Policy Question

The HTAC aims to answer the policy question:

Should Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) *be recommended for emergency use to reduce COVID-19 cases, severe infection, and deaths?*

Recommendation

The HTAC **recommends the emergency use of** *Pfizer-BioNTech COVID-19 Vaccine* (BNT162b2) to reduce the burden of COVID-19 among identified priority groups aged 16 years and older.

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

Criterion	HTAC Judgment
Can *Pfizer-BioNTech COVID-19 Vaccine* significantly reduce the magnitude and severity of COVID-19?	**Yes**. *Pfizer-BioNTech COVID-19 vaccine,* with 95% efficacy has the potential to reduce the disease burden by averting a significant number of symptomatic infections and deaths given sufficient vaccine coverage.
Is *Pfizer-BioNTech COVID-19 Vaccine* safe and efficacious?	**Yes**, it is efficacious for preventing symptomatic COVID-19 based on high certainty of evidence. However, at present, the reported treatment effect of *Pfizer-BioNTech COVID-19 Vaccine* on hospitalized cases due to COVID-19 is still *inconclusive* based on low certainty of evidence. Further, the current evidence on preventing severe cases remains unclear (based on effect size and certainty of evidence) to strongly conclude its benefit for this outcome 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 high certainty of evidence. As with the reported treatment effect of *Pfizer-BioNTech COVID-19 Vaccine,* the long-term safety outcomes are inconclusive based on low to very low certainty of evidence.
Is *Pfizer-BioNTech COVID-19 Vaccine* affordable and feasible to use in a national immunization program (viability)?	**Yes,** it is affordable. The share of the cost to implement the vaccination using the *Pfizer-BioNTech COVID-19 Vaccine* will constitute 31.63% of the total allocated budget for

	vaccination and will cover 30% of the 70 million target vaccinees for 2021. Yes, it is feasible despite challenges in the implementation because of logistical requirements. In addition, 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 *Pfizer-BioNTech COVID-19 Vaccine* reduce out-of-pocket (OOP) expenses of households due to COVID-19?	Based on current evidence, it is uncertain whether *Pfizer-BioNTech COVID-19 Vaccine* will reduce out-of-pocket expenses of households due to COVID-19.
Does *Pfizer-BioNTech COVID-19 Vaccine* possess the characteristics that are desired by key stakeholders? (Social Impact)	**Yes**. Based on short-term outcomes, *Pfizer-BioNTech COVID-19 Vaccine* generally possesses most of the characteristics desired by key stakeholders except for wide and equitable coverage, given the logistical requirements for this vaccine.
Does *Pfizer-BioNTech COVID-19 Vaccine* reduce or not further add to existing inequities in the health system?	**Yes.** *Pfizer-BioNTech COVID-19 Vaccine* reduces inequities due to personal (e.g., age, race/ethnicity) and clinical characteristics (e.g., presence of comorbidities). However, it does not address inequities related to geographical barriers.

Pfizer-BioNTech COVID-19 Vaccine passed the preferred 70% efficacy threshold, reducing the risk of symptomatic COVID-19 with consistent high efficacy observed across age (including 'at-risk' older adults) and groups with co-morbidities. The vaccine likewise passed specifications for short-term safety outcomes, with few reported moderate local and systemic reactions and no serious adverse events or deaths resulting from vaccination, to date. However, a longer follow-up period is needed to establish concrete evidence on the long-term safety outcomes of *Pfizer-BioNTech COVID-19 Vaccine*, duration of protection, as well as its capacity to reduce the occurrence and/or severity of COVID-19.

Though projected costs show the vaccine to be affordable, more data are needed to establish its cost-effectiveness in terms of preventing COVID-19 mortality, lowering hospitalization, and reducing the incidence of asymptomatic cases. Further, current data remains inconclusive concerning its capacity to reduce out-of-pocket expenses.

Nonetheless, the HTAC emphasizes that, based on best available evidence, the clinical benefits such as decreased symptomatic infection outweigh known short-term risks.

The HTAC 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
- 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 P*fizer-BioNTech COVID-19 vaccine*:

- Real-world effectiveness in the Philippine context particularly focused on the following:
    - Overall effectiveness in reducing COVID-19 cases, hospitalizations and deaths and in 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 and 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 other emerging SARS-CoV2 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 16 years of age
- Best practices, challenges and barriers in implementation across different localities

Current Evidence on *Pfizer-BioNTech COVID-19 Vaccine*

The table below summarizes the appraisal of available evidence on *Pfizer-BioNTech COVID-19 Vaccine* against the HTAC evaluation framework.

Further, the following appendices are provided herewith for further details on the evidence considered:

Appendix 1. Evidence for criterion 2 - Clinical Efficacy and safety
Appendix 2. Evidence for criterion 3 - Affordability and Viability
Appendix 3. References
Appendix 4. Acknowledgement

Note that a separate report for further details on the evidence for criteria *Social Impact* and *Responsiveness to Equity* shall be published.