## Rationale on updating the HTAC recommendation on *Pfizer-BioNTech COVID-19 Vaccine (BNT162b2)*

In lieu of evolving evidence on COVID-19, the HTAC hereby releases its updated recommendations on the emergency use of *Pfizer-BioNTech COVID-19 Vaccine (BNT162b2).*

Further, on 28 May 2021, the Philippine FDA has granted an amended EUA to Pfizer Inc, Philippines on *Pfizer-BioNTech COVID-19 Vaccine (BNT162b2)* to include individuals 12 years of age and older in its indication for active immunization for the prevention of COVID-19 caused by SARS-CoV-2.

The table below summarizes the EUA amendments on the details of *Pfizer-BioNTech COVID-19 Vaccine (BNT162b2):*

| Details | EUA issued 14 January 2021 | Amended EUA issued 28 May 2021 |
|---|---|---|
| **Indication** | For active immunization for the prevention of COVID-19 caused by SARS-CoV-2 in *individuals 16 years of age and older* | For active immunization for the prevention of COVID-19 caused by SARS-CoV-2 in *individuals 12 years of age and older* |
| **Packaging** | 195 multiple dose vials<br>(after dilution each vial contains 5 doses of 0.3 mL) | 25 and 195 multiple dose vials<br>(after dilution each vial contains 6 doses of 0.3 mL) |
| **Manufacturer** | Pfizer Manufacturing Belgium NV - Puurs, Belgium | Pharmacia and Upjohn Company LLC, Kalamazoo, Michigan USA |

Given its expanded population, the vaccine remains as a 2-dose regimen administered intramuscularly 3 weeks apart. The vaccines should be stored -80 to -60 degrees Celsius prior to dilution.

## AMENDMENTS

The following sections in the previous HTAC ES on *Pfizer-BioNTech COVID-19 Vaccine (BNT162b2)* are amended as follows:

| **Version 1**<br>***(as of 02 February 2021)*** | **Version 2**<br>***(as of 25 June 2021)*** |
|---|---|
| The HTAC recommends the emergency use of *Pfizer-BioNTech COVID-19 Vaccine (BNT162b2)* to reduce the burden of COVID-19 among identified priority groups aged 16 years and older. | **The HTAC maintains its recommendation for the emergency use of *Pfizer-BioNTech COVID-19 Vaccine (BNT162b2)* to reduce the burden of COVID-19, based on updated evidence review.**<br><br>The HTAC recognizes that *Pfizer-BioNTech COVID-19 Vaccine (BNT162b2)* is likely to give protection against COVID-19 and has an acceptable short term safety among population aged 12 to 15 years old. However, given the current global limitation in vaccine supply, **the HTAC maintains its recommendation among identified priority groups aged 16 years and older only**.<br><br>This is also aligned with the WHO SAGE Roadmap for Prioritizing Use of COVID-19 Vaccines in the Context of Limited Supply dated 13 November 2021 (which guides our national vaccination prioritization plan) to prioritize high vaccine coverage in the high-risk populations before proceeding to vaccination of children and adolescents who are at low-risk of severe disease.<br><br>Once supply limitations are resolved and high vaccination coverage is achieved for higher priority groups, this recommendation may be revised to expand to the younger population. |

## Summary of HTAC judgement and considerations in formulating its recommendation for the vaccine:

| Criterion | HTAC Judgment | |
|---|---|---|
| | **Version 1** ***(as of 02 February 2021)*** | **Version 2** ***(as of 25 June 2021)*** |
| *Can Pfizer-BioNTech COVID-19 Vaccine significantly reduce the magnitude and severity of COVID-19?* | *Yes. Pfizer-BioNTech COVID-19* Vaccine, with 95% efficacy has the potential to reduce the disease burden by averting a significant number of symptomatic infections and deaths given sufficient vaccine coverage. | *Yes. Pfizer-BioNTech COVID-19 Vaccine* has the potential to reduce the disease burden among 16 years and older by averting a significant number of symptomatic infections and deaths given sufficient vaccine coverage. It is also likely to give protection among adolescents aged 12-15 years old. |
| *Is Pfizer-BioNTech COVID-19 Vaccine safe and efficacious?* | Yes, it is efficacious for preventing symptomatic COVID-19 based on high certainty of evidence. However, at present, the reported treatment effect of Pfizer-BioNTech COVID-19 Vaccine on hospitalized cases due to COVID-19 is still inconclusive based on low certainty of evidence.<br><br>Further, the current evidence on preventing severe cases remains unclear (based on effect size and certainty of evidence) to strongly conclude its benefit for this outcome based on low certainty of evidence. The duration of protection cannot be assessed given the current data.<br><br>Yes, it is safe in the known short-term safety outcomes, based on high certainty of evidence. As | Based on the interim results of the additional Phase 1-2-3 trial on *Pfizer-BioNTech COVID-19 Vaccine* (Frenck et al. 2021) for adolescents aged 12-15 years old *[cut-off analysis date: 13 March 2021]:*<br><br>**Yes**, it is likely efficacious for preventing symptomatic COVID-19 among adolescents aged 12-15 years old, based on moderate certainty of evidence. Further, immunogenicity data on adolescents demonstrated noninferiority when compared with young adults aged 16 to 25 years old.<br><br>Currently, there were no reported vaccine efficacy of *Pfizer-BioNTech COVID-19 Vaccine* among adolescents aged 12-15 years old against symptomatic COVID-19 with comorbidities, symptomatic COVID-19 among Asians, hospitalization due to COVID-19, death due to |

| | | |
|---|---|---|
| | with the reported treatment effect of Pfizer-BioNTech COVID-19 Vaccine, the long-term safety outcomes are inconclusive based on low to very low certainty of evidence. | COVID-19, asymptomatic COVID-19, and new COVID-19 variants.<br><br>The duration of protection cannot be assessed given the current data.<br><br>**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.<br><br>On the other hand, there are no updated published Phase III interim results for the efficacy and safety of *Pfizer-BioNTech COVID-19 Vaccine* among 16 years of age and older; however, based on real-world effectiveness data, the vaccine demonstrated clinical benefits in reducing risk of symptomatic COVID-19, severe COVID-19, hospitalization due to COVID-19, death due to COVID-19, asymptomatic COVID-19, and against new COVID-19 variants among 16 years of age and older. |

| | | |
|---|---|---|
| Is Pfizer-BioNTech COVID-19 Vaccine affordable and feasible to use in a national immunization program (viability)? | Yes, it is affordable.<br><br>The share of the cost to implement the vaccination using the *Pfizer-BioNTech COVID-19* Vaccine will constitute 31.63% of the total allocated budget for vaccination and will cover 30% of the 70 million target vaccinees for 2021.<br><br>Yes, it is feasible despite challenges in the implementation because of logistical requirements. In addition, there is still a need for training of vaccinators to ensure product integrity across the entire supply chain and close monitoring of adverse events. | **Yes.** It is affordable. The share of the cost to implement vaccination using *Pfizer-BioNTech COVID-19 Vaccine* will constitute 27.40% of the total allocated budget for vaccination and will cover 28.57% of the 70 million target vaccinees for 2021.<br><br>The HTAC notes that there are significant challenges in vaccine implementation using *Pfizer-BioNTech COVID-19 Vaccine* in terms of storage, transport, and handling. Similar to other vaccines, there is still a need for training to: ensure product integrity across the entire supply chain; and, close monitoring of adverse events with emphasis on medical supervision and management on special populations. |
| *Does Pfizer-BioNTech COVID-19 Vaccine reduce out-of-pocket (OOP) expenses of households due to COVID-19?* | Based on current evidence, it is uncertain whether Pfizer-BioNTech COVID-19 Vaccine will reduce out-of-pocket expenses of households due to COVID-19. | **Yes.** Based on interim results from the clinical trials, *Pfizer-BioNTech COVID-19 Vaccine* showed vaccine efficacy to reduce risk for symptomatic COVID-19 among 12 years old and older.<br><br>Thus, *Pfizer-BioNTech COVID-19 Vaccine* has the potential to reduce out-of-pocket expenses of Filipino households due to averted costs of isolation and treatment due to COVID-19. |
| *Does Pfizer-BioNTech COVID-19 Vaccine possess the characteristics that are desired by key stakeholders?* | Yes. Based on short-term outcomes, Pfizer-BioNTech COVID-19 Vaccine generally possesses most of the characteristics desired by key stakeholders except for wide and equitable coverage, given the logistical requirements for this vaccine. | No revision. |

| | | |
|---|---|---|
| *Does Pfizer-BioNTech COVID-19 Vaccine reduce or not further add to existing inequities in the health system?* | Yes. Pfizer-BioNTech COVID-19 Vaccine reduces inequities due to personal (e.g., age, race/ethnicity) and clinical characteristics (e.g., presence of comorbidities). However, it does not address inequities related to geographical barriers. | No revision. |

The following sections describe the additional evidence considered in this updated HTAC recommendation.