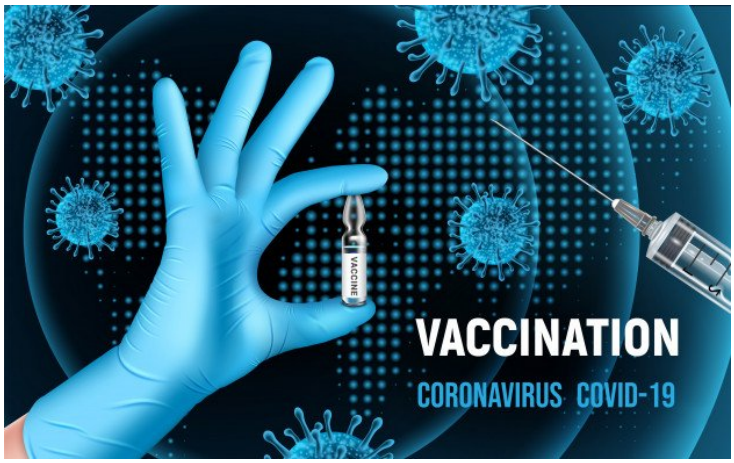
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Singapore approves Pfizer-BioNTech COVID-19 vaccine

December 14, 2020 | News

First shipment expected by end-December; Two dose vaccine regime to be administered 21 days apart



The Health Sciences Authority (HSA) has granted an authorization 14 Dec 2020 under the Pandemic Special Access Route (PSAR) for the Pfizer-BioNTech COVID-19 vaccine to be used in Singapore for the prevention of COVID-19. 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.

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 was only granted interim authorization after the data submitted by Pfizer-BioNTech was assessed by HSA to demonstrate that the vaccine meets the required safety, efficacy, and quality standards. The vaccine demonstrated a high vaccine efficacy of 95% (95% reduction of symptomatic COVID-19 disease in a vaccinated group of people).

Based on the data accrued to-date, the safety profile of the Pfizer-BioNTech COVID-19 vaccine was generally consistent with other registered vaccines. 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. 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.

Know your body's response to the vaccine:

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.

Singapore provides regulatory agility and flexibility through PSAR:

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. Such regulatory agility and flexibility allow for speedier development and evaluation.

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

Continuous Review of Data until Registration

As a condition for the interim authorization 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. 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 yet. Pfizer and BioNTech will also continue to study the safety of the vaccines in certain subpopulations such as pregnant women and children. HSA will continue to review the data to ensure that the benefits of the vaccine continue to outweigh the known risks with longer-term follow-up. Once 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 authorization to full registration.

Associate Professor Chan Cheng Leng, Group Director of Health Products Regulation Group, HSA, "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".