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Health Ministry approves AstraZeneca COVID-19 vaccine Vaxzevria for emergency use

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First doses are expected to be available in the coming weeks



AstraZeneca's COVID-19 vaccine, *Vaxzevria* (ChAdOx1-S [Recombinant]), formerly AZD1222, has been granted a special approval for emergency use in Japan for active immunisation of individuals aged 18 years and older, to prevent COVID-19 caused by SARS-CoV-2.

The Japanese Ministry of Health, Labour and Welfare granted the approval based on positive Phase III efficacy and safety data from the Oxford University-led clinical trial programme in the UK, Brazil and South Africa, and a Phase I/II trial in Japan.

Japan's Pharmaceuticals and Medical Devices Agency recommends that the use of *Vaxzevria* should be limited to adults and administered intramuscularly as two 0.5 mL doses given four to 12 weeks apart, with an interval greater than eight weeks being preferable to maximise its efficacy. This dosing regimen was shown in clinical trials to be well-tolerated and effective in preventing symptomatic COVID-19, with no severe cases and no hospitalisations more than 14 days after the second dose.[1]

Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, said: "We continue to expand global access to our vaccine and today's approval brings us one step closer to providing *Vaxzevria* to the people of Japan who urgently need protection from coronavirus. We are proud to have produced a vaccine for the world, which is playing a leading role in the global fight against the pandemic, with more than 400 million doses now supplied by AstraZeneca and sub-licensees to 165 countries."

Production of the vaccine in Japan is already underway, and the first doses are expected to be available in the coming weeks.