On-going Review of Benefit and Risk of Authorized COVID-19 Vaccine 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

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 will conduct 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 29 April 2021 to review the benefit-risk balance of CoronaVac based on the latest information available. 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 29 April 2021, 423 800 persons received the first dose of CoronaVac while 304 900 persons among the above received their second dose.

6. CoronaVac has been approved for emergency use in over 34 countries. The efficacy of CoronaVac is mainly supported by the primary efficacy analysis in Brazilian Phase 3 study as previously submitted and there has been no further significant updates from clinical studies so far.

7. Based on the information available from the Ministry of Health of Chile, preliminary vaccine effectiveness study in Chile showed vaccine effectiveness of 66.96% to prevent symptomatic COVID-19 14 days after vaccination with second dose. The vaccine effectiveness to reduce hospital admission and ICU admission and to prevent death were 84.84%, 88.55% and 80.44%, respectively. Preliminary information also demonstrated vaccine effectiveness of 49.6% with at least one dose of CoronaVac in setting of epidemic P.1 variant transmission in Brazil, compared to those matched unvaccinated subjects.

8. Neutralization studies demonstrated immunogenic responses towards UK B.1.1.7, Brazilian P.1, and South African B.1.351 variants, but the neutralizing activity was less effective for the variants, and especially for the South African B.1.351 variant.

9. The authorization applicant demonstrated that a global pharmacovigilance system is in place and adverse events are well monitored especially in China.

10. According to the global safety data and analysis in March 2021, a total of 76 million doses of CoronaVac were vaccinated worldwide in which over 20 million doses were administered to elderly at or above 60 years of age. There is no new safety signal identified. There is no thrombosis or hemiplegia related death cases reported so far. The incidence of death cases after vaccination is lower than the general annualized mortality rate and there is no abnormal increase of death rate after vaccination.

11. According to the safety data in China, it was noted that the incidences of peripheral facial nerve palsy (also known as “Bell’s Palsy”), sudden deafness,

brachial plexus neuritis/polyneuritis, Guillain Barre Syndrome, and thrombocytopenic purpura are well below the disease background rate and did not reveal a pattern confirming causal relationship with CoronaVac, and it was considered that there were no safety signal generated.

12. There was also no overseas regulatory update regarding the use of CoronaVac.

13. The local pharmacovigilance system was also found to be effective. The Advisory Panel noted a number of Bell's palsy cases reported after CoronaVac vaccination. Preliminary analysis suggested that there might be a potential association and The University of Hong Kong has already started to conduct a study of the association between Bell's palsy and CoronaVac as requested by the Expert Committee on Clinical Events Assessment Following COVID-19 Immunisation pending further follow-up and final analysis. Meanwhile, summary information of relevant Bell's palsy case reports have been provided to the authorization applicant, Sinovac, for global monitoring.

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

Overall benefit-risk

15. 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

16. The Advisory Panel considered, as of 29 April 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
29 April 2021