HEALTH SCIENCES AUTHORITY
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HSA GRANTS INTERIM AUTHORISATION FOR NUVAXOVID COVID-19 VACCINE BY NOVAVAX IN SINGAPORE

The Health Sciences Authority (HSA) had granted an interim authorisation under the Pandemic Special Access Route (PSAR) for Nuvaxovid COVID-19 vaccine (Nuvaxovid) by Novavax to be used in Singapore for the prevention of Coronavirus Disease 2019 (COVID-19) in individuals aged 18 years and above on 3 February 2022. The vaccination regimen comprises two five-microgram doses of Nuvaxovid to be administered 3 weeks apart. The first batch of Nuvaxovid is expected to arrive in Singapore in the next few months.

2 HSA has reviewed that the vaccine meets the quality, safety and efficacy standards, and that the benefits outweigh the risks for the Singapore population. Two groups of experts from HSA's Medicines Advisory Committee and Panel of Infectious Diseases Experts were also consulted and agreed with HSA's recommendation for PSAR authorisation.

HSA's Evaluation of Available Safety and Efficacy Data

3 HSA's clinical review was based on two Phase 3 clinical studies conducted in the USA, Mexico and the UK, comprising more than 40,000 clinical trial participants aged between 18 and 95 years. The results showed that Nuvaxovid demonstrated a vaccine efficacy of approximately 90% against symptomatic COVID-19 and 100% in preventing severe COVID-19. It showed consistent efficacy against the Alpha variant, but there was no data on the Delta and Omicron variants, as these variants were not prevalent at the time Novavax conducted the clinical trials.

4 Based on the data accrued from the clinical trials to-date, the safety profile of Nuvaxovid was generally consistent with other registered vaccines in Singapore. Some common side effects that vaccine recipients may experience include injection site pain and/or tenderness, fatigue, headache and muscle pain. These symptoms are reactions generally associated with vaccinations and expected as part of the body's natural response to build immunity against COVID-19. These side effects usually resolve on their own within a few days.

5 As with all vaccines, there will always be a small proportion of susceptible persons who may experience severe allergic reactions upon vaccination. They include those with a history of anaphylaxis (i.e., rapid onset of severe allergic reactions). In such cases, immediate medical attention should be sought. Persons who develop anaphylaxis to the first dose of Nuvaxovid should not be given the second dose. Safety and efficacy data in severely immunocompromised persons and those under the age of 18 are not available yet. Hence, no recommendation can be made for the use of the vaccine in these individuals.

Active Monitoring and Continuous Review of Data

6 As a condition for the interim authorisation under PSAR, Novavax is required to monitor the longer-term efficacy of Nuvaxovid to determine the duration of protection against COVID-19. Novavax is also required to follow up on the safety of the vaccine over a longer period to determine its overall safety profile, including in special populations such as immunocompromised persons, pregnant women and children. HSA will actively review evolving vaccine effectiveness and safety data to ensure that the benefits of the vaccine continue to outweigh the known risks. PSAR interim authorisation may be terminated at any time; for example, if new data suggests that the benefits no longer outweigh the risks. To obtain full registration, Novavax will need to submit the complete dataset based on prevailing international standards[1].

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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/.

[1] HSA's current requirements are based on the scientific standards set out by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

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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.