HEALTH SCIENCES AUTHORITY
PRESS RELEASE
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HSA AUTHORISES THE USE OF COMIRNATY COVID-19 VACCINE BY PFIZER IN YOUNG CHILDREN AGED 6 MONTHS THROUGH 4 YEARS

The Health Sciences Authority (HSA) has authorised Pfizer's Comirnaty COVID-19 vaccine on 28 September 2022, for the prevention of Coronavirus Disease 2019 (COVID-19) in children aged 6 months through 4 years. This is the second vaccine authorised for use in Singapore by HSA for young children[1]. HSA had also previously authorised the Comirnaty vaccine for adults and older children aged 5 years and above[2].

2 HSA has carefully considered the clinical data and assessed that the benefits outweighed the risks for use of Comirnaty in children aged 6 months through 4 years. In making this regulatory decision, HSA also consulted experts from its Medicines Advisory Committee and Panel of Infectious Diseases Experts.

3 The vaccination regimen for the primary series in this age group consists of three 3-microgram doses – the first two doses to be administered three weeks apart, followed by a third dose to be administered at least 8 weeks after the second dose. Official vaccination recommendations on the use of this vaccine will be issued by the Expert Committee on COVID-19 Vaccination and the Ministry of Health when ready.

Evaluation of Available Safety and Efficacy Data in Young Children

4 The clinical data was based on an ongoing Phase 2/3 study conducted by Pfizer, involving about 1,800 participants aged 6 months through 4 years. The results showed that the immune response in young children with a three-dose primary series was comparable to that in adults aged 16 to 25 years who received two higher doses of 30 micrograms as the primary series vaccine. Hence, it can be inferred that three doses of the vaccine may provide a similar level of protection in young children as that of two doses in adults.

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[1] HSA Extends the Use of Spikevax COVID-19 Vaccine by Moderna to the Younger Population Aged 6 Months to 17 Years Old

[2] HSA Grants Interim Authorisation for First COVID-19 Vaccine in Singapore;
HSA Extends the Use of Pfizer-BioNTech COVID-19 Vaccine to Adolescents of Ages 12 to 15;
HSA Extends the Use of Comirnaty COVID-19 Vaccine by Pfizer-BioNTech to Children of Ages 5 to 11.

5 Local real-world data in children aged 5 to 11 years had shown that vaccine effectiveness against the Omicron subvariants was estimated to be around 40% for symptomatic disease and remained high at more than 80% for protection against COVID-related hospitalisations for children receiving two doses of Pfizer vaccines. Hence, it could reasonably be expected that the vaccine would similarly protect younger children aged 6 months through 4 years from severe outcomes of COVID-19 such as multisystem inflammatory syndrome (MIS-C) and other potential complications. There was also preliminary data from a secondary analysis of COVID-19 cases in the clinical study, which suggested that the vaccine efficacy was estimated to be around 73%. However, the evidence was limited and should be interpreted with caution.

6 Safety data from the clinical studies also showed that adverse events in young 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 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.

Safeguards and Ongoing Safety Monitoring

7 While there were no cases of serious adverse events such as myocarditis/pericarditis (inflammation of the heart muscle) reported in the clinical study with Comirnaty, HSA recommends that caregivers of young 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.

8 HSA will continue to actively monitor the safety of the vaccine and require Pfizer to submit data from the on-going clinical study to ensure that the benefits of the vaccine continue to outweigh the risks. HSA will take the necessary actions and provide updates to the public if any significant safety concerns are identified.

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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/.

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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.