



**HEALTH SCIENCES AUTHORITY
PRESS RELEASE
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HSA AUTHORISES THE UPDATED COMIRNATY VACCINE BY PFIZER TARGETING OMICRON SUBVARIANTS

The Health Sciences Authority (HSA) has on 12 September 2023 authorised the updated Comirnaty vaccine by Pfizer to be used in Singapore for the prevention of Coronavirus Disease 2019 (COVID-19) in individuals aged 6 months and above.

2 The vaccine is an updated version of the original Comirnaty Vaccine to target current Omicron subvariants. This ensures that the vaccine continues to be protective as the virus evolves. In line with international recommendations, the updated vaccine comprises a monovalent (single) component that corresponds to the Omicron XBB.1.5 variant. There are no other changes to the quality, safety, and efficacy of the vaccine and the updated vaccine is expected to retain the favourable benefit-risk balance of the original Comirnaty Monovalent Vaccine.

3 In reviewing the updated vaccine, HSA had considered the extensive data accrued from the previous versions of Comirnaty Vaccine, as well as additional data which demonstrated that the updated vaccine could enhance the immune responses against the predominant circulating Omicron subvariants including XBB.1.5, EG.5 (Eris), as well as the emerging BA.2.86. Based on the totality of evidence, and with the support of the Medicines Advisory Committee and the Panel of Infectious Diseases Experts, HSA has assessed that the overall evidence supported authorisation of the updated Comirnaty Vaccine.

4 As SARS-CoV-2 continues to evolve and new variants emerge, regular updating of approved COVID-19 vaccines would be necessary to ensure the continued effectiveness of the vaccines. Such changes include replacement of strain, antigen, or coding sequence according to international recommendations. This approach is not new and has been established for seasonal influenza vaccines which are updated every 6 months.

5 As with all other vaccines and medicines registered in Singapore, HSA will actively monitor and review evolving effectiveness and safety data to ensure that the benefits of the vaccine continue to outweigh the known risks.

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.