Rationale for updating the HTAC recommendation on *Janssen Ad26.COV2.S (COVID-19) Vaccine*

In lieu of evolving evidence on COVID-19, the HTAC releases its updated recommendations on the emergency use of *Janssen Ad26.COV2.S (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 *Janssen Ad26.COV2.S (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 *Janssen Ad26.COV2.S (COVID-19) Vaccine* are amended as follows:

Criterion 1: Responsiveness to magnitude and severity

1.1 Can the Janssen Ad26.COV2.S (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 the Janssen Ad26.COV2.S (COVID-19) Vaccine significantly reduce the magnitude and severity of COVID-19?

Version 1	Version 2
(as of 29 April 2021)	(as of 25 June 2021)
Yes. Janssen Ad26.COV2.S (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

Evidence on clinical efficacy and safety remains the same.

Criterion 3: Affordability and Viability

Costing revisions were necessary to reflect the changes in the cost of vaccine consumables, logistics, and operations. Refer to Appendix 2 for details in the costing analysis findings presented here.

3.1 Is Janssen Ad26.COV2.S (COVID-19) Vaccine affordable?

EVIDENCE CONSIDERED

Version 1 (as of 29 April 2021)

Based on the projected calculations, the total cost of rolling out vaccination with Janssen Ad26.COV2.S (COVID-19) Vaccine for 6M Filipinos in 2021 (i.e., target vaccinees for this vaccine profile identified in the vaccination roll out plan) will amount to Php 3,908,301,680.

Version 2 (as of 25 June 2021)

Based on the projected calculations, the total cost of rolling out vaccination with Janssen Ad26.COV2.S (COVID-19) Vaccine for 6M Filipinos in 2021 (i.e., target vaccinees for this vaccine profile identified in the vaccination roll out plan) will amount to Php 3,601,839,841.58.

HTAC JUDGMENT

3.1. Is Janssen Ad26.COV2.S (COVID-19) Vaccine affordable?

Version 1	Version 2
(as of 29 April 2021)	(as of 25 June 2021)
Yes. The vaccine is affordable since the budget for the purchase and use of Janssen Ad26.COV2.S (COVID-19) Vaccine for the target number of vaccinees has been allocated.	No revision.

3.2 What are the budget implications of using Janssen Ad26.COV2.S (COVID-19) Vaccine?

EVIDENCE CONSIDERED

Version 1 (as of 29 April 2021)

Version 2 (as of 25 June 2021)

The total cost of vaccination per individual, which accounts for other costs such as consumables, hauling and storage, and operations, was computed to be Php 651.38.

The potential budget impact of the use of Janssen Ad26.COV2.S (COVID-19) Vaccine to the national government to cover 6 million Filipinos was calculated at about Php 3.91B.

With 6M Filipinos to be vaccinated, it is estimated that 4.74% of the total allocated budget for vaccination will go to 8.57% of the 70 million target vaccinees for 2021.

The total cost of vaccination per individual, which accounts for other costs such as consumables, hauling and storage, and operations, was computed to be Php 600.31.

The potential budget impact of the use of Janssen Ad26.COV2.S (COVID-19) Vaccine to the national government to cover 6 million Filipinos was calculated at about Php 3.6B.

With 6M Filipinos to be vaccinated, it is estimated that 4.37% of the total allocated budget for vaccination will go to 8.57% of the 70 million target vaccinees for 2021.

HTAC JUDGMENT

3.2. What are the budget implications of using the Janssen Ad26.COV2.S (COVID-19) Vaccine?

Version 1 (as of 29 April 2021)	Version 2 (as of 25 June 2021)
The share of the population to be vaccinated using the said vaccine is highly commensurate to the share of the cost of the <i>Janssen Ad26.COV2.S</i> (COVID-19) Vaccine to the total vaccine budget	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 Janssen Ad26.COV2.S (COVID-19) possess the characteristics desired by key stakeholders (i.e. on public acceptability)?

EVIDENCE CONSIDERED

V1 (as of 29 April 2021)

6) Public acceptability

 Evidence: No brand-specific study has been conducted to provide evidence for this characteristic. V2 (as of 25 June 2021)

6) Public acceptability

Based on the <u>national survey</u> 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 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 PhilHealth. Likewise, Senate Bill No. 2015 was filed to establish the government vaccine indemnification program and provide funds for such.

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 COVID-19 establishes the National Vaccine Indemnity Fund to provide funds and PhilHealth to authorize compensation to any person inoculated through the vaccination program, in the case and of death 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 Vaccine COVID-19 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 the Janssen Ad26.COV2.S (COVID-19) possess the characteristics desired by key stakeholders (i.e. on public acceptability)?

Version 1	Version 2
(as of 29 April 2021)	(as of 25 June 2021)
Based on short-term outcomes, Janssen Ad26.COV2.S (COVID-19) possesses most of the characteristics desired by key stakeholders.	No revision.

Criterion 6: Responsiveness to equity

• Evidence on responsiveness to equity remains the same.