Policy Question

The HTAC aims to answer the policy question:

Should ***Sputnik V Gam-COVID-Vac COVID-19 Vaccine (Gamaleya Sputnik V Vaccine)*** be recommended for emergency use to reduce COVID-19 cases, severe infection, and deaths?

Recommendation *(as of 12 April 2021)*

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

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

Criteria	HTAC Judgment
Can *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* significantly reduce the magnitude and severity of COVID-19?	**Yes**. *Sputnik V Gam-COVID-Vac COVID-19 Vaccine*, with 91.1% efficacy, has the potential to reduce the disease burden by averting a significant number of symptomatic infections and deaths assuming sufficient vaccine coverage.
Is *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* efficacious and safe?	Based on the interim results of the Phase III trial on *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* (Logunov et al, 2021) *[cut-off analysis: date: 24 November 2020]:* **Yes**, it is efficacious for preventing symptomatic COVID-19 based on high certainty of evidence. However, there is no reported data on the efficacy against symptomatic COVID-19 in the population with comorbidities, asymptomatic COVID-19, and hospitalization due to COVID-19. Currently, the reported evidence on vaccine efficacy of *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* against severe COVID-19 has low certainty of evidence based on a wide confidence interval and short follow-up period. 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 are inconclusive based on low certainty of evidence. It should not be given to individuals below 18 years old, to those with a known history of hypersensitivity to any component of the

	vaccine, history of severe allergic reactions, those with acute infectious and non-infectious diseases, flares of chronic diseases, and pregnant women and breastfeeding women (Ministry of Health of the Russian Federation, 2020). While vaccination is not contraindicated in other special populations, the vaccine should be used with caution in cases of the following (based on the package insert): chronic liver and kidney disease, endocrine disorders (apparent thyroid function abnormalities and diabetes mellitus in decompensation stage), serious diseases of the hematopoietic system, epilepsy and other CNS diseases, acute coronary syndrome and acute cerebrovascular event, myocarditis, endocarditis, pericarditis.
Is *Sputnik V Gam-COVID-Vac 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 vaccination using *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* will constitute 21% of the total allocated budget for vaccination and will cover 21% of the 70 million target vaccinees for 2021. According to the Department of Finance, the price of *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* offered to the Philippine government is equal to or better than the price offered to all countries outside of Russia. **Yes**, it is feasible as there are no significant barriers in vaccine implementation using *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* 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 *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* reduce out-of-pocket (OOP) expenses of households due to COVID-19?	**Yes**. Noting its efficacy against symptomatic COVID-19, based on current evidence, *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* has the potential to reduce out-of-pocket expenses of Filipino households due to averted treatment and isolation costs for mild COVID-19.
Does *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* possess the characteristics desired by key stakeholders? (Social Impact)	**Yes.** Based on short term outcomes, *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* possesses most of the characteristics desired by key stakeholders.
Does *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* reduce or not further add to existing inequities in the health	**Yes.** Because of non-stringent logistic requirements, *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* does not aggravate health inequities related to inoculation of recipients residing in isolated and disadvantaged locations. The trial population did not include important groups such as individuals aged 18 and

system?	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 *Sputnik V Gam-COVID-Vac COVID-19 Vaccine*:

- 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 *Sputnik V Gam-COVID-Vac COVID-19 Vaccine*

The table below summarizes the appraisal of available evidence on *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* 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