衞生防護中心
Centre for Health Protection

# Scientific Committee on Emerging and Zoonotic Diseases and Scientific Committee on Vaccine Preventable Diseases

## Consensus Interim Recommendations on the Use of CoronaVac in Hong Kong (As of February 19, 2021)

## Introduction

The ongoing COVID-19 pandemic causes a significant disease burden worldwide. In Hong Kong, cases and outbreaks continue to be reported. COVID-19 vaccines are safe and effective to protect people from disease. On 19 February 2021, the Scientific Committee on Emerging and Zoonotic Diseases (SCEZD), the Scientific Committee on Vaccine Preventable Diseases (SCVPD), and the Expert Advisory Panel to Chief Executive (EAP) reviewed the data and latest scientific evidence, and provides recommendation on the circumstances for the use of COVID-19 vaccine CoronaVac in Hong Kong.

## Emergency Use Approval for COVID-19 vaccines in Hong Kong

2. To facilitate timely access to COVID-19 vaccines without compromising proper regulatory decision-making, the WHO encourages countries' regulatory authorities to develop and implement regulatory pathways to use a risk-based approach to assess the quality, safety and efficacy of vaccines. Emergency approval, and/or expedited fast-track regulatory pathways should be in place as part of pandemic preparedness.

In Hong Kong, given the nature of the threat from COVID-19, the Government has put in place a legislative framework (Cap 599K) to enable the public to gain early access to promising vaccines when those products have not yet received full registration approval. An Advisory Panel on COVID-19 Vaccines (AP), comprising experts from relevant fields and sectors, has been set up to advise the Secretary for Food and Health on the authorization of COVID-19 vaccines for emergency use based on the available data concerning safety, efficacy, quality and scientific evidence, and on matters related to administration of the vaccine(s). Healthcare providers should refer to details regarding use of the individual product advised by the AP.

3. On 16 February 2021, the AP reviewed data and information regarding the safety, efficacy and quality of the CoronaVac submitted by Sinovac and published the Report on Evaluation of Safety, Efficacy and Quality of CoronaVac COVID-19 Vaccine (Vero Cell) Inactivated on 18 February 2021. The AP considered that, based on the totality of scientific evidence on safety, efficacy and quality as available and the post-authorization measures to be taken, the benefits of CoronaVac outweight its risks for use in Hong Kong for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 18 years of age or older during the current pandemic situation. The AP recommended that the first and second vaccine dose should be received with an interval of 28 days. The AP recommended that the appropriateness of using CoronaVac in elderly of 60 years old or above should be advised by the Joint SCEZD and SCVPD under the Centre for Health Protection.

## Meeting of the JSC-EAP on 19 February 2021

4. After the AP had completed the review of CoronaVac's application for Emergency Use Approval on 16 February 2021, the JSC-EAP convened a meeting on 19 February 2021 to provide interim recommendations to the Government on the use of CoronaVac in Hong Kong. Thus far, phase III clinical studies of CoronaVac have not been published in peer-reviewed journal or available as preprints. The JSC-EAP reviewed the data and information available, based on materials submitted to AP by Sinovac Biotech (Hong Kong).

5. This interim recommendation might be updated based on additional safety and efficacy data from phase III clinical trials, international

developments and conditions of the Emergency Use Approval.

## Recommendations on use of CoronaVac

### Indications

6. CoronaVac is an inactivated vaccine indicated for active immunisation against COVID-19 caused by SARS-CoV-2 in individuals aged 18 years or older.

7. The benefit of using CoronaVac generally exceeds the risk of not using any vaccines in persons aged 60 or above. Phase I and II data on individuals aged 60 or above showed that the vaccine is safe and immunogenic. There is limited phase III efficacy data for individuals aged 60 or above because of small sample size.

### Dosage and Dosing Schedule

8. CoronaVac should be administered intramuscularly. Each dose (0.5ml) consist of 600SU of inactivated SARS-CoV-2 virus as antigen.

9. According to Sinovac, the vaccination schedule of 2 doses administered at 28 days apart is currently recommended.

10. Currently, there is limited information on the safety, immunogenicity and efficacy of receiving vaccine outside the recommended schedule. If more than 28 days have elapsed, the second dose should be given as soon as possible. There is no need to repeat the series.

11. There are no data on the interchangeability of COVID-19 vaccines. It is strongly advised that individuals complete the vaccination series with the same vaccine.

### Contraindications and precautions

12. For contraindications and precautions of using CoronaVac, one should refer to product insert provided by Sinovac.

13. Anaphylaxis refers to a severe and immediate allergic reaction that include clinical signs and symptoms such as hives, nausea, dizziness, hypotension (abnormally low blood pressure), swelling, or wheezing (respiratory distress). Anaphylaxis may occur following COVID-19 vaccination. Emergency equipment (including epinephrine injection) and measures to manage anaphylaxis should be in place and immediately available, irrespective of the vaccination settings. All persons should be observed for 30 minutes after vaccination of CoronaVac. Health care professionals should give immediate attention and management to vaccinees suspected of anaphylaxis, and promptly transfer patients to accident and emergency departments of public hospitals for further assessment and management. Doctors should report anaphylaxis and other adverse events following vaccination according to prevailing pharmacovigilance guidance.

14. Any inadvertent administration of COVID-19 vaccine should be reported according to prevailing pharmacovigilance guidance.

## Other considerations for use of COVID-19 vaccines

### Prior infection of COVID-19

15. While there are limited safety and efficacy data of CoronaVac in individuals previously infected with COVID-19, prior COVID-19 infection is not considered as a contraindication to COVID-19 vaccination.

### Individuals exposed to SARS-CoV-2

16. There is currently no evidence on the safety and efficacy of COVID-19 vaccination as post-exposure prophylaxis.

### Administration with other vaccines

17. Thus far there has been no interaction studies on the three COVID-19 vaccines with other prophylactic vaccines and/ or medications. In general, inactivated vaccines can be administered concurrently whereas an interval of 28

days is usually recommended for administration of live vaccines[a]. No clinical study has been carried out on the evaluation of immune response with other vaccines on the immunogenicity at the same time (before, after or at the same time). Professionals should be consulted when concomitant use.

18. There is increasing evidence that co-circulation of SARS-CoV-2 and influenza viruses could have a significant impact on morbidity and mortality, and poor outcome in co-infected individuals[b]. In the context of the global pandemic of COVID-19, it is particularly important to ensure people who are at greater risk from infections or complications of both influenza and COVID-19, such as health care workers and older adults, can access and receive seasonal influenza vaccine (SIV)[c]. SIV can reduce the risk of influenza infection and related complications, which could relieve the burden on healthcare system during the COVID-19 pandemic. Recommendations on SIV for the 2020-21 Season in Hong Kong, including the priority groups recommended, remains in effect.

## Impact of vaccine delivery on non-pharmaceutical interventions

19. COVID-19 vaccines are safe and effective to protect people from disease. At the current phase of the vaccination programme, there is limited evidence on the effects of vaccination on transmission; and there are constraints in vaccine availability. Population level protection will not be achieved in the short term. Vaccination is only one of the tools in the overall public health response to COVID-19. The combination of non-pharmaceutical interventions (NPIs) with vaccination will allow for maximum protection against the virus. There is a need to continue public health strategies on NPIs, including social distancing, good hand hygiene and wearing a mask in public, to reduce the risk of transmission. Government advice on NPIs should continue to be followed by vaccinated individuals, as well as those who have not yet been vaccinated. Any

[a] US CDC. Epidemiology and Prevention of Vaccine-Preventable Diseases Chapter 2: General Recommendations on Immunization. Accessed 28 December 2020. Available at https://www.cdc.gov/vaccines/pubs/pinkbook/genrec.html.

[b] Stowe J. et al. Interactions between SARS-CoV-2 and Influenza and the impact of coinfection on disease severity: A test negative design. medRxiv 2020.09.18.20189647; Accessed on 15 December 2020. Available at https://doi.org/10.1101/2020.09.18.20189647

[c] World Health Organization. Guiding principles for immunization activities during the COVID-19 pandemic: interim guidance, 26 March 2020. Accessed 15 December 2020. Available at https://apps.who.int/iris/handle/10665/331590

changes to NPIs should be gradual and carefully monitored. Delays in vaccine supply and suboptimal vaccine uptake would mean that NPIs measures would need to be kept in place for longer.

## Further work

20. The interim recommendation on the use of CoronaVac was formulated based on available published data and information provided to the AP by the vaccine company thus far. Efforts should be made to closely monitor on the long-term safety, effectiveness and coverage of the vaccine, and the vaccine efficacy when administered to older adults where currently there is limited scientific evidence. Rare adverse events, as well as the occurrence of antibody-dependent enhancement (ADE) and vaccine associated enhanced respiratory diseases (VAERD), are potential concerns of newly developed COVID-19 vaccines that are unlikely to be adequately observed in phase III clinical studies. The global emergence of variants of concern and its effect on the effectiveness of COVID-19 vaccination should also be followed up closely and reviewed timely.

## February 2021