	active immunization against SARS-CoV-2 Virus infection for age ≥18years.
WHO EUL status	EUL granted on November 3, 2021

The package insert is available via: https://www.fda.gov.ph/wp-content/uploads/2021/04/COVAXIN-Product-Info.pdf

Pursuant to the role of the Health Technology Assessment Council (HTAC) to develop coverage recommendations particularly in the selection and financing of COVID-19 vaccines for the COVID-19 Vaccine Implementation for 2022, this assessment follows the HTAC evaluation framework to assess COVID-19 vaccines using the following criteria: (1) responsiveness to magnitude and severity; (2) clinical efficacy and safety; (3) affordability and viability; (4) household financial impact; (5) social impact; and (6) responsiveness to equity.

Policy Question

The HTAC aims to answer the policy question:
Should the DOH use ***Covaxin* as primary homologous vaccination** in the 2022 COVID-19 Vaccination Program to reduce COVID-19 cases, severe infection, and deaths.

Recommendations *(as of 29 November 2021)*

The HTAC recommends the inclusion of *Covaxin* in the Philippine National Deployment and Vaccination Plan for COVID-19 Vaccines for the general population aged 18 years and above, given that it has passed the safety, efficacy and other criteria of HTAC and provided that there is sufficient budget to cover its implementation after pending supply negotiations for 2022.

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

Criterion	HTAC Judgment
Can Covaxin significantly reduce the magnitude and severity of COVID-19 in the general population?	**Yes**. *Covaxin* has the potential to reduce the disease burden by averting a significant number of symptomatic infections assuming sufficient vaccine coverage.
Is Covaxin safe and efficacious for the general population?	**Yes.** Covaxin passed the preferred vaccine efficacy threshold against symptomatic COVID-19 and severe COVID-19 for the general population aged 18 years and older up to at least 14 days after dose 2 based on Phase III RCT with moderate to high certainty of evidence. In addition, based on real world evidence, Covaxin showed low rates of breakthrough infections (2.2%) among healthcare workers at around one month after dose 2 (Singh et al. 2021). Covaxin also induced immune response in the general population at 1-2 months (56 days) after dose 2 (Ella et al. 2021). Covaxin also passed the preferred vaccine efficacy threshold against symptomatic COVID-19 caused by the Delta variant for the general population aged 18 years and older based on the existing clinical trial (Ella et al.

	2021). Real world evidence also showed that Covaxin can potentially reduce the odds of any SARS-CoV-2-infection, COVID-19 hospitalization, and COVID-19 deaths caused by the Delta variant compared to no vaccination (Battacharya et al. 2021). More data are needed for assessing vaccine effectiveness among healthcare workers. Short-term safety of Covaxin is acceptable. However, further follow-up data is needed to establish longer-term safety. Covaxin passed the benefit risk profile assessment in the general population based on efficacy, effectiveness and short term safety data.
Is Covaxin affordable and feasible to use in a national immunization program for the general population?	The affordability of *Covaxin* cannot be assessed currently due to the lack of information on allocated budget and indicative volumes. The health, economic, and social benefits of using Covaxin may mitigate the negative impacts of COVID-19, such as deaths, medical costs, loss of productivity, social disruption and unprecedented challenges in the health system.
Does Covaxin reduce out-of-pocket (OOP) expenses of households due to COVID-19?	**Yes.** Based on current evidence, *Covaxin* has the potential to reduce out-of-pocket expenses in the general population due to averted costs of isolation and treatment of mild, moderate, and severe COVID-19.
Does Covaxin possess the characteristics that are desired by key stakeholders?	**Yes**. Based on short-term outcomes, Covaxin possesses most of the characteristics desired by key stakeholders for its use among the general population 18 years and above.
Does Covaxin reduce or not further add to existing inequities in the health system?	**Yes.** Because of its non-stringent logistic requirements, *Covaxin* does not aggravate health inequities related to inoculation of recipients residing in isolated and disadvantaged locations. However, the trial population also did not include important vulnerable groups such as individuals with impaired immune systems, and pregnant and lactating women. Further, real world studies did not perform subgroup analysis of *Covaxin's* effectiveness in these vulnerable groups.

In the development of this recommendation, the HTA Council has appraised and considered the evidence review of the Philippine COVID-19 Living Clinical Practice Guidelines Group on the following sub-themes of evidence on COVID-19 vaccines:

- Efficacy, effectiveness and safety to the general population
- Efficacy and effectiveness against variants of concern in the general population

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

Finally, the HTAC recommends the conduct of research to address the current gaps in evidence with regard to the use of the *Covaxin*:

- 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 other 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 *Whole Virion, Inactivated, Corona Virus Vaccine (Covaxin)*

The table below summarizes the appraisal of available evidence on *Covaxin* based on the HTAC evaluation framework.

In addition, the following appendices are provided for further details:

- Appendix 1: Links to LCPG Report on Clinical Efficacy, Effectiveness and Safety of *Covaxin*
- Appendix 2: LCPG RoB Appraisal Tool for Observational Studies
- Appendix 3: GRADE Tables
- Appendix 4: RoB Assessment of Studies from COVID-NMA