Should the DOH use ***Sinopharm* as primary homologous vaccination** in the 2022 COVID-19 Vaccination Program to reduce COVID-19 cases, severe infection, and deaths?

Recommendations *(as of 29 November 2021)*

The HTAC recommends the inclusion of *Sinopharm* in the Philippine National Deployment and Vaccination Plan for COVID-19 Vaccines for the general population aged 18 years and above, given that it has passed the safety, efficacy and other criteria of HTAC and provided that there is sufficient budget to cover its implementation after pending supply negotiations in 2022.

The HTAC considered the following criteria in formulating its recommendation for the vaccine:

Criterion	HTAC Judgment
Can Sinopharm significantly reduce the magnitude and severity of COVID-19 in the general population?	**Yes**. *Sinopharm* has the potential to reduce the disease burden by averting a significant number of symptomatic infections assuming sufficient vaccine coverage.
Is Sinopharm safe and efficacious for the general population?	**Yes,** it is efficacious for preventing symptomatic COVID-19 and any infection (including asymptomatic cases) in the general population aged 18 years and above, based on high certainty of evidence. It is likely that *Sinopharm* also provides protection against severe COVID-19, based on low certainty of evidence (Al Kaabi et al., 2021). *Sinopharm* has demonstrated low rates of breakthrough infection and protection against severe COVID-19, hospitalization and death due to COVID-19 among the general population (Al Hosani et al., 2021; Badano et al., 2021; Jahromi et al. 2021). Currently, there is no data on the efficacy or effectiveness of *Sinopharm* against variants of concern. **Yes**, the safety profile of *Sinopharm* is acceptable based on short-period follow-up (moderate to high certainty of evidence). However, further follow-up data is needed to establish the longer-term safety profile. Real world studies and safety reports also showed an acceptable safety profile of *Sinopharm.*
Is Sinopharm affordable and feasible to use in a national immunization program for the general population?	**Yes,** it is affordable. The share of the cost to implement vaccination using *Sinopharm* will constitute 0.86% of the total allocated budget for vaccination (Php 711 M of the Php82.5 B total budget) and will cover 0.52% of the 97 million target vaccinees for primary homologous vaccination. **Yes**, it is feasible as there are no significant challenges in vaccine implementation using *Sinopharm* in terms of storage, transport, and handling.
Does Sinopharm reduce out-of-pocket (OOP) expenses of households due to COVID-19?	**Yes.** Based on current evidence, Sinopharm has the potential to reduce out-of-pocket expenses in the general population due to averted costs of isolation and treatment of mild, moderate, and severe COVID-19.
Does Sinopharm possess the characteristics that are	**Yes.** Based on short-term outcomes, Sinopharm possesses most of the characteristics desired by key

desired by key stakeholders?	stakeholders for its use among the general population 18 years and above.
Does Sinopharm reduce or not further add to existing inequities in the health system?	**Yes**. Because of non-stringent logistic requirements, Sinopharm will not aggravate health inequities related to inoculation of recipients residing in isolated and disadvantaged locations. However, there is currently limited evidence on the efficacy and effectiveness of *Sinopharm* as a primary vaccine in special populations such as the older population and individuals with comorbidities.

In the development of this recommendation, the HTA Council has appraised and considered the evidence review of the Philippine COVID-19 Living Clinical Practice Guidelines Group on the following sub-themes of evidence on COVID-19 vaccines:

- Effectiveness and safety to the general population
- Efficacy and effectiveness against variants of concern in the general population

The HTA Council further emphasizes the need to enforce strict conditions for the emergency use of health products to safeguard against eventualities:

- Transparency and accountability in the processes of allowing emergency use of health products, especially for the public health response;
- Continuous collection of safety and effectiveness data in the context of clinical trials and actual use in the real world;
- Close monitoring of recipients and safeguards for expected and unexpected adverse events that may arise from the use of health products under an EUA;
- National coordination of the emergency use under the Philippine FDA and the DOH; and
- Cascading of complete information to vaccinees and healthcare providers on potential risks and benefits, and securing of informed consent with regard to receiving the intervention.

Finally, the HTAC recommends the conduct of research to address the current gaps in evidence with regard to the use of the *Sinopharm*:

- Real-world effectiveness in the Philippine context particularly focused on the following knowledge gaps:
    - Effectiveness in reducing COVID-19 cases, hospitalizations and deaths, and preventing outbreaks and transmission of disease across the population
    - Effectiveness in reducing asymptomatic infection
    - Duration of protection
    - Impact of the timing and number of doses received
    - Probable need for booster dosing
    - Differences in the effectiveness of the vaccine among special populations (i.e., elderly, individuals with comorbidities, pregnant and lactating women, immunocompromised patients)
    - Effectiveness of the vaccine against emerging SARS-CoV-2 viral strains

- Continuous safety surveillance and monitoring of all adverse events especially severe allergic reactions, Bell's palsy, serious adverse events such as thrombosis-thrombocytopenia syndrome (TTS), myocarditis and other adverse events of special interest (AESI) following vaccination
    - Across the general population
    - In special populations: elderly, patients with comorbidities, pregnant and lactating women, immunocompromised individuals
- Randomized controlled trials should also be done among populations not currently included in clinical trials: children below 18 years of age
- Best practices, challenges, and barriers in implementation across different localities
- Monitoring of unexpected or additional costs associated with vaccine implementation.

Current Evidence on *Sinopharm*

The table below summarizes the appraisal of available evidence on *Sinopharm* based on the HTAC evaluation framework.

In addition, the following appendices are provided for further details:

- Appendix 1: Review on Sinopharm by the Philippine Living Clinical Practice Guidelines Group
- Appendix 2: Risk of Bias Assessment Method (LCPG Group)
- Appendix 3: GRADE Table (HTAC Appraisal)
- Appendix 4: Risk of Bias Assessment (LCPG Group Appraisal)
- Appendix 5: Risk of Bias Assessment (COVID-NMA)
- Appendix 6: Risk of Bias Assessment (HTAU Appraisal)
- Appendix 7: Costing table