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 (February 2023)

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 Health ("S for Health") on (i) whether to authorize a vaccine for the purpose of carrying out a Government vaccination programme or other reasonable purpose specified by the S for Health, 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 S for Health 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 S for Health 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 15 February 2023 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 30 January 2023, about 6.9 million, 6.8 million, 5.8 million, 1.0 million and 48 551 persons received the first, second, third, fourth and fifth doses 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 of 3 years old and above, and it is noted that CoronaVac has been suggested for children aged 6 months to 3 years as "off-label" use.

6. CoronaVac has been approved for use in 62 countries or regions, and it was approved for the World Health Organization ("WHO") Emergency Use Listing ("EUL") on 1 June 2021. In November 2022, the WHO has extended the use of CoronaVac under EUL to individuals aged ≥3 years. The efficacy of the primary course of CoronaVac in adults and children above 6 months is primarily supported by the efficacy analysis in various Phase 3 studies including immunobridging studies. The efficacy of the third and fourth doses of CoronaVac is also supported by immunogenicity studies that demonstrated a significant increase of neutralising antibodies although the neutralising response against the Omicron variant was notably lower.

7. Real-world data from different countries continues to demonstrate that the vaccine effectiveness against infection declines over time after primary and booster vaccination, and reduces significantly against the Omicron variant when compared to the wild-type strain or other previous variants. However, the vaccine effectiveness against hospitalisation, severe disease or fatal case remains at a high level after both homologous and heterologous third dose during the Omicron-predominance period.

8. Local data also demonstrated that CoronaVac provided substantial protection from COVID-19 associated hospitalisation and moderate-to-severe disease in children and adolescent due to SARS-CoV-2 variant of concern.

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 November 2022, about three billion doses of CoronaVac have been distributed worldwide. No new important safety signal is identified. There is 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.

13. Additional dose of current or variant vaccines might be needed to maintain and sustain the protection against subsequent waves of SARS-CoV-2 caused by the Omicron variant or future variants with similar escape potential.

Overall Conclusion

14. The Advisory Panel considered, as at 15 February 2023, 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
15 February 2023