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 2021)

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 30 September 2021 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 of 29 September 2021, 2 854 100 persons received the first dose of Comirnaty while 2 653 900 persons among the above received their second dose.

6. Comirnaty has been approved for emergency use in over 90 countries or regions. The efficacy of Comirnaty 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 that the vaccine efficacy against COVDI019 was 91% through up to six months of follow up.

7. The real world data in Canada, Israel, Qatar, United States and United Kingdom showed different degrees of decline in vaccine effectiveness, reflecting some waning of protection over time, particularly for the Delta variant and elder population. However, the vaccine is still considered to be effective, especially for the prevention against infections associated with severe outcomes.

8. Having reviewed the vaccine effectiveness and immunogenicity data, there may be a need for additional dose / booster of vaccine in the future particularly for certain groups with high risk of infection, or against the emergence of variants of concern. The issue would be further reviewed when more data to be submitted by the authorization applicant becomes available.

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 been included as one of the adverse events following immunization for local active monitoring.

11. On 15 September 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, after balancing the risks and benefits in the light of the local epidemic situation, recommended those aged 12 to 17 to receive one dose of the Comirnaty. The Advisory Panel, having reviewed the local COVID-19 epidemic situation and comparing the risks and benefits of receiving the second dose of Comirnaty by those aged 12 to 17, agreed to the above updated recommendation.

12. The Advisory Panel also advised that the Government should continue to monitor the global and local epidemic situation and relevant clinical data on Comirnaty, and recommended the Government to consider undertaking scientific research studies such as immunogenicity study and benefit/risk ratio modelling study related to the efficacy of providing the second dose of Comirnaty to those aged 12 to 17.

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 current pandemic situation, the overall benefit-risk profile of Comirnaty remains favourable.

Overall Conclusion

15. The Advisory Panel considered, as of 30 September 2021, the benefits of Comirnaty continue to outweigh its risks and there are no recommended changes regarding the use of this vaccine in Hong Kong, except that people aged 12 to 17 are recommended to receive one dose of Comirnaty, under the current pandemic situation.

Advisory Panel on COVID-19 Vaccines
30 September 2021