Policy Question

The HTAC aims to answer the policy question:

Should **COVID-19 Vaccine (ChAdOx1-S [recombinant]) *(COVID-19 Vaccine AstraZeneca)*** be recommended for emergency use to reduce COVID-19 cases, severe infection, and deaths?

Recommendation

The HTAC **recommends the emergency use of *COVID-19 Vaccine AstraZeneca*** to reduce the burden of COVID-19 among eligible populations aged 18 years and older .

While there is insufficient direct evidence regarding efficacy and safety for ages 56 years and older based on the interim results of the Phase III trial on *COVID-19 Vaccine AstraZeneca* (Voysey et al, 2020) *[cut-off analysis: date: 04 November 2020]*, protection is expected given the immunogenicity profile seen in this age group and based on the experience of other countries with other vaccines, according to the European Medicines Agency (EMA). Using COVID-19 Vaccine AstraZeneca for the population aged 56 years and above is deemed acceptable. Further findings are expected from ongoing studies, which include a greater number of elderly participants.

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

Criteria	HTAC Judgment
Can *COVID-19 Vaccine AstraZeneca* significantly reduce the magnitude and severity of COVID-19?	**Yes**. *COVID-19 Vaccine AstraZeneca*, with 62% efficacy has the potential to reduce the disease burden by averting a significant number of symptomatic infections and deaths assuming sufficient vaccine coverage.
Is *COVID-19 Vaccine AstraZeneca* efficacious and safe?	Based on the interim results of the Phase III trial on *COVID-19 Vaccine AstraZeneca* (Voysey et al, 2020) *[cut-off analysis: date: 04 November 2020]:* **Yes**, it is efficacious for preventing symptomatic COVID-19 based on moderate certainty of evidence. COVID-19 Vaccine AstraZeneca may also reduce hospitalization due to COVID-19 based on low certainty of evidence. However, we note that the vaccine efficacy precision is low for this outcome.

	Currently, the reported vaccine efficacy of *COVID-19 Vaccine AstraZeneca* on severe COVID-19 and asymptomatic COVID-19 is still inconclusive based on 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 are inconclusive based on low certainty of evidence. 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. While vaccination is not contraindicated in other special populations who were excluded in the analysis/trials (i.e., immunocompromised patients, pregnant and lactating women), close medical supervision will be required.
Is *COVID-19 Vaccine AstraZeneca* affordable and feasible to use in a national immunization program (viability)?	**Yes.** It is affordable. The share of the cost to implement vaccination using *COVID-19 Vaccine AstraZeneca* will constitute 21.45% of the total allocated budget for vaccination and will cover 40% of the 70 million target vaccinees for 2021. **Yes**, it is feasible as there are no significant barriers in vaccine implementation using *COVID-19 Vaccine AstraZeneca* 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 *COVID-19 Vaccine AstraZeneca* reduce out-of-pocket (OOP) expenses of households due to COVID-19?	**Yes.** Based on interim *results from the clinical trial, COVID-19 Vaccine AstraZeneca showed vaccine efficacy to reduce risk for hospitalization due to COVID-19 by 87.6%, based on low certainty of evidence. Thus, COVID-19 Vaccine*

	AstraZeneca has the potential to reduce out-of-pocket expenses of Filipino households due to reduction of hospitalizations.
Does *COVID-19 Vaccine AstraZeneca* possess the characteristics desired by key stakeholders? (Social Impact)	**Yes.** Based on short term outcomes, *COVID-19 Vaccine AstraZeneca* possesses most of the characteristics desired by key stakeholders.
Does *COVID-19 Vaccine AstraZeneca* reduce or not further add to existing inequities in the health system?	**Yes.** Because of non-stringent logistic requirements, *COVID-19 Vaccine AstraZeneca* **does not aggravate** health inequities related to inoculation of recipients residing in isolated and disadvantaged locations. We also note that the trial population did not include important groups such as individuals aged 18 and below, immunocompromised individuals, pregnant and lactating women.

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 *COVID-19 Vaccine AstraZeneca*:

- 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.

Current Evidence on *COVID-19 Vaccine AstraZeneca*

The table below summarizes the appraisal of available evidence on *COVID-19 Vaccine AstraZeneca* against 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