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 Vaccines[1]
(February 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 25 January 2021, the COVID-19 vaccine, namely Comirnaty COVID-19 mRNA Vaccine (BNT162b2) Concentrate for Dispersion for Injection 30 micrograms/dose ("Comirnaty-30") by Fosun Industrial Co., Limited ("Fosun"), has been authorized under the Regulation. Subsequently, Comirnaty 10 micrograms/dose Concentrate for Dispersion for Injection COVID-19 mRNA Vaccine (nucleoside modified) ("Comirnaty-10") and Comirnaty 3 micrograms/dose Concentrate for Dispersion for Injection COVID-19 mRNA Vaccine (nucleoside modified) ("Comirnaty-3") were authorized on 30 September 2022, and Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose Dispersion for Injection COVID-19 mRNA Vaccine (nucleoside modified) ("Comirnaty-Bi") was authorized on 10 November 2022.

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

1 Comirnaty COVID-19 mRNA Vaccines include Comirnaty COVID-19 mRNA Vaccine (BNT162b2) Concentrate for Dispersion for Injection 30 micrograms/dose ("Comirnaty-30"), Comirnaty 10 micrograms/dose Concentrate for Dispersion for Injection COVID-19 mRNA Vaccine (nucleoside modified) ("Comirnaty-10"), Comirnaty 3 micrograms/dose Concentrate for Dispersion for Injection COVID-19 mRNA Vaccine (nucleoside modified) ("Comirnaty-3") and Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose Dispersion for Injection COVID-19 mRNA Vaccine (nucleoside modified) ("Comirnaty-Bi").

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.

4. The Advisory Panel conducted its meeting on 15 February 2023 to review the benefit-risk balance of Comirnaty vaccines based on the latest available information. The benefit-risk analysis of Comirnaty vaccines is summarised below.

Benefit-Risk Analysis of Comirnaty

5. In Hong Kong, as at 30 January 2023, about 6.9 million, 6.8 million, 5.8 million, 1.0 million and 48 551 persons received the first, second, third, fourth and fifth doses of the authorized COVID-19 vaccines respectively. Comirnaty-30, Comirnaty-10 and Comirnaty-3 are authorized for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus in individuals aged 12 years and above, aged 5 to 11 years and aged 6 months to 4 years respectively. Moreover, Comirnaty-Bi has been authorized for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 12 years of age and older who have previously received at least a primary vaccination course against COVID-19.

6. Comirnaty vaccines have been approved for use in over 100 countries or regions. The efficacy of the primary course and booster doses of Comirnaty-30, Comirnaty-10 and Comirnaty-3 in individuals of 6 months or above is mainly supported by the primary efficacy analysis in the pivotal multinational Phase 3 studies with the updated efficacy analysis up to six months of follow up as well as immunogenicity studies. The efficacy of Comirnaty-Bi as booster dose is supported by clinical studies with improved magnitude and breadth of neutralizing activity to the Omicron sublineages (including BA.4/5, BQ.1.1 and XBB subvariants) as compared to the original vaccine.

7. Real-world data from different countries continues to support the effectiveness of the primary course and booster doses of Comirnaty-30, Comirnaty-10 and Comirnaty-3. There is a gradual decline in the vaccine effectiveness against infection over time after the primary course as well as the booster doses of vaccination, due to waning immunity and the emergence of the Omicron strains. Nevertheless, the protection conferred by the booster doses against severe disease or death was found to be more robust and relatively more durable.

8. Real-world vaccine efficacy data consistently demonstrated the additional protection conferred by a booster dose of Comirnaty-Bi against serious outcomes

(hospitalisation and death), particularly in older adults and symptomatic infection. However, the durability of the protection and the optimal timing for further boosting with Comirnaty-Bi, as well as the effectiveness of the vaccine as a primary course, are yet to be determined.

9. 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 updating of the product information.

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 Comirnaty vaccines has been assured by certification and appropriate testing for quality control.

Overall Benefit-Risk

12. The identified risks associated with the use of Comirnaty vaccines 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 vaccines and in view of the current and anticipated epidemic situation, the overall benefit-risk profile of Comirnaty vaccines remains favourable.

13. Additional dose of current or variant vaccines might be needed to maintain and sustain the protection against subsequent waves of SARS-CoV-2 caused by the Omicron variant or future variants with similar escape potential.

Overall Conclusion

14. The Advisory Panel considered, as at 15 February 2023, the benefits of Comirnaty vaccines 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
15 February 2023