EPI Routine vaccines
Pentavalent, Hexavalent and traditional EPI vaccines

Industry Consultation
UNICEF Supply Division
25-26 January 2012
Presentation Overview

Pentavalent vaccine evolution – where are we now?

Moving forward 2013 and beyond

Other traditional EPI vaccines: DTP, DT, HepB, BCG
Vaccine Security: Ensuring the uninterrupted, sustainable supply of affordable vaccines of assured quality

The concept of Vaccine Security continues to guide our approach to secure and supply routine vaccine for countries EPI programmes.

For the future we will focus on:

• Balancing supply and demand to ensure supply security
• Focusing on both price and cost of products, ensuring that more elements of affordability are incorporated
• Enabling the future EPI schedule
A changing EPI schedule – catalysed by GAVI support for introduction of HepB and Hib containing vaccines

The transition from DTP has been challenging to forecast accurately and is now resulting in stock-outs and a global shortage of pre-qualified DTP pre-qualified vaccine.
Pentavalent introduction via GAVI support and UNICEF procurement (as of end 2011)

In 2012 65 out of 67 GAVI eligible countries will have introduced pentavalent vaccines, the majority with procurement through UNICEF.
Pentavalent vaccine demand and pricing

Steep demand growth in the past years, expecting growth to continue but at a slower pace in the next 4 year period as programmes reach full implementation.
Declining prices due to new supplier base and availability of multidose vials.
Procurement objectives: 2000 – 2012

Procurement objectives 2000-2005 focused on:
- enabling accelerated introduction and use of new vaccines
- making available products that met countries needs and preferences
- creating a market that would be sustainable with affordable pricing

In 2006 the GAVI Board approved 3 specific procurement objectives that guided UNICEF procurement:

1. A healthy market: ensuring the sustainable quantity of supply through a diverse supplier base
2. Select products and presentations that best meet the need of client countries
3. Achieving a long term affordable price that countries can eventually finance in a sustainable manner
Assessment of pentavalent vaccine procurement objectives for the 2010-2012 procurement round

<table>
<thead>
<tr>
<th>Objective</th>
<th>Assessment (2010-2012)</th>
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<tbody>
<tr>
<td>1. A healthy market: ensuring the sustainable quantity of supply through a diverse supplier base</td>
<td>1. Growth in supplier base, but still volatile; 2 new suppliers, 2 de-listed. Today sufficient pentavalent to supply all countries, but requiring close management</td>
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<tr>
<td>2. Select products and presentations that best meet the need of client countries</td>
<td>2. Introduction of 2 new presentations, enabling a shift in demand from small vials towards 10 dose vials</td>
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<tr>
<td>3. Achieving a long term affordable price that countries can eventually finance in a sustainable manner</td>
<td>3. Starting to see reduction in WAP due to new supplier base and multidose vials.</td>
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The initial offer and award volumes for 2010-2012 for Pentavalent vaccines

With increased demand quantities and increased competition, we expected price to decrease. Even with an expanded supplier base, the WAP is only just below $3.00. However, the newer lower priced products give a positive indication of lower prices ahead…
Current procured volumes and WAP development for 2010-2012 for Pentavalent vaccines

...that already started to materialize with the additional awards made during the period, and we are now looking at a WAP for 2012 of $2.33 per dose across all presentations.

Note: the offered quantity and forecasts reflect the 2009 situation
With increased demand quantities and increased competition, we expected price to decrease. Need continued focus on affordable prices from manufacturers.
Pentavalent 2010-2012: Increasing demand and significant changes in the supplier base

Supply complexity:
Delays in pre-qualification timelines, supplier de-listings, recall, availability delays, engaging alternative supply.

We appreciate manufacturers' flexibility and responsiveness, avoiding prolonged disruptions to immunization programmes.

Demand changes:
Supporting introduction of 10 dose vials (in 19 countries so far)
Uncertainty during this period around the introduction plans of India and Nigeria
New presentations meeting country demand

19 countries introduced 10 dose vials in 2011.
Moving Forward: In November 2011 the GAVI Board approved the GAVI Supply and Procurement Strategy that will guide GAVI supported procurement through UNICEF

GAVI Vaccine Supply and Procurement Objectives

1. Balance of supply/demand
   • Ensure sufficient availability to at least meet total GAVI demand
   • Provide consistent uninterrupted supply to GAVI countries.

2. Cost of vaccine to GAVI and countries
   • Minimize cost per course
   • Minimize cost implications

3. Appropriate and innovative vaccines
   • Procurement of appropriate, quality vaccines to meet GAVI country needs
   • Foster an environment for innovative vaccines

Information: Communicate timely, transparent and accurate market information
Moving forward:
What market are we entering in 2013?

Demand: Growing at a slower pace, and with higher visibility than in the past, as the majority of countries already have introduced.

Some fragmentation of funding streams.
- GAVI financing still supports the majority of the demand.
- Co-financed doses are increasing towards 1/5 of the demand in a couple of years
- Graduated countries represent a small portion of expected demand for 2016.

Remaining demand uncertainties in GAVI countries: India scale-up plan, timing of co-financed demand, graduated countries procurement strategy, and impact of longer term more combination vaccines (hexa) on penta demand.

Supply: Market has been growing, but is still unstable
- Expected to stabilize with increased capacity and more presentations over the period
- Positive signals on more affordable pricing from the growing supplier base
Total demand projections for pentavalent vaccine through UNICEF 2013-2016

- Forecasts will be refined prior to tender issuance
- Assumptions:
  - India will introduce and use pentavalent in 8 states throughout the period, but this may increase. India demand will be specified in the tender and we will request specific delivery terms for India.
  - GAVI Graduated countries procure through UNICEF

- Co-financing increases from current around 10% towards 25% of the GAVI financed demand in 2015.
- India assumption 8 states.
- Includes forecasts from GAVI graduated countries in 2016
Pentavalent vaccine – Demand scenario by country product preference

- Based on the currently expressed country preference – may change over time
- Does not include any future hexavalent that could impact demand / preference
- Reliability of supply – higher with lyophilized production?
  - Requesting feedback from manufacturers to help inform countries’ future demand preferences.
The other future…..
Initial 2012 – 2018+ IPV containing vaccine scenarios

Standalone IPV anticipated to be the preferred product during the eradication and tOPV-bOPV switch phases

The following IPV scenarios for potential use of IPV in polio eradication, have been created based on guidance input from programme partners.

They represent a combination of routine and campaign activities, with 1 or 2 dose scenarios for the eradication phase, and 3 early scenarios for future demand of IPV in combinations.

Low cost hexavalent anticipated to be the preferred product in the 'post-OPV' period, 2017-2018.
A programmatic demand scenario for IPV – Consolidated demand plus India. Up to 58 million full dose equivalents w/India.

*ID quantities are shown as full dose equivalents and based on 2 dose schedule*
An affordable hexavalent would need to be available before universal introduction and use of IPV. This is an **unconstrained** scenario; there would need be a transition from the ID stand alone product to Hexa, this would not happen over night in 2017.
Strategic tender issues - Innovations in procurement

Objective for the Pentavalent tender: **Securing supply**, bringing stability to the market while achieving affordable vaccine prices and enable future development of the EPI schedule, in alignment with the GAVI SPS objectives.

Opportunity to provide innovative proposal features to help us achieve exceptional results.

- We invite all interested to provide proposals. All valid offers are considered and help inform the award strategy, including on how much demand to keep open for later awards.

- We will be working with GAVI partners to explore various possibilities to achieve the objectives.
Innovative elements - products, offers and awards

We are requesting feedback on the approach to make sure we ask in a way that will solicit the best offers:

• Meeting the call for lower, affordable prices
• Increased focus on products that enable in-country logistics and distribution:
  low shipping volume and cold chain requirements, primary container volumes and characteristics, different presentations that can meet countries' needs etc.
• Include offers and information on potential alternatives such as lyophilized/liquid, DTaP, and alternatives.
• We will also request that proposals inform of / or offer future hexavalent vaccines, focusing on the plans and milestones for decision making.
Period covered by the tender: 2013-2016

4 years – to consider the supply pipeline, opportunity to secure long term attractive offers

In 2016, inclusion of demand from graduated GAVI countries procuring through UNICEF.

Include scenarios requesting hexavalent product offers for the tender period and indications for the following 2 years (2017-2018).

• Demand will depend on polio programme progress, country IPV decision making, and affordable supply availability.
Tender timeline for pentavalent tender 2013 - onwards

January 2012: Pre-tender meeting for all relevant vaccines with manufacturers and partners

February: Feedback on tender strategies

End March: Issue tender documents with 6-8 week response time

May-August: Review offers, clarifications with manufacturers, consultations, internal review processes

September: Awards to manufacturers

Jan 2013 Start of supply from new contracts
Vaccine Security for traditional EPI routine vaccines

HepB, BCG, DTP, TT, Td, DT will tendered for together covering the period 2013-2015
DTP – an overview of procurement, awards and forecast

Declining demand due to transition to DTP combination vaccines
The challenge is to meet demand changes in a declining market trend.
Vaccine shortages in 2011/2012.
DTP – forecasted demand through UNICEF

Forecasts in doses per year

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<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
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<tbody>
<tr>
<td>DTP-10</td>
<td>12,000,000</td>
<td>6,000,000</td>
<td>6,000,000</td>
<td>6,000,000</td>
</tr>
<tr>
<td>DTP-20</td>
<td>220,000</td>
<td>310,000</td>
<td>350,000</td>
<td>380,000</td>
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Objective will be to secure sustained supply at affordable prices from more than one supplier to ensure flexibility and supply security. 2016 forecasts is included to show the continued expected demand level.

Tender will also include DT demand:

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<th>2015</th>
<th>2016</th>
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<tbody>
<tr>
<td>DT-10</td>
<td>1,200,000</td>
<td>1,250,000</td>
<td>1,300,000</td>
<td>1,400,000</td>
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</tbody>
</table>
Declining demand due to transition to DTP combination vaccines
GAVI no longer funds stand alone HepB vaccine
Still demand from some countries that use HepB birth dose
Expecting HepB market to stabilize at this lower level.
HepB – forecasted demand through UNICEF

Forecasts in doses per year

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<thead>
<tr>
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<th>2015</th>
<th>2016</th>
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<tbody>
<tr>
<td>HepB-10</td>
<td>23,000,000</td>
<td>16,000,000</td>
<td>18,000,000</td>
<td>19,000,000</td>
</tr>
<tr>
<td>HepB-1</td>
<td>1,200,000</td>
<td>1,300,000</td>
<td>1,350,000</td>
<td>1,450,000</td>
</tr>
<tr>
<td>HepB-6</td>
<td>13,000</td>
<td>13,000</td>
<td>14,000</td>
<td>14,000</td>
</tr>
<tr>
<td>HepB-2</td>
<td>75,000</td>
<td>75,000</td>
<td>80,000</td>
<td>85,000</td>
</tr>
</tbody>
</table>

Objective will be to secure sustained supply at affordable prices from multiple suppliers.
Stable demand levels for BCG vaccine – this is expected to continue

Complex and varying funding sources backing the demand at individual country level – stable funding at the aggregate level
**BCG – forecasted quantities through UNICEF**

Forecasts in doses per year

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<tr>
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<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
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</thead>
<tbody>
<tr>
<td>BCG-20</td>
<td>118,000,000</td>
<td>122,000,000</td>
<td>125,000,000</td>
<td>125,000,000</td>
</tr>
</tbody>
</table>

Tender objective is to ensure continued Vaccine Security for a basic childhood vaccine

Focus on achieving affordability and multiple suppliers for continued future supply of this vaccine
Tender timeline for traditional EPI vaccines 2013 - onwards

January 2012: Pre-tender meeting for all relevant vaccines with manufacturers and partners

February: Tender issuance

Mid April: Tender closure

April - June: Review offers, clarifications with manufacturers, consultations, internal review processes

June: Awards to manufacturers

Jan 2013: Start of supply from new contracts
Thank You