



Republic of the Philippines

DEPARTMENT OF SCIENCE AND TECHNOLOGY



**CALL FOR STAKEHOLDER COMMENTS ON THE PRELIMINARY RECOMMENDATION OF THE HEALTH TECHNOLOGY ASSESSMENT (HTA) COUNCIL ON *HEXAVALENT VACCINE (diphtheria, tetanus and pertussis (acellular component), hepatitis B [rDNA], poliomyelitis [inactivated] and Haemophilus influenzae type B conjugate vaccine [adsorbed])***

*Published as of 05 March 2025*

As of 05 March 2025, the Health Technology Assessment (HTA) Council has completed the evidence appraisal on the assessment of **hexavalent vaccine for active immunization of infants to prevent diphtheria, tetanus, pertussis, poliomyelitis, hepatitis b, and invasive disease due to *Haemophilus influenzae type b*** for possible inclusion in the Philippine National Formulary (PNF). As of review, there are two (2) Philippine FDA-approved hexavalent vaccines [i.e., (1) DTaP-HBV-IPV-Hib (pre-filled glass syringe+ Hib in vial); and, (2) DTaP-HBV-IPV-Hib (pre-filled glass syringe)] eligible for HTA. As such, the HTA Council hereby makes public its **preliminary recommendation** on the **non-inclusion in the PNF and thus the non-government financing of hexavalent vaccine, for stakeholder feedback/comments.**

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

	<b>Hexavalent vaccine</b> for active immunization of infants to prevent diphtheria, tetanus, pertussis, poliomyelitis, hepatitis b, and invasive disease due to <i>Haemophilus influenzae type b</i>
<b>Population</b>	All infants on or before 1 year of age
<b>Intervention</b>	Hexavalent vaccine (Diphtheria, Tetanus, Acellular pertussis, Hepatitis B, Inactivated Poliomyelitis and <i>Haemophilus influenzae</i> Type B conjugate vaccine, adsorbed)
<b>Comparator</b>	Separate formulations of: Pentavalent [diphtheria, tetanus, pertussis, hepatitis B, <i>Haemophilus influenzae</i> type b (DTwP-HepB-Hib)] vaccine; and, Inactivated poliovirus vaccine (IPV)

Diphtheria, tetanus, pertussis, hepatitis B, poliovirus, and *Haemophilus influenzae* type B (HiB) are serious vaccine-preventable infectious diseases. Among the vaccine-preventable infectious diseases in the Philippines, the [DOH Field Health Services Information System \(FHSIS\) Annual Report from 2014-2023](#) reported the following local epidemiological data:

- **Diphtheria** - increase in reported cases between 2017 to 2020 for most age groups, followed by a decline in 2020-2021, and a resurgence of cases in 2023 across all age groups, except for adults aged 50–64 years old

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- **Pertussis** - sharp increase in reported cases from 2017 to 2018 in 1 to 49 years old while a gradual increase in individuals < 1 year old and 50 years old and above, followed by a decline across all age groups from 2020 onwards
- **Non-neonatal tetanus** - increase in reported cases was observed in all age groups in 2019 compared to the previous years
- **Viral hepatitis** - increase in reported cases for the majority of age groups in 2020 was observed, with a decline in 2021 to 2022, and a slight increase in cases across age groups in 2023
- **Influenza** - increase in reported cases was observed across all age groups from 2020 to 2022, followed by a gradual decrease in 2023

Additionally, based on the [Global Polio Surveillance 2022-2024](#):

- **Poliomyelitis** - the Philippines was at medium high risk in 2022

Currently, pentavalent (DTwP-HepB-Hib) vaccine and IPV are PNF-listed counterpart vaccines for hexavalent vaccines. These vaccines are already being implemented in the current routine immunization of the DOH NIP.

Based on the reviewed evidence (guideline recommendations, safety surveillance data, local costing analysis), **the HTA Council recommends the non-inclusion in the PNF and thus the non-government financing of hexavalent vaccine.**

Overall, the HTA Council recognizes that hexavalent vaccines will result in a simpler immunization schedule and thus, better compliance and easier implementation. However, compared to vaccines already included in the DOH NIP as noted above [i.e., 1) pentavalent [DTwP-HepB-Hib] vaccine and 2) IPV], both hexavalent vaccines [i.e., 1) DTaP-HBV-IPV-Hib (pre-filled glass syringe + Hib in vial) and 2) DTaP-HBV-IPV-Hib (pre-filled glass syringe)] **will incur much higher costs** (i.e., Php 17.1 billion and Php 9.02 billion, respectively) **compared to pentavalent vaccine and IPV** (i.e., Php 1.7 billion), **and is projected to exceed the 2025 NIP budget** (i.e., Php 5.4 billion). Nonetheless, the HTA Council is open to conducting reevaluation of these hexavalent vaccines once their costs become more affordable. Finally, the HTA Council also recommends:

1. Strengthening efforts to increase vaccine coverage of the current pentavalent vaccine and IPV; and
2. Improving the safety surveillance and reporting of all NIP vaccines.

Below are the evidence reviewed by the HTA Council:

- **WHO, DOH and Local Medical Society Recommendations**
  - There is no specific recommendation by WHO on the use of hexavalent vaccine. Nevertheless, the [WHO Routine Immunization Program \(2024\)](#) recommends DTP containing vaccines for children with a minimum age of 6 weeks. Further, diphtheria, pertussis, tetanus, Haemophilus influenzae type B, Hepatitis B (HepB), and polio are recommended for the Essential Programme on Immunization (EPI) ([WHO, n.d.](#)).
  - Hexavalent vaccine is not yet listed in the WHO Essential Medicines List (EML). Nevertheless, we note that the separate components of this vaccine are included in the EML. To note, only one of the Philippine FDA-approved hexavalent vaccines [i.e., DTaP-HBV-IPV-Hib (pre-filled glass syringe) hexavalent vaccine] is WHO-prequalified.
  - Hexavalent vaccine is not yet included in the DOH Omnibus Health Guidelines (OHG) but the 2023 [DOH OHG for Children 10 years](#) recommends pentavalent vaccine and inactivated polio vaccine (IPV) for all infants on or before 1 year of age. Infants aged 13 to 23 months are also recommended to get these vaccines during catch-up immunization in public health facilities or as part of catch-up programs. To note, the DOH National Immunization Program (NIP) procures pentavalent (DTwP-HepB-Hib) vaccine and IPV separately in line with the DOH OHG.
  - The [Pediatric Infectious Disease Society of the Philippines \(PIDSP\)](#) has no recommendations for hexavalent vaccine but recommends DTwP-HiB-HepB, other DTaP combinations and IPV given at a minimum age of 6 weeks.

- **Review of Safety Surveillance**

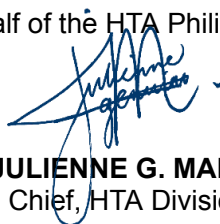
- Based on review of safety surveillance for Philippine FDA-approved hexavalent vaccines:
    - **DTaP-HBV-IPV-Hib (pre-filled glass syringe + Hib in vial)**- 31 reported adverse events (AE) from Dec 2019 to March 2024
      - Non-serious case - 30 (96.77%)
      - Serious case - 1 (3.23%)
        - *The report noted that due to insufficient information (i.e., time to onset, medical history, information on concomitant disease or medication), a causality assessment cannot be provided*
    - **DTaP-HBV-IPV-Hib (pre-filled glass syringe)** - 7 reported AE from 2022 to 2024
      - Unsolicited AEs - 5 (71.43%)
      - Solicited AEs - 2 (28.57%)
  - There is no available local safety surveillance report for pentavalent vaccines.
  - Based on the safety surveillance report for IPV:
    - Poliomyelitis vaccine (Inactivated) brand A: No reported adverse event from 2023 to 2024
    - Poliomyelitis vaccine (Inactivated) brand B: No reported adverse event since 2011
- **Comparative Costing**
    - The comparative cost analysis shows the following:
      - *Vaccination cost per vaccinee*
        - **Intervention**
          - **DTaP-HBV-IPV-Hib (pre-filled glass syringe + Hib in vial)**: Php 7,720.56
          - **DTaP-HBV-IPV-Hib (pre-filled glass syringe)**: Php 4,058.18
        - **Comparator**
          - **Pentavalent vaccine + IPV**: Php 767.55
      - *Total Budget Impact for infants less than 1 year old*
        - **Intervention**
          - **DTaP-HBV-IPV-Hib (pre-filled glass syringe + Hib in vial)**: Php 17.1 billion (estimated to consume 314.91% of the 2025 NIP budget)
          - **DTaP-HBV-IPV-Hib (pre-filled glass syringe)**: Php 9.02 billion (estimated to consume 165.53% of the 2025 NIP budget)
        - **Comparator**
          - **Pentavalent vaccine + IPV**: Php 1.7 billion (estimated to consume 31.31% of the 2025 NIP Budget)

For the supporting evidence reviewed and discussed by the HTA Council in coming up with this preliminary recommendation, please refer to: <https://tinyurl.com/PrelimRecommHexaVax>. All comments, inputs, and/or appeals on the above preliminary recommendation may be submitted until **19 March 2025 (Wednesday)**, for the consideration of the HTA Council, through email at [hta@dost.gov.ph](mailto: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:



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