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Singapore extends use of Pfizer-BioNTech COVID-19 vaccine to adolescents

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The Health Sciences Authority (HSA) at Singapore has extended the authorisation of Pfizer-BioNTech COVID-19 vaccine for use in adolescents of ages 12 to 15 years for the prevention of 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.

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.

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.

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.