Policy Question

The HTAC aims to answer the policy question:

Should ***COVID-19 Vaccine Moderna*** be recommended for emergency use to reduce COVID-19 cases, severe infection, and deaths?

Recommendation *(as of 28 May 2021)*

The HTAC **recommends the emergency use of *COVID-19 Vaccine Moderna*** to reduce the burden of COVID-19 among the population 18 years of age and older. However, in the future, when supply is no longer a problem, there might be a need to reassess given its relatively high cost compared to other vaccines.

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

Criteria	HTAC Judgment
Can *COVID-19 Vaccine Moderna* significantly reduce the magnitude and severity of COVID-19?	**Yes.** *COVID-19 Vaccine Moderna* has the potential to reduce the disease burden by averting a significant number of symptomatic infections, and likely severe COVID-19, assuming sufficient vaccine coverage.
Is *COVID-19 Vaccine Moderna* efficacious and safe?	Based on interim results of published peer-reviewed Phase III trial on *COVID-19 Vaccine Moderna [cut-off analysis date: 21 November 2021]* (Baden et al., 2021): **Yes**, it is efficacious for preventing symptomatic COVID-19 *(high certainty of evidence).* It is likely that the vaccine also protects against severe COVID-19 *(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. The WHO interim recommendations for the use of this vaccine noted that a history of anaphylaxis to any component of the vaccine, including polyethylene glycol, is a contraindication to vaccination and that

	should anaphylaxis occur after the first dose, the second dose of the vaccine should not be given.
Is *COVID-19 Vaccine Moderna* affordable and feasible to use in a national immunization program (viability)?	**Yes.** However, the vaccine has a relatively higher budget impact to the government compared to other vaccines. The share of the population to be vaccinated using the said vaccine is disproportionate to the share of the cost of the *COVID-19 Vaccine Moderna* in the total vaccine budget. This would entail utilization of 22.92% of the total national budget for vaccination to cover 9.29% of the target vaccinees for *COVID-19 Vaccine Moderna* for 2021. However, procurement of higher priced vaccines could address issues of low or uncertain supply. When supply is no longer a problem, there might be a need to reassess the vaccine in terms of affordability. **Yes**, it is feasible as there are no significant barriers to vaccine implementation using *COVID-19 Vaccine Moderna* in terms of storage, transport, and handling. 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 *COVID-19 Vaccine Moderna* reduce out-of-pocket (OOP) expenses of households due to COVID-19?	**Yes.** Noting its efficacy against symptomatic COVID-19 including severe COVID-19, based on current evidence, *COVID-19 Vaccine Moderna* 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 *COVID-19 Vaccine Moderna* possess the characteristics desired by key stakeholders? (Social Impact)	**Yes.** Based on short term outcomes, *COVID-19 Vaccine Moderna* possesses most of the characteristics desired by key stakeholders.
Does *COVID-19 Vaccine Moderna* reduce or not further add to existing inequities in the health system?	**Yes**. The non-stringent logistic requirements (ie., -25 to -15 degrees Celsius) allow it to be utilized widely.

In the development of this recommendation, the HTA Council has appraised the following evidence:

- Interim results of the Phase III clinical trial on *COVID-19 Vaccine Moderna* (Baden et al., 2021, US FDA Briefing Document, WHO SAGE, EMA Public Assessment Report)

- Phase I/II trials conducted in the US for populations 18 years old and above (NCT04813796: Jackson et al., 2020 and Anderson et al., 2020; NCT04405076: Chu et al., 2021).
- Real world evidence on vaccine effectiveness and safety

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 *COVID-19 Vaccine Moderna*:

- 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 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 Moderna*

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