DAY 2

DTwP Containing Vaccines: DTwP, Pentavalent & Hexavalent Vaccines
Outline - DTwP Containing Vaccines

1. General Updates
2. Tender Recap
3. Vaccine updates
   o DTwP
   o Pentavalent
   o Hexavalent
4. Summary and Way Forward
In Q1 2022, UNICEF launched a multi-phase DTwP-containing vaccine tender to proceed with awards for DTwP, pentavalent and hexavalent for the period 2023-2027, while allowing management of cross-antigen demand development during the introduction and supply transition towards hexavalent.

In June 2023 Gavi recommended to proceed with the funding, design and roll-out of the DTwP-containing vaccine boosters program, which was approved in principle in 2018 and paused since 2020. The program is currently under development and countries will potentially be able to submit applications to Gavi for support from Q1, 2024.

In June 2023 Gavi Board approved the investment on hexavalent vaccine. The program is currently under development, and it is expected that the funding window will be opened in Q1 2024 for countries to apply and switch over from pentavalent and IPV.

UNICEF published a DTwP-containing vaccine market note in June 2023, which will be updated regularly moving forward.
The long-term aim of the tender strategy focuses on maintaining a healthy market and an affordable price for DTwP and pentavalent vaccines, as well as the IPV market, while allowing the market development of the hexavalent vaccine.

Phase I
- In Q1/Q2 2022
  - DTwP
    - 100% demand awarded in 2023 & 2024
    - 80% demand awarded in 2025
    - 2 Suppliers on LTA
  - Pentavalent
    - 100% demand awarded in 2023 & 2024
    - 80% demand awarded in 2025
    - 70% demand awarded in 2026 & 2027
    - 4 Suppliers on LTA
  - Hexavalent
    - No WHO PQed vaccines yet
    - Awards or Conditional Awards

Phase II
- In Q2/Q3 2024
  - Awards for DTwP, pentavalent and hexavalent will be based on updated demand scenarios for 2025, 2026 and 2027, while considering interdependencies across the three vaccines following the implementation of hexavalent and DTwP boosters programs

Additional Phases
- In 2026 or 2027
  - Will be considered depending on market dynamics

DTwP Forecast
Penta Forecast
Hexa Forecast
WHO recommends 6 doses of tetanus containing vaccines to be protected through life (3 primary series plus 3 booster doses)

Demand though UNICEF is mainly driven by the countries that implement the DTwP 4th-dose with booster vaccination in the second year of life

DTwP standalone demand through UNICEF is relatively low (average 7.5M doses annually) and from 20-25 countries. Five countries account for 70% of the annual demand.

The current market capacity is sufficient to cover the demand as it stands now. However, supply availability for DTwP vaccine requires continued and close collaboration to ensure the right bulk allocation between the different DTwP containing vaccines.

Gavi’s decision to un-pause the DTwP booster program, may have an impact in the future demand of DTwP vaccine, depending on countries decision on the choice of vaccine for boosters.
Pentavalent demand and WAPs have been relatively stable during 2017-2022.

UNICEF anticipated that total demand for routine immunization of pentavalent vaccine would reach approximately 632 million doses during 2023-2027 (tender period). Projected WAPs for 2023-2027 are expected to remain relatively stable.

In principle, pentavalent demand for routine immunization is expected to decline progressively as the hexavalent market develops. However, such progressive decline would only occur upon the introduction of Hexavalent vaccine in 2024.

On the other hand, catch-up and recovery (CU&R) immunization plans will most likely result in a significant increase of pentavalent demand in the short term:
- Demand materialization is largely expected in 2024 & 2025,
- Increased coverage rates achieved during CU&R and maintained over time could further increase routine immunization demand in the subsequent years.

Moreover, the DTwP-containing vaccine boosters program could further increase pentavalent demand in the near future, should countries opt for pentavalent vaccine as the second year of life (2YL) booster.

UNICEF will closely work with manufacturers to secure supply availability in due time, following confirmation of demand volumes for CU&R and DTwP 2YL booster.
Hexavalent Updates

- **Gavi Board approved investment on Hexavalent in June 2023:**
  - Followed by the program design/implementation as well as the *update and consolidation of demand scenarios*.
  - First country applications are expected in Q1 2024,
  - Commencement of supply is expected in Q2 2024 (subject to WHO PQ of 1st vaccine),
  - UNICEF and partners will manage demand generation during the early years of the program in order to ensure both a suitable balance of demand and supply as well as the long-term health of the pentavalent and IPV markets.

- **Hexavalent vaccine pipeline:**
  - First WHO PQ is expected in Q4 2023,
  - Four additional WHO PQs are expected in 2024 (2) and 2026 (2).

- **UNICEF Conditional Awards for Phase I:**
  - 2 hexavalent LTAs for supply in 2024 -2025 subject to WHO PQ for:
    - Demand from Gavi countries eligible for Hexavalent support,
    - Demand from MICs and Gavi countries non-eligible for Hexavalent support.
  - UNICEF has recently published [hexavalent prices](#) under these LTAs.
Ongoing work for catch-up and recovery plans will determine the additional demand requirements for pentavalent vaccine in 2024 and 2025. UNICEF will closely work with manufacturers to secure supply availability in due time.

UNICEF will continue working with Alliance Partners on the development and implementation of the hexavalent program, to ensure a suitable balance of demand and supply during the early years, as well as to ensure the long-term health of the pentavalent and IPV markets.

Following the approval of the DTwP-containing vaccine boosters program:
- UNICEF will collaborate with partners on the design and implementation of the DTwP-containing vaccine boosters program,
- UNICEF acknowledges the need of estimating demand scenarios, in consideration of countries’ decision for the choice of vaccine,
- UNICEF will work with manufacturers to ensure sufficient supply to support the program without disrupting the supply of DTwP-containing vaccines for routine programs.

Timing and scope (volume) of phase II of the tender will be determined considering the impact of hexavalent and DTwP-containing vaccine boosters programs, the timelines for the hexavalent vaccines WHO PQs as well as the updated demand scenarios for DTwP-containing vaccines.

Phase II of Tender to be launched in Q2/Q3 2024
THANK YOU

VACCINE INDUSTRY CONSULTATION 2023