Policy Question

The HTAC aims to answer the policy question:

Should ***SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]*** be recommended for emergency use to reduce COVID-19 cases, severe infection, and deaths?

Recommendation *(as of 08 April 2021)*

The HTAC maintains its **recommendation for the emergency use of *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]*** to reduce the burden of COVID-19 in a healthy population, 18-59 years of age, with low risk of exposure to COVID-19 infection.

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

Criteria	HTAC Judgment
Can *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]* significantly reduce the magnitude and severity of COVID-19?	**Yes**. *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]* has the potential to reduce the disease burden by averting a significant number of symptomatic infections assuming sufficient vaccine coverage.
Is *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]* efficacious and safe?	Based on a report of an interim results of unpublished Phase III trial on *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac] in Brazil* [Palacios, 2021) *(cut-off analysis: date: 16 December 2020)]*. **Yes**, it is efficacious for preventing symptomatic COVID-19 based on moderate certainty of evidence. It may reduce the risk of severe cases and hospitalization due to COVID-19, based on very low certainty of evidence. The duration of protection cannot be assessed given the current data. **Yes**, it is safe in the known short-term safety outcomes, based on moderate certainty of evidence. Meanwhile, its long term safety outcomes cannot be determined given the short duration of observation at the time of the reports. It should not be given to individuals below 18 years old and to those with a known history of severe allergic reaction to any component of the vaccine, and who is febrile, patient in acute illness period and acute attack of chronic disease.

	The product insert also highlights precaution among the following special populations: immunocompromised patients, people with neurological conditions and, people with bleeding disorders.
Is *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]* affordable and feasible to use in a national immunization program (viability)?	**Yes.** It is affordable but the total budget allocation is not proportionate to the target vaccinees. The share of the cost to implement vaccination using *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]* will constitute 47.83% of the total allocated budget for vaccination and will cover 36% of the 70 million target vaccinees for 2021. According to the Department of Finance, the price of SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac] offered to the Philippine government is equal to or better than the price offered in other Southeast Asian countries. **Yes**, it is feasible as there are no significant barriers in vaccine implementation using *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]* in terms of storage, transport, and handling. However, there is still a need for training of vaccinators to ensure product integrity across the entire supply chain and close monitoring of adverse events.
Does *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]* reduce out-of-pocket (OOP) expenses of households due to COVID-19?	**Yes**. Based on interim results of the Brazil trial, *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]* may reduce the risk of hospitalization due to COVID-19. Thus, *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]* has the potential to reduce out-of-pocket expenses of Filipino households due to averted costs of isolation, treatment and hospitalization costs.
Does *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]* possess the characteristics desired by key stakeholders? (Social Impact)	**Yes.** Based on short term outcomes, *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]* possesses most of the characteristics desired by key stakeholders.
Does *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]* reduce or not further add to existing inequities in the health system?	**Yes.** Because of non-stringent logistic requirements, *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]* does not aggravate health inequities related to inoculation of recipients residing in isolated and disadvantaged locations. The trial population did not include important vulnerable groups such as individuals with impaired immune

	systems, and pregnant and lactating women. Further, the vaccine is contraindicated to those with a known history of severe allergic reaction to any component of the vaccine, and who is febrile, patient in acute illness period and acute attack of chronic disease.

The evidence review on efficacy and safety included the following:

- Zhang et al., 2021 (18-59 years old), (published manuscript) - China Phase I/II trial
- Wu et al., 2021 (60 years old and above), (published manuscript) - China Phase I/II trial
- Palacios et al., 2021 (sponsor submission) - Brazil Phase III trial, interim results
- Unal et al., 2021 (personal communication) Turkey Phase III trial, interim results
- Rusmil et al., 2021 (sponsor submission) - Indonesia Phase III trial, interim results
- Bueno et al, 2021 (preprint article) - Chile Phase III trial

Of these trials, the HTA Council found that only the data from the Brazil trial (Palacios et al, 2021) are useful for the following reasons:

- The study reached at least 50% of their target sample size with at least 2 months median follow up after the 2nd dose. Based on the interim report dated February 2021, the proportion of trial subjects analyzed after receiving two doses was 79.87% in the vaccine arm and 78.46% in the placebo arm;
- The methodology was well-described;
- Patients included in the observation are well-accounted for;
- Data showed acceptable safety based on short term follow up period; and
- The study reported clinically meaningful outcomes on the prevention of COVID-19 infection, severe cases and hospitalization

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;

- Cascading of complete information to vaccinees on potential risks and benefits, and securing of informed consent with regard to receiving the intervention; and
- Just compensation mechanisms and provisions for medical management of adverse events for patients and vaccinees assured by the national government

Finally, the HTAC recommends the conduct of research to address the current gaps in evidence with regard to the use of the *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]*:

- Real-world effectiveness in the Philippine context particularly focused on the following:
    - 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 and 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.