

Ministers

Department of Health and Aged Care

This content relates to a former minister

TGA provisionally approves Pfizer COVID-19 vaccine for 5 to 11-year-olds

The Therapeutic Goods Administration has provisionally approved the Comirnaty (Pfizer) vaccine as safe and effective for use among 5 to 11-year-old children in Australia.

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Vaccinating 5 to 11-year-old children in Australia against COVID-19 is a significant step closer, with the Therapeutic Goods Administration (TGA) provisionally approving the Comirnaty (Pfizer) vaccine as safe and effective for use among this age group.

Subject to final considerations and recommendations from the vaccination experts on the Australian Technical Advisory Group on Immunisation (ATAGI), and other related approvals, the Australian Government will start rolling out the Pfizer vaccine to 5 to 11-year-olds from 10 January 2022.

The Government expects to receive ATAGI's recommendations on how to incorporate this safe and effective vaccine into Australia's COVID-19 vaccination program over the coming weeks.

Subject to advice from ATAGI, vaccinating the approximately 2.3 million children aged 5 to 11 in Australia will build on the rapid uptake of vaccination among children aged 12 to 15. In just eleven weeks, more than 76.6% of this group have had at least one dose of vaccine, with 67.5% having completed their two-dose course of vaccination.

Across the country, 87.9% of Australians aged 16 or over are fully vaccinated. More than 92.8% have had at least one dose of COVID-19 vaccine.

The TGA's provisional approval of the Pfizer vaccine for 5 to 11-year-olds was based on a careful evaluation of available data to support its safety and efficacy among this age group.

The vaccine dose approved by the TGA for children aged 5 to 11 is the same safe and effective vaccine used for other age cohorts, however is one-third the dose approved for those aged 12 and over.

The Pfizer vaccine for 5 to 11-year-olds will be distributed to vaccine providers in different packaging to the vaccine approved for people 12 and over, and will be clearly differentiated by being dispensed from orange-capped vials instead of grey or purple capped vials.

As with other age groups, the use of this vaccine in children aged 5-11 years should be given in two doses at least 3 weeks apart.

Already, significant planning work has been undertaken involving the COVID-19 Vaccines Taskforce, the states and territories primary health professionals in relation to how the vaccination rollout will be extended to children in this age group.

It is expected the vaccines would initially be made available through General Practices Aboriginal Health Services, community pharmacies and state and territory clinics.

Once the final ATAGI advice is received, further information on how to book a COVID-19 vaccination will be provided.

The Commonwealth Government will continue to work closely with vaccine providers and states and territories as a priority to provide the opportunity for children aged 5 to 11 to receive a first dose of this COVID-19 vaccine in the lead up to and in parallel with school returning in 2022.

The Government has an agreement in place with Pfizer to receive sufficient supply of the paediatric vaccine for the entire population of children aged 5 to 11 in Australia.

The first shipment of children's doses are due to arrive in Australia by early January 2022 and will undergo the same rigorous batch testing processes in the TGA laboratories as other batches of COVID-19 vaccines.

The TGA is also currently evaluating an application from Moderna for its COVID-19 vaccine to be used in Australia for children aged 6 to 11 and the Government already has supply deals in place to make it available should it be approved by the TGA and recommended by ATAGI.

This two step TGA and ATAGI assessment and approval process is the same rigorous process followed for all COVID-19 vaccine approvals in Australia.

Former ministers:

[The Hon Greg Hunt MP](#)