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]
(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 25 January 2021, 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 Original/Omicron BA.4-5") 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 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

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

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 the 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 Comirnaty vaccines based on the latest available information was circulated to Members of the Advisory Panel. The benefit-risk analysis of Comirnaty vaccines is summarised below.

Benefit-Risk Analysis of Comirnaty Vaccines

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. 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 Original/Omicron BA.4-5 is 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 series and booster doses of Comirnaty-30, Comirnaty-10 and Comirnaty-3 is primarily supported by the vaccine efficacy analyses and immunogenicity endpoints in several pivotal Phase 1/2/3 clinical trials. Recent real-world data from different countries continues to support the effectiveness of the primary series and booster doses of the vaccines. The latest analysis in the United States ("U.S.") demonstrated early effectiveness of a complete three-dose primary series of Comirnaty-3 against symptomatic infection in children aged 3 to 4 years, yet the durability of protection remains to be determined.

7. The efficacy of booster doses of Comirnaty Original/Omicron BA.4-5 in adults and adolescents was inferred from the vaccine efficacy data of Comirnaty vaccines targeting the original strain, and further supported by immunogenicity data of Comirnaty Original/Omicron BA.4-5 as a fourth dose from a Phase 3 trial. Recent real-world data consistently demonstrated additional protection conferred by a booster dose of Comirnaty Original/Omicron BA.4-5 against serious disease outcomes (hospitalisation and death) in adults and immunocompromised individuals. Protection against infection was modest and rapidly-waning during the predominant period of BQ.1 and XBB sublineages. Improved magnitude and breadth of neutralising activity to Omicron subvariants (including XBB

sublineages) was also observed with a bivalent booster compared with a monovalent booster. Further boosting may thus be beneficial for populations at a high risk of severe outcomes or at increased risk of exposure. However, the immune persistence of further booster doses is yet to be determined.

8. The authorization applicant demonstrated that a global pharmacovigilance system is in place through which 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 show that myocarditis and pericarditis are rare, while the outcomes are considered to be manageable and mitigated by updating of the product information. Furthermore, latest analyses did not identify an increased rate of ischaemic stroke in any age group after boosting with Comirnaty Original/Omicron BA.4-5, while the previous signal detected in older adults in a U.S. monitoring system had attenuated.

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

10. The quality of imported batches of Comirnaty vaccines has been assured by certification and appropriate quality control testing conducted.

Overall Benefit-Risk

11. The identified risks associated with the use of Comirnaty vaccines are addressed through the provision and updating of relevant product information to support safe use of the products. 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 remains favourable.

12. Additional doses of current or bivalent vaccines might be necessary, particularly for the high-risk populations, to maintain and sustain the protection against severe SARS-CoV-2 infection caused by Omicron sublineages.

Overall Conclusion

13. The Advisory Panel considered, as at 4 July 2023, the benefits of Comirnaty vaccines continue to outweigh their risks and there are no recommended changes regarding the use of the vaccines in Hong Kong under the current epidemic situation.