UNICEF Pentavalent-Hexa 2021+ Pre-Tender Industry Consultation 19th SEPTEMBER 2019
Presentation Outline

1. Context
   ▪ Gavi Board decision
   ▪ Hexa strategic alignment
   ▪ Value Based Assessment

2. Demand scenarios and assumptions

3. Pentavalent Tender:
   ▪ Objectives
   ▪ Scope
   ▪ Duration
   ▪ Modality

4. Summary of feedback and response to questionnaire

5. Timelines
1. CONTEXT

Gavi Board decision
Hexa strategic alignment
Value Based Assessment
• **Approved support for D, T & P vaccines** (Td, DTwP, pentavalent) to be used as booster doses beginning in 2021

• **Approved support for inactivated poliovirus vaccine (IPV)**, with country financing arrangements subject to alignment with the final parameter setting for Gavi 5.0 at the June 2019 Board meeting*

• **Approved in principle support of wP-Hexavalent vaccine**, subject to a vaccine being licenced, recommended for use by WHO, WHO pre-qualified and that market attributes support the successful implementation of Hexavalent

---

The development of capacity for **standalone IPV remains the main priority** for Gavi Alliance as part of the effort to eradicate polio

---

All Gavi Board decisions are “**subject to the availability of funding for the 2021-2025 period and alignment with the final parameter setting for Gavi 5.0 at the June 2019 Board meeting.**”

---

*Gavi’s Board approved IPV co-financing arrangements post-2020 in its June 2019 session*
Conditions to open a funding window for Hexavalent

**Condition 1:** Hexavalent vaccines that are candidates for Gavi support should achieve IPV immunogenicity targets as per WHO’s SAGE recommendations.

**Condition 2:** Hexavalent vaccines are priced in line with value-based principles. The target price premium for a full Hexavalent schedule (3+1) should not exceed a [confidential premium] over the price of the base schedule including a DTP-containing booster during the 2\textsuperscript{nd} year of life.

**Condition 3:** The supply security of IPV stand-alone and DTP-containing vaccines is not compromised or impacted by the adoption of Hexavalent.

**Condition 4:** Gavi Partners define a policy for country access to manage the potential mismatch between demand and supply for Hexavalent.

**Condition 5:** When Hexavalent demand matures (e.g. 4 to 6 years after 1\textsuperscript{st} introduction), two or more Hexavalent manufacturers can supply the market with a capacity of at least 20% of Gavi71 demand each.
Next steps if conditions are met

When/if conditions are met, submit to Gavi Board for window of support

**Product Portfolio Management Principles**

- Consistent with SAGE recommendation and WHO position paper
- WHO prequalified
- **Reliable supply base**
- Estimated cost should account for any increased procurement costs that are commensurate with evidence-based benefits
- Respond to country demand and preferences

* The development of capacity for standalone IPV remains the main priority for Gavi Alliance as part of the effort to eradicate polio
TENDER DYNAMICS:

- Objectives
- Scope
- Duration
- Modality
Tender Scope:
- Duration: **2021-2027**

- Products:
  - wP Pentavalent
  - DTwP
  - Hexavalent
  - Hep B
  - aP containing combination vaccines
  - IPV

- Request for Proposal (RFP) covering total forecasted demand from Gavi supported and middle income countries procuring through UNICEF, for the whole duration of the tender.

- Modality:
  - Multi-phased tender
With long term goal of maintaining wP Pentavalent vaccine healthy markets, the following tender specific objectives are developed for this UNICEF tender:

1. **Balance of supply and demand**

   Ensure sufficient supply and flexibility in the vaccine mix (DTP/Pentavalent/IPV/Hexavalent) to cover demand for Gavi and non-Gavi countries

   - Ensure supply capacity of IPV standalone and availability of DTP containing (Penta) are not adversely affected, for countries that want to continue with the stand alone vaccines in their program.
   - Ensure sufficient and uninterrupted availability of Hexavalent, once a product becomes WHO pre-qualified and introduced in countries.

- **Hexavalent vaccine is an option for immunization, while Penta and IPV standalone will remain to be required.**
Objectives of the next tender 2/3

2. Cost of vaccine to Gavi and countries

*Minimize the cost implications of vaccines included in the tender to Gavi and countries while ensuring sustainable prices for manufacturers:*

- Ensure DTP stand alone and Pentavalent vaccine prices remain affordable.

- The value of future Hexavalent vaccines will be benchmarked against the reference cost of a fully vaccinating a child with 3 doses of Pentavalent, 2 full-doses of IPV, and a DTP-containing booster + premium. Premium drivers (eg. saved delivery costs) will be taken into consideration.

- Tiered pricing for Hexavalent and aP containing vaccines, for Gavi and non-Gavi countries, will be taken into consideration.

- Award multiple suppliers to continue a competitive supplier base that represent innovation and pipeline that is attractive to UNICEF & Gavi market.
3. Appropriate and innovative vaccines

Value innovation and product development in the pipeline, targeted to UNICEF/Gavi markets.
DEMAND SCENARIOS & ASSUMPTIONS
## Demand forecast – Assumptions

### Pentavalent

- 3 scenarios: Low, medium and high are taken into consideration

- For long term forecast, variables include: coverage, coverage growth rates, wastage rates, population growth rates, singling out large countries (Nigeria and DRC)

### DTP-containing booster

- Variables include: initial introduction year and ramp-up, country prioritization, coverage (DTP3 discounted). All else is identical to Penta

- As the Board has approved support to countries the use of DTP in combination for booster dose, it is expected that initial self-financing countries will opt for use of penta/hexa in their program

### Hexavalent

- 3 scenarios based on pentavalent base scenario: low, medium and high

- Variables include: initial introduction year (2023-25), ramp-up, country prioritization (income group, risk of polio, number of introductions).

- All else is identical to Penta base scenario

### IPV

- Demand through UNICEF post 2023
DTP/Pentavalent Demand Forecast (w/o Hexavalent) – Primary series and booster (2nd year of life)

- **Primary series (Pentavalent):** coverage, coverage growth rates (higher coverage growth assumed for large countries with current low coverage rate), wastage rates, population growth.
- **Booster 2nd year of life (Pentavalent or DTP):** initial introduction year and ramp-up, country prioritization, coverage. All else is identical to Primary series.
- **Global market** includes all countries using wP-Pentavalent: Gavi 71, non-Gavi countries procuring through UNICEF, PAHO or self-procuring.

*NB: demand forecast can be subject to minor changes before finalization of the Strategic Demand Scenarios (SDS) in Oct-2019*
DTP/Pentavalent Demand Forecast (w/o Hexavalent) – Primary series and booster (2\textsuperscript{nd} year of life)

- **Primary series (Pentavalent):** coverage, coverage growth rates (higher coverage growth assumed for large countries with current low coverage rate), wastage rates, population growth.
- **Booster 2\textsuperscript{nd} year of life (Pentavalent or DTP):** initial introduction year and ramp-up, country prioritization, coverage. All else is identical to Primary series.
- **Gavi market** includes Gavi 71 countries using wP-Pentavalent (i.e. Gavi 73 excl. Georgia and Armenia)

*NB: demand forecast can be subject to minor changes before finalization of the Strategic Demand Scenarios (SDS) in Oct-2019*
DTP/Pentavalent and Hexavalent Demand Forecast –
Primary series and booster (2\textsuperscript{nd} year of life)

**Parameters**

- **Hexavalent:**
  - 3 scenarios [High, Medium and Low] based on date of switch, number of countries to switch, ramp-up at country level
  - Other parameters same as Pentavalent (e.g. population growth ...)
  - Schedules used: 4-dose in Gavi countries and 3-dose in non-Gavi countries

---

\textbf{Hexavalent demand forecast}

\textbf{Impact of Hexavalent on DTP/Pentavalent}

(*) : Hexavalent demand by Gavi-supported countries is \textit{subject to a funding window opened by the Gavi Board}

NB: demand forecast can be subject to minor changes before finalization of the Strategic Demand Scenarios (SDS) in Oct-2019
DTP/Pentavalent and Hexavalent* Demand Forecast – Primary series and booster (2\textsuperscript{nd} year of life)

- **Hexavalent:**
  - 3 scenarios [High, Medium and Low] based on date of switch, number of countries to switch, ramp-up at country level
  - Other parameters same as Pentavalent (e.g. population growth ...)
  - Schedules used: 4-dose in Gavi countries and 3-dose in non-Gavi countries

\(*)\): Hexavalent demand by Gavi-supported countries is **subject to a funding window opened by the Gavi Board**

NB: demand forecast can be subject to minor changes before finalization of the Strategic Demand Scenarios (SDS) in Oct-2019
Potential demand to be included in the tender

**Assumptions/Considerations:**

**Pentavalent (2021+):** Gavi (primary + 2\textsuperscript{nd} YoL booster) + MICs.

**Hexa:** non-Gavi through UNICEF timebound awards + Gavi from 2024

**DTP:** booster dose for initial self financing are included in Penta/Hexa demand, other countries are included as DTP standalone.

**HepB:** HepB birth dose from 2022 - 2027

**aP:** demand from countries that forecast aP vaccine through UNICEF

**IPV:** offers will be requested for supply starting from 2023
HepB vaccine: Demand forecast

- **2019 – 2021**, with possibility for extension by additional 12 months
- 2 suppliers awarded + 1 conditional award.
- **2023+:**
  - to be included in next Penta tender
  - Gavi program introduction support *only for the delivery platform* of HepB birth dose, but vaccine cost continue to be financed by countries
  - Gavi support is expected to have slow increment on demand, not exceeding 30 mds by 2027
➢ 2019 – 2021, with possibility for extension by additional 12 months
➢ 2 suppliers awarded
➢ 2023+ to be included in next Penta tender
➢ Gavi support for **delivery platform** of DTP booster dose in the second year of life, and possibility to use combination vaccine (Penta or Hexa)
   ➢ Normal co-financing policy will apply for countries that decide to use DTwP in combination
➢ Vaccine cost continues to be financed by countries
➢ DTP demand assumption 2022+: initial self-financing countries are likely to opt for Penta/Hexa, others with DTP standalone.
**Phase I: (Q2 2020)**

**Penta**
- 2021-2023: Full Award
- 2024-2025: up to 80%
- 2026-2027: up to 60% of demand

**UNICEF reserves the right to leave the last two years unawarded, if the objectives of the tender are not met.**

**Hexa:**
- No awards, if no PQ vaccine.
- Conditional award 2022-23 for MICs demand, if dossier for WHO PQ is submitted.

**DTP/Penta:** (*interchangeable award for booster dose*)
- 2023 - 2025: award full demand.
- 2026-2027: leave unawarded, to obtain more visibility on product choice.

**aP:** award timebound LTAs from 2021+

---

**Phase II: (end 2022 early 2023)**

**Penta:**
- 2024-2025: remaining volume
- 2026-2027: depending on Hexa demand/supply landscape, make additional up to 20% *interchangeable awards* or no awards if objectives are not met.

**Hexa:**
- 2023: timebound for MICs
- 2024: up to 20 mil ds (Gavi + MICs)
- 2025: up to 32 mil ds (Gavi + MICs)

**HepB:** Awards from 2023+

---

**Phase III: (mid/Q1 2025)**

**Penta:**
- 2026-2027: Award the remaining quantities (interchangeable)

**Hexa:**
- 2025: remaining 8 mil ds
- 2026-2027: full volume of demand

**DTP/Penta, Hexa:**
- 2026-2027: award based on countries’ demand.

---

**Proposed tender duration and phases**

2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027
Dear Supplier,

In preparation of the upcoming tender for supply of Pentavalent vaccine(s), UNICEF seeks your feedback to some of the aspects of the tender, which was presented during the industry webinar, on August 22nd.

You are kindly requested to provide your input by **End September 4th, 2019**.

1. **Duration:**
   (please indicate one preferred option, and rationale for your preferred option)
   
   a. 3 years
   Comments: ........................................
   
   b. 5 years
   Comments: ........................................
   
   c. 7 years
   Comments: ........................................

Outcomes of Industry Consultation Questionnaire
SUMMARY

• Questionnaire was sent out to 6 WHO pre-qualified Pentavalent suppliers;
  
  • 2 follow up consultations

  • 6 written responses received
1. Tender Duration: 3, 5, 7, ....

❖ 7 years:
  • The longer the better.
  • provides good visibility on demand
  • allows for long term production planning, and thereby more predictability.

➢ 3 years:
  X is a good period to prepare a plan both in terms of production and pricing.
  X Capacity allocation plan for supply to 7 years is challenging.
  X Suggested tender system is very complicated.
  X Too many uncertainties.
2. Tender Scope: **wP Pentavalent + Hexa + IPV + DTwP + Hep B + aP combination**

• **wP Pentavalent only:**
  - Hexavalent vaccine procurement is not foreseen in UNICEF program for Gavi countries in next 3 years.
  - It is extremely difficult to suggest hexavalent price during the development stage
  - Prefer a separate tender due to complexities in process.
  - Prefer to have all tenders separately

• **Full scope:**
  - IPV bulk will be produced for both IPV Standalone & Hexavalent therefore it makes more sense to consolidate the demand forecasts under the same umbrella.

• No aP, focus on wP!
1. Why cap the procurement of Hexavalent vaccine at 65 mds/yr and that too delay it until 2027?
2. Why is the introduction of Hexavalent for Gavi countries is planned only in 2024? Could you consider an earlier introduction of Hexavalent? What would be the conditions?
3. If suppliers show that their supply capacity is higher, could the Hexavalent volumes increase?
4. The Hexa range is huge: between 50-250 Md – how long in advance will the producers know which demand scenario is chosen (Low, Mid, High)?
5. Value Based Pricing: Hexavalent needs to be seen as a completely new product resulting from years of development and not as an addition of already existing vaccines.
6. Condition 5 states that when several manufacturers will introduce Hexa, each manufacturer has to supply at least 20% of Hexavalent demand. Why such a constraint? Why not to allow manufacturers to propose less than 20% of demand?
7. Any procurement preference envisaged between manufacturers of Hexavalent vaccine that received funding support from partner organizations?
8. Will tiered pricing be considered for all vaccines or only for Hexa?
9. What are the MICs targeted by Unicef to be part of the tender?
10. Could you clarify Unicef position regarding wP Hexa local registration process and what may be expected by countries?
11. Given the size, scope and complexity of such Tender, would UNICEF consider extending the preparation and closing date?
12. aP: the details of product mix, tentative timelines to commence and volumes.
NEXT STEPS
Timeline (Tentative)

- **22 Aug.**: Industry webinar
- **19 Sep.** - **20-30 Sep**: Internal analysis & reflection
- **26th Sep.**: PRG Consultation
- **30 Sep.**: Industry webinar
- **30 Oct.**: Procurement Strategy finalization
- **30 Nov.**: Tender Issuance
- **15 Dec.**: Tender closure
- **20 Feb.**: Evaluation of offers and deliberation on awards
- **Feb. – May**: Award finalization – Phase I
- **30 June**: Finalization of award

*Time line does not indicate the internal processes and partners and PRG consultations*
Thank you