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 (July 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 14 July 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. As of 13 July 2021, 1 100 700 persons received the first dose of CoronaVac while 764 000 persons among the above received their second dose.

6. CoronaVac has been approved for emergency use in over 40 countries 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 Brazilian Phase 3 study as previously submitted. A newly published Phase 3 study conducted in Turkey among about 11 000 volunteers also supported the efficacy and safety of CoronaVac that the vaccine efficacy is found to be 83.5% at 14 days after the second dose of vaccination when compared with placebo group. The adverse event profile as reported in the Turkish study is similar to those reported in previous studies.

7. The real world data in Brazil, Chile and Indonesia continued to support the efficacy of CoronaVac. The vaccine effectiveness study in Chile which was recently published demonstrated CoronaVac was 65.9% effective to prevent symptomatic COVID-19, 87.5% effective to prevent hospitalization, 90.3% effective to prevent admission to ICU and 86.3% effective to prevent death. Immunogenicity studies also demonstrated CoronaVac may be effective against the various variants of concern but the neutralization antibody levels were reduced especially for Beta and Delta variants.

8. 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 June 2021, a total of 782 million doses of CoronaVac were vaccinated worldwide. There is no new safety signal identified. There was also no overseas regulatory update regarding the use of CoronaVac.

9. The local pharmacovigilance system was also found to be effective. Local data identified that there is a signal of risk of Bell's palsy after receiving CoronaVac and the incidence is very rare. The authorization applicant has already

updated the package insert of CoronaVac to include such safety information accordingly.

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

Overall benefit-risk

11. 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

12. The Advisory Panel considered, as of 14 July 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
14 July 2021