Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

01 October 2021

HON. FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

Dear Secretary Duque:

Greetings!

By virtue of Republic Act 11223, otherwise known as the Universal Health Care (UHC) Act, health technology assessment (HTA) shall be institutionalized as a fair and transparent priority-setting mechanism to provide financing and coverage recommendations on health technologies to be funded by the Department of Health (DOH) and the Philippine Health Insurance Corporation (PhilHealth).

In light of the public health emergency, the Health Technology Assessment Unit (HTAU) has been reviewing COVID-19 technologies, including COVID-19 vaccines. In line with the procurement plans of the government for the National COVID-19 Vaccination Program for the 2022 implementation, the Health Technology Assessment Council (HTAC) respectfully submits **its recommendations on pediatric vaccination** of the following COVID-19 vaccines:

- Pfizer-BioNTech COVID-19 vaccine
- COVID-19 Vaccine Moderna
- COVID-19 Vaccine AstraZeneca
- SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac]
- Janssen Ad26.COV2.S (COVID-19) Vaccine

The **HTAC maintains its recommendation to use Pfizer-BioNTech COVID-19 Vaccine among adolescents aged 16 to 17 years** and **extends this recommendation for use in children aged 12 to 15 years.** Also, HTAC recommends **extending the use of COVID-19 Vaccine Moderna among children aged 12 to 17 years.** Moreover, HTAC recommends **compliance to standard vaccination program protocols** in introducing vaccines for children with only Emergency Use Authorization (EUA).

Furthermore, this recommendation shall be revisited to possibly include children younger than 12 years old once data for this age group becomes available.

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On the other hand, **HTAC does not currently recommend the use of AstraZeneca, CoronaVac, and Janssen among children and adolescents** (12 to 17 years old) due to current limited clinical evidence on their use in the pediatric population.

The criteria considered by HTAC in crafting its recommendations for pediatric vaccination as well as the summary of evidence are shown in the annex of this letter.

We thank you for the opportunity to be of assistance to the Department of Health.

Respectfully yours,

For the Health Technology Assessment Council (HTAC):

Marita V. T- Reyes

MARITA V. TOLENTINO-REYES, MD
Chair, HTAC

Approval of the HTAC Recommendation:

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

CC: Undersecretary Charade B. Mercado-Grande
Undersecretary Maria Rosario Singh-Vergeire

Annex A: HTAC Criteria Judgments and Evidence Considered Per COVID-19 Vaccine Brand

Domain	Pfizer-BioNTech COVID-19 Vaccine	COVID-19 Vaccine Moderna	COVID-19 Vaccine AstraZeneca	SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac]	Janssen Ad26.COV2.S (COVID-19) Vaccine
HTAC Recommendation for emergency use for the different vaccines	The HTAC recommends the use of Pfizer-BioNTech among children aged 12 to 15 years. This recommendation shall be revisited to possibly include children younger than 12 years old once data for this age group becomes available. The HTAC further recommends compliance to standard vaccination program protocols in introducing vaccines for children with only an EUA.	The HTAC recommends the use of Moderna among children aged 12 to 17 years. This recommendation shall be revisited to possibly include children younger than 12 years old once data for this age group becomes available. The HTAC further recommends compliance to standard vaccination program protocols in introducing vaccines for children with only an EUA.	Due to current limited clinical evidence and lack of Philippine FDA-issued EUA for the use of these vaccines for the pediatric population, the HTAC does not currently recommend AstraZeneca, CoronaVac, and Janssen for populations below 18 years.		
Can it significantly reduce the magnitude and severity of COVID-19 in the pediatric population?	**Yes**, COVID-19 Vaccines have the potential to reduce the disease burden by averting a significant number of infections in the pediatric population (12 to less than 18 years old) including symptomatic and severe COVID-19 assuming sufficient vaccine coverage. The efficacy has not been studied among children < 12 years old.		Cannot be assessed due to limited evidence.		

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Is it efficacious and safe?	**Efficacy/ Effectiveness** **Yes.** *Pfizer-BioNTech* passed the preferred vaccine efficacy threshold against symptomatic COVID-19 and severe COVID-19 for the pediatric population aged 12-15 years old (Frenck et al., 2021), based on moderate certainty of evidence. Immunogenicity data on adolescents aged 12 to 15 years also demonstrated noninferiority when compared with young adults aged 16 to 25 years old. Current real-world studies (Bickel et al.; Seigel et al.; Delahoy et al., Gargano et al.; Public Health England) suggest its potential clinical benefits in terms of symptomatic	**Efficacy/ Effectiveness** **Yes.** *Moderna* has passed the preferred vaccine efficacy threshold against symptomatic COVID-19 for the pediatric population aged 12 to 17 years old (Ali et al., 2021), based on moderate certainty of evidence. Immunogenicity data on adolescents also demonstrated noninferiority when compared with young adults aged 18 to 25 years old. Real-world effectiveness of *Moderna* in the pediatric population cannot be assessed due to lack of data.	**Efficacy/ Effectiveness** Currently, there is limited evidence on the efficacy and effectiveness of *AstraZeneca* in the pediatric population aged 18 years and below.	**Efficacy/ Effectiveness** Currently, there is limited evidence on the efficacy of *CoronaVac* in the pediatric population. However, there is currently available evidence limited to one immunogenicity trial (Han et al. 2021). It showed that *CoronaVac* was deemed highly immunogenic in children aged 3 to 17 years old, with geometric mean titers generally higher than adults aged 18 years and older. Further studies are anticipated to strongly conclude its evidence for efficacy and effectiveness for the pediatric population aged 18 years and below.	**Efficacy/ Effectiveness** Currently, there is limited evidence on the efficacy and effectiveness of *Janssen* in the pediatric population aged 18 years and below.

	COVID-19, moderate to severe COVID-19, and hospitalization due to COVID-19.				
	Efficacy/ Effectiveness against Variants **Yes.** Real-world evidence in individuals aged 16 and older across 4 studies [Lopez Bernal et al. (UK); Nasreen et al. (Canada); Dagan et al. (Israel); Barlow et al. (US)] showed that *Pfizer-BioNTech* passed the vaccine effectiveness in preventing symptomatic COVID-19 caused by Delta, Alpha, Beta, and Gamma variants. However, an Israel MOH report showed that it did not pass the minimum VE for symptomatic COVID-19 caused by the Delta variant. Another US study (Griffin et al.), although it did not report vaccine	**Efficacy/ Effectiveness against Variants** **Yes.** Real-world evidence in individuals aged 16 and older in one study [Nasreen et al. (Canada)] showed that *Moderna* passed vaccine effectiveness against symptomatic COVID-19 caused by Alpha and Delta variants. One real-world study in Canada (Nasreen et al.) showed that the vaccine also passed the minimum VE against severe COVID-19 caused by Alpha and Delta variants. We noted that these studies evaluating effectiveness against variants of concern included both children and adults.	**Efficacy/ Effectiveness against Variants** Currently, there is limited evidence on the efficacy and effectiveness of *AstraZeneca* against variants of concern in the pediatric population aged 18 years and below.	**Efficacy/ Effectiveness against Variants** While there are countries using this vaccine for the pediatric population (e.g., Chile, China, Indonesia), there are no available reports on efficacy and effectiveness against variants of concern detected from these countries. Moreover, the trial of *CoronaVac* on the pediatric population did not evaluate its efficacy against variants of concern.	**Efficacy/ Effectiveness against Variants** Currently, there is limited evidence on the efficacy and effectiveness of *Janssen* against variants of concern in the pediatric population aged 18 years and below.

	effectiveness, showed a decrease in rates of infection caused by the Delta variant in fully vaccinated individuals compared to partially vaccinated and unvaccinated individuals. Israel MOH report showed that *Pfizer-BioNTech* passed the VE against severe COVID-19 caused by the Delta variant. Meanwhile, one real-world study in Canada (Nasreen et al. 2021), showed that the vaccine also passed the minimum VE against severe COVID-19 caused by the Alpha variant but failed against severe COVID-19 caused by the Delta variant. We noted that these studies evaluating effectiveness against variants of concern included both children and adults.				

	Safety **Yes.** Based on the current evidence from the phase III clinical trial with high certainty of evidence (Frenck et al.) and real-world safety reports (Hause et al., 2021, Bicket et al.), the short-term safety of *Pfizer-BioNTech* for the pediatric population (12 to 15 years old) is acceptable. However, further follow-up data are needed to establish longer-term safety. Despite the rare cases of myocarditis and pericarditis that have been reported following vaccination of young adults with the Pfizer-BioNTech (Pepe et al., Lane et al.), the benefits still outweigh the risks for vaccination in this population.	**Safety** **Yes.** Based on the current evidence from the phase III clinical trial with high certainty of evidence (Ali et al), the short-term safety of *Moderna* for the pediatric population (12 to 17 years old) is acceptable. However, further follow-up data are needed to establish longer-term safety. Despite the rare cases of myocarditis and pericarditis that have been reported following vaccination of young adults with the *Moderna* (Pepe et al., Lane et al.), the benefits still outweigh the risks for vaccination in this population.	**Safety** Currently, there is limited evidence on the overall safety of *AstraZeneca* for children and adolescents below 18 years.	**Safety** Currently, there is limited evidence on the safety of *CoronaVac* for the pediatric population. Current available evidence from the Phase I/II trial shows that short-term safety in children and adolescents aged 3 to 17 years old was found to be similar to the adult population. Further studies are anticipated to strongly conclude on its safety for this age group.	**Safety** Currently, there is limited evidence on the overall safety of *Janssen* in children and adolescents aged below 18 years old.

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Is it affordable and feasible to use in a national immunization program?	**Yes, vaccinating children and adolescents aged 12 to 17 years using Pfizer and Moderna is affordable.** According to the DOF, the supply of Pfizer-BioNTech and Moderna procured in 2021 are sufficient to vaccinate the pediatric population aged 12 to 17, thus, its implementation will not incur an additional cost from the 2022 budget.		Affordability was not assessed for these brands due to limited clinical evidence in the pediatric population. Further, these vaccines currently do not have EUA for the pediatric population.		
	Yes, vaccinating children and adolescents aged 12 to 17 years using Pfizer and Moderna is feasible. Although the implementation was generally challenging due to the intricacies in the storage, handling, and preparation of these vaccines, the NVOC implemented measures and ensures proper training and preparation prior to the rollout to mitigate these challenges.		Feasibility was not assessed for these brands due to limited clinical evidence in the pediatric population. Further, these vaccines currently do not have EUA for the pediatric population.		
Does it reduce out-of-pocket expenses of households due to COVID-19?	**Yes.** Based on current evidence, the COVID-19 Vaccine has the potential to reduce out-of-pocket expenses of Filipino households due to averted costs of isolation and treatment of mild, moderate, and severe COVID-19.		Out-of-pocket expenses were not assessed for these brands due to limited clinical evidence in the pediatric population. Further, these vaccines currently do not have EUA for the pediatric population.		

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Does it possess characteristics desired by key stakeholders?	**Yes.** *Pfizer-BioNTech* and *Moderna* have been issued an EUA by the FDA Philippines for the pediatric population. Results of a survey conducted by the DOH-HPB on the acceptability of the pediatric population showed that COVID-19 vaccination is acceptable to adolescents (12 to 17 years old). Another survey administered by a US-based University suggests that vaccinating children against COVID-19 is acceptable to parents of children and adolescents below 18 years old. However, as it is an online survey, the study had limitations in terms of representativeness of the study population, i.e. lack of representation of the population without internet access. Meanwhile, we noted that the program implementers foresee additional challenges and complexity to the current COVID-19 vaccination implementation by expanding it to the pediatric population, i.e. the need for additional human and logistical resources to accommodate the pediatric population. The assurance of meeting all public health measures to students, teachers, and other school personnel is an important consideration in the reopening of schools .		**No.** AstraZeneca, CoronaVac, and Janssen have not yet received an EUA from the Philippine FDA for the pediatric population.		

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Does it reduce or not further add to existing inequities in the health system?	**Yes, pediatric vaccination will reduce inequities in the health system,** assuming that the decision to vaccinate children is made in consultation with stakeholders, and pediatric vaccination shall be rolled out following the country's prioritization criteria, cognizant of the following**:** ● Burden of COVID-19 to the pediatric population, especially those with comorbidities; ● Sufficient supply to cover the pediatric population per DOF		Not assessed for this domain for these brands due to limited clinical evidence in the pediatric population. Further, these vaccines currently do not have EUA for the pediatric population.		