CALL FOR STAKEHOLDER COMMENTS ON THE PRELIMINARY RECOMMENDATION OF THE HEALTH TECHNOLOGY ASSESSMENT (HTA) COUNCIL ON TETANUS, DIPHTHERIA, AND ACELLULAR PERTUSSIS (Tdap) VACCINE AS BOOSTER IMMUNIZATION AGAINST TETANUS, DIPHTHERIA, AND PERTUSSIS FOR GRADE 1 STUDENTS (6-7 years old), GRADE 7 STUDENTS (11-12 years old) AND PREGNANT WOMEN

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As of 02 May 2025, the Health Technology Assessment (HTA) Council has completed the evidence appraisal on the assessment of **Tetanus, Diphtheria, and Acellular Pertussis (Tdap) Vaccine as booster immunization against tetanus, diphtheria, and pertussis for Grade 1 students (6-7 years old), Grade 7 students (11-12 years old) and pregnant women** for possible government financing. **The HTA Council hereby releases its preliminary recommendation on the said health technology for stakeholder feedback and comments from 02 May (Friday) to 19 May (Monday) 2025**.

The population, intervention, and comparator (PIC) set by the HTA Council for the said evaluation are shown in the table below, for your reference:

Population	Grade 1 students (6-7 years old), Grade 7 students (11-12 years old) and pregnant women
Intervention	Tetanus, Diphtheria, and Acellular Pertussis (Tdap) Vaccine as booster immunization
Comparator	Tetanus Diphtheria (Td) Vaccine

Currently, the National Immunization Program (NIP) rolls out the pentavalent vaccine (DPT-HepB+Hib) as a primary series vaccine which gives protection against five diseases including diphtheria, tetanus, and pertussis. For the booster dose, the NIP currently implements the Td vaccine for Grade 1 and Grade 7 students as part of the school-based immunization program, and for pregnant women. While Td vaccine offers continued protection against diphtheria and tetanus, it does not provide immunity against pertussis. In response to the 2024 pertussis outbreak, the Department of Health (DOH) has identified the need to introduce a booster dose specifically targeting pertussis. The Tdap vaccine, which is the only available booster providing pertussis protection for older children >7 years old, adolescents, and pregnant women, was proposed by the DOH as a replacement for Td vaccine to expand disease coverage for the same target population.

As a preliminary recommendation, the HTA Council does not recommend the government financing of Tdap vaccine at this time given that the primary series coverage is still low (less than the WHO recommendation of 90%) **and that there is insufficient NIP budget to cover the shift from Td vaccine to Tdap vaccine.** In order to fully realize the protective benefits of Tdap

vaccine, the HTA Council recommends to prioritize improving the primary series coverage and allocating sufficient financial resources for Tdap vaccine implementation, before considering the shift from Td vaccine to Tdap booster vaccination program.

This HTA Council preliminary recommendation draws from the following evidentiary bases:

- **Burden of the disease**
  Tetanus, diphtheria and pertussis are serious vaccine-preventable infectious diseases. Among the vaccine-preventable infectious diseases in the Philippines, the DOH Field Health Services Information System (FHSIS) Annual Reports from 2018-2023 provided the following local epidemiological data:
    - **Tetanus** - The total number of reported cases decreased from 730 in 2019 to 158 in 2020. However, cases increased to 302 in 2021, then declined again to 238 in 2022 and 130 in 2023. The highest number of cases were observed among the 15–49 years old, 1–4 years old, and 5–9 years old age groups. The FHSIS did not report data on deaths from 2018 to 2023.
    - **Diphtheria** - Reported diphtheria cases increased from 86 in 2019 to 189 in 2020. From 2020 to 2022, cases declined to 90, but increased again to 250 in 2023. Cases were most frequent among the 15–49 years old, 1–4 years old, and 5–9 years old age groups. The FHSIS did not report data on deaths from 2018 to 2023.
    - **Pertussis** - The total number of reported pertussis cases declined from 2018 to 2023, with the highest incidence in the 15–49 years old, 1–4 years old, and 5–9 years old age groups. Although the DOH has not yet posted the official number of pertussis cases for 2024, outbreaks were declared in several cities and provinces, including Quezon City, Iloilo, and Cavite (UNICEF, 2024; PhilStar, 2024). While the FHSIS did not report data on deaths due to pertussis, case-based surveillance from the Philippine Integrated Disease Surveillance and Response (PIDSR) showed a decrease in pertussis-related deaths from 2018 to 2021, followed by a sharp increase from 2 deaths in 2022 to 48 deaths in 2023.

- **Relevant Recommendations/Guidelines**
    - Each component of Tdap (tetanus, diphtheria, pertussis) vaccine is listed in the WHO EML and recommended by the WHO for Expanded Program on Immunization (EPI) program. However, the Tdap combination vaccine is not included in the WHO EML (removed in 1999) to avoid unduly complicating the list as advised by the WHO Department of Vaccines and Biologicals, since various combination products are intended for different groups of people.
    - The 2015 World Health Organization (WHO) statement that high coverage (≥90%) of routine immunization in infants must be in place prior to the introduction of pertussis booster vaccination of adolescents and adults.
        - The main aim of pertussis vaccination is to reduce the risk of severe pertussis in infants and young children, due to the high morbidity and mortality caused by the disease in this age group. All children worldwide should be immunized against pertussis. Every country should seek to achieve early and timely vaccination initiated at 6 weeks and no later than 8 weeks of age, and maintain high coverage (≥90%) with at least 3 doses of assured quality pertussis vaccine at all levels (national and subnational). A high vaccination coverage using a whole-cell pertussis wP type of primary series (i.e., pentavalent vaccine) is needed before implementing a Tdap booster which contains aP antigen, since wP type of primary series establishes a robust immune response compared to a more rapidly waning immunity from aP vaccinations.

- Data from FHSIS annual reports (2018-2024) and NIP data for 2024 (communications) indicate that the full vaccination coverage of the primary series (Dose 1 to Dose 3) of DTP-containing vaccines has remained below this threshold (≥90%), ranging only from 58.27% to 78.02% during the said period.

- The WHO (2024) suggests vaccination of pregnant women with one dose of Tdap vaccine (in the 2nd or 3rd trimester and preferably at least 15 days before the end of pregnancy) as a strategy additional to routine primary infant pertussis vaccination in countries with high or increasing infant mortality/morbidity from pertussis.
- In addition, multiple clinical practice guidelines recommend booster vaccination against tetanus, diphtheria and pertussis across the target populations, provided that individuals have completed the primary series with DTP-containing vaccines:
  - **Children (covers Grade 1 students ages 6-7 yo):**
    - The PHEx: Pediatric Immunization (2023) recommends: (a) pertussis-containing vaccine booster for children who completed the Diphtheria-Tetanus-Pertussis- (DTP) primary series; (b) tetanus toxoid-containing vaccine booster for infants and children who completed a 3-dose primary series of tetanus toxoid-containing vaccine
    - The PIDSP (2025) recommends the following routine vaccination schedule: (a) 1 dose Tdap vaccine (considered as 3rd booster for DTP) for ages 7-18 years old; (b) Tdap booster doses every 10 years for those who have completed their DTP doses (If Tdap vaccine is not available, Td vaccine can be given).
    - The DOH OHG for Children (2023) recommends Tdap vaccine as a booster for ages 9-15. However, DOH is considering revising the OHG to expand the target population up to Grade 1 students (6-7 years old.
  - **Adolescents (cover Grade 7 students ages 11-12 yo):**
    - The PHEx (2023) recommends a pertussis vaccine booster for adolescents after completing the Diphtheria-Pertussis-Tetanus (DPT) primary series.
    - The DOH OHG for Adolescents (2023) recommends Tdap vaccine as a booster for ages 9-15.
    - The PIDSP (2025) recommends the following routine vaccination schedule: (a) 1 dose Tdap vaccine (considered as 3rd booster for DTP) for ages 7-18 years old; (b) Tdap booster doses every 10 years for those who have completed their DTP doses (If Tdap vaccine is not available, Td vaccine can be given).
  - **Pregnant Women**:
    - The DOH OHG for Adolescents (2023) recommends any tetanus toxoid-containing booster for pregnant adolescents with complete primary series.
    - The DOH OHG for Adults (2023) recommends any tetanus toxoid-containing vaccines if complete with primary series containing tetanus toxoid.
    - The PIDSP (2025) recommends one dose of Tdap vaccine at 27 to 36 weeks AOG for previously vaccinated pregnant adolescents with DTP/Td/Tdap.
    - The Philippine Society for Microbiology and Infectious Diseases (PSMID) (2018) recommends adults who anticipate close contact with an infant < 12 months (which includes pregnant women) to receive one dose of Tdap vaccine to prevent transmission of pertussis.

- **Comparative costing analysis**
  - *Cost of Vaccination per individual*
    - ***Intervention: Tdap vaccine***
      - ➢ Pregnant Women: Php 1,396.63 - Php 2,570.16 (price range across different vaccine brands)
      - ➢ Grade 1 & 7 Students: Php 698.31 - Php 1,285.08 (price range across different vaccine brands)
    - ***Comparator: Td vaccine***
      - ➢ Pregnant Women: Php 35.44
      - ➢ Grade 1 & 7 Students: Php 70.87
  - *Total Budget Impact*

    The total budget impact was calculated in two 5-year phased transition strategies assuming that the NIP budget (PHP 5.45 B) and Td vaccine budget (PHP 208.49 M) from Years 1-5 will remain the same:
    - ***Strategy 1: 5 -Year Phased transition per population***

      Based on NIP's plans, in Years 1 and 2, the transition from Td vaccine to Tdap vaccine will focus on pregnant women; then in Years 3 and 4, the transition will expand to include Grade 1 students. By Year 5, the transition will cover Grade 1 students, Grade 7 students, and pregnant women.
      - ➢ ***Intervention: Tdap*** vaccine (Php 3.23 B to Php 12.26 B across different brands) exceeds the budget for Td vaccination (Php 208.49 M) and covers a large portion (59.22% to 224.99%) of the total NIP budget (Php 5.45 B) which may displace funds for other vaccines.
      - ➢ ***Comparator: Td*** vaccine (Php 163.78 M to Php 338.12 M) only exceeded the budget for Td vaccination (Php 208.49 M) starting year 3 and covers 3.01% up to 6.20% only of the total NIP budget from Year 1 to Year 5.
    - ***Strategy 2: 5-Year Phased transition by priority regions***

      Based on NIP's plans, Strategy 2 will start with regions with the highest pertussis cases covering all three subpopulations (i.e., Grade 1, Grade 7, Pregnant Women). For Year 1, the top 3 regions were considered in the calculation, and more regions were added per year for the succeeding years until Year 5.
      - ➢ ***Intervention: Tdap*** vaccine (Php 1.76 B to Php 12.26 B across different brands) exceeds the budget for Td vaccination (Php 208.49 M) and covers a large portion (32.53% - 224.99%) of the total NIP budget which may displace funds for other vaccines.
      - ➢ ***Comparator: Td*** vaccine (Php 89.19 M to Php 338.12 M) only exceeded the budget for Td vaccination (Php 208.49 M) starting year 3 and covers 1.64% up to 6.20% only of the total NIP budget

    As anticipated, in terms of budget impact, the total cost of implementing Tdap vaccine to all the target populations in both phased transition strategies far exceeds that of Td vaccine, based on the comparative cost analysis conducted. While Strategy 2 (phased transition by priority regions) will be less costly than Strategy 1 (phased transition per population), the Tdap vaccine implementation program for both strategies would consume a large portion up to 224.99% of the total NIP budget (PHP 5.45 B). As presented above, Td vaccine implementation would only consume a maximum of 6.20% of the NIP budget in both strategies.

- **Challenges and Mitigation Plans**

The challenges encountered by the NIP resulting in the low coverage of primary series vaccination of DTP-containing vaccines (pentavalent vaccine) and their corresponding mitigation plans according to DOH Disease Prevention and Control Bureau (DPCB), are as follows:

- *Demand side*
  Cultural beliefs and a lack of awareness about the availability of healthcare services have resulted in low vaccination rates, particularly in far-flung areas. The economic constraints, such as transportation costs and lost wages, have also discouraged families from completing the required vaccine doses.
  - These can be addressed by bolstering health education campaigns; providing financial and logistical support especially for remote areas; intensifying catch-up vaccination campaigns following WHO recommendation; integrating immunization with other essential health services; and, strengthening collaboration among governments, private organizations, and international agencies to reach underserved populations.

- *Supply side*
  Supply shortages, including nationwide stockouts in 2024, along with difficulties in accessing healthcare facilities in many remote areas, have contributed to the low coverage of the primary series vaccination for DTP-containing vaccines (pentavalent).
  - These can be addressed by improving vaccine supply chain management to prevent stockouts and ensure consistent availability in all health facilities; and, expanding mobile vaccination teams and house-to-house immunization drives to enhance access to vaccination services for remote and underserved communities.

It is recommended that the proposed mitigation plans for the challenges on the demand and supply sides be implemented to improve the low coverage of the primary series of DTP-containing vaccines, and achieve the WHO-recommended target of ≥90%.This will maximize the potential impact of introducing the Tdap booster in the future.

For the supporting evidence reviewed and discussed by the HTA Council in coming up with this preliminary recommendation, please refer to: https://tinyurl.com/PrelimRecommTdapBoosterVaccine. All comments, inputs, and/or appeals on the above preliminary recommendation may be submitted until **19 May 2025 (Monday)**, for the consideration of the HTA Council, through email at hta@dost.gov.ph. Please use the prescribed form for appeals indicated in the official HTA Philippines website [https://hta.dost.gov.ph/appeals-2/]. **Appeals not following the prescribed format, and those submitted beyond the deadline shall not be entertained**.

Should you have any questions or concerns regarding the preliminary recommendation, please do not hesitate to contact us through the same email address or *via telephone call at (02) 8837 2071 loc. 4100*.

Thank you very much and best regards.

On behalf of the HTA Philippines:

ANNE JULIENNE G. MARFORI, RPh, MSc
Division Chief, HTA Division

JACINTO BLAS V. MANTARING III, MD, MSc
Chairperson, HTA Council