Rationale on updating the HTAC recommendation on *SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac]*

Considering the evolving evidence on COVID-19 vaccines, the HTAC releases its updated recommendations on the emergency use of *SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac]*. Further, there was a necessity to revisit the HTAC recommendation dated 08 April 20121 which recommends the vaccine to the healthy population with low risk of exposure aged 18 to 59 years old due to the following reasons:.

- On 24 May 2021, the World Health Organization Strategic Advisory Group of Experts (WHO SAGE) released their interim recommendation for the use of *SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac]* wherein they recommended the use of the said vaccine in persons aged 18 years and above.
- In a letter dated 07 April 2021 to the Department of Health, the Philippine FDA expressed that they have no objections to using the aforementioned vaccine on individuals aged 60 and above.
- Use of vaccines in senior citizens was allowed as stated in Department Memorandum released by DOH on 08 April 2021 (DM 2021-0175) and an advisory from the National COVID-19 Vaccination Operations Center (NVOC Advisory No. 27).

AMENDMENTS

The following sections compare versions 1 and 2 of the HTAC recommendations:

HTAC Recommendation:

Version 1 ***(as of 08 April 2021)***	**Version 2** ***(as of 30 July 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 updates its **recommendation for the emergency use of *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]*** to reduce the burden of COVID-19 in the general population aged 18 years and older.

Summary of HTAC judgement and considerations in formulating its recommendation for the vaccine:

Criterion	**HTAC Judgment**	
	Version 1 ***(as of 08 April 2021)***	**Version 2** ***(as of 30 July 2021)***
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.	No revisions.
Is *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]* efficacious and safe?	Based on a report of interim results of an unpublished Phase III trial on *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac] in Brazil* [Palacios, 2021) *(cut-off analysis: date: 16 December 2020)]*.	Based on the preprint of a Phase III trial on *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]* in Brazil [Palacios, 2021 *(cut-off analysis date: 16 December 2020)]* and Turkey [Tanriover et al. 2021 *(cut-off analysis:*

	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.	*16 March 2021)*]**.** **Yes**, it is efficacious for preventing symptomatic COVID-19 based on moderate to high certainty of evidence. Additionally, based on real-world effectiveness data, the vaccine has also demonstrated clinical benefits in reducing the risk of symptomatic COVID-19, hospitalization due to COVID-19, and death due to COVID-19 in the general population including older adults (≥60 years old). WHO noted that current evidence from observational studies together with immunogenicity results suggest that *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]* is likely to have a protective effect in older persons, although whether at an equivalent level as in younger adults remains to be shown in further studies. Current evidence on immunogenicity against variants of concern is inadequate. More studies of better quality are anticipated to establish more conclusive evidence on SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]'s effectiveness against variants of concern. 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. In terms of safety in older adults (≥60 years old), trials showed that adverse event rates are lower in older adults compared to the 18-59 year-old population. While Bell's Palsy is considered a rare adverse event following immunization with *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]* based on the analysis of the HK Department of Health, the HTAC deems that the benefits of vaccination outweigh the the risks as all reported cases of Bell's Palsy were deemed not serious. It should not be given to individuals below 18 years old pending results of ongoing clinical trial results in children and adolescents and to those with a known history of severe allergic reaction to any component of the vaccine, and to a patient who is febrile, in an acute illness period, or has an acute attack of a chronic illness. 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	**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%	**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 23.52% of the total allocated budget for vaccination and will cover 17.86% of the 70 million target

program (viability)?	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.	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 challenges 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]* (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.	**Yes.** Noting its efficacy and effectiveness against symptomatic COVID-19 including hospitalization due COVID-19, based on current evidence, *SARS-CoV-2 Vaccine (Vero cell), Inactivated [CoronaVac]* has the potential to reduce out-of-pocket expenses of Filipino households due to averted treatment and isolation costs for mild, moderate and severe COVID-19.
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.	No revision.