**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 (January 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 12 January 2022 to review the benefit-risk balance of Comirnaty based on the latest available information. The benefit-risk analysis of Comirnaty is summarized below.

**Benefit-Risk Analysis of Comirnaty**

5. Comirnaty was indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals aged 12 and older. In Hong Kong, as at 11 January 2022, 5.05 million, 4.71 million, and 0.56 million persons received the first, second and third vaccine dose.

6. Comirnaty has been approved for emergency use in about 100 countries or regions. The efficacy of Comirnaty in individuals of 12 years or above is mainly supported by the primary efficacy analysis in the pivotal multinational Phase 3 study as reported previously. It is furthered supported with the updated efficacy analysis through up to six months of follow up.

7. The real world data from different countries continued to support the efficacy of Comirnaty. Although the vaccine effectiveness might be reduced due to time elapse and prevalence of variant strains, the protection, especially against severe disease and hospitalization, remained to be high.

8. The third dose of Comirnaty is found to boost the protection against symptomatic disease and hospitalization. Preliminary data demonstrated an enhanced immune response from the third dose of Comirnaty against the Omicron variant.

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.

10. The local pharmacovigilance system was also found to be effective and there was no new safety signal identified locally. Myocarditis and pericarditis have already been included as one of the adverse events following immunization for local active monitoring.

11. On 23 December 2021, the Scientific Committee on Vaccine Preventable Diseases, and the Scientific Committee on Emerging and Zoonotic Diseases under the Centre for Health Protection of the Department of Health, together with the Chief Executive's Expert Advisory Panel, recommended that people who are not vaccinated should receive vaccination as soon as possible to protect from severe illness and

complications. For individuals aged 18 years and above who have received two doses of Comirnaty or CoronaVac, a third dose of Comirnaty is strongly recommended while this dose is recommended to be administered as soon as possible six month after the second dose. The Advisory Panel, having reviewed the available studies of effectiveness of COVID-19 vaccines against Omicron variant and overseas recommendations on use of COVID-19 vaccines, agreed to the above updated recommendation.

12. Having reviewed the relevant efficacy and safety data published, the Advisory Panel also suggested allowing children aged 5 to 11 to receive a fractional dose (i.e. one-third of a dose) of Comirnaty for adults for "off-label use" and to make reference to the recommendations of relevant scientific committees for implementing the vaccination programme.

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

*Overall Benefit-Risk*

14. The identified risks associated with the use of Comirnaty were addressed through provision and update 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 current and anticipated pandemic situation, the overall benefit-risk profile of Comirnaty remains favourable.

## Overall Conclusion

15. The Advisory Panel considered, as at 12 January 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 and anticipated pandemic situation.

**Advisory Panel on COVID-19 Vaccines**
**12 January 2022**