

Australia provisionally approves Moderna's COVID-19 vaccine for 6-11 years old

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Further advice on the rollout of SPIKEVAX to this age group will be provided to Government by the Australian Technical Advisory Group on Immunisation (ATAGI)



The Therapeutic Goods Administration (TGA) in Australia has provisionally approved the Moderna COVID-19 vaccine, SPIKEVAX, for use in individuals aged 6 years and older.

The decision follows the provisional approvals granted by the TGA to Moderna for the use of SPIKEVAX in individuals aged 12 years and older on 3 September 2021, and on 7 December 2021 the SPIKEVAX booster dose for use in adults 18 years and older.

As for other age groups, the use of this vaccine in children aged 6-11 years should be administered as 2 doses at least 28 days apart.

The same vaccine preparation employed for older age groups will be used, however, a lower dose of 0.25 mL (50 micrograms) will be given to children 6-11 years, compared to the 0.5 mL (100 microgram) dose used for those 12 years and older.

In making this regulatory decision, the TGA carefully considered data from the KidCOVE clinical trial, which was conducted at multiple sites throughout Canada and the United States and included up to 4,000 participants aged 6 to 11 years. The study demonstrated that the immune response to the vaccine in children was similar to that seen in older age groups.

Clinical trials also showed that the safety profile in children is similar to that seen in adults. The most frequent adverse events seen in clinical trials in children aged 6-11 years were short-term and included injection site pain, redness and/or swelling, axillary (groin) swelling or tenderness, fatigue, headache, fever and muscle pain. Provisional approval of this vaccine for individuals 6 years and older is valid for two years.