

Vaxzevria receives full Marketing Authorisation in the EU for the prevention of COVID-19

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Full Marketing Authorisation based on totality of efficacy and safety data confirming the benefits of Vaxzevria

AstraZeneca's COVID-19 vaccine, *Vaxzevria* (ChAdOx1-S [Recombinant]), has been granted full Marketing Authorisation (MA) in the European Union (EU).

Vaxzevria was originally granted a conditional Marketing Authorisation (cMA) due to the urgency of the COVID-19 pandemic. As there continues to be sufficient evidence of safety and efficacy confirming the benefits of *Vaxzevria*, the European Medicines Agency (EMA) has now granted a full MA. This decision follows positive recommendation for a full MA by The Committee for Medicinal Products for Human Use (CHMP) of the EMA.

The MA covers the use of *Vaxzevria* in both a primary vaccination series, and as both a heterologous (with an approved mRNA COVID-19 vaccine) or homologous (all the same vaccine) third dose booster.

Iskra Reic, Executive Vice President, Vaccines and Immune Therapies, AstraZeneca, said: "The move from conditional to full marketing authorisation for *Vaxzevria* is an important confirmation by the EMA of the safety and efficacy of *Vaxzevria*, demonstrating that the benefits continue to outweigh the potential risks. *Vaxzevria* is estimated to have helped save over six million lives in the first year of vaccination, which reflects the strength of the evidence showing *Vaxzevria*'s protection against severe disease and death caused by COVID-19."

Vaxzevria has been demonstrated to be effective against all forms of COVID-19 from mild symptomatic to severe disease including hospitalisation and death, according to clinical studies and real-world evidence. These include an expert review of data from 52 real-world studies that showed that *Vaxzevria* and the available mRNA COVID-19 vaccines provide equally effective protection against hospitalisation and death from COVID-19 following three doses.¹ There is also a substantial body of evidence supporting boosting with *Vaxzevria* following all primary vaccination schedules tested to date.²⁻¹⁴

AstraZeneca and its global partners have released over three billion doses of *Vaxzevria* to more than 180 countries, and approximately two-thirds of these doses have been delivered to low- and lower-middle-income countries. In the first year of its roll-out, it is estimated that *Vaxzevria* has helped save more than six million lives worldwide.¹⁵

Notes

Vaxzevria (ChAdOx1-S [Recombinant], formerly AZD1222)

AstraZeneca COVID-19 vaccine was invented by the University of Oxford. It uses a replication-deficient chimpanzee viral vector based on a weakened version of a common cold virus (adenovirus) that causes infections in chimpanzees and contains the genetic material of the SARS-CoV-2 virus spike protein. After vaccination, the surface spike protein is produced, priming the immune system to attack the SARS-CoV-2 virus if it later infects the body.

Vaxzevria is a 'viral vector' vaccine, which means a version of a virus that cannot cause disease is used as part of the vaccine, leaving the body knowing how to fight it if it is exposed to the real virus later. This vaccine technology has been used by scientists over the past 40 years to fight other infectious diseases such as the flu, Zika, Ebola and HIV.

Vaxzevria is estimated according to model outcomes to have helped save over six million lives in the first year of vaccination.¹⁵ *Vaxzevria* has an acceptable safety profile, according to clinical studies and real-world evidence from tens of millions of people globally. Based on the millions of people vaccinated with *Vaxzevria*, very common adverse reactions reported included: headache, nausea, myalgia, arthralgia, injection site tenderness/pain/warmth/pruritus, fatigue, malaise, pyrexia, and chills. The majority of adverse reactions were mild to moderate in severity and usually resolved within a few days of vaccination. *Vaxzevria* is approved for COVID-19 primary vaccination schedule and first booster on top of a primary schedule in both homologous and heterologous settings.

Under a sub-license agreement with AstraZeneca, the vaccine is manufactured and supplied by the Serum Institute of India under the name COVISHIELD.

AstraZeneca

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Contacts

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