HEALTH SCIENCES AUTHORITY
PRESS RELEASE
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HSA GRANTS INTERIM AUTHORISATION FOR SINOVAC-CORONAVAC VACCINE IN SINGAPORE

The Health Sciences Authority (HSA) granted an interim authorisation today under the Pandemic Special Access Route (PSAR) for Sinovac-CoronaVac, an inactivated SARS-CoV-2 vaccine developed by Sinovac Biotech, to be used for the prevention of Coronavirus Disease 2019 (COVID-19) in individuals aged 18 years and above. The application is for a vaccination regime that requires two doses of the vaccine to be administered 28 days apart.

Review of Data from Sinovac

2 Sinovac Biotech submitted the PSAR application for Sinovac-CoronaVac to HSA in December 2020. HSA requested for more manufacturing and clinical data from the company, which subsequently submitted clarifications in July and August 2021 to supplement the initial data following HSA's queries.

3 HSA has conducted a careful and thorough review of the additional data, and took into consideration the current worldwide COVID-19 public health emergency and taking into account the public health needs in Singapore of having non-mRNA vaccines as an option for individuals who are medically unsuitable to receive mRNA vaccines. Experts from HSA's Medicines Advisory Committee and Panel of Infectious Diseases Experts were consulted in reaching the decision for interim authorisation for the vaccine under PSAR. Read more about PSAR.

Vaccine Efficacy

4 HSA's clinical review was based primarily on the data from the Phase III study conducted in Brazil which demonstrated vaccine efficacy[1] of 51% against non-Delta variants, which meets the threshold of 50% set by the World Health Organisation (WHO) for Emergency Use Listing (EUL)[2]. This means that there is a 51% reduction of symptomatic COVID-19 disease in a vaccinated group of people as compared to a similarly sized group of unvaccinated people.

[1] Vaccine efficacy is the degree to which a vaccine prevents a disease under controlled conditions in a clinical trial.
[2] https://www.who.int/publications/m/item/who-target-product-profiles-for-covid-19-vaccines

5 HSA also reviewed data from pre-clinical studies, clinical trials in human volunteers, manufacturing and quality controls, as well as supplemental data from a real-world effectiveness study in Chile which involved over 10 million participants aged 16 years and above. At the data cut-off in May 2021, Sinovac-CoronaVac demonstrated vaccine effectiveness of 66% against the Alpha and Gamma variants. The Chile study also showed that the vaccine offered more than 86% protection against other COVID-19 disease outcomes such as hospitalisation, admission to ICU and death.

6 The company did not submit data on the vaccine's protection against the Delta variant. The vaccine efficacy / effectiveness in persons with co-morbidities such as diabetes, cardiovascular diseases, cancers, as well as in immunocompromised patients, remains inconclusive as there was insufficient data in these subpopulations in both the clinical trial and real-world study. There was also a lack of data in older adults aged 60 years and above in the Phase III clinical trial in Brazil. Nonetheless, HSA took into consideration the supplemental evidence from the Chile study which showed that the effectiveness in the older population was consistent with that observed in the overall population. Based on this data, HSA is currently not setting any upper age limit for the use of Sinovac-CoronaVac.

7 When considering the use of the vaccine, doctors should carefully assess the benefit-risk of using Sinovac-CoronaVac for the specific individual and follow the recommendations of MOH's Expert Committee on COVID-19 Vaccination. Doctors should also inform the individual of the documented clinical efficacy of the vaccine.

Vaccine Safety

8 Based on the data accrued from clinical trials to-date, the safety profile of Sinovac-CoronaVac was generally consistent with other registered vaccines used in immunisation against other diseases. Some common side effects that vaccine recipients may experience include headache, injection site reaction, muscle pain and general discomfort after vaccination. 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 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 hypersensitivity to the vaccine or its components. In the case of Sinovac-CoronaVac, local data as of 18 October 2021 showed that the incidence of severe allergic reactions was 0.003% of doses administered. In such cases, immediate medical attention should be sought.

Persons who develop anaphylaxis or severe allergic reactions to the first dose of the vaccine should also not be administered the second dose.

10 As there was insufficient data on the use of Sinovac-CoronaVac in pregnant women, severely immunocompromised persons, persons with co-morbidities and those under the age of 18, no recommendations can be made by HSA for use in these sub-populations.

Regulatory Considerations for Granting PSAR Interim Authorisation

11 HSA's decision to grant PSAR interim authorisation for Sinovac-CoronaVac took into consideration that the vaccine met the minimum technical requirements for use during a pandemic, given the urgent public health needs. As PSAR is only an interim authorisation, the company is required to submit the complete dataset based on prevailing international standards[3] to obtain a full registration.

12 HSA will continue to actively review evolving vaccine effectiveness and safety data to ensure that the benefits of the vaccine continue to outweigh the known risks. The PSAR interim authorisation may also be terminated at any time; for example, if new data suggests that the benefits no longer outweigh the risks.

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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.

[3] 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).

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.