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 (June 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. At the meeting on 15 February 2023, it was agreed that the Advisory Panel would continue to review the benefit-risk profiles of the authorized vaccines through circulation of papers until all the vaccine preparations migrated to registration under Pharmacy and Poisons Regulations, Cap. 138A, if there was no significant concern on safety, efficacy and/or quality of the vaccines.

4. On 28 June 2023, the paper on review of the benefit-risk balance of CoronaVac based on the latest available information was circulated to Members of the Advisory Panel. The benefit-risk analysis of CoronaVac is summarised below.

Benefit-Risk Analysis of CoronaVac

5. In Hong Kong, as at 16 May 2023, about 6.9 million, 6.8 million, 5.8 million, 1.1 million and 90 277 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 aged 3 years 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 60 countries or regions, and it was approved by the World Health Organization ("WHO") under Emergency Use Listing ("EUL") on 1 June 2021.

7. The efficacy of the primary series and booster doses of CoronaVac is primarily supported by the vaccine efficacy analyses and immunobridging endpoints in various clinical trials.

8. In addition to the previous real-world data from different countries which demonstrated the effectiveness and immunogenicity of homologous booster doses of CoronaVac, a recent study further showed a boost in humoral response after heterologous boosting with one to two doses of Comirnaty vaccines targeting the original strain of SARS-CoV-2. Nonetheless, the persistence and breadth of immune response elicited by multiple homologous and heterologous booster doses against the Omicron XBB sublineages are yet to be observed. A local study further suggested that more vaccine doses received were associated with greater reductions in duration of COVID-19-related hospitalisation, suggesting potential additional benefits of vaccination beyond protection against severe outcomes of COVID-19.

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 as of March 2022, about three billion doses of CoronaVac had 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, particularly for the high-risk populations, might be needed to maintain and sustain the protection against severe SARS-CoV-2 infection caused by Omicron sublineages.

Overall Conclusion

14. The Advisory Panel considered, as at 4 July 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
4 July 2023