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HEALTH SCIENCES AUTHORITY
PRESS RELEASE
10 DECEMBER 2021

HSA EXTENDS THE USE OF COMIRNATY COVID-19 VACCINE BY PFIZER-BIONTECH TO CHILDREN OF AGES 5 TO 11

The Health Sciences Authority (HSA) has extended the authorisation of Comirnaty COVID-19 Vaccine by Pfizer-BioNTech for use in children of ages 5 to 11 years for the prevention of Coronavirus Disease 2019 (COVID-19) on 10 December 2021. The vaccination regimen is to be administered as a two-dose primary series, 21 days apart, but given at a lower dose (10 micrograms) than that used for individuals aged 12 years and above (30 micrograms). This is the first COVID-19 vaccine authorised in Singapore for use in the 5 to 11 age group.

2 On 25 November 2021, Pfizer-BioNTech submitted data to HSA to extend the use of the Comirnaty Vaccine to children aged 5 to 11 years for the prevention of COVID-19. HSA has conducted a thorough evaluation of the data in consultation with two groups of experts from HSA's Medicines Advisory Committee and Panel of Infectious Diseases Experts. Based on the current available data, the benefits outweighed the risks for use in the young population, and the vaccine met the quality, safety and efficacy standards.

3 Concurrently, Pfizer-BioNTech had submitted an application to transition the current interim authorisation for the Comirnaty Vaccines under the Pandemic Special Access Route (PSAR) to product registration. HSA has assessed that the data accrued to-date on the manufacturing process and the clinical studies is sufficient to register the vaccine, with effect from 10 December 2021.

HSA's Evaluation of Available Safety and Efficacy Data in Children

4 HSA had reviewed the clinical data for this subgroup which showed that 10 micrograms of the Comirnaty Vaccine induced a robust immune response that was comparable to that with 30 micrograms observed in individuals aged 16 to 25 years. The vaccine efficacy was estimated to be 90.7% based on an ongoing Phase 2/3 study in children aged 5 to 11 years. A total of 2,186 participants were randomised to receive either the vaccine or the placebo: 1,450 participants received the vaccine and 736 participants received the placebo. During follow up, there were 3 cases of COVID-19 in the vaccine group and 16 cases in the placebo group. Most of the cases occurred during the period of July to September 2021 when the Delta variant was prevalent.

5 The overall safety profile of the vaccine in children aged 5 to 11 years, based on safety follow-up data with a median duration of 2 months after vaccination, was observed to be comparable to that seen in adults and adolescents. Side effects such as injection site pain, fatigue, headache, chills and fever were generally reported less frequently and were milder in severity in the children compared to adolescents. These side effects generally resolved on their own within a few days.

Safeguards and Ongoing Safety Monitoring

6 While there were no reports of myocarditis / pericarditis or anaphylaxis observed in the clinical study, given the relatively small number of subjects in the clinical trial, and the potential risks of these rare adverse events, HSA has required Pfizer-BioNTech to continue to provide information on the safety and efficacy of the vaccine in this younger age group. HSA will review emerging data from ongoing studies and real-world use to ensure that the benefits of the vaccine continue to outweigh any risks, as well as to detect any potential safety signals.

7 Associate Professor Chan Cheng Leng, Group Director of Health Products Regulation Group, HSA, said, “HSA has carefully evaluated the scientific data on the use of Comirnaty Vaccine in children and assessed that vaccination remains a critical tool during the pandemic. To safeguard our young children, HSA will continue to actively monitor the safety profile of the Comirnaty Vaccine and will take swift regulatory actions should any safety concern emerge.”

Other Information

8 The Comirnaty Vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine when it was granted PSAR interim authorisation for individuals aged 16 years and above in December 2020[1]. HSA extended the authorisation for use in adolescents aged 12 to 15 years in May 2021[2], and has also recently authorised the booster dose for the Comirnaty Vaccine.

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[1] https://www.hsa.gov.sg/announcements/press-release/interimauth-firstcovid19vaccine
[2] https://www.hsa.gov.sg/announcements/press-release/hsa-extends-the-use-of-pfizer-biontech-covid-19-vaccine-to-adolescents-of-ages-12-to-15 :

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.