HEALTH SCIENCES AUTHORITY
PRESS RELEASE
14 SEPTEMBER 2022

HSA GRANTS INTERIM AUTHORISATION FOR FIRST BIVALENT COVID-19 BOOSTER VACCINE IN SINGAPORE

The Health Sciences Authority (HSA) has granted interim authorisation under the Pandemic Special Access Route (PSAR) for Spikevax Bivalent Original/Omicron COVID-19 vaccine by Moderna on 14 September 2022. It comprises two components that target the original SARS-CoV-2 strain and the Omicron BA.1 variant respectively, and is an updated version of the Moderna COVID-19 vaccine that is based only on the original SARS-CoV-2 strain.

2 It is authorised for use as a booster vaccine in individuals aged 18 years and above, who have received primary series vaccination with COVID-19 vaccines. The booster shot is a single dose comprising the two components:

- 25 micrograms targeting the original SARS-CoV-2 strain, and
- 25 micrograms targeting the Omicron BA.1 variant.

Official vaccination recommendations using this booster vaccine will be issued by the Expert Committee on COVID-19 Vaccination and the Ministry of Health in due time.

3 HSA has carefully reviewed the data from Moderna's pre-clinical studies, clinical trials in human volunteers, manufacturing and quality controls, and assessed that the benefits outweighed the risks for use of the bivalent vaccine as a booster to protect against COVID-19 as the virus continues to evolve. In making this regulatory decision, HSA also consulted experts from its Medicines Advisory Committee and Panel of Infectious Diseases Experts.

HSA's Evaluation of Available Safety and Efficacy Data

4 HSA's clinical review was based on an ongoing Phase 2/3 trial conducted by Moderna in individuals aged 18 years and above:

- The results showed that the bivalent booster vaccine elicited a strong immune response against the Omicron BA.1 variant, while preserving the immune response against the original SARS-CoV-2 strain.

- The preliminary data from an exploratory analysis also suggested that the vaccine may stimulate antibodies against Omicron BA.4/5, as well as other variants such as Alpha, Beta, Delta, and Gamma.

Hence, it could be reasonably expected that the bivalent booster vaccine can enhance the immunity against the Omicron variants, while maintaining the base protection conferred by the original vaccine.

5 Safety data from the clinical studies showed that the bivalent vaccine was generally well-tolerated and the safety profile was consistent with what is known for the original Spikevax vaccine. The adverse events were mostly mild-to-moderate, such as injection site pain and/or tenderness, fatigue, headache and muscle pain. These reactions are generally associated with vaccinations and expected as part of the body's natural response to build immunity against COVID-19. They usually resolve on their own within a few days.

Active Monitoring and Continuous Review of Data

6 HSA will continue to actively monitor the safety of the vaccine and require Moderna to submit data from the on-going clinical study, to ensure that the benefits of the vaccine continue to outweigh the risks when used during the Covid-19 pandemic. HSA will take the necessary actions and provide updates to the public if significant safety concerns are identified.

7 Dr Choong May Ling, Mimi, Chief Executive Officer of HSA, shared, "The COVID-19 pandemic has evolved significantly with recent surges around the world due to the rapid spread of highly transmissible variants such as Omicron. Updated COVID-19 vaccines such as bivalent vaccines are expected to offer broader immunity against circulating variants, while retaining critical protection against severe disease and death. HSA, as the authority protecting and advancing public health and safety, will continue to conduct rigorous and efficient assessments to facilitate the Singapore population's access to critical vaccines and medicines."

HEALTH SCIENCES AUTHORITY
SINGAPORE
14 SEPTEMBER 2022

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 medicines, 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.