On-going Review of Benefit and Risk of Authorized COVID-19 Vaccine 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

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, 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 will conduct 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 29 April 2021 to review the benefit-risk balance of Comirnaty based on the latest information available. 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 16 years of age and older. As of 29 April 2021, 473 400 persons received the first dose of Comirnaty while 175 700 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 submitted and preliminary unpublished information indicated that the efficacy is maintained as 91.3% at six months after the second dose of vaccination.

7. The real world data in Israel, the United Kingdom ("UK") and Denmark further supported the efficacy of Comirnaty that the vaccine effectiveness was found to be around 90% at 7 days after two doses of vaccination. A study at the United States on two mRNA vaccines including Comirnaty also demonstrated similar finding of 90% vaccine effectiveness among those fully immunized.

8. There are published studies conducted to evaluate the neutralization potency of Comirnaty on variant strains. These studies demonstrated that Comirnaty generated roughly similar neutralization effect against the UK B.1.1.7 variant, Brazil P.1 variant as the wild-type virus. The neutralization against the South African B.1.351 variant was found to be significantly reduced but still robust. A case control study also suggested that vaccine breakthrough infections were more frequent with both UK B.1.1.7 and South African B.1.351 variants when compared with the wild type. A combination of vaccination with non-pharmacological interventions would therefore be essential to control the spread of the virus.

9. There is also preliminary unpublished information suggesting high vaccine efficacy in adolescents 12 to 15 years of age.

10. 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.

11. According to the global safety data and analysis by authorization applicant, there has been no new significant safety signal identified so far. Diarrhoea and vomiting were newly identified as adverse reactions which will be added to the package insert accordingly. Dizziness, paraesthesia and tachycardia were recently evaluated to be a risk, and subject to further evaluation, they will be considered to be added to the package insert. Thromboembolic events, including those associated with thrombocytopenia were evaluated and determined not to be a risk. The review conducted by European Medicines Agency concurred with the conclusion that it did not reveal a pattern confirming causal relationship of immune thrombocytopenia with Comirnaty. The analysis of death cases, including cardiovascular and sudden deaths, did not identify any new risk particularly in the comorbidity of elderly population.

12. Preliminary evidence also demonstrated safety of use of mRNA vaccines including Comirnaty, in pregnant persons and further study on the use of Comirnaty in pregnancy is ongoing.

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

14. The Advisory Panel noted that the packaging defects of the vial caps of Comirnaty of the imported batches were rectified promptly and the vaccine manufacturer confirmed that the quality of the vaccines was found to be intact. There was no evidence indicating that there were any safety risks for the affected batch of vaccines. The quality of the subsequent imported batches of Comirnaty has been assured by certification and appropriate testing for quality control.

Overall Benefit-Risk

15. The identified risks associated with the use of Comirnaty are addressed through provision and update of relevant product information to support safe use of the product. Risks had 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

16. The Advisory Panel considered, as of 29 April 2021, that there are currently no new safety issues identified though continuous monitoring is required. The benefits of Comirnaty continue to outweigh its risks and there are no recommended changes regarding the use of this vaccine.

Advisory Panel on COVID-19 Vaccines
29 April 2021