HEALTH SCIENCES AUTHORITY
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HSA EXTENDS THE USE OF SPIKEVAX COVID-19 VACCINE BY MODERNA TO THE YOUNGER POPULATION AGED 6 MONTHS TO 17 YEARS OLD

The Health Sciences Authority (HSA) has extended the authorisation of Moderna's Spikevax[1] COVID-19 vaccine via the Pandemic Special Access Route (PSAR) on 24 August 2022, for the prevention of Coronavirus Disease 2019 (COVID-19) in individuals of the following age groups:

a) 6 months to 5 years; administered as a course of two 25 microgram doses;
b) 6 to 11 years; administered as a course of two 50 microgram doses; and
c) 12 to 17 years; administered as a course of two 100 microgram doses.

2 HSA has carefully considered the data from two clinical studies in children and adolescents, and assessed that the benefits outweighed the risks for use of Spikevax in individuals aged 6 months and above. In making this regulatory decision, HSA also consulted expert advice from the Medicines Advisory Committee and Panel of Infectious Diseases Experts.

Evaluation of Available Safety and Efficacy Data in Adolescents and Children

3 The clinical data was based on two ongoing Phase 2/3 studies conducted by Moderna, comprising more than 3,700 adolescents aged 12 to 17 years and 6,000 children aged 6 months to 11 years, respectively. The results showed that the antibody levels following two doses of Spikevax administered 28 days apart as primary vaccination were comparable to those seen in adults (18 to 25 years old) in whom vaccine efficacy had been demonstrated. Hence, it can be inferred that the vaccine may provide similar level of protection in the younger populations.

4 Locally, real-world evidence in adults has shown reduced vaccine effectiveness, which was estimated to be around 40%, against the Omicron subvariants. Similarly in the clinical study, results in young children aged 6 months to 5 years old have shown that the vaccine was 37% to 50% effective in preventing COVID-19. Nonetheless, the

[1] The Spikevax vaccine has been known as the Moderna COVID-19 vaccine when it was granted PSAR interim authorisation for individuals aged 18 years and above in February 2021. (https://www.hsa.gov.sg/announcements/press-release/hsa-grants-interim-authorisation-for-moderna-covid-19-vaccine-in-singapore)

data in adults continued to show that the vaccine confers high protection of 80% against severe disease. Hence, it is reasonably expected that the vaccine would similarly protect children from severe outcomes of COVID-19 such as multisystem inflammatory syndrome in children (MIS-C) and other potential complications.

5 Safety data from the clinical studies also showed that adverse events in adolescents and children were similar to those reported in adults. The adverse events were mild-to-moderate and commonly reported with childhood vaccination, such as injection site pain, fever, fatigue and headache. These symptoms are reactions generally associated with vaccinations and expected as part of the body's natural response to build immunity against COVID-19. These symptoms generally resolve on their own within a few days.

Safeguards and Ongoing Safety Monitoring

6 Post-market surveillance data of mRNA vaccines has suggested a potential risk of myocarditis (inflammation of the heart muscle) in young adults and adolescents. While there were no cases of myocarditis reported in the clinical studies with Spikevax, the risks could not be excluded. Hence, HSA recommends that caregivers of younger children should monitor for signs and symptoms of myocarditis such as chest pain, breathing difficulty, etc., as well as take precautions to minimise rigorous physical activity following vaccination.

7 HSA will continue to actively monitor the safety of the vaccine and require Moderna to submit on-going data on the safety and efficacy of the vaccine, to ensure that the benefits of the vaccine continue to outweigh the risks. HSA will take necessary actions and provide updates to the public if significant safety concerns are identified.

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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/.

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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.