

## Australia grants provisional approval to AstraZeneca's COVID-19 vaccine

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The Therapeutic Goods Administration (TGA) has granted provisional approval to AstraZeneca for its COVID-19 vaccine, making it the second COVID-19 vaccine to receive regulatory approval in Australia.

COVID-19 Vaccine AstraZeneca is provisionally approved and included in the Australian Register of Therapeutic Goods (ARTG) for the active immunisation of individuals 18 years and older for the prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2. The use of this vaccine should be in accordance with official recommendations and given in two separate doses.

TGA's regulatory approval allows the second dose to be administered from 4 to 12 weeks after the first. The Australian Technical Advisory Group on Immunisation has recommended that the interval between first and second dose is 12 weeks.

Provisional approval of this vaccine is valid for two years and means it can now be legally supplied in Australia.

Initial supply of this vaccine will be imported into Australia from overseas, however it is anticipated that ongoing supply will be manufactured in Australia. Prior to supply of vaccines manufactured onshore, AstraZeneca will submit further information and data to the TGA to confirm that onshore manufacturing will meet strict quality standards.