Rationale for updating the HTAC recommendation on *Sputnik V Gam-COVID-Vac COVID-19 Vaccine*

In lieu of evolving evidence on COVID-19, the HTAC releases its updated recommendations on the emergency use of *Sputnik V Gam-COVID-Vac COVID-19 Vaccine*.

HTAC recommendation *(as of 25 June 2021)*

Based on current evidence reviewed and presented in this updated evidence summary, the HTAC retains its recommendation supporting the emergency use of *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* to reduce the burden of COVID-19 among the population 18 years of age and older.

AMENDMENTS

The following sections in the previous HTAC ES on *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* are amended as follows:

Criteria 1: Responsiveness to magnitude and severity

1.1 Can *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* significantly reduce the magnitude and severity of COVID-19?

CURRENT EVIDENCE:

As of 02 June 2021, the total number of cases has exceeded more than 170 million cases and breached the 3.5 million mark in terms of the total number of deaths globally.

In the Philippines, the cumulative number of laboratory-confirmed COVID-19 cases has already exceeded 1,240,716 cases with total deaths reported at 21,158 as of 02 June 2021. Based on the latest DOH-Epidemiology Bureau data (as of 14 June 2021), the young and productive age groups (20-49 years old) have the most exposure and highest prevalence of the disease. However, the most vulnerable are the senior citizens (>60 years old) who have the highest case fatality rate (CFR) of 8.20% and comprise around 64% of COVID-19 deaths. In addition, individuals with existing comorbidities such as chronic kidney disease (CKD), chronic obstructive pulmonary disease (COPD), other pulmonary, cardiovascular and blood diseases are also vulnerable with CFR reported at around 13.36 to 77.85%.

HTAC JUDGMENT *1.1 Can Sputnik V Gam-COVID-Vac COVID-19 Vaccine significantly reduce the magnitude and severity of COVID-19?*	
Version 1 (as of 12 April 2021)	**Version 2 (as of 25 June 2021)**
Yes. *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* has the potential to reduce the disease burden by averting a significant number of symptomatic infections and deaths assuming sufficient vaccine coverage.	No revision.

Criterion 2: Clinical Efficacy and Safety

New supporting evidence are added on **Criterion 2 - Clinical efficacy/effectiveness and safety:**

2.1 What is the efficacy of Sputnik V Gam-COVID-Vac COVID-19 Vaccine in terms of reducing the incidence and/or severity of COVID-19 in the general and vulnerable populations?

CURRENT EVIDENCE:

CLINICAL TRIAL DATA ON EFFICACY

Evidence on efficacy remains the same.

REAL WORLD DATA ON EFFECTIVENESS

The LCPG report dated May 20, 2021 included one retrospective study among healthcare workers in Buenos Aires which used Gam-COVID-Vac in 80% of its population. As of 27 March 2021, Buenos Aires was able to administer 1,408,614 doses of COVID-19 vaccines. Of these, 486,062 were administered to healthcare workers. Sputnik V Gam-COVID-Vac COVID-19 Vaccine was used in 81% of these doses. The remaining 19% used AstraZeneca (10.3%) and Sinopharm (8.7%).

- The study of Luzuriaga (2021) noted the effectiveness of the vaccine among HCWs with a 35% decline in infection rates among the vaccinated population compared to 10% increase in infection rates among the general population during the study's observation period from March 2020 to March 27, 2021.

HTAC JUDGMENT *2.1. What is the efficacy of Sputnik V Gam-COVID-Vac COVID-19 Vaccine in terms of reducing the incidence and/or severity of COVID-19 in the general and vulnerable populations?*	
Version 1 **(as of 12 April 2021)**	**Version 2** **(as of 25 June 2021)**

Sputnik V Gam-COVID-Vac COVID-19 Vaccine passed the minimum VE threshold against symptomatic COVID-19. *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* reported a minimum median follow-up period of 27 days and vaccine efficacy of 91.1%. The reported follow-up period for the said vaccine falls short of the 2-month median follow-up after completion of full vaccination regimen as set by the HTAC to exclude any effect due to innate immunity or immediate post-vaccination neutralization antibody titers of short duration. This 2-month median follow-up period that the HTAC has set is consistent with the recommendation of WHO (2020), US FDA (2021) and other regulatory agencies. However, the HTAC accepts the short follow-up period because it deems that the 91.1% vaccine efficacy is unlikely to become lower than 50% with a longer follow-up period. Rates of disease onset were similar for the vaccine and placebo groups until about 16 to 18 days after the first dose. Thereafter, the number of cases in the vaccine group increased much more slowly than in the placebo group indicating an effect of early and sustained protection over at least 80 days (Appendix 1, Figure 1). Further, the interim results reached the target number of events to trigger an interim analysis described in the trial protocol, and was the basis for the EUA issued by the Philippine FDA.	No revision.

2.3 What are the safety issues and incidence of adverse events caused by the *Sputnik V Gam-COVID-Vac COVID-19 Vaccine*?

CURRENT EVIDENCE:

CLINICAL TRIAL DATA ON SAFETY

Evidence on efficacy remains the same.

REAL WORLD DATA ON SAFETY

The DOH-HTA Unit found one surveillance (prospective cohort) study on real world safety of *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* among healthcare workers in Buenos Aires, Argentina (last search: 15 Jun 2021).

- The study of Pagotto, et. al (preprint) (05 Feb 2021) assessed the safety of the vaccine among healthcare workers where 487 (71.3%) of the 683 HCWs experienced at least one adverse event. Among local reactions, 54% reported pain at the injection site while 11% recorded redness and swelling. Among systemic reactions, 40% had fever, 5% had diarrhea while 68% experienced new or worsened muscle pain. On the other hand, five percent had serious adverse events that required medical evaluation and one inpatient. Nevertheless, no events of special interest were observed.

Regulatory agencies and ministries of health were also searched for reports on safety of *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* after its rollout. However, as of this writing, only the Philippine FDA and Ministerio de Salud Argentina had an accessible published report. Date of the last search is June 17, 2021.

- Philippine FDA - 30,109 doses administered as of 06 June 2021
  - 239 adverse events reports
    - 2 reports were classified as serious (nature of SAE was not specified)
    - Most common adverse events were general symptoms and examinations (i.e. increase in blood pressure and increase in heart rate).
- Ministerio de Salud Argentina (as of 14 March 2021)
  - 26, 443 adverse events were reported.
  - 25, 426 (96.6%) events were related to the vaccine.
  - The most common AEs were headache and/or myalgia and/or arthralgia (33.2%) and fever with headaches and/or myalgia (38.8%).

The potential budget impact of the use of *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* to the national government to cover 15 million Filipinos was calculated at about Php 17.4 billion. It is estimated that 21.1% of the total allocated budget for vaccination will go to 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.	The potential budget impact of the use of *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* to the national government to cover 10 million Filipinos was calculated at about Php 11.36 billion. It is estimated that 13.77% of the total allocated budget for vaccination will go to 14.29% 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.

HTAC JUDGMENT *3.2. What are the budget implications of using Sputnik V Gam-COVID-Vac COVID-19 Vaccine?*	
Version 1 (as of 12 April 2021)	**Version 2 (as of 25 June 2021)**
The share of the cost of *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* to the total vaccine budget is considered proportionate to the share of the population to be vaccinated using the said vaccine.	No revision

Criterion 4: Household financial impact

Evidence on household financial impact remains the same.

Criterion 5: Social impact

The HTAC notes the additional evidence regarding the public acceptability of COVID-19 vaccines and availability of mechanisms to manage any untoward serious adverse reactions following vaccination. Other evidence considered in ES V1 for this criterion remains valid.

5.1. ***Does the Sputnik V Gam-COVID-Vac COVID-19 Vaccine possess the characteristics desired by key stakeholders (i.e. on public acceptability)?***

EVIDENCE CONSIDERED

V1 (as of 12 April 2021)	V2 (as of 25 June 2021)
6) Public acceptability - Evidence: No brand-specific study has been conducted to provide evidence for this characteristic.	**6) Public acceptability** Based on the national survey conducted by the Social Weather Station from 28 April to 02 May 2021: - 63% of the 1,200 respondents aged 18 years and above picked the United States as one of their preferred country sources of vaccines. This was followed by China which was selected by 19% of the respondents. Meanwhile, 13% of the respondents also opted for the United Kingdom, 12% included Russia, and 3% picked India as one of their preferred country sources of vaccines. The certainty of the evidence provided by published and real world data that support the favorable recommendation, if appropriately communicated, will increase public acceptability of vaccines.
7) Availability of mechanisms to compensate vaccine recipients for any untoward event following vaccination - Evidence: There has been no official issuance yet but the DOH already announced that all untoward events following vaccination shall be covered by	**7) Availability of mechanisms to manage any untoward serious adverse reactions following vaccination** - Evidence: Republic Act 11525 or the COVID-19 Vaccination Program Act of 2021 establishes the COVID-19 National Vaccine Indemnity Fund to provide funds and

PhilHealth. Likewise, Senate Bill No. 2015 was filed to establish the government vaccine indemnification program and provide funds for such.	authorize PhilHealth to pay compensation to any person inoculated through the vaccination program, in the case of death and permanent disability. In response to RA 11525, PhilHealth released PhilHealth Circular No. 2021-0007 last 17 June 2021. The circular, otherwise known as the "Implementing Guidelines on the Coverage of COVID-19 Vaccine Injury due to Serious Adverse Effects (SAEs) following immunization resulting in hospitalization, permanent disability or death under the COVID-19 National Vaccine Indemnity Fund (The COVID-19 Vaccine Injury Compensation Package), aims to provide coverage for cases of hospital confinement, permanent disability, or death due to SAEs from the use of COVID-19 vaccines administered through the COVID-19 vaccination program.

HTAC JUDGMENT *5.1. Does Sputnik V Gam-COVID-Vac COVID-19 Vaccine possess the characteristics desired by key stakeholders (i.e. on public acceptability)?*	
Version 1 (as of 12 April 2021)	**Version 2 (as of 25 June 2021)**
Based on short-term outcomes, *Sputnik V Gam-COVID-Vac COVID-19 Vaccine* possesses most of the characteristics desired by key stakeholders.	No revision.

Criterion 6: Responsiveness to equity

- Evidence on responsiveness to equity remains the same.