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 (July 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 14 July 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 12 years of age and older. As of 13 July 2021, 1 564 000 persons received the first dose of Comirnaty while 1 089 500 persons among the above received their second dose.

6. Comirnaty has been approved for emergency use in over 70 countries. The efficacy of Comirnaty is mainly supported by the primary efficacy analysis in the pivotal multinational Phase 3 study as previously.

7. The real world data in Israel, Qatar and UK continued to support the efficacy of Comirnaty that the vaccine effectiveness was found to be maintained at around 90%. Although the effectiveness and immune response against those variant of concerns might be reduced, the vaccine is considered to retain protective immunity. The Qatar study showed the vaccine effectiveness against Beta variant infection is about 75% and the UK study showed that it was about 87.9% against the Delta variant infection.

8. Various studies were conducted to evaluate the neutralization potency of Comirnaty on variant strains. These studies demonstrated that Comirnaty generated robust neutralization effect against different variants of concerns but it is noticed that the effect is reduced for the Beta and Delta strains. A combination of vaccination with non-pharmacological interventions would therefore be essential to control the spread of the virus.

9. The authorization applicant demonstrated that a global pharmacovigilance system is in place that the important risks and missing information as identified in the risk management plan and adverse events of special interest are well monitored.

10. According to the reviews conducted by overseas drug regulatory authorities, global safety data and analysis by authorization applicant, there were reported cases of myocarditis and pericarditis and they occurred more often after

the second dose and in younger adult male. It is considered that myocarditis and pericarditis may occur in very rare cases following vaccination with Comirnaty. It is noted from Fosun that an application to include the relevant safety information in the package insert would be submitted for consideration. Healthcare professionals and vaccinated people should be alert to the signs and symptoms of myocarditis and pericarditis.

11. 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.

12. The quality of imported batches of Comirnaty has been assured by certification and appropriate testing for quality control. The stability data provided by the authorization applicant supported the extension of shelf life of thawed vial stored at 2℃ to 8℃ from 5 days to one month (i.e. 31 days).

Overall Benefit-Risk

13. 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

14. The Advisory Panel considered, as of 14 July 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 under the current pandemic situation.

Advisory Panel on COVID-19 Vaccines
14 July 2021