Policy Question

The HTAC aims to answer the policy question:

Should ***Janssen Ad26.COV2.S (COVID-19) Vaccine*** be recommended for emergency use to reduce COVID-19 cases, severe infection, and deaths?

Recommendation *(as of 29 April 2021)*

The HTAC **recommends the emergency use of *Janssen Ad26.COV2.S (COVID-19) Vaccine*** to reduce the burden of COVID-19 among the population 18 years of age and older.

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

Criteria	HTAC Judgment
Can *Janssen Ad26.COV2.S (COVID-19) Vaccine* significantly reduce the magnitude and severity of COVID-19?	**Yes.** *Janssen Ad26.COV2.S (COVID-19) Vaccine* has the potential to reduce the disease burden by averting a significant number of symptomatic infections, moderate to severe/critical infection, severe/critical infection, and hospitalization due to COVID-19 assuming sufficient vaccine coverage.
Is *Janssen Ad26.COV2.S (COVID-19) Vaccine* efficacious and safe?	Based on interim results of published peer-reviewed Phase III trial on *Janssen Ad26.COV2.S (COVID-19) Vaccine [cut-off analysis: date: 22 January 2021)]* (Sadoff et al., 2021a): **Yes**, it is efficacious for preventing: - symptomatic *(high certainty of evidence)* - moderate to severe/ critical COVID-19 cases *(high certainty of evidence)* - hospitalization due to COVID-19 *(moderate certainty of evidence)* - severe/critical cases *(moderate 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 high certainty of evidence. Meanwhile, its long term safety outcomes cannot be determined given the short duration of observation at the time of the reports. Although vaccination appears to be associated with an extremely rare but potentially fatal thrombosis with

	thrombocytopenia syndrome (TTS), the HTAC deems the benefits far outweigh the risks. Pending stronger evidence of the association and consensus from stringent regulatory agencies, the HTAC finds no reason at this time not to recommend the use of the vaccine as approved by the FDA Philippines. However, measures against TTS must be included in all protocols for addressing adverse effects. The WHO interim recommendations for the use of this vaccine noted that a history of anaphylaxis to any component of the vaccine is a contraindication to vaccination.
Is *Janssen Ad26.COV2.S (COVID-19) Vaccine* affordable and feasible to use in a national immunization program (viability)?	**Yes.** It is affordable as the share of the population to be vaccinated using the said vaccine is highly commensurate to the share of the cost of the *Janssen Ad26.COV2.S (COVID-19) Vaccine* to the total vaccine budget. The share of the cost to implement vaccination using *Janssen Ad26.COV2.S (COVID-19) Vaccine* will constitute 4.74% of the total allocated budget for vaccination and will cover 8.57% of the 70 million target vaccinees for 2021. **Yes**, it is feasible as there are no significant barriers to vaccine implementation using *Janssen Ad26.COV2.S (COVID-19) Vaccine* in terms of storage, transport, and handling. Its one-dose requirement facilitates the completion of the vaccination schedule especially for those experiencing difficulty in returning for a second dose thereby improving compliance. In addition, the price per dose as well as the logistical and operational costs allow it to be utilized widely which can provide an opportunity to improve equitable access to COVID-19 vaccines. The non-stringent logistic requirements (i.e., 2 to 8 degrees Celsius) allows it to be utilized widely. However, we recommend that the DOH devise an efficient supply chain management that would take into account the three-month shelf life of the vaccine especially in ensuring the stability of the vaccines, from distribution up to administration to all target areas especially geographically isolated and disadvantaged areas (GIDA). Further, 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 *Janssen Ad26.COV2.S (COVID-19)*	**Yes.** Based on interim results from the clinical trials, *Janssen Ad26.COV2.S (COVID-19) Vaccine* reduces the risk

Vaccine reduce out-of-pocket (OOP) expenses of households due to COVID-19?	for any symptomatic COVID-19, moderate to severe/critical COVID-19, hospitalization due to COVID-19, and severe/critical COVID-19. Further, its 1-dose requirement also reduces possible productivity loss and other non-medical costs related to having to go back for a second dose. Thus, *Janssen Ad26.COV2.S (COVID-19) Vaccine* has the potential to reduce out-of-pocket expenses of Filipino households due to averted costs of isolation, treatment and hospitalization due to COVID-19.
Does *Janssen Ad26.COV2.S (COVID-19) Vaccine* possess the characteristics desired by key stakeholders? (Social Impact)	**Yes.** Based on short term outcomes, *Janssen Ad26.COV2.S (COVID-19) Vaccine* possesses most of the characteristics desired by key stakeholders.
Does *Janssen Ad26.COV2.S (COVID-19) Vaccine* reduce or not further add to existing inequities in the health system?	**Yes**. The non-stringent logistic requirements (ie., 2-8 degrees Celsius) allows it to be utilized widely. However, we recommend that the DOH devise an efficient supply chain management that would take into account the three-month shelf life of the vaccine especially in ensuring the stability of the vaccines, from distribution up to administration to all target areas especially geographically isolated and disadvantaged areas (GIDA).

In the development of this recommendation, the HTA Council has appraised peer-reviewed interim results of a Phase III clinical trial on *Janssen Ad26.COV2.S (COVID-19) Vaccine* (Sadoff et al., 2021a).

The HTA Council also noted the results of Phase I/II trials conducted in the US and Belgium for populations 18-55 years old and 65 years old and above.

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 and healthcare providers 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 *Janssen Ad26.COV2.S (COVID-19) Vaccine*:

- 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) 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.

Current Evidence on *Janssen Ad26.COV2.S (COVID-19) Vaccine*

The table below summarizes the appraisal of available evidence on *Janssen Ad26.COV2.S (COVID-19) Vaccine* based on the HTAC evaluation framework.

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

- Appendix 1. Evidence on evaluation criterion 2 - Clinical Efficacy and Safety
- Appendix 2. Evidence on evaluation criterion 3 - Affordability and Viability
- Appendix 3. References
- Appendix 4. Acknowledgment