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)

Comirnaty COVID-19 mRNA Vaccine (BNT162b2) Concentrate for Dispersion for Injection (April 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 25 January 2021, the COVID-19 vaccine, namely Comirnaty COVID-19 mRNA Vaccine (BNT162b2) Concentrate for Dispersion for Injection ("Comirnaty") by Fosun Industrial Co., Limited ("Fosun"), 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 April 2022 to review the benefit-risk balance of Comirnaty based on the latest available information. The benefit-risk analysis of Comirnaty is summarised below.

Benefit-Risk Analysis of Comirnaty

5. In Hong Kong, as at 13 April 2022, about 6.5 million, 5.9 million, and 3 million persons received the first, second and third dose of the authorized COVID-19 vaccines respectively. Comirnaty is authorized for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus in individuals aged 12 and above, and a fractional dose (i.e. one-third) of Comirnaty is also suggested for children aged 5 to 11 as "off-label" use.

6. Comirnaty has been approved for emergency use in over 100 countries or regions. The efficacy of Comirnaty in individuals of 5 years or above is mainly supported by the primary efficacy analysis in the pivotal multinational Phase 3 studies with the updated efficacy analysis through up to six months of follow up.

7. Real world data from different countries continued to support the efficacy of Comirnaty. There is a gradual decline in vaccine effectiveness against infection over time after the primary course of vaccination, due to waning immunity and the emergence of variant strains, especially the Omicron variant. However, the effectiveness is preserved at a higher level against hospitalisation and death and that remains to be relatively more durable.

8. Available evidence suggested that the first booster dose (i.e. the third dose) leads to improvement of protection that the vaccine effectiveness against infection is restored even during the Omicron-predominant period, though it may still be reduced over time. Sustainable and high vaccine effectiveness against hospitalisation and death continues to be demonstrated while the waning is slight in magnitude.

9. As regards the second booster dose (i.e. the fourth dose), evolving evidence showed that there is additional and sustainable benefit on the effectiveness against severe illness caused by the Omicron variant as compared with the first booster, although the protection against infection appears to be short-lived.

10. The authorization applicant demonstrated that a global pharmacovigilance system is in place in that the important risks and missing information as identified in the risk management plan and adverse events of special interest are well monitored. Evolving

safety data continues to support that myocarditis and pericarditis are rare risks while the outcome is considered manageable and mitigated by the update of the product information.

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

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

Overall Benefit-Risk

13. The identified risks associated with the use of Comirnaty have been addressed through provision and updating 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 Comirnaty and in view of the current and anticipated epidemic situation, the overall benefit-risk profile of Comirnaty remains favourable.

Overall Conclusion

14. The Advisory Panel considered, as at 14 April 2022, the benefits of Comirnaty 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
14 April 2022