UNICEF Deep-dive
2020, Vaccine Industry Consultation
## UNICEF’s Tentative Vaccine Tender Calendar for the upcoming period

<table>
<thead>
<tr>
<th>VACCINE</th>
<th>Q4 2020</th>
<th>Q1 2021</th>
<th>Q2 2021</th>
<th>Q4 2021</th>
<th>Q1 2023</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covid-19 vaccine</td>
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<td>Human Rabies vaccine</td>
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<td>Rabies immunoglobulin</td>
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<td>SH 2021 seasonal influenza vaccine</td>
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<td>mOPV2 Bulk</td>
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<tr>
<td>NH 2021/22 seasonal influenza vaccine</td>
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<tr>
<td>Rota</td>
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<td>TCV</td>
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<td>Td</td>
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<tr>
<td>Hep A</td>
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<td>IPV</td>
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<td>Penta</td>
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<td>BCG</td>
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INFLUENZA

Deep-dive
• Background and challenges
• Feedback from the industry
• Gavi learning agenda for seasonal influenza
• Tender timelines
• Key takeaways
Background & Challenges

- Immunization programmes, vaccines, and auxiliary supplies for seasonal influenza are primarily funded through a country’s own health budget.

- Due to limited funding, seasonal influenza programmes are often not implemented in LICs and MICs.

- Historically, UNICEF has procured limited quantities of influenza vaccine on behalf of countries.

- UNICEF often receives requests for supply of seasonal influenza vaccine late and after suppliers have determined the production volume for the global market.

- Due to COVID-19, the demand for seasonal influenza vaccines through UNICEF has increased during 2020, and realized late which let to constrained availability for countries procuring through UNICEF. UNICEF plans to tender earlier to counter this risk.
## Feedback from the industry

**What should UNICEF do differently to incentivize your participation in the future tenders for seasonal influenza vaccines?**

<table>
<thead>
<tr>
<th>Feedback from the industry</th>
<th>Measures taken by UNICEF</th>
</tr>
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<tbody>
<tr>
<td>• Tender one year in advance to block the doses for UNICEF.</td>
<td>• Advance tender timelines</td>
</tr>
<tr>
<td>• Multi-year tender and LTA</td>
<td>• Stakeholders reminded of:</td>
</tr>
<tr>
<td>• UNICEF take risks and commit to pay for the doses even they are not materialised into orders.</td>
<td>o the short window for production planning and supply</td>
</tr>
<tr>
<td></td>
<td>o importance of timely and accurate forecasting</td>
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<tr>
<td></td>
<td>• Published a Supply Note on Seasonal Influenza Vaccines in English &amp; French.</td>
</tr>
<tr>
<td></td>
<td>• Working with countries to improve longer-term forecast accuracy.</td>
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</tbody>
</table>
• **Background**: only 8% of Gavi eligible countries have seasonal influenza immunization programmes, and most countries in the African region do not have national influenza immunization policies.

• **Purpose of the learning agenda**: “to assess the feasibility and impact of routine influenza immunization of health workers (HWs) to support epidemic and pandemic influenza preparedness in order to inform decisions in the next Vaccine Investment Strategy”.

• **Duration of the project**: 2021 – 2022

• **Targeted countries**: Cote d’Ivoire, Kenya & Uganda

• **Targeted population/demand**: approx. 123,000 doses for Health workers (included in the 2021 SH flu tender forecast)

• **Projected vaccine delivery & intro date**: SH 2021 season (Apr-May 2021) & SH 2022 season (Apr-May 2022).
Tender Timelines

**SH 2021**
- Demand consolidation
- Issue RFP
- RFP closes
- Contract award/PO placement
- In-country delivery

**NH 2021/22**
- Demand consolidation
- Issue RFP
- RFP closes
- Contract award/PO placement
- In-country delivery
Key takeaways

• For SH 2021 and NH 2021/22 season, the tender schedule has been advanced to achieve better alignment with the industry’s planning and manufacturing timeline.

• UNICEF Supply Division continue to work with countries and partners to improve forecast accuracy and long-term demand planning to enable multi-year tenders.

• Industry to take into account the Seasonal Influenza Vaccine demand through UNICEF when planning production levels.

• The SH 2021 tender demand: 428,200 doses (including Gavi learning agenda demand)
• 6 WHO pre-qualified manufacturers, of which 5 awarded by UNICEF

• Available in 4 different presentations, and interchangeable, though countries regulatory requirement challenges cross allocation.

• UNICEF procures on behalf of 75 countries – Gavi supported and Middle Income Countries.

• Mature market with global capacity exceeding global demand.
End year off-take is estimated at 94% to forecast;

Slower materialization of some forecasts incl. self-finance quantities for Angola, Ethiopia, Kenya, Madagascar, Somalia

Synchronization of demand with supply was challenged due to lack of capacity amongst some manufacturers, although the gap is narrowing in Q4

Supply gap mitigated through close coordination across awarded manufacturers and recipient countries to allocate and schedule shipments according to country priorities and available supply

Additional awards of 4.8 mil ds made in 2020 to bridge supply gaps
Extension of current Penta Tender to cover 2021 - 2022

**Rationale:**
- In view of COVID-19 related re-prioritizations
- Programmatic priorities and allocation of resources
- Market uncertainty following impact of COVID-19
- Difficult to formulate an offer to Penta/Hexa tender for 2022+
- Not possible to engage with countries regarding Hexa demand, given other programmatic priorities

**Priorities:**
- Program continuity with no interruptions - ensuring supply meets demand.
- Maximizing resources where they are mostly needed.
- The need for having longer visibility for manufacturers to enable making business plans, and decisions on potential prioritization and allocation of resources – if and when needed.

- The Long-Term Portfolio Penta/Hexavalent/HepB/DTP Tender will be issued in Q4 2021, to cover supply period from 2023

- 22 Aug 2019: pre-tender Webinar
- 19 Sep 2019: VIC industry Consultation
- 15 April 2020: Industry Consultation on 2 years’ extension
Penta awards made for Supply Period 2021 - 2022

• All bidders of WHO pre-qualified pentavalent vaccines were invited to revise or confirm their standing offer to UNICEF RFP-DAN-2016-502178, to cover supply period 2021 - 2022.
  - RFP Issued: 06 May 2020
  - Closing date: 21 May 2020
  - Awards made: Early August.
  - 5 manufacturers awarded for 2021 - 2022

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Number of doses</th>
<th>Number of Suppliers</th>
<th>Weighted Average Price per dose (USD)</th>
<th>Number of doses</th>
<th>Number of Suppliers</th>
<th>Weighted Average Price per dose (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penta 1 dose</td>
<td>53,113,000</td>
<td>4</td>
<td>$1.14</td>
<td>54,093,000</td>
<td>3</td>
<td>$1.13</td>
</tr>
<tr>
<td>Penta 10 dose</td>
<td>99,006,000</td>
<td>4</td>
<td>$0.79</td>
<td>102,600,000</td>
<td>4</td>
<td>$0.78</td>
</tr>
<tr>
<td>Totals</td>
<td>152,119,000</td>
<td>4</td>
<td></td>
<td>156,693,000</td>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>
- Volume has stabilized at around 150 – 160 mil ds
- 35 / 65 split between 1 and 10 dose respectively
- WAPs remain stable;
  - 1 dose: 2021 – 2022 at same level as 2020
  - 10 dose: 2021 – 2022 increased by 16% from 2020, $0.69 → $0.79
  - Overall WAP: 2021 – 2022: Increased by 6% from 2020, $0.845 → $0.90
**Rationale:**
- Advancement in product development and more visibility on Hexa demand and supply.
- Provides opportunity for more dialogue and communication with the industry to increase clarity.
- Provides a longer planning horizon and more certainty of demand to manufacturers.
- The need for having longer visibility for manufacturers to enable making business plans, and decisions on potential prioritization and allocation of resources.
- Hexavalent demand and assumptions to be synchronized with IPV requirements.
Tender Timeline 2023+

PRG
- Tender Strategy
- Country consultation
- Demand Finalization

Internal Processes:

Tender Issuance
- Tender Issuance
- Technical and Financial Evaluation
- Adjudication

Tender Closure

Award issuance

PRG
- Internal processes

Q1 2021
Q2 - Q3 2021
Q4 2021
Q1 2022
Q2 2022
PCV
Deep-dive
Background

Worldwide, an estimated 14.5 million cases of serious PD occur annually in children under 5 yr, resulting in 476,000 deaths in 2008 and 944,000 deaths in 2015, most of which occur in LICs and MICs.

WHO recommends that PCV should be included in every country’s National Immunization Program (NIP), especially in countries with high PD burden.

The AMC initiative has opened access to PCV in low and lower-middle income countries, with unprecedented low prices of PCV, 2.0 per dose

80% of Gavi 73 countries, have introduced PCV.
Only 30% of MICs have introduced PCV.

Affordability remains a key challenge, in the mist of budget constraints in most MICs, fortunately Indonesia is eligible and has successfully completed the application and approval process to gain access to the AMC.

In support of UNICEF Strategic Plan goal that every child survives and thrives, UNICEF mandate and focus over the next period is to ensure every child has access to immunization regardless of geography and income.

Key areas of focus over the next strategic period include: Availability of supply at affordable prices for MICs (e.g. PCV introductions in MICs to bridge the gap in PCV access).
Market overview

Supply meets demand

- Five options available to meet country presentation preferences
- Sufficient buffer capacity, subject to presentation preference
- Diverse NRA base, USA, Belgium and India
- A more competitive market in the long term

Table 1 WHO Prequalified Pneumococcal Conjugate Vaccines

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Vaccine Type</th>
<th>Doses / Course</th>
<th>WHO PQ</th>
<th>Presentation</th>
<th>Form.</th>
<th>Shelf life</th>
<th>VVM</th>
<th>Cold Chain Vol / Dose</th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSK (Belgium)</td>
<td>PCV10</td>
<td>3</td>
<td>2009</td>
<td>1-dose vial</td>
<td>Liquid</td>
<td>48 months</td>
<td>30</td>
<td>11.50 cm³</td>
<td>2-8°C</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>2-dose vial</td>
<td>Liquid</td>
<td>48 months</td>
<td>30</td>
<td>4.80 cm³</td>
<td>2-8°C</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>4-dose vial</td>
<td>Liquid</td>
<td>36 months</td>
<td>30</td>
<td>2.40 cm³</td>
<td>2-8°C</td>
</tr>
<tr>
<td>Pfizer (USA)</td>
<td>PCV13</td>
<td>3</td>
<td>2010</td>
<td>1-dose vial</td>
<td>Liquid</td>
<td>36 months</td>
<td>30</td>
<td>12.00 cm³</td>
<td>2-8°C</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>4-dose vial</td>
<td>Liquid</td>
<td>36 months</td>
<td>30</td>
<td>3.50 cm³</td>
<td>2-8°C</td>
</tr>
<tr>
<td>SII (India)</td>
<td>PCV10</td>
<td>3</td>
<td>2019</td>
<td>1-dose vial</td>
<td>Liquid</td>
<td>36 months</td>
<td>30</td>
<td>14.06 cm³</td>
<td>2-8°C</td>
</tr>
<tr>
<td></td>
<td>PCV10</td>
<td>3</td>
<td>2019</td>
<td>5-dose vial</td>
<td>Liquid</td>
<td>36 months</td>
<td>30</td>
<td>3.51 cm³</td>
<td>2-8°C</td>
</tr>
</tbody>
</table>
• The excess doses on contract for 2020 will be rolled over to adjust volumes in 2023 onwards
• Earlier switches to SII’s PCV, will extend the duration of contracted supply with current suppliers beyond 2024
• Additional doses on contract will be needed before 2023/2024
• AMC donors committed the left-over of USD 188M to the Gavi AMC for COVAX
Drivers of increased demand

- Additional Gavi allocation of 3.6mds for DRC and call forward of 3mds of their 2021 allocation to be delivered in 2020.
- Roll over of pending 2019 doses to 2020 total of 7mds
- New PCV introduction in Indonesia
Assessment of AMC objectives

✓ To **accelerate the development** of pneumococcal vaccines that meet developing country needs as specified in the Target Product Profile;
  - The Pneumo ADIP was initiated in 2003 by Gavi, preceding the development of PCV13 and PCV10
  - Development of MDV presentations that specifically met the needs of the receiving countries
  - There are now several candidate PCV’s under development

✓ To **bring forward the availability** of effective pneumococcal vaccines for developing countries by guaranteeing the initial purchase price for a limited quantity of new vaccines that represents value for money and incentivizes manufacturers to invest in scaling-up production capacity to meet developing country vaccine demand;
  - There was adequate supply within the first five years to meet demand
  - Tail price was maintained below the tail price cap of $3.50 per dose

✓ To **accelerate vaccine uptake by ensuring predictable vaccine pricing** for countries and manufacturers, including binding commitments by participating companies to supply the vaccines at low, long-term and sustainable prices;
  - There was accelerated introductions, reaching +80% in the first decade
  - Tail price has decreased over the period to a sustainable level for countries, up to 43% reduction in comparison to tail price cap

✓ To **pilot the effectiveness of the AMC mechanism** as an incentive for needed vaccines and to learn lessons for possible future AMCs;
  - Lessons learned are being applied for COVAX
**MICs, PCV market evolution**

- UNICEF procures a wide range of vaccines for Self-financing Middle Income Countries (MICs) through a variety of procurement modalities depending on the vaccines and market situations.
- Whereas LTA’s are in place for several traditional vaccines with **price parity** between Gavi countries and MICs, PCV pricing is tiered based on manufacturer’s pricing policies.

<table>
<thead>
<tr>
<th>Year</th>
<th>Description</th>
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<tbody>
<tr>
<td>2012</td>
<td>- The first MIC’s tender issued in 2012 did not yield expected results.</td>
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<td></td>
<td>- The challenges highlighted by industry included low visibility on long</td>
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<td></td>
<td>term demand amongst other market complexities.</td>
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<tr>
<td>2013-2017</td>
<td>- Following this, ad hoc tenders were done to fulfil country specific PCV</td>
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<td>supply for MICs on annual basis without long term demand and budget</td>
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<td></td>
<td>commitments.</td>
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<td></td>
<td>- UNICEF has been working with MICs to develop long-term demand</td>
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<tr>
<td></td>
<td>commitments.</td>
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<tr>
<td>2018</td>
<td>- UNICEF considered several contractual modalities with flexibility to</td>
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<td></td>
<td>improve and unlock affordable PCV access in MICs.</td>
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<tr>
<td></td>
<td>- The key components included Tiered pricing, Volume commitments, Multi-</td>
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<tr>
<td></td>
<td>year demand quantification and Financial backing.</td>
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<tr>
<td>2019</td>
<td>- For MICs that had already introduced PCV prior to 2019, UNICEF has</td>
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<tr>
<td></td>
<td>established LTA’s.</td>
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<tr>
<td></td>
<td>- Contractual frameworks and new financing mechanisms specifically</td>
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<td></td>
<td>developed for MICs are in place for PCV-naïve MICs to facilitate</td>
</tr>
<tr>
<td></td>
<td>introduction.</td>
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<tr>
<td>2020+</td>
<td>- UNICEF has applied the lessons learnt from PCV MICs in securing access</td>
</tr>
<tr>
<td></td>
<td>to other vaccines (HPV and Rota).</td>
</tr>
<tr>
<td></td>
<td>- UNICEF has established LTA’s for PCV vaccines at record low prices</td>
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<tr>
<td></td>
<td>not more than twice AMC tail price.</td>
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</tbody>
</table>
Next steps

• To secure additional doses on contract to bridge uncontracted supply for the years spanning 2024 to 2030 through the issuance of a non-AMC tender in 2021.

• Support eligible countries that are pending PCV introduction to submit applications.

• Shape demand to ensure a healthy market.
THANK YOU