HEALTH SCIENCES AUTHORITY
PRESS RELEASE
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HSA GRANTS INTERIM AUTHORISATION FOR FIRST COVID-19 VACCINE IN SINGAPORE

The Health Sciences Authority (HSA) granted an authorisation today under the Pandemic Special Access Route (PSAR) for the Pfizer-BioNTech COVID-19 vaccine to be used in Singapore for the prevention of Coronavirus Disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus. The vaccination regime submitted by Pfizer-BioNTech requires two doses of vaccine to be administered 21 days apart, in individuals aged 16 years and above.

2 HSA's review of the available clinical data found that the benefits of the Pfizer-BioNTech COVID-19 vaccine outweigh the known risks. The vaccine demonstrated a high vaccine efficacy of 95%. Based on the data accrued to-date, the safety profile of the Pfizer-BioNTech COVID-19 vaccine was generally consistent with other registered vaccines.

3 HSA reviewed data from the pre-clinical studies done in laboratories, clinical trials in human volunteers, manufacturing and quality controls, and considered the conditions for the safe distribution and supply of the vaccine. Two groups of experts from HSA's Medicines Advisory Committee and Panel of Infectious Diseases Experts, comprising medical doctors and infectious diseases specialists, were consulted during the review to ensure that the vaccine is safe, efficacious and of good quality based on the data submitted to-date, and that the benefits outweigh the known risks for the Singapore population.

Rolling Data Submission for Speedier Evaluation

4 The Pfizer-BioNTech COVID-19 vaccine was granted interim authorisation under the Pandemic Special Access Route (PSAR). This regulatory pathway facilitates access to critical novel vaccines, medicines and medical devices during a pandemic such as the current COVID-19 pandemic.

5 Using PSAR, HSA can start evaluating new vaccines, medicines and medical devices from the early stages of clinical studies, as and when real-time data is submitted by companies on a "rolling", or staggered basis, instead of waiting for the full data set to be submitted before starting our evaluation. This gives HSA more time

to review the submitted data while companies continue with further clinical trials and development concurrently. The clinical trials have also been designed to be innovative and efficient, enabling the companies to conduct multiple trials concurrently, while maintaining the scientific rigour. Such regulatory agility and flexibility allow for speedier development and evaluation.

6 As with other new vaccines, the data submitted by Pfizer-BioNTech was robustly and thoroughly reviewed by HSA's regulators, and international scientific standards were applied during the evaluation. The vaccine was only granted interim authorisation after the data submitted by Pfizer-BioNTech was assessed by HSA to demonstrate that the vaccine meets the required safety, efficacy and quality standards, and that the benefits of the vaccine outweigh the known risks.

7 Dr Choong May Ling, Mimi, Chief Executive Officer of HSA shared, "HSA regulators were able to complete the evaluation of the Pfizer-BioNTech COVID-19 vaccine in the shortest possible time by working expeditiously on the available rolling data, instead of waiting for the full data set to be submitted before starting our evaluation, while upholding high standards of quality, safety and efficacy, and following the same rigorous processes as used to register vaccines in normal times. HSA's assessment and recommendations were also supported by our Medicines Advisory Committee and Panel of Infectious Diseases Experts before granting the interim authorisation to meet public health needs."

8 For more information on PSAR, refer to: https://www.hsa.gov.sg/therapeutic-products/register/special-access-routes/psar-emergency-therapeutic-product.

Vaccine Safety and Efficacy

9 HSA's review of the available clinical data found that the benefits of the Pfizer-BioNTech COVID-19 vaccine outweigh the known risks. The vaccine demonstrated a high vaccine efficacy of 95%. This means that there is a 95% reduction of symptomatic COVID-19 disease in a vaccinated group of people as compared to a similarly sized group of unvaccinated people. This vaccine efficacy was observed to be consistent across different age groups 16 years and older in over 40,000 clinical trial participants, whose ages ranged from 16 to 91 years.

10 Based on the data accrued to-date, the safety profile of the Pfizer-BioNTech COVID-19 vaccine was generally consistent with other registered vaccines used in the immunisation against other diseases, in that some people may experience side effects such as pain, redness, swelling at the injection site, fatigue, headache, muscle ache, fever, chills, vomiting, diarrhoea and joint pain after vaccination. While not everyone will experience these side effects, they are common and expected as part of the body's natural response so as to build immunity against COVID-19. These side effects usually

resolve within a few days. As with other established vaccines, in rare instances, a person who receives the vaccine may experience severe allergic reactions, such as difficulty breathing, wheezing, and swelling around the eyes and lips, and immediate medical attention should be sought. As a precautionary measure, anyone with a history of anaphylaxis (i.e., rapid onset of severe allergic reactions) should not receive the Pfizer-BioNTech vaccine. Pregnant women, immunocompromised persons and those under the age of 16 should also not receive the Pfizer-BioNTech vaccine as the safety and efficacy data on this group of persons is not available yet.

Continuous Review of Data

11 As a condition for the interim authorisation under PSAR, Pfizer and BioNTech are required to monitor the longer term efficacy of the vaccine to determine the duration of protection against COVID-19. This will augment the available data which shows that the vaccine continues to be effective for at least 2 months, with no signs of waning protection.

12 Pfizer and BioNTech are also required to continue to follow up on the safety of the vaccine for a longer period of time to determine its full safety profile. The current safety data has been accrued for about 20,000 vaccine recipients with a median duration of follow up of 2 months. No significant safety concerns have been detected.

13 The companies will also continue to study the safety of the vaccines in certain subpopulations such as pregnant women and children.

14 The companies must continue submitting the longer term follow up data to HSA to assure the continued effectiveness and safety of the vaccine. HSA will actively review the data to ensure that the benefits of the vaccine continue to outweigh the known risks.

15 When sufficient data is available for full registration, the companies will be required to file an application to transit the status of the product from PSAR interim authorisation to full registration.

16 HSA's PSAR interim authorisation is similar to the emergency use authorisation framework currently adopted by other regulatory jurisdictions such as Canada, the United States and the United Kingdom. HSA may terminate PSAR authorisation at any time; for example, if new data suggests that the benefits no longer outweigh the risks.

Active Vaccine Safety Monitoring

17 As with all other vaccines, some rare side effects may not be known at the time of HSA's authorisation and may only occur after the vaccine is used over a longer period of time and in much larger, diverse groups of people. HSA will conduct post-

market monitoring of the Pfizer-BioNTech Covid-19 vaccine to ensure that it continues to be safe for use. Said Associate Professor Chan Cheng Leng, Group Director of Health Products Regulation Group, HSA, “To safeguard our vaccine recipients, HSA will actively monitor the safety profile of Pfizer-BioNTech COVID-19 vaccine. We will draw on our network of healthcare professionals and international regulatory counterparts, as well as use data analytics to enable us to detect early safety signals. This will enable HSA to take swift regulatory actions should any safety concern emerge.”

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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/.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

About HSA’s Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA ensures that drugs, 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.