Overview of BCG through UNICEF
BCG procurement through UNICEF

• Historically the strategy by UNICEF has been to retain the existing supply base due to:
  ✓ Limited pipeline of manufacturers seeking WHO prequalification,
  ✓ Perception of limited market attractiveness by suppliers and

• Demand through UNICEF has been relatively stable over the past years.
Current status of BCG supply and demand

- 3 years of insufficient supply. Deficit of approx. 15 million doses each year, and challenging timing of availability
- UNICEF contracted with all 4 manufacturers with WHO prequalified BCG vaccine
- To meet growing demand UNICEF awarded the supply of an additional 37.82 million doses to increase its initial 2015 allocations from 107 to 144.82 million doses
Issues and Challenges 2015

- Total demand through UNICEF is about 152.2MDS.
- The current shortfall is 16.5 MDS for 2015.
- Supply shortfall 2014-2015 mainly constrained due to:
  - 2 suppliers have reduced 2015 availability by 50-95%.
  - The decrease in global availability affected other self procuring countries which then opted to procure through UNICEF.
  - Effects of the suppressed demand from 2014 that was carried over to 2015.
- During 2015, UNICEF, WHO and partners have taken a number of actions to mitigate the risk of interruption of immunization programmes.
Mitigating steps taken in 2015

- Extensive consultations with all 70+ countries receiving BCG through UNICEF.
  - Agree on critical dates for deliveries of vaccine, and
  - Advocate for reduction of wastage rates
  - Using buffer stocks in countries
- Extensive follow up with suppliers—managing every dose; just-in-time deliveries to avoid stock out; splitting every forecast
- Secured additional quantities from 2 manufacturers, and close follow up with pipeline manufacturers seeking WHO PQ.
- In consultation with WHO, and UNICEF Programme Advisors there was established allocation criteria to manage limited supply of BCG
Future forecast of demand for BCG vaccine to be procured through UNICEF

- Forecasts from countries indicate a continued demand for this vaccine over the medium term (2016-2018)
  - Procurement on behalf of about 70 - 80 countries that have indicated their intention to procure some or all their BCG requirements through UNICEF
  - High vaccine wastage rate ranging from 25%-85% (reported by countries to UNICEF in 2014 annual forecast exercise).

- Tender outcome; light at the end of the tunnel 😊
- Expect to have awards communicated mid November
- With the awards we will update the BCG Market note to update all stakeholders
WAY FORWARD - Opportunity of learning & change

• UNICEF SD
  – Engage programme partners on out of focus vaccine, and
  – Communicate what we know with suppliers, pipeline, countries and global programme partners

• Suppliers:
  – Communication to UNICEF and WHO on issues impacting short, medium and long term availability
    • Inform and consult with us early stage, pre-decision making if possible

• ‘the community’
  – Remain engaged in existing key vaccines
  – Assess unintended consequences when setting priorities or engaging with industry
Overview of HepB through UNICEF
Hepatitis B vaccine procurement through UNICEF

UNICEF procurement has stabilized around 20 million doses serving mainly the need for a birth dose of the vaccine in 25-30 countries

– The majority of the demand is in 10 dose vials
– Funding is country generated, and majority from 2 countries
Timing of demand and impact of large countries explain differences between forecasts, awards and procurement
• Tender will be issued in November 2015
• Tender period will cover 2016 (from Q2) and 2017, with potential extension through 2018
• Objective of the tender is to receive offers for availability of product at sustainable prices, and establish LTAs with multiple suppliers to enable access to the vaccines at time of need for countries
• Allowing for adjustments in case of programmatic shifts impacting demand after 2017
• UNICEF has occasional requests for HepB adult vaccine and will tender separately for this
Overview of DTP through UNICEF
DTwP vaccine procurement through UNICEF

DTP vaccine demand declining and stabilizing around 4 million doses
Still serving around 20 countries, using the vaccine as a booster dose
Historic procurement of DTwP in 10 & 20 dose vials

- Still serving around 20 countries with small individual demand
- Tough competition on access to DTwP vaccine
- Challenging to meet country-funded demand with long leadtimes
Status on forecasts, awards and procurement

- The graph shows tendered quantities, awarded quantities and actual procurement during the period.
- Variance due to inaccurate forecasts from a few large countries
• Will issue tender in November, covering the period 2016 (from Q2) through 2017, with potentially 1 year extension

• Stable demand forecast around 4 million doses, but small individual orders
DTaP – containing vaccines – UNICEF’s role?

• Limited demand through UNICEF and very limited availability to UNICEF, confirmed in the EOI outcome 2014 Q4.

• Increase in queries from MIC countries over the past year

• Plan to approach Industry in 1H 2016 with tender to have a formal and confidential forum to understand availability and challenges, enabling;
  • Updated information to countries
  • UNICEF to assess whether we should and can play a role in this market, potentially by establishing procurement arrangements (LTAs)

• Questions to industry:
  • What would be a relevant period to cover with a tender – from a supply availability perspective?
  • Update on timelines for projected potential availability to UNICEF
  • How long in advance would UNICEF need to establish agreements to access vaccine in the future?
Pentavalent Vaccine Presentation Outline

- Status
- Market look forward
- Implementing Healthy Market Framework
- New tender approach?
In 2014 all GAVI eligible countries had introduced the vaccine.
Pentavalent scale up in India

India pentavalent third phase scale up of pentavalent; coordination with Government of India, GAVI, 3 Suppliers, UNICEF country office
Pentavalent scale up in India

129 PO-lines
39 different Consignees, in 23 states and territories
63 million doses
The graph shows the development in procured volume, presentation specific WAPS, presentation quantity split over time for GAVI countries procuring through UNICEF.
The graph shows the procurement for non GAVI middle income countries procuring through UNICEF, and the price development over time.
Since 2012 the market has been relatively stable and competitive, but we do expect regular minor interruptions from single manufacturers.
## 2015 status of Pentavalent supply and demand

### Gavi Countries

<table>
<thead>
<tr>
<th></th>
<th>2 dose (lyo)</th>
<th>1 dose (liq)</th>
<th>10 dose (liq)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015 Forecasted</td>
<td>Level of projected</td>
<td>2015 Forecasted</td>
<td>Level of projected</td>
</tr>
<tr>
<td>Quantity</td>
<td>LTA utilisation</td>
<td>Quantity</td>
<td>LTA utilisation</td>
</tr>
<tr>
<td>634,000</td>
<td>127%</td>
<td>44,174,920</td>
<td>90.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>163,450,000</td>
<td>98.8%</td>
</tr>
</tbody>
</table>

### Non-Gavi Countries

<table>
<thead>
<tr>
<th></th>
<th>2 dose (lyo)</th>
<th>1 dose (liq)</th>
<th>10 dose (liq)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015 Forecasted</td>
<td>2015 Forecasted</td>
<td>2015 Forecasted</td>
<td></td>
</tr>
<tr>
<td>Quantity</td>
<td>Quantity</td>
<td>Quantity</td>
<td></td>
</tr>
<tr>
<td>-</td>
<td>821,050</td>
<td></td>
<td>8,557,000</td>
</tr>
</tbody>
</table>
**Pentavalent Supply and Demand 2016**

<table>
<thead>
<tr>
<th></th>
<th>Gavi Countries</th>
<th>Non-Gavi Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2 dose (lyo)</td>
<td>1 dose (liq)</td>
</tr>
<tr>
<td>2016 Forecasted</td>
<td>2016 Forecasted</td>
<td>2015 Forecasted</td>
</tr>
<tr>
<td>Quantity</td>
<td>Awarded quantities</td>
<td>Quantity</td>
</tr>
<tr>
<td>48,000</td>
<td>500,000</td>
<td>-</td>
</tr>
<tr>
<td>44,000,000</td>
<td>47,000,000</td>
<td>1,100,000</td>
</tr>
<tr>
<td>145,000,000</td>
<td>125,500,000</td>
<td>7,200,000</td>
</tr>
</tbody>
</table>

- 1 dose (liq) is projected to be slightly over-awarded in 2016
- 10 dose (liq) remaining unawarded quantity of 19.5 Mds

- Tender for 2016 will be issued in November
- Awards to be made as requirements materialize
Implementation
With GAVI countries fully introduced => focus moves to coverage and equity and support to phase 3 countries to ensure immunization gains do not diminish
Key in supporting these efforts are ensuring available, affordable vaccine, in the right presentations and presentation mix, for both GAVI 73 and MICs using pentavalent vaccine
GAVI and UNICEF strategic outlook

Gavi Phase 2016-2020 strategic goals

- Accelerate equitable uptake and coverage of vaccines
- Increase effectiveness and efficiency of immunisation delivery as an integrated part of strengthened health systems
- Improve sustainability of national immunisation programmes
- Shape markets for vaccines and other immunisation products

UNICEFs role in vaccine procurement:

- Strive towards healthy markets that supports continued availability, affordability and programmatic effectiveness in all UNICEF supplied countries
- Work with countries on improved forecasting, planning and funding solutions for sustainability
Pentavalent Roadmap – objectives for the upcoming tender

• **Balance of supply and demand**
  – Ensure sufficient supply of vaccine is available to at least meet total Gavi demand and demand from non-Gavi MICs
  – Provide consistent, uninterrupted supply to Gavi countries

• **Appropriate and innovative vaccines**
  – Ensure procurement of appropriate, quality vaccines to meet Gavi country needs
  – Foster an environment for innovative vaccines and delivery devices

• **Cost of vaccine to Gavi and countries**
  – Minimise the vaccine cost
  – Minimise the cost implications of vaccines to Gavi and countries

• **Information**
  – Information is a cross-cutting objective and enabler for all vaccines
Pentavalent Demand Forecasts 2017-2020

- Forecast for ‘Gavi countries’ procuring through Unicef
- Assumes countries maintain current presentation preference
- 4 years forecast, but tender duration is not decided yet
Pentavalent Demand Forecasts 2017-2020

- From a projected 15% in 2016, the self-financed portion is projected to increase to 28% by 2020, based on the latest GAVI policies.
- Offers and country demand will guide Gavi to offer other liquid presentations to countries (2 dose vial, 5 dose vial, cPAD).
- Non-GAVI long term forecasts are uncertain, considering including in GAVI tender.

### Country financed

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>15%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>19%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>21%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2019</td>
<td>25%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2020</td>
<td>28%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Demand

- **Presentation**
  - 10 dose
  - 1 dose
  - non GAVI

<table>
<thead>
<tr>
<th>Year</th>
<th>10 dose</th>
<th>1 dose</th>
<th>non GAVI</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>6,800,000</td>
<td>1,100,000</td>
<td>7,900,000</td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>2,800,000</td>
<td>650,000</td>
<td>3,450,000</td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>2,800,000</td>
<td>650,000</td>
<td>3,450,000</td>
<td></td>
</tr>
<tr>
<td>2019</td>
<td>2,800,000</td>
<td>650,000</td>
<td>3,450,000</td>
<td></td>
</tr>
<tr>
<td>2020</td>
<td>2,500,000</td>
<td>650,000</td>
<td>3,150,000</td>
<td></td>
</tr>
</tbody>
</table>
Experience has shown us that:

... we need multiple suppliers, to ensure security of supply and to maintain long-term competition. ... the major price shifts have been correlated with

- competition
- market production capacity
- publishing of pricing
- catalytic contracting incentives

... long duration tenders in themselves may not yield the best price-results

... there is industry and partner desire for greater transparency on the trade off considerations in the award decision making
Implementing the Healthy Market Framework (HMF)

Grounded in the GAVI Market Shaping objectives and the Pentavalent Roadmap

The Healthy Market Framework will be used to guide the development of the objectives and the evaluations of offers for the upcoming Pentavalent tender.

The elements have been captured in previous tenders, but the structure may differ from previous tenders.
What’s new – HOW to tender for 2017 +

Our focus is now on sustainability of the supply market and affordability for countries.

To ensure the current market conditions are leveraged, and opportunities for more frequent competition and price discovery are facilitated, we are considering advantages and disadvantages of different tender modalities, duration and frequency, including:

- **Annual tenders**, with bid openings….
- Tendering with **RFPs more frequently**; every 2 years…
- **Multi-round tender:**
  - Request for Proposal (RFP) covering a period of 3-4 years in total.
  - The RFP could include a schedule of planned, partial awards, with price publication after each award phase
  - Bidders would have the possibility of providing new updated offers for the remaining unwarded quantity before each new award stage.
The mechanics of a multi-round tender

Example Supply period

1st awards
2nd awards
Tender
2nd round offers

<table>
<thead>
<tr>
<th>Year</th>
<th>1st awardees ($m)</th>
<th>2nd awardees ($m)</th>
<th>Total ($m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2019</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2020</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Based on this first introduction, we invite you to provide feedback on how we structure the tender to solicit the best offers from you for this period.

Feedback can be given in plenary, in the scheduled side meetings or following the meeting.

Next week, we are convening a Procurement Reference Group to discuss options and provide advise and challenge.

As the procurement strategy is finalized, we will invite industry for a specific pre-tender meeting on the 2017+ tender, during second half of November 2015, to brief on objectives, expectations and any change in modality that we are introducing.

Target tender issuance: 18 December 2015
Thank you