

**On-going Review of Benefits and Risks of Authorized COVID-19 Vaccines in
Hong Kong under the Prevention and Control of Disease
(Use of Vaccines) Regulation (Cap. 599K, Laws of Hong Kong)**

**CoronaVac COVID-19 Vaccine (Vero Cell), Inactivated
(September 2021)**

Background

Under the Prevention and Control of Disease (Use of Vaccines) Regulation (“the Regulation”), Cap. 599K, Laws of Hong Kong, the Advisory Panel on COVID-19 Vaccines (“the Advisory Panel”) has been appointed by the Chief Executive to advise the Secretary for Food and Health (“SFH”) on (i) whether to authorize a vaccine for the purpose of carrying out a programme that is conducted by the Government to administer authorized vaccines to members of the public, or a section of the public, on an emergency basis, for preventing, protecting against, delaying or otherwise controlling the incidence or transmission of, or mitigating a serious or life-threatening condition arising from the specified disease (i.e. COVID-19) or other reasonable purpose specified by the SFH, by taking into consideration the safety, efficacy and quality of the vaccine; (ii) conditions to be attached to an authorization; and (iii) revocation of an authorization.

2. Since 18 February 2021, the COVID-19 vaccine, namely CoronaVac COVID-19 Vaccine (Vero Cell), Inactivated (“CoronaVac”) by Sinovac Biotech (Hong Kong) Limited (“Sinovac”), has been authorized under the Regulation.

Review by Advisory Panel

3. For providing advice to the SFH regarding authorization, the Advisory Panel conducts on-going review of the benefits and risks of authorized vaccines in order to protect public health. The Advisory Panel conducts regular meetings to review the latest available evidence and information related to the safety, efficacy and quality of authorized COVID-19 vaccines, and to offer appropriate advice to the SFH in a timely manner. Ad hoc meetings would also be arranged when it is necessary to conduct an urgent assessment of the benefit-risk balance of an authorized vaccine.

4. The Advisory Panel conducted its meeting on 30 September 2021 to review the benefit-risk balance of CoronaVac based on the latest available information. The benefit-risk analysis of CoronaVac is summarized below.

Benefit-Risk Analysis of CoronaVac

5. CoronaVac was indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 18 years of age and older. In Hong Kong, as of 29 September 2021, 1 626 500 persons received the first dose of CoronaVac while 1 511 900 persons among the above received their second dose.

6. CoronaVac has been approved for emergency use in over 50 countries or regions and it was approved for the World Health Organization Emergency Use Listing on 1 June 2021. The efficacy of CoronaVac is mainly supported by the primary efficacy analysis in the Brazilian Phase 3 study. The subsequent Turkish Phase 3 study also provided additional data to support its efficacy.

7. The real world data in Brazil, Chile and the Mainland of China showed different degrees of decline in vaccine effectiveness, reflecting some waning of protection over time, particularly for the variants and in elder population. The vaccine is still considered to be effective, especially for the prevention against infections associated with severe outcomes.

8. Having reviewed the vaccine effectiveness and immunogenicity data, there may be a need for additional dose / booster of vaccine in the future particularly for certain groups with high risk of infection, or against the emergence of variants of concern. The issue would be further reviewed when more data to be submitted by the authorization applicant becomes available.

9. The Advisory Panel noted the updated clinical and safety data on the use of CoronaVac in children of 3 to 17 years old and there were about 100 million doses administered in this age group in the Mainland of China. The extension of indication to the children population would be further reviewed subject to the availability of further confirmatory data.

10. The authorization applicant demonstrated that a global pharmacovigilance system is in place and adverse events are well monitored especially in China. According to the global safety data and analysis in early September 2021, about 1 867 million doses of CoronaVac were vaccinated worldwide. There was no new safety signal identified. There was also no overseas regulatory update regarding the use of CoronaVac.

11. The local pharmacovigilance system was also found to be effective and there was no new safety signal identified locally.

12. The quality of imported batches of CoronaVac has been assured by certification and appropriate testing for quality control.

Overall benefit-risk

13. The identified risks associated with the use of CoronaVac were addressed through provision of relevant product information to support safe use of the product. Risks have been evaluated in the context of the benefits of the product. Based on the available safety and efficacy information of CoronaVac and the current pandemic situation, the overall benefit-risk profile of CoronaVac remains favourable.

Overall Conclusion

14. The Advisory Panel considered, as of 30 September 2021, the benefits of CoronaVac continue to outweigh its risks and there are no recommended changes regarding the use of this vaccine in Hong Kong under the current pandemic situation.

**Advisory Panel on COVID-19 Vaccines
30 September 2021**