Pneumococcal Vaccine SDF AVI version 3.0

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Executive summary

- No financial or supply constraints
- Policy revisions and changes in country adoption decisions result in 54 introductions by 2015, all but 1 expected applying in 2011-2012
- Up to 20 NVS applications for PCV expected in May 2011, 26 including the 5 conditionally approved and 1 resubmission
- AMC demand exceeds 134m doses in 2016 per SDF v3.0 base case scenario
Graduating countries and 50% NVS threshold represent important demand opportunities

Evolution of Pneumo SDF from ADIP to V3 (2009-2030)
Since AVI in place very limited changes in countries interest in PCV
Forecasting process designed to ensure multiple input and verification points

1. **SVS benchmarks assumption**
   - SVS runs SDF and AF
   - SVS Sub team & GAVI Focal Point review draft SDF and AF
   - SVS incorporates feedback from subteam

2. **SVS benchmarks assumption**
   - GAVI PD confirms input into AF

3. **Feedback**
   - GAVI Finance develops financial forecasts
   - GAVI Forecast Review Board convenes
   - Expenditure Review Board approves forecasts

4. **Feedback**
   - AVI AMT / GAVI reviews and endorses SDF & AF
   - SVS incorporates feedback from AMT/GAVI
   - Director of AVI Approves SDF & AF and submits to GAVI F&O

**Assumption owners provide input**

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**AVI Pneumococcal SDF version 3.0**
### Finance & support*

- No global financial and supply constraints included into the base case strategic demand forecast;
- GAVI support based on revised eligibility approved by November 2009 Board and pilot prioritization policy approved by June 2010 Board
- **Applications round to re-start as per May 2011 with graduating countries grandfathered for the first round and NVS threshold at 50% DTP3**
- NVS applications evaluated on national metrics (no separate state / sub-national applications)
- After graduation from GAVI support countries assumed to be in condition to fully finance purchase of PCV
- **Co-financing policy revision (December 2010) fully incorporated, effective from 2012**
- GNI projections based on 2009 IRBD actual and CGD projections
- PAHO single price clause not impacting negatively manufacturers intention to supply

### Target Population

- Surviving Infants based on 2008 UN population prospect, medium variant for population, birth & infant mortality rates
- India population at state level based on Indian census (projected with UN growth rate)
### Products

- All products WHO pre-qualified, meet or exceed AMC profile and have suitable presentation
- Mix of international and developing countries suppliers ensures no capacity constraint:
  - Synflorix available since end Q1 2010¹, **Phase IV study in Kenya and Ethiopia assumed successful**,  
  - Prevnar13 available since Q3 2010²  
  - First DCMVN products to be available by 2016³ and acceptable from countries with their serotype coverage
- India preference for introduction with local manufacturer can be derogated in the first years
- Schedule = 6, 10 and 14 weeks of age with DTP or Pentavalent / No Booster – some countries as India may consider different schedule
- Presentation = 1-dose and 2-dose liquid vials (future DCVMN manufacturers may provide higher number of doses per vial)
- Supply availability sufficient assuming successful call-for-offer in 2011

### Logistics

- Wastage = 10% based on WHO guidance (to reflect an unknown mix of presentations ranging from 1 to >2 doses per vial) – for countries introducing Prevnar13 5% wastage assumed
- Buffer stocks = 25% of ∆ between forecast years
- Cold chain up scaling and financing available at central & local level in all countries

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¹ Synflorix: PQ subject to special conditions accompanying 2 dose vial presentation in March 2010; Kenya and other special cases only for post-introduction surveillance of 2-dose vial presentation
² Prevnar13: WHO PQ in August 2010, first shipments commenced in Q4 2010
³ Based on standard development timelines (see backup) of 5 years from phase 1 to pre-registration
## Introduction

- Introduction timing as per WHO Regional calls and other input received from WHO and UNICEF; introductions separated by 24 months unless documented input
  - Applying countries are assumed to introduce the year following application in absence of national cold chain or other infrastructure limitations
  - Delay applied if countries required multiple applications for GAVI support for other vaccines
  - Countries applying for 2 vaccines are assumed to introduce within of 2 years of approval as not to lose GAVI support
- Twelve months average preparation time required after Board/EC approval (based on Penta analogue) – preparation time required is expected to decrease to 11 months in 2012 and to 10 months from 2013 onwards.
- **India** phased introduction financed locally beyond GAVI cap – 11 states (same 10 states Introducing Penta + Orissa pilot) to introduce in 2016, remaining states after 2 yrs; graduation as country in 2020
- Chad and Somalia cannot apply for NVS because of low DTP coverage
- **Ethiopia** to introduce Q3 2011; **Pakistan** introduce in Q4 2011
- **Nigeria** to introduce in 2014 after taking advantage of 50% DTP3 NVS threshold for Penta and Pneumo
- **Indonesia** loses eligibility in 2011 and is not expected to apply before graduating; locally financed introduction from 2018

## Uptake

- Time to match reference coverage aligned with HepB/Penta analogue (Pneumo introduced with same schedule as Penta): 24 months for small countries / 36 for medium/large countries (>1 mln SI) / 48 months for very large countries (>3.5 mln SI)

## Coverage

- Reference coverage: DTP2 linear extrapolation based on DTP3/1 WHO/UNICEF 2010 estimates; Nigeria assumption for reference coverage is 63% in 2010
- Projected coverage: based on standard AVI coverage projections rules
Demand from GAVI 72 to peak at 207m doses in 2021

AVI SDF v3.0 BASE CASE - Total required supply from GAVI 72 including graduating countries

- Eligible
- India
- Other countries graduated*
- Graduating before introduction
- AVI SDF v2.0

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*Countries that introduced prior to graduation assumed to continue purchasing vaccines with their own funds when commitment ends*
From 2019, 4 large countries constitute almost 50% of demand
Importance of large countries can be seen now

Pneumo Strategic Demand Forecast Detail – 2011-2016

Millions of doses


18 40 71 96 112 134

2011

3 7 11 14 15

2012

6 8 9 9 9

2013

18 30 48 52 54

2014

50

2015

96

2016

78

All other countries DRC Ethiopia Pakistan Afghanistan Nigeria Bangladesh Total Introduce Countries (cumulative)
GAVI commitments > SDF because of time to peak, coverage, and target population assumptions

**Adjusted GAVI demand**
- Demand for approved countries based on GAVI commitments matching applications requested volumes
- Commitments cover only limited number of years (depending on cMYP), for outer years projections based on yearly growth rate from SDF applied to latest available committed volumes
  - Year 1 of commitment assumed including 25% buffer stock. Projections for countries with only one year of demand based on year 1 values w/o buffer stocks and steady state growth rate.
- If a country has no approved supply, SVS SDF v3.0 forecast is used
If countries are able to reach reference coverage in year 1, reference year demand grows by 13%
If cold chain and past application success delays are removed, demand materializes earlier.
Aggressive scenario and 1 year uptake assumption yield peak of 216 in 2018 for GAVI 72

AVI SDF v3.0 AGGRESSIVE & 1 YEAR UPTAKE - Total required supply from GAVI 72 including graduating countries

- Eligible
- India
- India graduated*
- Other countries graduated*
- AVI SDF v3.0 - BASE CASE

Countries that introduced prior to graduation assumed to continue purchasing vaccines with their own funds when commitment ends.
Thank you