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Australia provisionally approves Moderna's COVID-19 vaccine for kids below 6 yrs

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Therapeutic Goods Administration grants provisional approval for Moderna's COVID-19 Vaccine in children aged six months to five years



US-based Moderna has announced that the Therapeutic Goods Administration (TGA) in Australia has granted provisional registration for the use of Moderna's mRNA COVID-19 vaccine, Spikevax, in a two-dose series of 25 ug per dose for active immunization to prevent COVID-19 caused by SARS-CoV-2 in children aged 6 months to 5 years. Until now, children under six were the only age group not eligible for vaccination against COVID-19 in Australia.

Positive interim results from the Phase 2/3 KidCOVE study, announced on March 23, 2022, showed a robust neutralizing antibody response in the 6-month to 5 years of age group after a two-dose primary series of mRNA-1273, along with a favorable safety profile.

The KidCOVE study is being conducted in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services. The ClinicalTrials.gov identifier is NCT04796896.

Moderna is supporting the Australian Government on the COVID-19 programme implementation in children aged 6 months to five years upon receiving a recommendation from the Australian Technical Advisory Group on Immunisation (ATAGI). The TGA previously approved the use of Moderna's mRNA COVID-19 vaccine, Spikevax (elasomeran mRNA vaccine), for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals aged six years or over.