Market updates

Vaccine Manufacturer Consultation
October 2014, Copenhagen
Pneumococcal Conjugate Vaccines (PCV)
Demand and Forecast - PCV Procurement 2010-2017

Source: UNICEF Supply Division.
Forecast vs. Actual Demand (Historical)
Awards for 2010-2024

- Multiple long-term PCV Supply Agreements with two manufacturers for 1.46 billion doses covering a total duration from 2010 through 2023 / 2024

- No new manufacturers have communicated they would enter the market with a WHO prequalified PCV prior to 2018

Source: UNICEF Supply Division.
## Status of Country Introductions, Approvals and Future Potential Applications

*Note: = Graduating country.

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Source: UNICEF Supply Division based on GAVI’s SDF v9.0.
HOW CAN YOU ENGAGE WITH UNICEF TO MEET THE NEEDS OF CHILDREN?

Next Steps

- PCV manufacturers (pipeline) are encouraged to register with the AMC Secretariat and to communicate with UNICEF SD to start a close follow-up on their vaccine developments.

- $405 mio. of AMC donor funds remain available for future supply agreements (27% of AMC funds).

- Future Call for Supply Offer: based on SDF v10 and outcomes of the 2014 rounds of GAVI applications, UNICEF and Gavi will assess the situation and agree on the next steps.

- Producers with a PCV in pipeline will be invited to participate in the future tenders.
Rotavirus Vaccines
Demand and Forecast – Rotavirus Vaccine - Long Term

SDF v10: Rotavirus Total Required Courses for Gavi73 and non-Gavi Eligible LMICs

Assume supply constraints to lift in 2018

Source: Gavi SDFv10
Demand and Forecast – Rotavirus Vaccine 2011-2016

- RV1 procurement
- Cumulative carry-over

2011: 5.4
2012: 10.2
2013: 22.8
2014: 22.1
2015: 25.6
2016: (expected to be 30 million)

Chart shows the procurement and projections for RV1 and RV5 vaccines from 2011 to 2016.
Current situation

• 2 Long Term Arrangements for the supply of Rotavirus Vaccine with two manufacturers for 83.4 Million courses covering a total duration from 2012 through 2016.

• No new manufacturers have informed they would enter the market with a WHO prequalified Rotavirus Vaccine prior to 2019.

• Rotavirus vaccine availability has improved in 2014 due to positive supplier response to programmatic requirements.

• Unbalanced demand due to country choices that favor one product.

• Demand expected to exceed available supply by 2017/2018, this entailing delays in country introductions
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- Approved and Introduced
- Approved pending introduction
- Applied pending approval
- Countries not yet applied

Source: UNICEF Supply Division.
HOW CAN YOU ENGAGE WITH UNICEF TO MEET THE NEEDS OF CHILDREN?

• Rotavirus manufacturers (pipeline) are encouraged to communicate with UNICEF SD to start a close follow-up on their vaccine developments.

• Expectations on new formulations that will improve the supply landscape

• Future Tender: based on SDF v10 and outcomes of the 2014 rounds of GAVI applications, UNICEF will issue a new tender in Q2 2015 (to contract doses as from 2017)

• Producers with a Rotavirus Vaccine in pipeline will be invited to participate in the future tender.
Pentavalent vaccines
• All GAVI countries have introduced
• Both supply and demand markets are maturing
Product presentation preferences & price

Impact on price

- 10 dose vials
- Increased demand volume
- Increased competition and production capacity
Global pentavalent requirements are forecasted to stabilize over the next few years.

3 large country scale-ups in 2014-2016 drives the increase in this period. After this population growth and coverage increases drives the trend.

SDF v10.0: Pentavalent Total Required Supply for Gavi73 and non-Gavi Eligible LMICs

*Includes Not supported Gavi73 countries

Source: GAVI
UNICEF procures for MICs through annual tenders

- UNICEF procurement facilitate introduction of pentavalent in MICs, but countries will not necessarily continue to go through UNICEF.
- Annual tenders as demand through UNICEF is uncertain in the long term.
- The prices for MICs have dropped with the maturity of the market.
- Currently no price differentiation between MIC and GAVI countries for same term offers. Indicates that the competition and capacity is influencing the price.

![Graph showing the trend of doses in millions and price per dose in US$ from 2001 to 2016.](image)
WAY FORWARD - 2015 and beyond?

• Currently establishing award for 2015-2016

• Will still keep possibility of reviewing new products and manufacturers as they become pre-qualified

• Expect to issue new tender for 2017+ period

• From 2016 GAVI graduated countries become a demand tranche, for these countries sustainable low pricing is key

• UNICEF still see our procurement and the GAVI support as key market shaping portion of the global demand for this vaccine

• Objectives for the future will be to maintain competition and ample capacity, unlock lower prices, and explore how vaccine presentations can improve coverage and equity
BCG vaccines
• 100-120 million doses annual demand
• Supplied to more than 70 countries annually
• In recent years more than 80% is country-originated funding
• Demand forecasts for 2015 exceed current awards, and we are in dialogue with all WHO pre-qualified manufacturers on availability
Forecasts remain > 125 million doses

- Increased requirements in 2013 and 2014 as new countries came through UNICEF
- Forecasted demand 2015, 2016 and 2017, will be updated before tender issuance, based on recent country forecasts
Way Forward - 2015 and Beyond?

- Tender for supply 2016 and beyond will be issued in early 2015.

**Main Objectives of the Tender**
- To secure sufficient supply for countries procuring through UNICEF, and to provide market insight to countries procuring on their own.
- To maintain a healthy supply market with affordable vaccines, by providing manufacturers with accurate and long-term forecasts to aid long-term capacity and production plans.
- Engage with new potential WHO pre-qualified BCG manufacturers
HOW CAN YOU ENGAGE WITH UNICEF TO MEET THE NEEDS OF CHILDREN?

• For existing suppliers: Maintain effective relationship and communication with UNICEF to optimize synchronization of demand and production planning, and provide timely visibility on constraints.

• Keep UNICEF informed – and engage with us – if you have a BCG product aiming for WHO pre-qualification.
HPV vaccines

(Human Papilloma virus)
Where are we with HPV introductions?

- The Programme: GAVI supports routine introduction of HPV vaccine for girls, in the age range 9-13 years, and require a demo programme before supporting a national introduction.

- Still a new programme, the support window opened in 2012, the first countries started in 2013.
  - 21 countries have been approved for demonstration programme support to date.
  - Massive interest – almost 50% of the eligible countries have applied.
  - 3 countries have been approved for national introduction, only one has introduced to date.
  - Demo programmes are small scale < 15,000 girls, designed to inform countries and ensure successful national design when/if implemented.
  - Most countries have a school based programme, with a strategy for reaching out of school girls.
Demand development since the ‘High scenario’ presented in tender in 2012

• Significant changes to forecasts since the initial tender and the first GAVI projections due to:
  – Challenges in predicting country starts, particular for national introduction. More countries projected for 3 year demo programmes
  – Change in vaccination schedule from 3 dose to 2 dose recommendation
  – Programme design; different from the other child vaccines

• The RFP high scenario totaled 62 Mds for the 5 year period 2013-2017. The revised forecast (ADF) totals 27.4Mds for the period.
Procurement to date for GAVI supported programmes: Demos and National introduction, MIC procurement and forecasts
Short term demand forecast down, but the long term programme forecasts remain the largely the same

- Since mid 2014 all forecasts and support is based on a 2 dose schedule, while before it was all 3 dose schedule.

- SDF 10: 30 million girls immunised by end of 2020 (SDF v 6 from Nov 2012: 32 million girls)
- 15 countries are forecasted to start national introduction in 2016

Source: GAVI

**Base Unconstrained: Total Required Supply for 94 Countries by Financing**

- Slight drops in SDFv10 doses due to forecasting more countries conducting 3 year demos
- Move from 3 to 2 dose course drops demand by 33%
WAY FORWARD - 2015 and beyond?

- Demand forecasts revisions are under development and being shared.

- We intend to share an HPV Market note before year end.

- Expect to issue a new tender in for GAVI supported countries in 2016 to cover requirements from 2018 onwards.

- Demand from non-GAVI eligible countries will also be encouraged and supported.
  - This is procured with reference to our Middle Income Country (MIC) focus tender issued in 2012, or ad hoc tenders to meet specific needs.
  - UNICEF’s aim is still to be able to share prices and terms that MICs can access, to aid their decision making and encourage introduction to ensure equity and coverage of this vaccine amongst eligible girls.

- For both demand segments UNICEF is looking to engage with manufacturers that have long term sustainable pricing for countries. We expect the price trends to go down as demand increases.
Measles-containing vaccines
Where are we?

- Significant growth in demand in 2012-2013 for MR vaccine due to currently GAVI-funded introductions which is expected to continue into 2017-2018 and beyond

- Growth in demand for Measles vaccine due to larger age group campaigns, vaccinations following outbreaks and introduction of Measles Second Dose

- Growth in demand for MMR vaccines to be linked to the scaling up of the routine immunization
The main uncertainty is still on timing of MR introductions for the remaining countries.

Routine update is expected to remain at the same level globally. Proportion of MV and MR vaccine within routine demand will depend the timing of MR introductions.

Due to continuing outbreaks of measles and changing epidemiology, the uncertainty remains in Measles vaccine uptake. High probability that the Measles’ demand remains high.
WAY FORWARD - 2015 and beyond

GAVI funding available for MR introductions through wide-range campaigns is available until 2018

Next tender will be launched end of 2015 for all Measles-containing vaccines

Challenges for UNICEF

• To forecast accurately MR introductions and understand its impact on Measles monovalent demand as the decision is country-driven and dependent on country priorities

• To forecast accurately the overall demand due to changing epidemiology of measles
HOW CAN YOU ENGAGE WITH UNICEF TO MEET THE NEEDS OF CHILDREN?

• Secure sufficient supply for countries procuring through UNICEF

• UNICEF is looking for additional manufacturers of Measles-containing vaccines (MV, MR & MMR)

• Provide affordable prices

• Offer new vaccine presentations, for example: using 5-dose vials to reduce wastage rates and increase coverage

• Maintain efficient two-way communication on forecasts and production capacity
Tetanus-containing vaccines
Overall demand for Tetanus-containing vaccines remains at the same level around 160M doses per year.

There is a clear trend of increased Td uptake; however the switch from TT to Td vaccines is taking place at a slower rate than forecasted.
• Tender for supply 2016 and beyond to be issued in early 2015.

Challenges
• To forecast accurately the switch from TT to Td vaccine as the decision is based on country’s acceptance of the WHO recommendation and is dependent on countries’ priorities.
HOW CAN YOU ENGAGE WITH UNICEF TO MEET THE NEEDS OF CHILDREN?

• Maintain high quality and production capacity with affordable vaccines

• Visibility on production plans and their milestones to facilitate countries’ decision-making on switch from TT to Td
YF forecast 2014-2024 Unconstrained demand

Sources: GAVI/UNICEF/WHO

- Demand reaches 50-60 million doses/year between 2014-2021
- Main demand driver are the preventive campaigns
- Limited production capacity until 2017, just to cover routine and outbreak stockpile demand, but not enough for campaigns
Between 2007 and 2013 UNICEF has provided vaccine for campaigns to 13 countries.

The Yellow Fever market has historically been fragile due to production issues and delays, and WHO suspensions of manufacturers.

UNICEF has ensured sufficient availability to cover outbreak stockpile and routine demand, but there is not sufficient supply to fully cover all preventive campaigns.
WAY FORWARD - 2015 and beyond

• Keep improving visibility and reliability of supply and demand by sharing accurate forecast with the manufacturers

• Financial support from GAVI has been secured until 2021

• New tender will be release in 2017 for 2018+ period

• Continuing close engagement with suppliers
HOW CAN YOU ENGAGE WITH UNICEF TO MEET THE NEEDS OF CHILDREN?

• Ensure & secure adequate supply in order to meet demand for future years

• Offer the countries’ preferred format & presentation of 10 doses vials

• Maintain quality of production and product

• Continue focus on offering affordable prices
Cholera Vaccines
Where are we?

- UNICEF does not have a LTA for Cholera vaccines

- UNICEF responds to approximately one to three demand per year and for small quantity only
UNICEF has been asked to become the contracting agent for the International Coordinating Committee and GAVI starting in January 2016.

A tender will be issued in the second half of 2015 for an emergency stockpile and small campaign:

- 2M doses
- To secure additional doses to allow campaigns to take place in hot spots. The quantity is not determined yet, but we expect around 1M to 5M additional doses and increasing each year.
• Share with UNICEF your future plans in producing Cholera Vaccine

• Prepare and submit approval submission to WHO as soon as possible in order to be in a position to present proposals to UNICEF
Thank you