticipated date of regulatory approval by the Health Sciences Authority (HSA), & expedite funding considerations to improve patient access to clinically necessary treatments. Evidence submissions received from companies will inform MOH's subsidy decisions and serve to target funding to cost-effective drugs to optimize health benefits within finite resources.

ACE has developed a comprehensive document outlining core processes and methods that companies are expected to follow, by drawing on best practices from overseas health technology assessment (HTA) agencies, and contextualizing them to the Singapore setting.

Between January 2019 - September 2020, ACE invited comments from the SAPI market access project team on different sections of the guidelines as they were drafted to ensure that the proposed methods and processes were feasible to implement. Five meetings were also held during this period to allow SAPI members to highlight any areas which required clarification and discuss specific issues further with ACE. Following consultation with SAPI, ACE also invited all companies (not limited to SAPI) over 4 weeks to provide comments, and discussed any further changes to the guidelines resulting from the industry consultation with SAPI before the guidelines were finalized.

The guidelines and supporting documents will be launched in December 2020 and the process will be piloted from January 2021. ACE will also be holding an industry briefing in January 2021 to answer any outstanding questions about the new process.

On behalf of the SAPI Board of Directors, Priya Kudva Menon, General Manager for GSK Pharmaceuticals & Vaccines, who also serves as Chair of SAPI's Market Access Committee said, *"We are very thankful to ACE, particularly Fiona Pearce & Kwong Ng for the collaboration and transparent consultation opportunity extended to SAPI for the new company led submission process, a key enabler for driving early access for Innovative medicines for patients in Singapore & we look forward to continued partnership in the future."*

Fiona Pearce, Deputy Director and Senior Principal Lead Specialist (HTA) from ACE, Ministry of Health Singapore, said, *"ACE is grateful to the SAPI market access project team, and the consultants appointed by SAPI to oversee the consultation process, for helping to refine the*

guidelines and ensure that the proposed processes are feasible to implement. Through this collaboration, we have been able to evolve ACE's existing HTA processes to allow upstream evaluation of clinically necessary treatments and expedite funding considerations to improve affordability and access to medicines for patients in Singapore.”

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About SAPI

Singapore Association of Pharmaceutical Industries (SAPI) was founded in 1966 and was initially known as the Pharmaceutical Trade Association. In 1975, the Association changed its name to encompass a wider spectrum of pharmaceutical related business into the Association—namely the distributors, manufacturers, representative offices and affiliated companies.

Currently, SAPI comprises 41 members of which 33 are global R&D based biopharmaceutical companies in Singapore, with its members employing close to 10,000 people in the country. SAPI aims to make innovative medicine accessible to patients in Singapore. SAPI achieves this through a sustainable and valued partnership with healthcare professionals and providers, government, patient group stakeholders, and a reputation of consistent ethical behavior.