

**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
(September 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 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 (“Comirnaty”) by Fosun Industrial Co., Limited (“Fosun”), 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.

4. The Advisory Panel conducted its meeting on 19 September 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 18 September 2022, about 6.9 million, 6.7 million, 5.3 million and 0.4 million persons received the first, second, third, and fourth doses 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 use in over 100 countries or regions. The efficacy of Comirnaty in individuals of 5 years old 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 the primary course and booster dose of Comirnaty. There is a gradual decline in the vaccine effectiveness against infection over time after the primary course as well as the first booster dose of vaccination, due to waning immunity and the emergence of the Omicron strains. Nevertheless, the protection conferred by the first booster dose against severe disease or death was found to be more robust and relatively more durable.

8. As regards the second booster dose (i.e. the fourth dose), evolving evidence showed that there is additional benefit on the effectiveness against severe illness caused by the Omicron variant as compared with the first booster, although the protection against infection appeared to be short-lived. The long term effect and optimal timing for the second booster dose were 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 effective and there is no new safety signal identified locally.

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

Overall Benefit-Risk

12. 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.

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 19 September 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
19 September 2022**