HEALTH SCIENCES AUTHORITY
PRESS RELEASE
3 FEBRUARY 2021

HSA GRANTS INTERIM AUTHORISATION FOR MODERNA COVID-19 VACCINE IN SINGAPORE

The Health Sciences Authority (HSA) granted an interim authorisation today under the Pandemic Special Access Route (PSAR) for the Moderna COVID-19 vaccine to be used in Singapore for the prevention of Coronavirus Disease 2019 (COVID-19) in individuals aged 18 years and above. The vaccination regime submitted by Moderna requires two doses of vaccine to be administered 28 days apart.

2 HSA's review of the available clinical data found that the benefits of the Moderna COVID-19 vaccine outweigh the known risks. The vaccine demonstrated a high vaccine efficacy of 94%.

3 HSA reviewed data from pre-clinical studies, clinical trials in human volunteers, and manufacturing and quality controls. 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 Moderna COVID-19 vaccine is the second COVID-19 vaccine to be granted interim authorisation under PSAR[1]. 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 more data becomes available on a real-time basis, without having to wait 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

[1] The Pfizer-BioNTech vaccine was the first COVID-19 vaccine to be authorised for use in Singapore under PSAR. It requires two doses of vaccine to be administered 21 days apart in individuals aged 16 years and above, except for pregnant women and immunocompromised persons.

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. Read more about PSAR.

6 Dr Choong May Ling, Mimi, Chief Executive Officer of HSA shared, “HSA has applied the same rigorous evaluation processes, as with all vaccines, to ensure that the Moderna COVID-19 vaccine has met the required high standards of quality, safety and efficacy. Our Medicines Advisory Committee and Panel of Infectious Diseases Experts have supported HSA's recommendations to grant interim authorisation to the Moderna COVID-19 vaccine. HSA's evaluators will continue to conduct rigorous and efficient assessments to facilitate Singapore’s access to critical COVID-19 vaccines and medicines to support our nation’s battle against the COVID-19 pandemic.”

Vaccine Safety and Efficacy

7 HSA’s review of the available clinical data found that the vaccine demonstrated a high vaccine efficacy of 94%. This means that there is a 94% 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 based on a Phase III clinical trial conducted in over 30,000 clinical trial participants whose ages ranged from 18 to 95 years.

8 Based on the data accrued from clinical trials to-date, the safety profile of the Moderna COVID-19 vaccine was generally consistent with other registered vaccines used in immunisation against other diseases. Some common side effects that vaccine recipients may experience include pain, swelling at the injection site, fatigue, headache, muscle ache, fever, chills, vomiting, and joint pain after vaccination. Of these symptoms, some (such as fatigue, headache and muscle/joint ache) may be more severe in a small number of persons. These symptoms are reactions generally associated with vaccinations and expected as part of the body’s natural response so as to build immunity against COVID-19. These side effects usually resolve on their own within a few days.

9 As with all vaccines, there will always be a small proportion of susceptible persons who experience severe allergic reactions upon vaccination. They include those with a history of anaphylaxis (i.e., rapid onset of severe allergic reactions) or severe or multiple allergies to medicines and food. In such cases, immediate medical attention should be sought. As a precautionary measure, anyone with a history of anaphylaxis or severe or multiple allergies to medicines or food should not receive the Moderna COVID-19 vaccine. Pregnant women, severely immunocompromised persons and those under the age of 18 should also not receive the Moderna COVID-19 vaccine as the safety and efficacy data for these groups of individuals are not

available yet. Persons who develop anaphylaxis or severe allergic reactions to the first dose of the COVID-19 vaccine also should not receive the second dose.

Active Monitoring and Continuous Review of Data

10 As a condition for the interim authorisation under PSAR, Moderna is 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 at two months following the completion of the vaccination regime, with no signs of waning protection. Moderna is 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. Moderna will also continue to study the safety of the vaccines in certain subpopulations such as children.

11 HSA will actively review the data submitted by Moderna to ensure that the benefits of the vaccine continue to outweigh the known risks. When sufficient data is available for full registration, Moderna will be required to file an application to transit the status of the product from PSAR interim authorisation to full registration. HSA may terminate PSAR authorisation at any time; for example, if new data suggests that the benefits no longer outweigh the risks.

12 Associate Professor Chan Cheng Leng, Group Director of Health Products Regulation Group, HSA, said, “HSA will continue to monitor for safety signals from the COVID-19 vaccines in use in Singapore, using data analytics and drawing on our network of healthcare professionals and regulatory counterparts overseas. These collaborations and information exchange enable HSA to identify and respond promptly to any potential safety signals that may occur in our population. HSA will also continue to work with MOH and the Expert Committee on COVID-19 Vaccination to review the existing strict criteria for vaccination where necessary.”

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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.