FREQUENTLY ASKED QUESTIONS (FAQ) ABOUT VAXZEVRIA COVID-19 VACCINE

Q1: Which COVID-19 vaccine and what indication(s) is being registered?

A1: The Drug Control Authority (DCA) in its 354th meeting has granted AstraZeneca Sdn. Bhd's VAXZEVRIA SOLUTION FOR INJECTION (Manufacturer: AstraZeneca Nijmegen B.V., Netherlands) a CONDITIONAL REGISTRATION on 2nd March 2021. Subsequently, a second source of the same vaccine (Manufacturer: Siam Bioscience Co., Ltd., Thailand) was also granted conditional registration in the 358th DCA meeting on 4th June 2021.

Each vial of VAXZEVRIA contains 4ml (8 doses) or 5ml (10 doses).

Each dose (0.5ml) of VAXZEVRIA contains not less than 5 x 10^{10} viral particles of Chimpanzee Adenovirus encoding the SARS-CoV-2 Spike glycoprotein(ChAdOx1-S).

On 17th November 2021, the DCA in its 366th meeting has approved the use of this vaccine as a homologous booster and on 2nd June 2022, the DCA in its 373rd meeting has approved the use of this vaccine as a heterologous booster in individuals 18 year and above, may be administered at least 3 months after the primary vaccination of VAXZEVRIA or another authorised COVID-19 vaccine.

Q2: What are the conditions of the registration?

A2: Since the application was based on rolling submission of the latest data, the Product Registration Holder (PRH) will need to ensure all outstanding documents are 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 as soon as possible of any untoward events. The PRH is also required to conduct all activities planned under the Risk Management Plan (RMP) as well as submitting 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 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 clearly 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 may be given VAXZEVRIA?
A5: At the moment, there are limited clinical evidence to support vaccination in these population: immunocompromised, autoimmune disorders, pregnant or breastfeeding women. However, the decision to use the vaccine in these populations should be made in close consultation with a healthcare professional after considering the benefits and risks.

Q6: Who cannot be given VAXZEVRIA?
A6: 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)*].

VAXZEVRIA should not be given to individuals who have had a major blood clot occurring at the same time as having low levels of platelets (thrombocytopenia) after receiving any COVID-19 vaccine.

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 immunization program or was involved as a subject in a COVID-19 clinical study) or previously received passive antibodies therapy for COVID-19

Q7: How VAXZEVRIA is given?
A7: As a primary course, VAXZEVRIA should be injected into the deltoid muscle of the upper arm as a course of 2 doses (0.5mL each). The second dose is to be taken between 28 to 84 days after the first dose.
A booster dose of VAXZEVRIA may be given at least 3 months after the second dose of VAXZEVRIA or another authorised COVID-19 vaccine in individuals aged 18 years and above. The need for when and who to be given the booster dose will be determined by local recommendation.

Q8: How well does VAXZEVRIA prevent COVID-19?
A8: In the pooled analysis of the two on-going 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.

Q9: How long will VAXZEVRIA provide protection?
A9: 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.

Q10: Can people who have already had COVID-19 get VAXZEVRIA?
A10: 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. The need for when the vaccination after a SARS CoV-2 infection to be given will be determined by CITF.

Q11: Can children receive VAXZEVRIA?
A11: Currently in Malaysia, the vaccine is indicated for individuals 18 years of age and older. This is because there is not enough data 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.

Q12: What are the side effects of VAXZEVRIA?
A12: VAXZEVRIA can cause the following side effects:

- ***Very common side effects*** (may affect more than 1 in 10 people): headache, feeling sick (nausea), joint pain or muscle ache (myalgia or arthralgia), injection site tenderness, injection site pain, injection site warmth, injection site itching (pruritus), injection site bruising, feeling tired (fatigue), generally feeling unwell (malaise), feverishness and chills.
- ***Common side effects*** (may affect up to 1 in 10 people): injection site swelling, injection site redness (erythema), fever (≥38°C), pain in extremity, vomiting, diarrhoea, flu-like symptoms (such as high temperature, sore throat, runny nose, cough and chills, mild) and transcient decreased level of platelets (thrombocytopenia).
- ***Uncommon side effects*** (may affect up to 1 in 100 people): enlarged lymph nodes (lymphadenopathy), decreased appetite, sleepiness or feeling dizzy

(dizziness or somnolence), excessive sweating (hyperhidrosis) and itchy skin or rash (pruritus or urticaria), abdominal pain.

- ***Very rare side effects*** (may affect up to 1 in 10,000 people): major blood clots often in unusual locations (e.g., brain, bowel, liver, spleen) in combination with low level of blood platelets.
- ***Unknown side effects*** (cannot be estimated from the available data): severe allergic reaction (anaphylaxis), severe swelling of the lips, mouth, throat (which may cause difficulty in swallowing or breathing).

During 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)].

Q13: Can VAXZEVRIA cause thromboembolic events (blood clots) following vaccination?

A13:

Very rare blood clots in combination with low level of blood platelets, in some cases together with bleeding, has been observed following vaccination with VAXZEVRIA. This included some severe cases with blood clots in different or unusual locations (e.g., brain, bowel, liver, spleen) and excessive clotting or bleeding throughout the body. The majority of these cases occurred within the first three weeks following vaccination. Some cases had a fatal outcome. Fewer cases have been reported after the second dose compared to after the first dose.

Blood clots in the brain, not associated with low level of blood platelets have been observed very rarely following vaccination with VAXZEVRIA. The majority of these cases occurred within the first four weeks following vaccination. Some cases had a fatal outcome.

Very low levels of blood platelets (immune thrombocytopenia), that can be associated with bleeding, have been reported very rarely, usually within the first four weeks following vaccination with VAXZEVRIA.

Seek immediate medical attention if you develop shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain following vaccination

Also, seek immediate medical attention if you experience after a few days following vaccination severe or persistent headaches, blurred vision, confusion or seizures (fits) after vaccination, or experience unexplained bleeding or skin bruising or pinpoint round spots beyond the site of vaccination which appears after a few days.

Q14: What should I do after I am vaccinated?

A14: All individuals should continue to follow the preventive measures as recommended. Practice the 3Ws (Wash, Wear, Warn), avoid the 3Cs (Crowded space, Confined space, Close conversation), get vaccinated and boosted and practice TRIIS (Test, Report, Isolate, Inform and Seek Treatment).

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