FREQUENTLY ASKED QUESTIONS (FAQ) ABOUT VAXZEVRIA VACCINE

Q1: What vaccine is being registered?

A1: The Drug Control Authority (DCA) in its 354th meeting has granted **Vaxzevria Solution for Injection** (Product Registration Holder: AstraZeneca Sdn. Bhd.; Manufacturer: Medimmune Pharma B.V. Netherland) a CONDITIONAL REGISTRATION on 2nd March 2021.

Each vial of Vaxzevria contains 4ml (8 doses) or 5ml (10 doses). Subsequently, a second source of the same vaccine (from Thailand and South Korea) was also granted conditional registration in the 358th & 366th DCA meeting on 4th June 2021 & 17th November 2021, respectively. Each dose (0.5ml) of Vaxzevria contains not less than 5 x 10^{10} viral particles of recombinant, replicant-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike glycoprotein (ChAdOx1-S recombinant).

On 17th November 2021, the DCA in its 366th meeting concluded that a booster dose of Vaxzevria may be administered at least 6 months after the second dose in individuals aged 18 years and above.

Q2: What are the conditions of the registration?

A2: Since the registration application is via "Conditional Registration of Pharmaceutical Products during Disaster", the approval is based on rolling submission of the latest data, the Product Registration Holder (PRH) will need to ensure all outstanding documents are to be submitted and deemed satisfactory by NPRA according to the timeline given.

Apart from that, the PRH is required to monitor the safety profile of the registered vaccine and inform NPRA soonest possible of any untoward events. The PRH is also required to conduct all activities planned under the Risk Management Plan (RMP) as well as submit a Monthly Safety Summary Report to NPRA.

The validity of this conditional approval is one (1) year. During this period, the DCA will periodically be updated with all necessary information related to the quality, safety and efficacy of this vaccine. The conditional registration can be revoked if the conditions are not fulfilled by the PRH or if the benefit over risk of the vaccine is no longer deemed beneficial.

Q3: Why is Vaxzevria granted a conditional registration?

A3: Clinical studies for Vaxzevria are currently still on-going. The current interim analysis provided show a positive benefit over risk and hence making this available to the nation. However, further monitoring of the efficacy and safety will be needed in order to ensure that the benefit-risk balance of this vaccine remains positive.

Q4: Who can be given Vaxzevria?
A4: Vaxzevria is indicated for the active immunization to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals **18 years of age and older**. The use of this vaccine should be in accordance with the recommendations by the Ministry of Health Malaysia.

Q5: Who can't be given Vaxzevria?
A5: Vaxzevria should not be given to individuals who are known to have allergic reactions to any of the ingredients in the vaccine [*L-Histidine, L-Histidine hydrochloride monohydrate, Magnesium chloride hexahydrate, Polysorbate 80 (E 433), Ethanol, Sucrose, Sodium chloride and Disodium edetate (dihydrate)*].

The second dose of the vaccine **should not be given** to individuals who had a severe allergic reaction after the first dose of this vaccine.

Q6: Can immunocompromised individuals receive Vaxzevria?
A6: At the moment, there is insufficient clinical evidence to support vaccination in immunocompromised individuals, including those receiving immunosuppressant therapy. However, these recommendations may change as more clinical data is obtained. Please speak to your doctor to identify if you may be a suitable candidate to receive the vaccine.

Q7: If I have the following conditions, or receiving or have received these treatments, can I receive the vaccine?
A7: Please consult your doctor if you:

- have any form of allergies, bleeding disorder, or taking any blood thinning medications
- recently or currently receiving treatment for cancer, organ or stem cell transplantation
- had a previous history of COVID-19 infection, had previously received another COVID-19 vaccine (whether during an immunisation program or was involved as a subject in a COVID-19 clinical study), or previously received passive antibodies therapy for COVID-19.

You may receive the vaccine even if you have the above conditions. However, please speak with your doctor before deciding if you are a suitable candidate.

Q8: How is Vaxzevria given?
A8: As a primary course, Vaxzevria should be injected into the deltoid muscle of the upper arm in a course of 2 doses (0.5mL each). The second dose is to be taken between 4 and 12 weeks (28 to 84 days) after the first dose. A booster dose of Vaxzevria may be given approximately 6 months after the second dose in individuals aged 18 years and above. The need for when and whom to be given the booster dose will be determined by local recommendations.

Q9: How well does Vaxzevria prevent COVID-19?
A9: In the pooled analysis of the two ongoing Phase III clinical trials, the vaccine was 59.5% (95%CI 45.8-69.7) effective in preventing symptomatic COVID-19 disease following completion of 2 doses of the vaccine regime. This fulfilled the efficacy standard as recommended by WHO, where the primary efficacy endpoint point estimate for a placebo-controlled efficacy trial should be at least 50%, and the lower bound of confidence interval (CI) should be >30%. More data is expected from ongoing Phase III trials on a rolling review basis.

Q10: How long will Vaxzevria provide protection?
A10: As the clinical trial is still currently ongoing, no data is available to inform about the duration of protection that the vaccine will provide. This however will be made known once updated data is available.

Q11: Can people who have already had COVID-19 get Vaxzevria?
A11: Available data indicate that Vaxzevria is safe when given in people with evidence of prior COVID-19 disease. Since previously infected individuals can be at risk of COVID-19 (i.e. reinfection), vaccination may be offered to them. However, please speak with your doctor before deciding if you are a suitable candidate.

Q12: Can pregnant or breastfeeding women receive Vaxzevria?
A12: Pregnant or breastfeeding women were excluded from the clinical trials. Since no data on the safety and efficacy of this vaccine is available in these populations, current evidence is unable to make recommendations for these groups until further available data is obtained. However, please speak to your doctor to identify if you may be a suitable candidate to receive the vaccine.

Q13: Can the elderly receive Vaxzevria?
A13: The vaccine is indicated for people aged 18 years and above. However, based on the currently available clinical data, there is a limited number of subjects aged 55 years and above recruited and analyzed therefore the data in this population are limited. Based on early phase data, administration of Vaxzevria to individuals aged 55 years and above has shown adequate and similar neutralizing antibody titres as in younger adults. At present, it is recommended that vaccination for people aged 55 and above should be cautiously considered, its necessity should be evaluated based on their health condition and exposure risk.

Q14: Can children receive Vaxzevria?
A14: Currently in Malaysia, the vaccine is indicated for individuals 18 years of age and older. This is because there is not enough data yet to determine the effectiveness and safety of this vaccine in those under 18 years old. Hence children below the age of 18 should not take the vaccine until further data is made available.

Q15: What are the side effects of Vaxzevria?

A15: Vaxzevria can cause the following side effects:

- Very common side effects (may affect more than 1 in 10 people): headache, nausea, injection site tenderness, pain, warmth, itching or bruising, fatigue, malaise, feverishness, chills, muscle ache, and joint pain.
- Common side effects (may affect up to 1 in 10 people): injection site swelling or redness, fever (≥38°C), vomiting, diarrhea, pain in the extremities (hand and foot), flu-like symptoms (such as high temperature, sore throat, runny nose, cough and chills) and thrombocytopenia (low levels of blood platelets).
- Uncommon side effects (may affect up to 1 in 100 people): lymphadenopathy (enlarged lymph nodes), decreased appetite, dizziness, somnolence, excessive sweating, itchy skin, rash and abdominal pain.
- Very rare (may affect up to 1 in 10,000 people): thrombosis in combination with thrombocytopenia (major blood clots in combination with low levels of blood platelets).
- The majority of adverse reactions were mild to moderate in severity and usually resolved within a few days of vaccination. When compared with the first dose, adverse reactions reported after the second dose were milder and reported less frequently.
- There is a remote chance that the vaccine could cause a severe allergic reaction even though the causal relationship has not been ascertained yet. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. Signs of a severe allergic reaction can include difficulty in breathing, swelling of your face and throat, a fast heartbeat, a bad rash all over your body or dizziness and weakness.

  Recipient will be monitored 15 minutes after the administration of this vaccine at the vaccination center.

During the marketing of Vaxzevria in Malaysia, NPRA will monitor its use to ensure effectiveness and safety. Please inform your healthcare providers or report any side effects to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers > Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Q16: Can Vaxzevria cause thromboembolic events (blood clots) following vaccination?

A16: Based on the known clinical data, thromboembolic events are not among the known or typical side effects of Vaxzevria. Following vaccination of Vaxzevria, major blood clots in combination with low levels of blood platelets have been observed very rarely (with a frequency less than 1 in 10,000 vaccinated individuals). Blood clots can occur in blood vessels of the heart, brain or other organs. The majority of the events

occurred within the first 21 days following vaccination and occurred in individuals aged 18-59 years old.

It is important to seek immediate medical attention if you develop symptoms such as confusion, seizures, shortness of breath, chest pain, leg swelling, leg pain, persistent abdominal pain following vaccination.

Also, please seek immediate medical attention if you experience after a few days severe or persistent headaches or blurred vision after vaccination, or experience skin bruising or pinpoint round spots beyond the site of vaccination which appears after a few days.

Q17: What should I do after I am vaccinated?
A17: All individuals should continue to follow the country's SOP. Practice the 3Ws (**Wash**, **Wear**, **Warn**) and avoid the 3Cs (**Crowded** space, **Confined** space, **Close** conversation).

For further information regarding **Vaxzevria Solution for Injection***, please refer to the Package Insert and Patient Information Leaflet.*

Vaxzevria Solution for Injection (Netherlands)(MAL21036009ACZ)
https://quest3plus.bpfk.gov.my/pmo2/detail.php?type=product&id=MAL21036009ACZ

Vaxzevria Solution for Injection (Thailand) (MAL21066001ACSZ)
https://quest3plus.bpfk.gov.my/pmo2/detail.php?type=product&id=MAL21066001ACSZ

Vaxzevria Solution for Injection (South Korea) (MAL21116002ASZ)
https://quest3plus.bpfk.gov.my/pmo2/detail.php?type=product&id=MAL21116002ASZ

Date of revision: 21 February 2022