FREQUENTLY ASKED QUESTIONS (FAQ) ABOUT CORONAVAC 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 **CoronaVac Suspension for Injection COVID-19 Vaccine (Vero Cell), Inactivated** (Product Registration Holder: Pharmaniaga Lifescience Sdn Bhd; Manufacturer: Sinovac Lifescience Co. Ltd, Beijing, China) a CONDITIONAL REGISTRATION on 2nd March 2021. Subsequently, a second source of the same vaccine (Manufacturer: Pharmaniaga Lifescience Sdn. Bhd., Malaysia) was also granted conditional registration in the 356th meeting on 23rd April 2021.
Each vial of CoronaVac contains either 0.5ml (single dose) or 1.0ml (multi-dose).
Each dose (0.5ml) of CoronaVac contains 600 SU (equivalent to 3µg) of inactivated SARS-CoV-2 antigen.

On 1st October 2021, the DCA in its 364th meeting has approved the use of this vaccine to individuals aged 12 years and above, an extension of the previous conditional registration approved indication to individuals aged 18 years of age and above.

Subsequently, on 17th November 2021, the DCA in its 366th meeting has approved the booster dose (0.5ml) of this vaccine, which shall be administered at least 3-6 months after the second dose among individuals aged 18 years and older.

On 3rd March 2022, the DCA in its 370th meeting has approved the use of this vaccine to individuals aged 5 to 11 years with the same dose as approved previously for individuals aged 12 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 National Pharmaceutical Regulatory Agency (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 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 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 CoronaVac granted a conditional registration?
A3: Clinical studies for CoronaVac 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 CoronaVac?
A4: CoronaVac is indicated for the active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals **5 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 CoronaVac?
A5: CoronaVac should not be given to individuals;

a. who are known to have allergic reactions to any of the ingredients in the vaccine (Aluminium hydroxide, disodium hydrogen phosphate, monosodium dihydrogen phosphate, sodium chloride, sodium hydroxide);
b. with severe neurological conditions (e.g. transverse myelitis, Guillain-Barré syndrome, demyelinating diseases);
c. with uncontrolled severe chronic diseases

The second dose of the vaccine **should not be given** to individuals who have a severe allergic reaction (e.g. acute anaphylaxis, angioedema, dyspnoea) after the first dose of this vaccine.

Q6: Can the following populations receive CoronaVac?
A6: At the moment, there are insufficient clinical evidence to support vaccination in these population: Impaired immune function (patients with malignant tumour, nephrotic syndrome, AIDS) including those receiving immunosuppressant therapy. Use of CoronaVac in these individuals should be in consideration of a potentially lowered immune response. Human immunoglobulin injections should be given at least one-month interval before or after the administration of the vaccine to avoid lowered immune response.

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;

- have acute diseases, acute exacerbation of chronic diseases, severe chronic diseases, allergies and fever, diabetes, convulsions, epilepsy, encephalopathy and mental illness or family history of mental illness;
- 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 CoronaVac given?
A8: CoronaVac 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 14 to 28 days after the first dose. A booster dose of CoronaVac may be given approximately 3-6 months after the second dose 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.

Q9: How well does CoronaVac prevent COVID-19?
A9: Based on the interim analysis of the Phase III clinical trial in Brazil, the vaccine was 50.65% (95.38%CI: 35.66-62.15) effective in preventing symptomatic COVID-19 disease following completion of two doses of the vaccine regime.

On the other hand, the outcome of the primary efficacy analysis from a Phase III clinical trial conducted in Turkey showed that vaccine efficacy was 91.90% (95%CI 76.95-97.93) against the symptomatic COVID-19 cases when given 2 doses of 0,14-day schedule.

Additionally, in another ongoing Phase III study in Indonesia, the efficacy of this vaccine in preventing symptomatic confirmed cases of COVID-19 occurring at least 14 days after the second dose of vaccine was 51.98%.

These data 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%.

Q10: How long will CoronaVac provide protection?
A10: As the clinical trial is still currently ongoing, no data is available on 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 CoronaVac?
A11: Available data indicate that CoronaVac 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 elderly receive CoronaVac?

A12: The vaccine is indicated for people aged 5 years and above. However, based on the current available clinical data, there is limited number of subjects aged 60 years and above recruited and analysed therefore the data in this population are limited. Based on early phase data, administration of CoronaVac to individuals aged 60 years and above has shown adequate and similar neutralizing antibodies titres as in younger adults. At present, it is recommended that vaccination for people aged 60 and above should be cautiously considered, its necessity should be evaluated based on their health condition and exposure risk.

Q13: Can children receive CoronaVac?

A13: Currently in Malaysia, the vaccine is indicated for individuals 5 years of age and above. This is because there is not enough data yet to determine the effectiveness and safety of this vaccine in those under 5 years old. Hence children below the age of 5 should not take the vaccine until further data is made available.

Q14: What are the side effects of CoronaVac?

A14: CoronaVac can cause the following side effects following primary or booster vaccination:

- Very common side effects (may affect more than 1 in 10 people): injection site pain, tiredness, headache.
- Common side effects (may affect up to 1 in 100 people): injection site swelling, myalgia, nausea, diarrhoea, arthralgia, cough, chills, pruritus, loss of appetite, rhinorrhoea, sore throat, nasal congestion, abdominal pain.
- Uncommon side effects (may affect up to 1 in 1000 people): burning sensation, vomiting, hypersensitivity, abnormal skin and mucosa, fever, tremors, flushing, oedema, dizziness, drowsiness.
- Rare side effects (may affect up to 1 in 10,000 people): muscle spasms, periorbital oedema, nose bleed/epistaxis, abdominal distension, constipation, hyposmia, ocular congestion, hot flushes, hiccups, conjunctival congestion.
- Not known side effects (cannot be estimated from the available data): severe allergic reaction.
- 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 15-30 minutes after the administration of this vaccine at the vaccination centre.

During marketing of CoronaVac 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)].

Q15: What should I do after I am vaccinated?
A15: 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 **CoronaVac Suspension for Injection COVID-19 Vaccine (Vero Cell), Inactivated***, please refer to the Package Insert and Patient Information Leaflet.*

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