HEALTH SCIENCES AUTHORITY
PRESS RELEASE
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HSA EXTENDS THE USE OF PFIZER-BIONTECH COVID-19 VACCINE TO ADOLESCENTS OF AGES 12 TO 15

The Health Sciences Authority (HSA) has extended the authorisation of Pfizer-BioNTech COVID-19 vaccine for use in adolescents of ages 12 to 15 years for the prevention of Coronavirus Disease 2019 (COVID-19). The vaccination regimen is the same as that for adults, i.e. two doses of the vaccine to be administered 21 days apart.

2 The Pfizer-BioNTech COVID-19 vaccine was granted interim authorisation under the Pandemic Special Access Route (PSAR) for individuals aged 16 years and above in December 2020. At that time, the data in individuals aged below 16 years was not yet available. As a condition for interim authorisation under PSAR, Pfizer and BioNTech were required to continue to study the safety and efficacy of the vaccines in other subgroups and submit the relevant data for HSA's review.

3 On 13 April 2021, Pfizer and BioNTech submitted an application to extend the vaccination population for the Pfizer-BioNTech COVID-19 vaccine to adolescents aged 12 to 15 years old to HSA. HSA's review of the clinical data for this subgroup found that the Pfizer-BioNTech COVID-19 vaccine induced a robust immune response and demonstrated a high vaccine efficacy of 100%. This vaccine efficacy was based on the on-going Phase 3 clinical trial, which enrolled over 2,000 participants aged 12 to 15 years.

4 Based on the safety data available from a median follow-up duration of 2 months after vaccination, the overall safety profile of the vaccine in adolescents was comparable to that observed in adults. The side effects include injection site pain, fatigue, headache, chills and fever. They generally resolved on their own within a few days.

5 Pfizer and BioNTech will continue to follow up on the safety and efficacy of the vaccine in the clinical study for up to 2 years to determine its full safety profile in this subgroup. HSA will also continue to closely monitor the safety of the vaccine to ensure that it continues to be safe for use in this population.

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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 drugs, 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.