HEALTH SCIENCES AUTHORITY
PRESS RELEASE
25 OCTOBER 2022

HSA AUTHORISES COMIRNATY BIVALENT (ORIGINAL/OMICRON BA.4/5) COVID-19 BOOSTER VACCINE BY PFIZER IN SINGAPORE

The Health Sciences Authority (HSA) has granted interim authorisation under the Pandemic Special Access Route (PSAR) for Comirnaty Bivalent (Original/Omicron BA.4/5) COVID-19 Vaccine by Pfizer on 11 October 2022. This vaccine is an updated version of the original Comirnaty vaccine and comprises two mRNA components:

- 15 micrograms targeting the original SARS-CoV-2 strain, and
- 15 micrograms targeting the Omicron BA.4 and BA.5 variants[1].

2 Comirnaty Bivalent (Original/Omicron BA.4/5) Vaccine is authorised for use as a booster vaccine in individuals aged 12 years and above, who have received COVID-19 primary series vaccination. Official vaccination recommendations on the use of this booster vaccine will be issued by the Expert Committee on COVID-19 Vaccination and the Ministry of Health when ready.

3 The authorisation of Comirnaty Bivalent (Original/Omicron BA.4/5) is based on the totality of available evidence, including Pfizer's non-clinical studies, clinical trials with different variant-updated vaccines, and the quality and manufacturing processes. Based on the available information, HSA has assessed that the benefits are expected to outweigh the risks for use of Comirnaty Bivalent (Original/Omicron BA.4/5) Vaccine as a booster to protect against COVID-19 as the virus continues to evolve. In making this regulatory decision, HSA also consulted experts from its Medicines Advisory Committee and Panel of Infectious Diseases Experts.

HSA's Evaluation of Available Safety and Efficacy Data

4 The SARS-CoV-2 virus mutates very quickly, with Omicron being the predominant variant in recent months. It is thus important that COVID-19 vaccines are updated to protect the public against the circulating variants of concern (VOC) and continue to be safe for use. As it takes several months for the development and manufacturing of updated versions of the vaccine and the clinical studies to be completed, HSA's assessment is based on a large body of evidence from various

[1] The Omicron BA.4 and BA.5 variants are also referred to as Omicron BA.4/5 collectively in this press release.

clinical and non-clinical studies, as well as data on the manufacturing process to support the safety, efficacy and quality of the vaccine.

5 As the clinical study by Pfizer for Comirnaty Bivalent (Original/Omicron BA.4/5) Vaccine is still under way, the assessment of the efficacy of the vaccine was based primarily on an earlier Phase 3 clinical study conducted in individuals aged above 55 years with Comirnaty Bivalent (Original/Omicron BA.1) Vaccine. HSA considers such data as relevant taking into account that these Omicron subvariants are closely related. The study showed that the bivalent vaccine elicited a stronger immune response against the targeted Omicron BA.1 subvariant, while still maintaining an adequate response against the original SARS-CoV-2 strain. This indicates that bivalent vaccines provide a broader immunity and better protection against the SARS-CoV-2 virus.

6 The observed immune responses were further supported by the on-going Phase 2/3 clinical study with the bivalent (Original/Omicron BA.4/5) vaccine, where a preliminary analysis in a subset of 80 participants aged 18 years and above showed consistent trends of higher immune responses against the Omicron BA.4/5 subvariant and continued response against the original SARS-CoV-2 strain. Additional results are expected as the study progresses and continues to generate more data.

7 Based on the overall data, HSA has assessed that there is a sufficient body of evidence to support the safe use of the Comirnaty Bivalent (Original/Omicron BA.4/5) vaccine and to extend its use to adults and adolescents aged above 12 years based on the following:

- It is known that the younger population generally develops a higher immune response compared to the older population due to the gradual weakening of the immune system as a person ages. Hence, it is expected that the bivalent vaccine would trigger comparable or better immune response in adolescents than older adults; and
- As the original Comirnaty vaccine has been approved across these age groups, there is a large amount of real-world data from local and overseas surveillance studies supporting its effectiveness and safety. It is reasonable to conclude that the variant-updated bivalent vaccines will retain similar effectiveness and safety profiles.

8 Safety data from the clinical studies showed that the bivalent vaccine was generally well-tolerated and the safety profile was consistent with what is known for the original vaccine, for which a large amount of safety data is available. The adverse events were mostly mild-to-moderate, such as injection site pain and/or tenderness, fatigue, headache and muscle pain. These reactions are generally associated with vaccinations and expected as part of the body’s natural response to build immunity against COVID-19. They usually resolve on their own within a few days.

Active Monitoring and Continuous Review of Data

9 HSA will continue to actively monitor the safety of the vaccine and require Pfizer to submit data from the ongoing clinical study for the bivalent (Original/Omicron BA.4/5) vaccine, to ensure that the benefits continue to outweigh the risks. HSA will take the necessary actions and provide updates to the public if significant safety concerns are identified.

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About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit http://www.hsa.gov.sg/.

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About HSA's Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA ensures that medicines, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.