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 (April 2022)

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 14 April 2022 to review the benefit-risk balance of CoronaVac based on the latest available information. The benefit-risk analysis of CoronaVac is summarised below.

Benefit-Risk Analysis of CoronaVac

5. In Hong Kong, as at 13 April 2022, about 6.5 million, 5.9 million, and 3 million persons received the first, second and third dose of the authorized COVID-19 vaccines respectively. CoronaVac is authorized for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 3 years of age and above.

6. CoronaVac has been approved for emergency use in 60 countries or regions and it was approved for the World Health Organization Emergency Use Listing on 1 June 2021. The efficacy of the primary course of CoronaVac is mainly supported by various Phase 3 efficacy analyses in different countries. The efficacy of the third dose of CoronaVac is also supported by immunogenicity studies that demonstrated a significant increase of neutralizing antibodies.

7. Real-world data from different countries showed that the vaccine effectiveness against infection declines over time after two-dose vaccination, and reduces significantly against the Omicron variant when compared to the wild-type strain or other previous variants.

8. With the administration of a homologous third dose, the vaccine effectiveness against infection and immunogenicity would increase but at a smaller extent than using a heterologous third dose. However, the vaccine effectiveness against hospitalisation, severe disease, or fatal cases remains at a substantially high level for both homologous and heterologous third dose during the Omicron-predominance period. Further evaluation of cellular immune response from inactivated vaccine would be needed to evaluate the benefit of CoronaVac against the variants.

9. 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 March 2022, about 1 380 million people have been vaccinated with CoronaVac worldwide. No new important safety signal is identified. There is also no overseas regulatory update regarding the use of CoronaVac.

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

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

Overall benefit-risk

12. The identified risks associated with the use of CoronaVac have been 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 in view of the current and anticipated epidemic situation, the overall benefit-risk profile of CoronaVac remains favourable.

Overall Conclusion

13. The Advisory Panel considered, as at 14 April 2022, 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 epidemic situation.

Advisory Panel on COVID-19 Vaccines
14 April 2022