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 (January 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 12 January 2022 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 of 3 years of age and older. In Hong Kong, as at 11 January 2022, 5.05 million, 4.71 million, and 0.56 million persons received the first, second and third vaccine 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 and Indonesian Phase 3 studies also provided additional data to support its efficacy.

7. The vaccine effectiveness is continually supported by real world studies conducted in different countries. Neutralisation studies continued to demonstrate immunogenic response against different variants, but there were different degrees of decline suggesting waning of protection over time. The third dose of CoronaVac is found to boost the immunity and protection against SARS-CoV-2 virus. However, it is noted that heterologous third dose administration might have better immunogenic response and effectiveness, especially against the Omicron variant. The vaccine is still considered to be effective, especially for the prevention against infections associated with severe outcomes.

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 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.

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

10. On 23 December 2021, the Scientific Committee on Vaccine Preventable Diseases, and the Scientific Committee on Emerging and Zoonotic Diseases under the Centre for Health Protection of the Department of Health, together with the Chief Executive's Expert Advisory Panel, recommended that people who are not vaccinated should receive vaccination as soon as possible to protect from severe illness and complications. For individuals aged 18 years and above who have received two doses of Comirnaty or CoronaVac, a third dose of Comirnaty is strongly recommended while this dose is recommended to be administered as soon as possible six month after the second dose. The Advisory Panel, having reviewed the available studies of effectiveness of

COVID-19 vaccines against Omicron variant and overseas recommendations on use of COVID-19 vaccines, agreed to the above updated recommendation.

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 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 in view of the current and anticipated pandemic situation, the overall benefit-risk profile of CoronaVac remains favourable.

Overall Conclusion

13. The Advisory Panel considered, as at 12 January 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 and anticipated pandemic situation.

Advisory Panel on COVID-19 Vaccines
12 January 2022