

EPI in development: BCG, HepB, Hib and DTP-containing vaccines

**Supplier meeting
UNICEF Supply Division 3-4 April 2008
Meredith Shirey**

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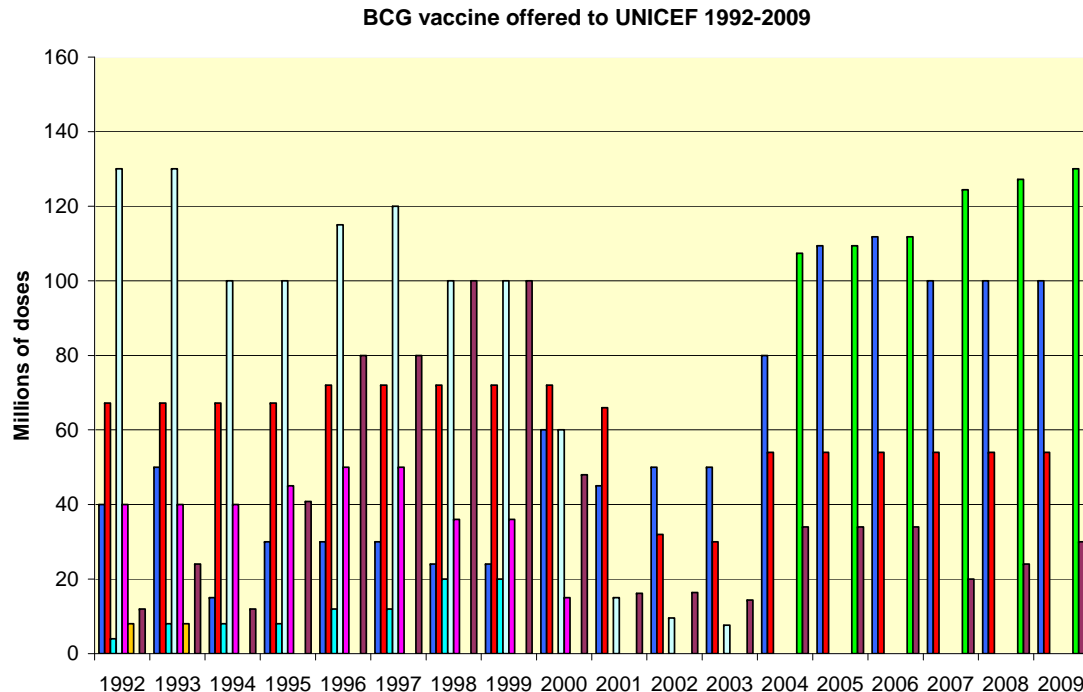
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BCG

Briefing Sheet: BCG

Criteria	Status
Demand Profile	
Presentation	20 dose vials
Quantity	110m – 120m doses per year
Activity Split: Routine, Campaign	100% Routine
Demand Volatility: Urgency of Need, Reliability of Demand	Relatively stable demand, volatility from country entrance/exit (UNICEF Procurement); planned demand for 63 countries in 2008
Anticipated duration of Demand	Continuous
Trends	Marginal increase annually
Market Profile	
Development Stage	Post Mature Market
Market Status	4 WHO PQ vaccines
Trends	Stable
Forecast Accuracy	Good
Funding Profile	Multiple sources, complex but reliable
Contracting	LTA following RFP
Supply Status	Good
Comments:	

BCG – Quantities offered to UNICEF

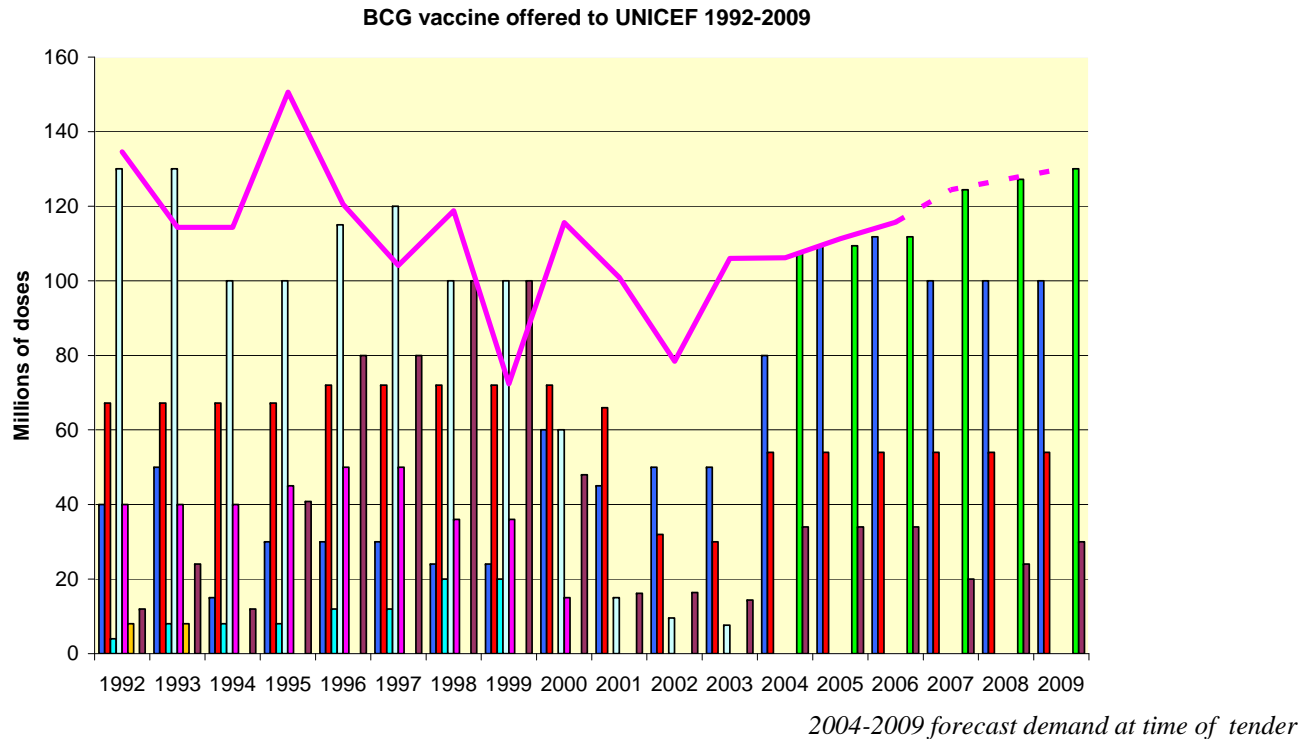


Historically multiple suppliers offering quantities to UNICEF

Market downturn reversed during 2004-2006 tender period following implementation of Vaccine Security Strategy

4 manufacturers offered quantities in the last tender

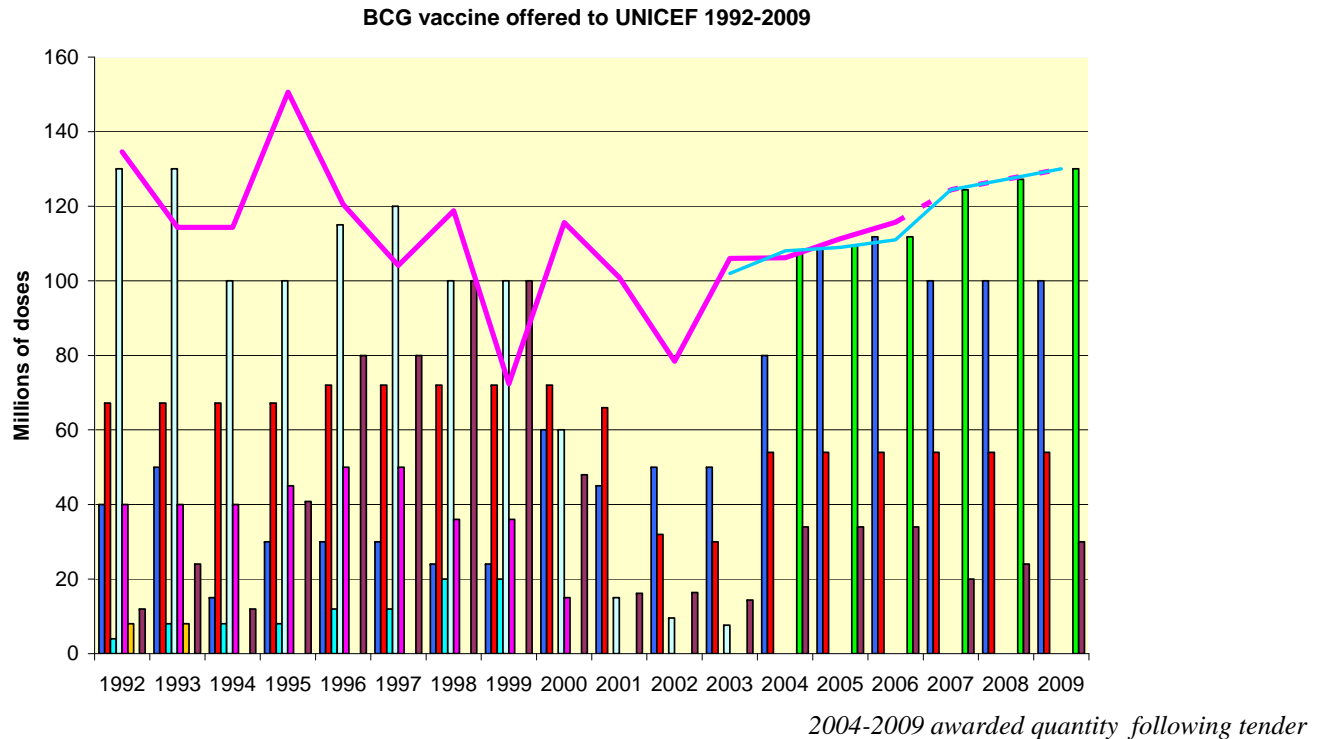
BCG – Quantities offered to UNICEF



Following the Vaccine Supply crisis, Awards were made to multiple suppliers meeting the forecasted demand requirements from countries

4 Suppliers have LTAs currently

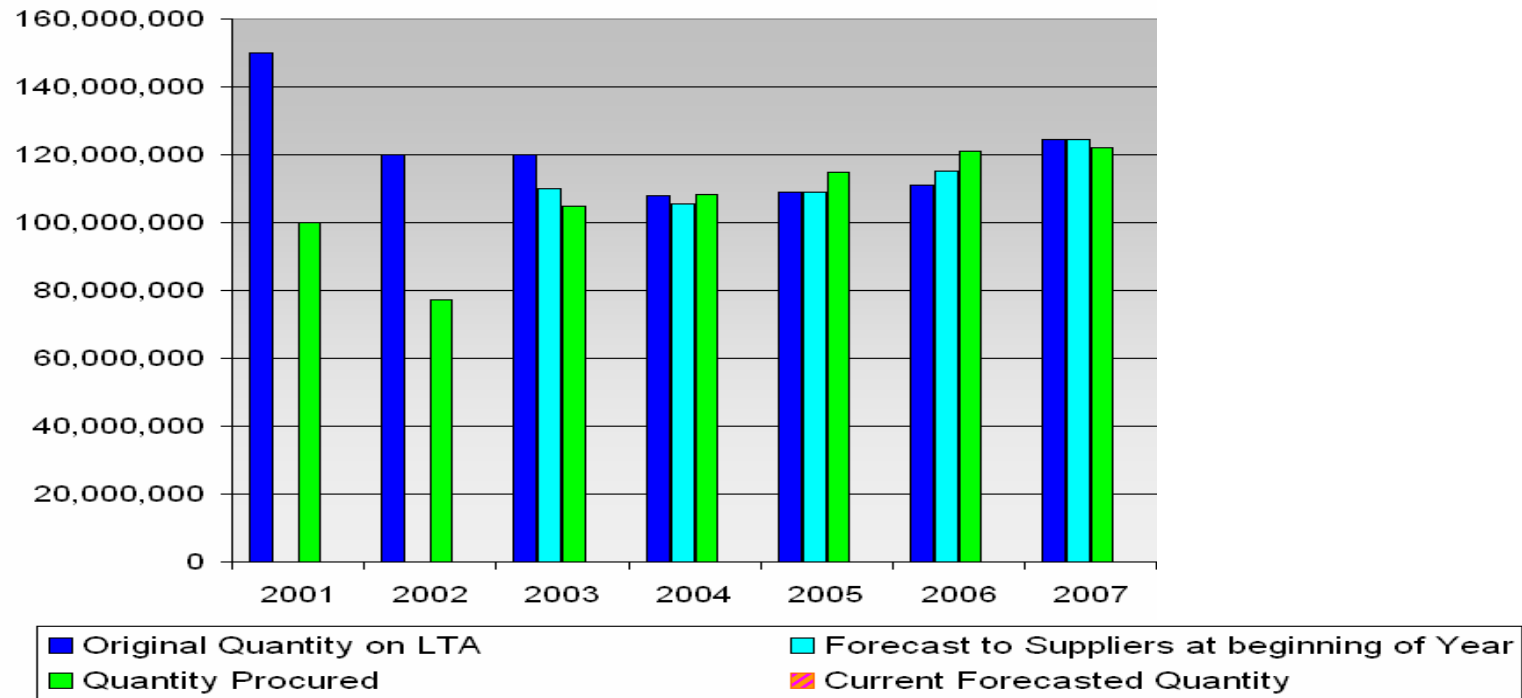
BCG – Quantities offered to UNICEF



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BCG – Procurement Overview - Historical

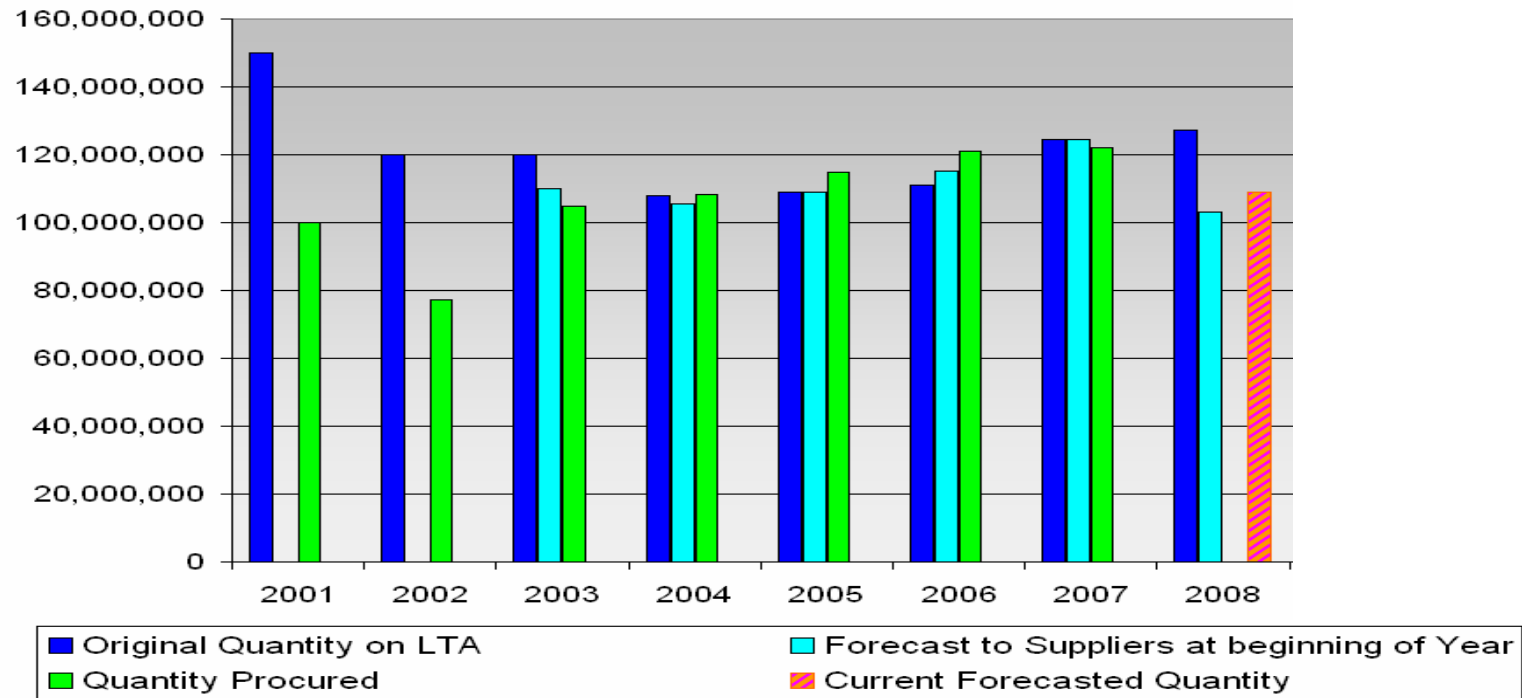


Relatively stable demand, fluctuations occurring due to countries exiting or entering UNICEF Procurement

Improved forecasting over time

2008 reduced quantities due to Pakistan self procurement

BCG – Procurement Overview - Current

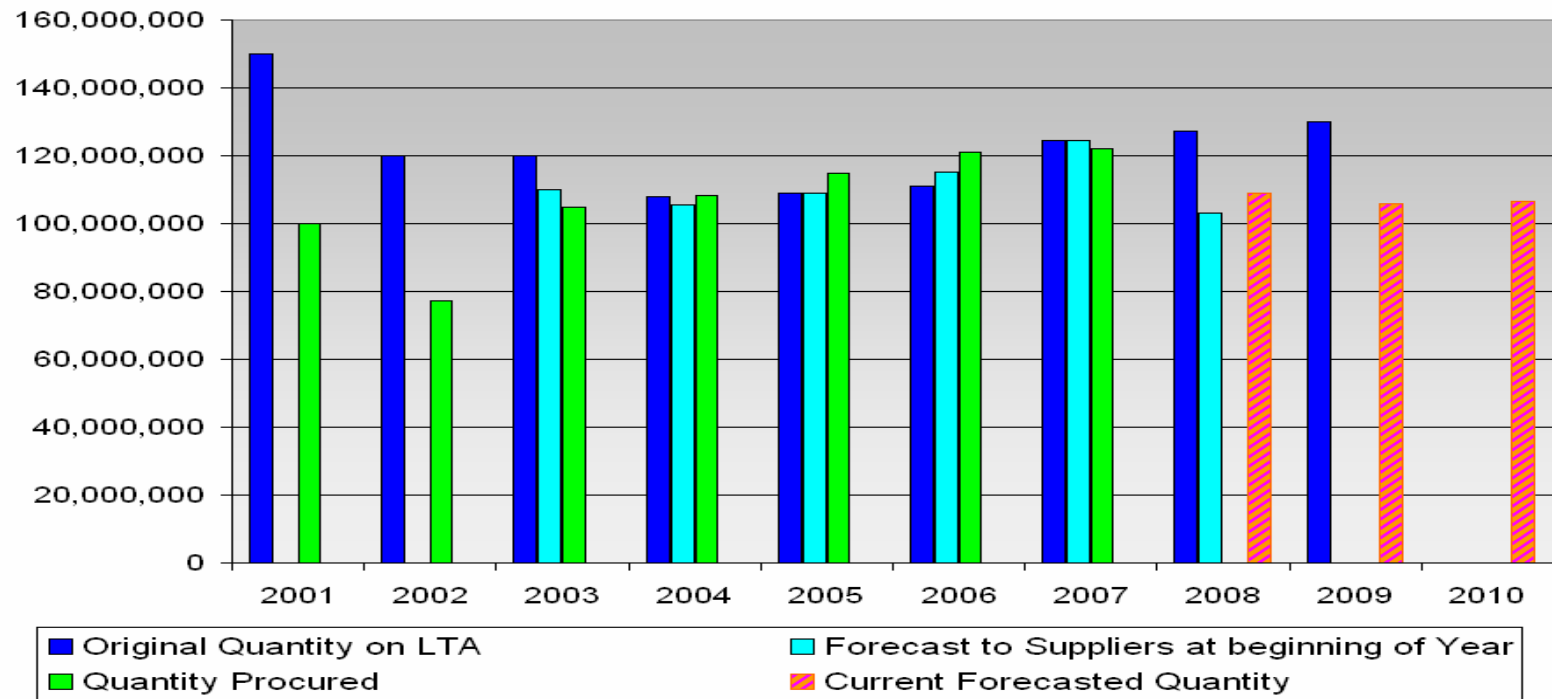


Relatively stable demand, fluctuations occurring due to countries exiting or entering UNICEF Procurement

Improved forecasting over time

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BCG – Procurement Overview - Future



Relatively stable demand, fluctuations occurring due to countries exiting or entering UNICEF Procurement

Improved forecasting over time

2008 reduced quantities due to Pakistan self procurement

HepB

Briefing Sheet: HepB

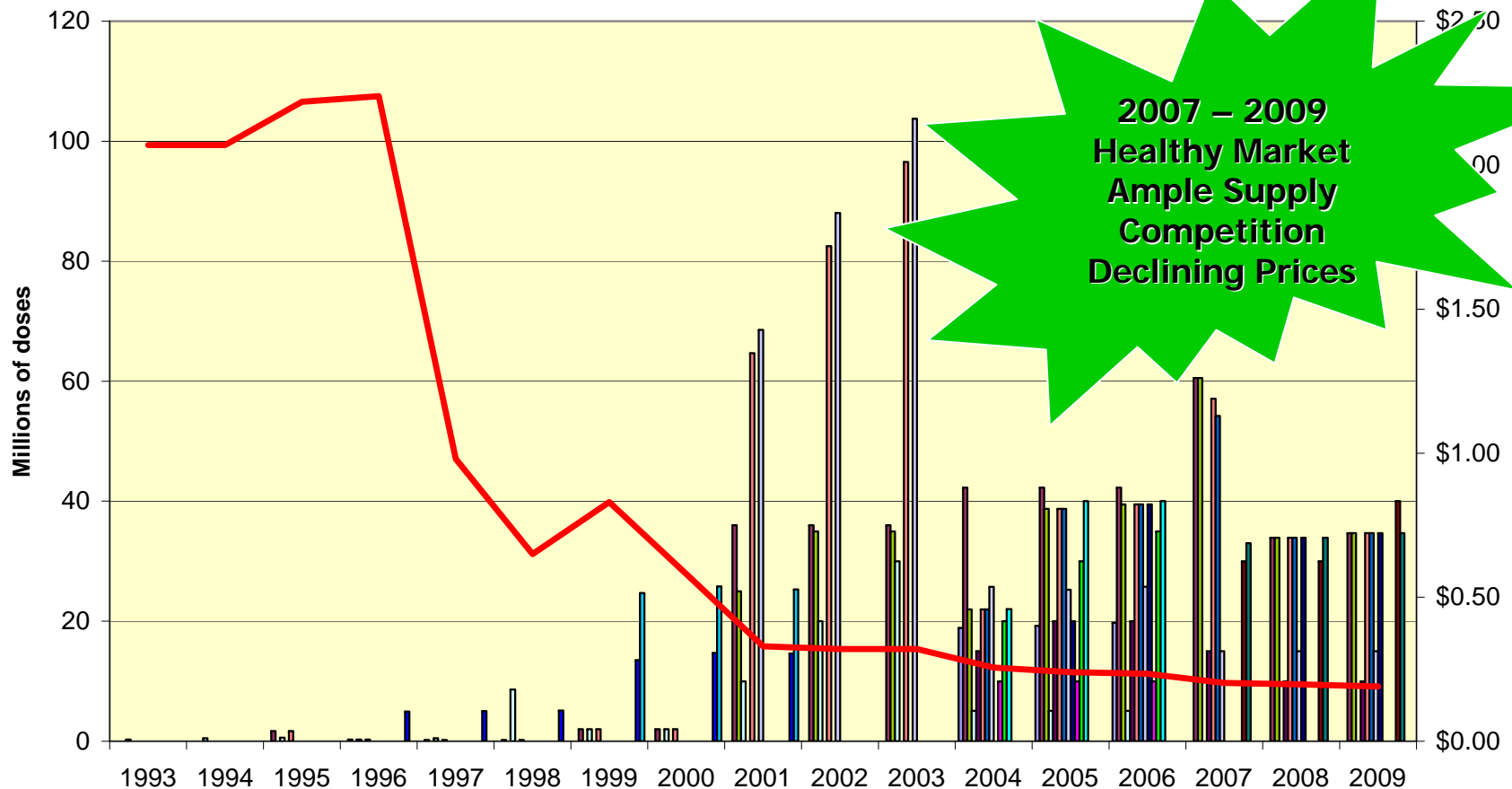
Criteria	Status
Demand Profile	
Presentation	1, 2, 6 & 10 dose vials
Quantity	~60 m doses (2008) + ~45 m doses for India
Activity Split: Routine, Campaign	100% Routine
Demand Volatility: Urgency of Need, Reliability of Demand	Planned demand for 32 countries in 2008 (18 GAVI/14 Non-GAVI). Volatility of demand due to a few large countries (GAVI & Non-GAVI).
Anticipated duration of Demand	Continuous
Trends	Decreasing as countries introduce combination vaccines
Market Profile	
Development Stage	Mature
Market Status	9 WHO PQ vaccines
Trends	Stable
Forecast Accuracy	Poor in 2007
Funding Profile	Multiple sources, complex but reliable. GAVI phasing out.
Contracting	LTA following RFP (GAVI & non-GAVI)
Supply Status	Good

Comments: Good supply base, but will need to focus on managing a reduced demand to maintain supply to a few countries.

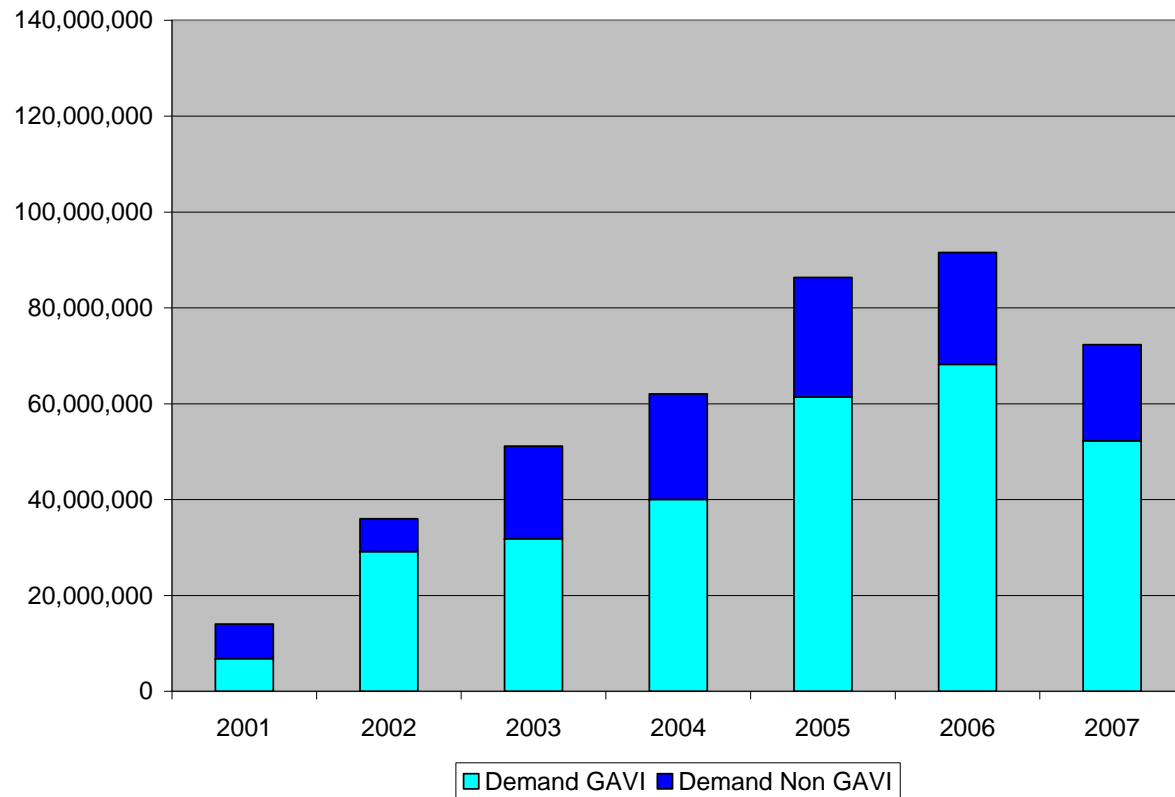
HepB market is healthy:

Entrance of multiple suppliers over time has resulted in substantial availability and a significant reduction in price

HepB vaccine offered to UNICEF 1993-2009

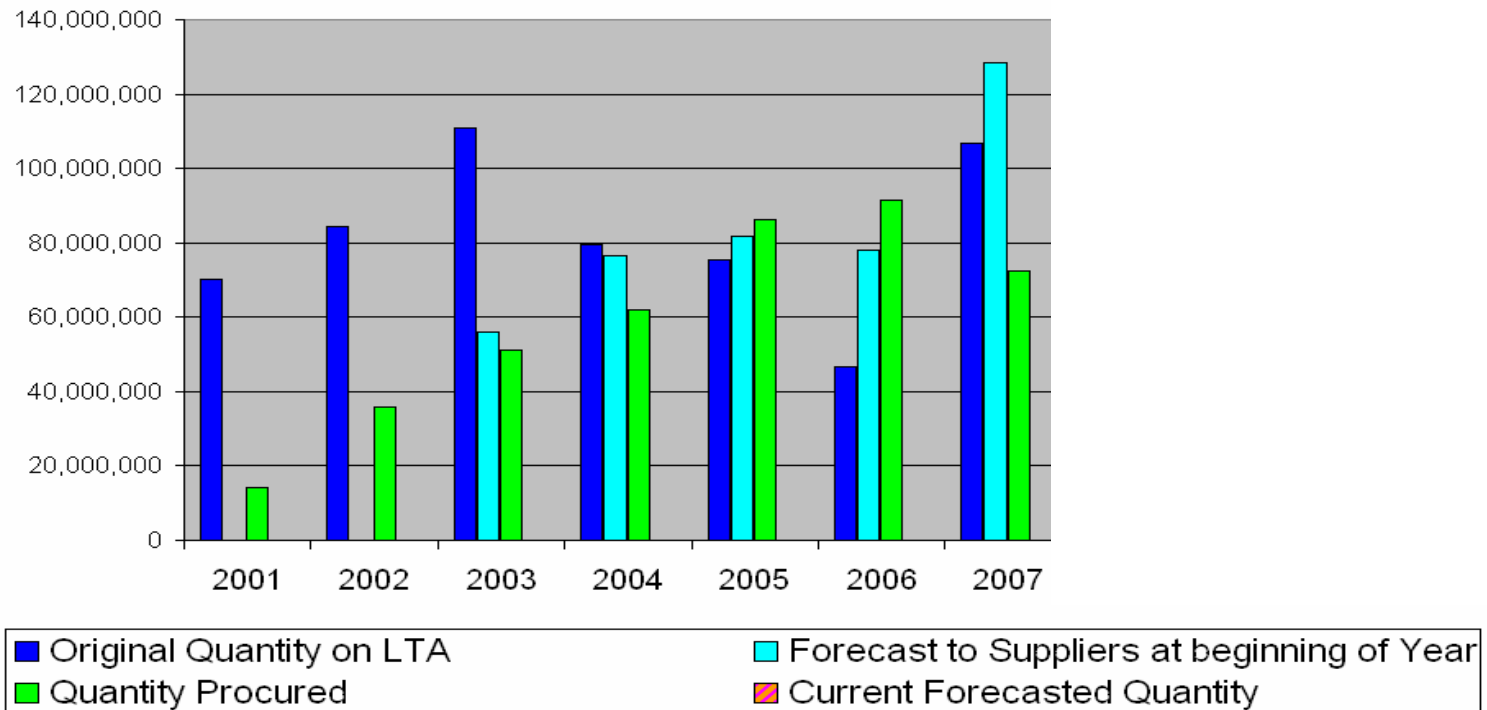


Majority of HepB demand has been from GAVI-supported countries, but Non-GAVI countries still represent a significant segment





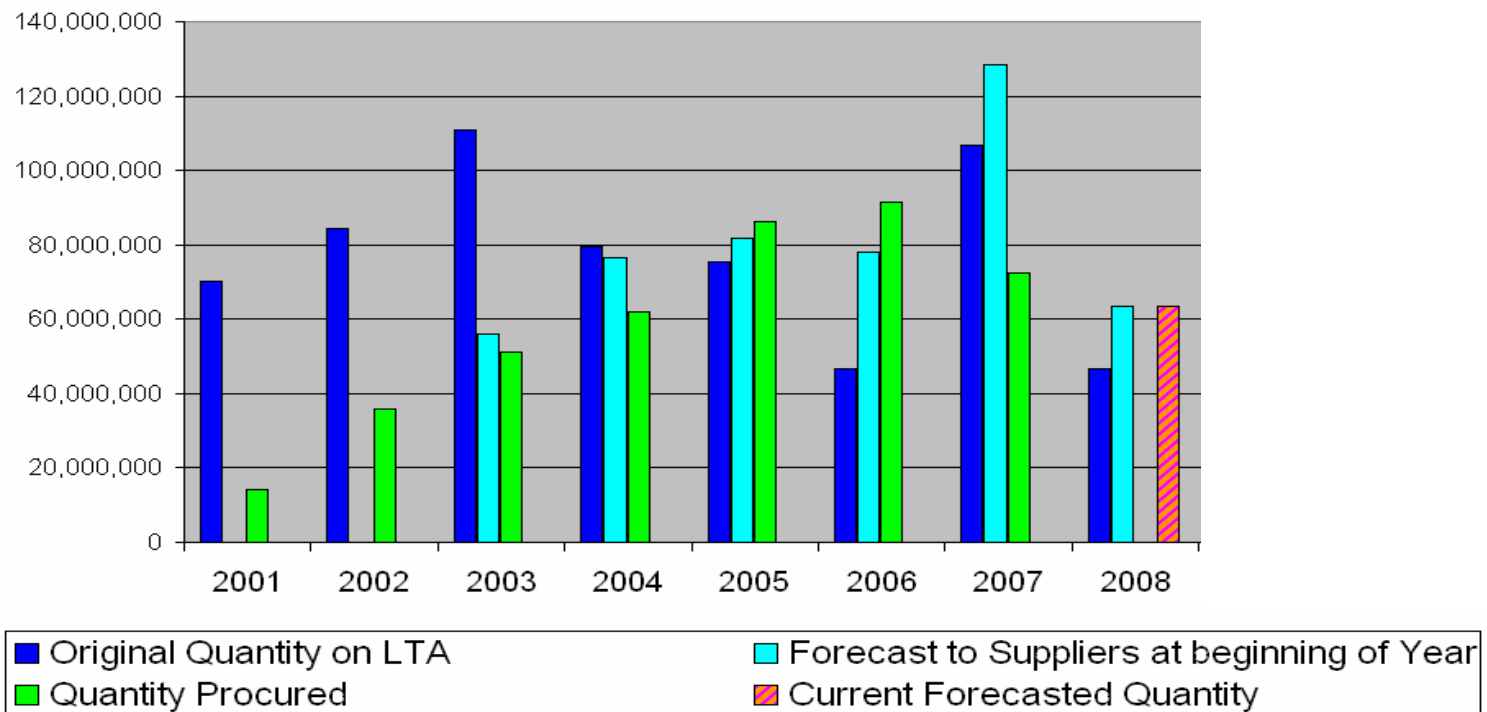
HepB – Procurement Overview - Historical



- Forecast dependent on a few large countries (Bangladesh, India, Nigeria & Philippines)
- Demand decreasing as countries introduce combination vaccines (GAVI-supported countries)

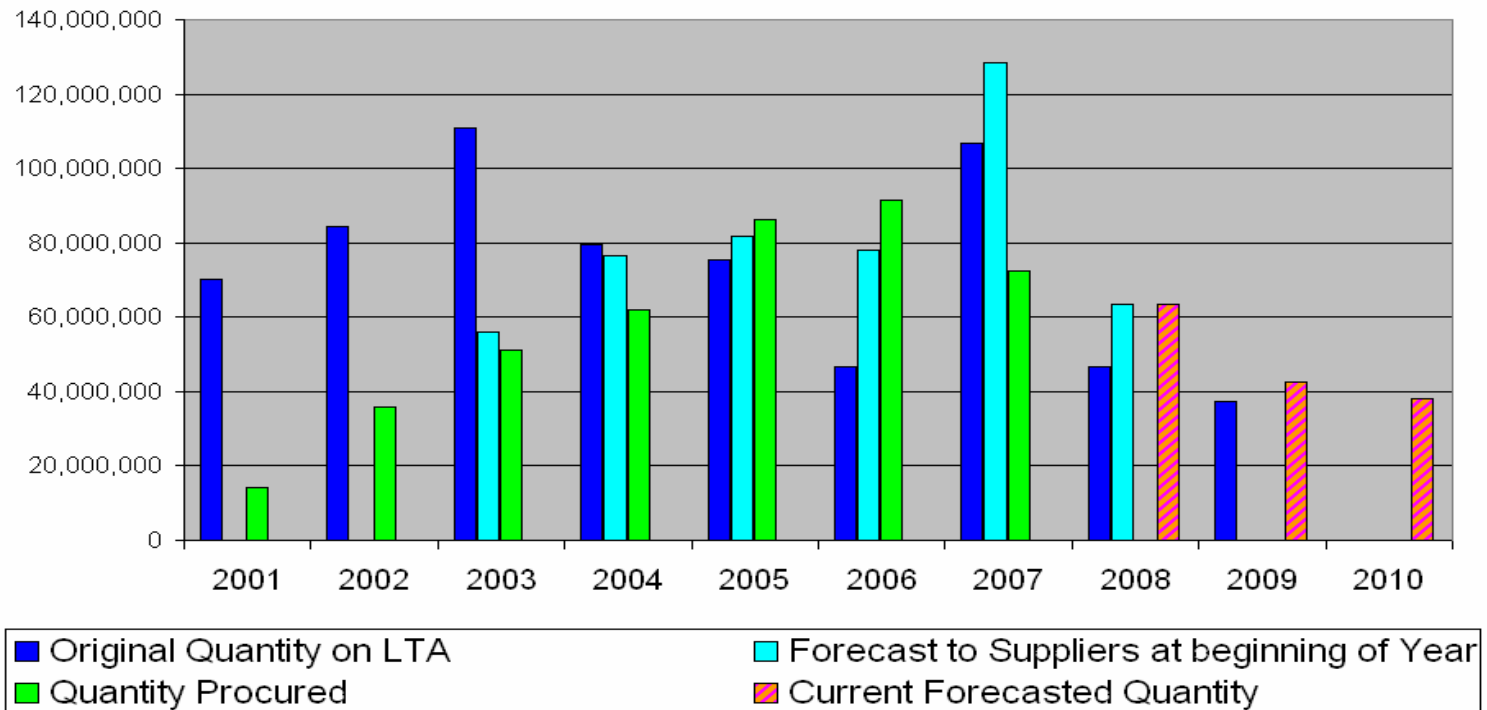


HepB – Procurement Overview - Current



- Forecast dependent on a few large countries (Bangladesh, India, Nigeria & Philippines)
- Demand decreasing as countries introduce combination vaccines (GAVI-supported countries)

HepB – Procurement Overview - Future



- Forecast dependent on a few large countries (Bangladesh, India, Nigeria & Philippines)
- Demand decreasing as countries introduce combination vaccines (GAVI-supported countries)

DTP

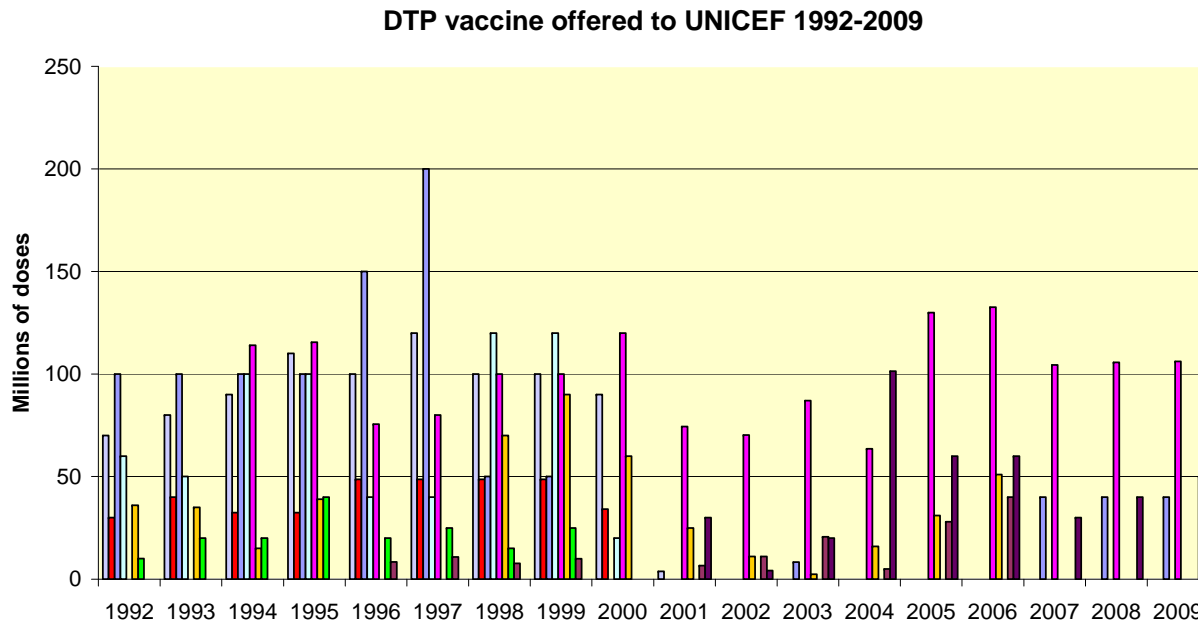
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Briefing Sheet: DTP

Criteria	Status
Demand Profile	
Presentation	10 dose and 20 dose vials
Quantity	60-70 million doses per year
Activity Split: Routine, Campaign	100% Routine
Demand Volatility: Urgency of Need, Reliability of Demand	Decreasing demand, global volatility depends on four key countries. Possibility of drastic decline in demand in the next two years. Planned demand for 34 countries in 2008
Anticipated duration of Demand	2009 could see further reduction in demand as countries switch to combined vaccines.
Trends	Decreasing
Market Profile	
Development Stage	Exit strategy
Market Status	3 WHO PQ vaccines
Trends	Stable
Forecast Accuracy	Good
Funding Profile	Multiple sources, reliable and stable
Contracting	LTA following RFP
Supply Status	Good
<p>Comments: The strategy for the DTP market beyond 2008 would focus on managing a decreasing demand to maintain supply to a few countries.</p>	

DTP – Quantities offered to UNICEF

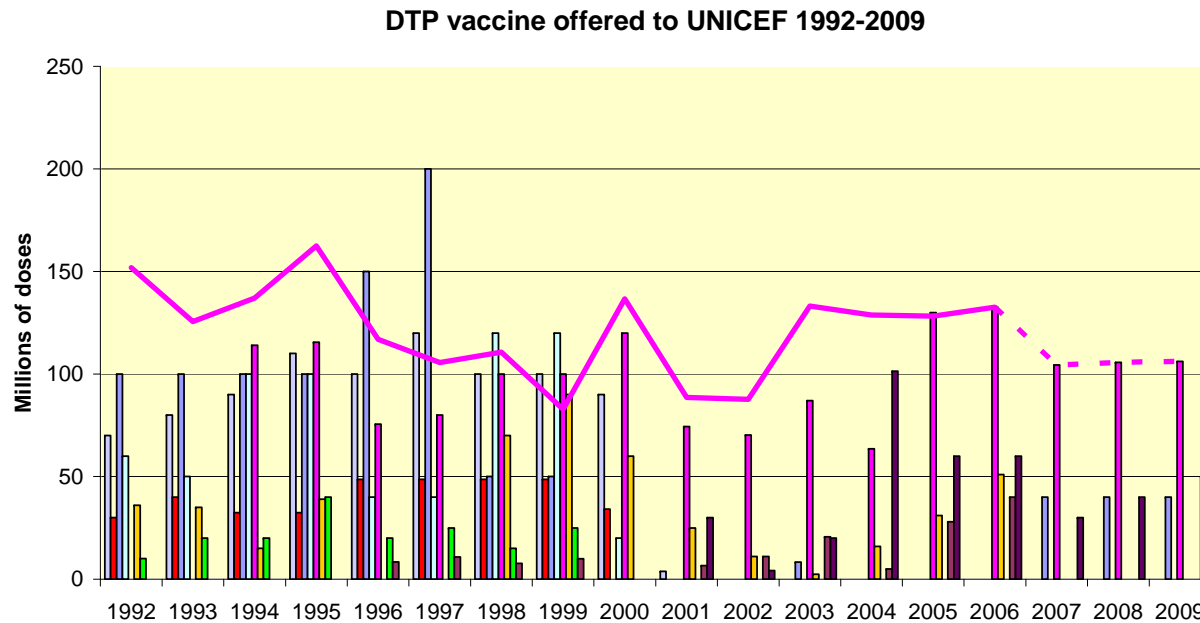


Historically multiple suppliers offering quantities to UNICEF

Market downturn reversed during 2004-2006 tender period following implementation of Vaccine Security Strategy

3 manufacturers offered quantities in the last tender

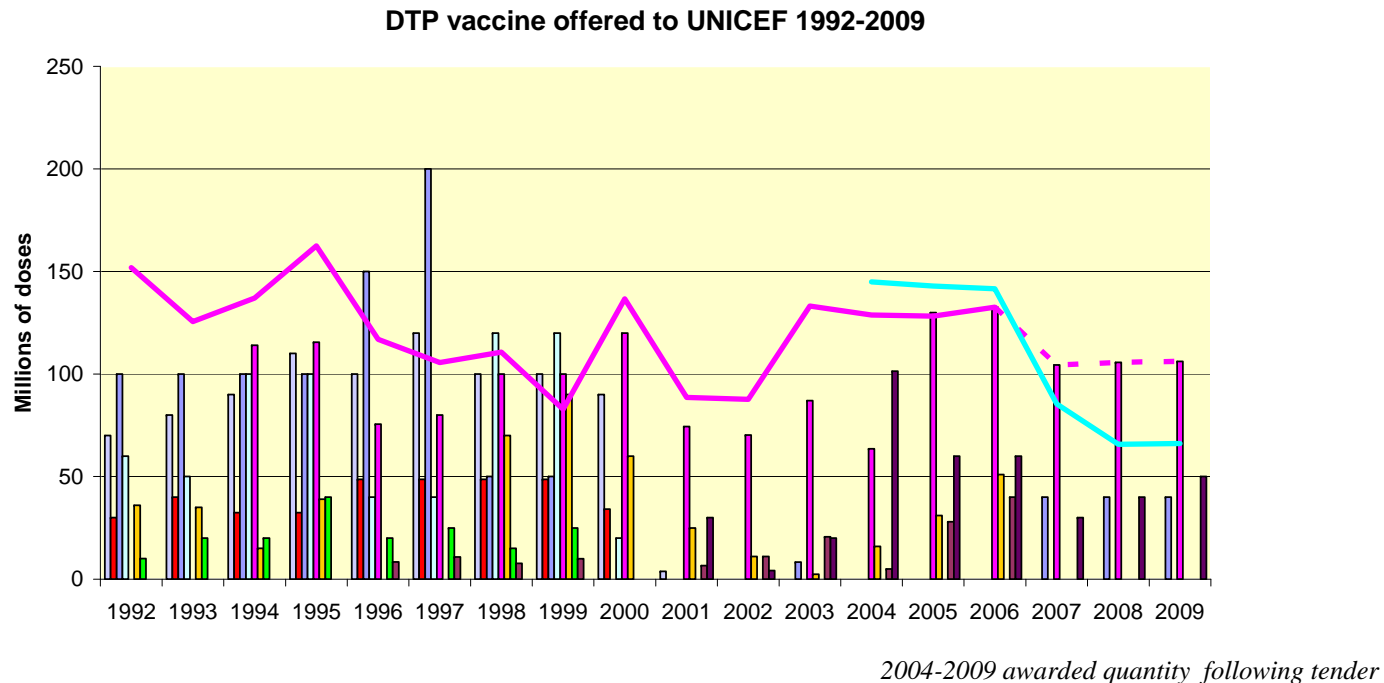
DTP – Quantities offered to UNICEF



2004-2009 forecast demand at time of tender

Awards were made to multiple suppliers to ensure vaccine security
3 Suppliers have LTAs currently

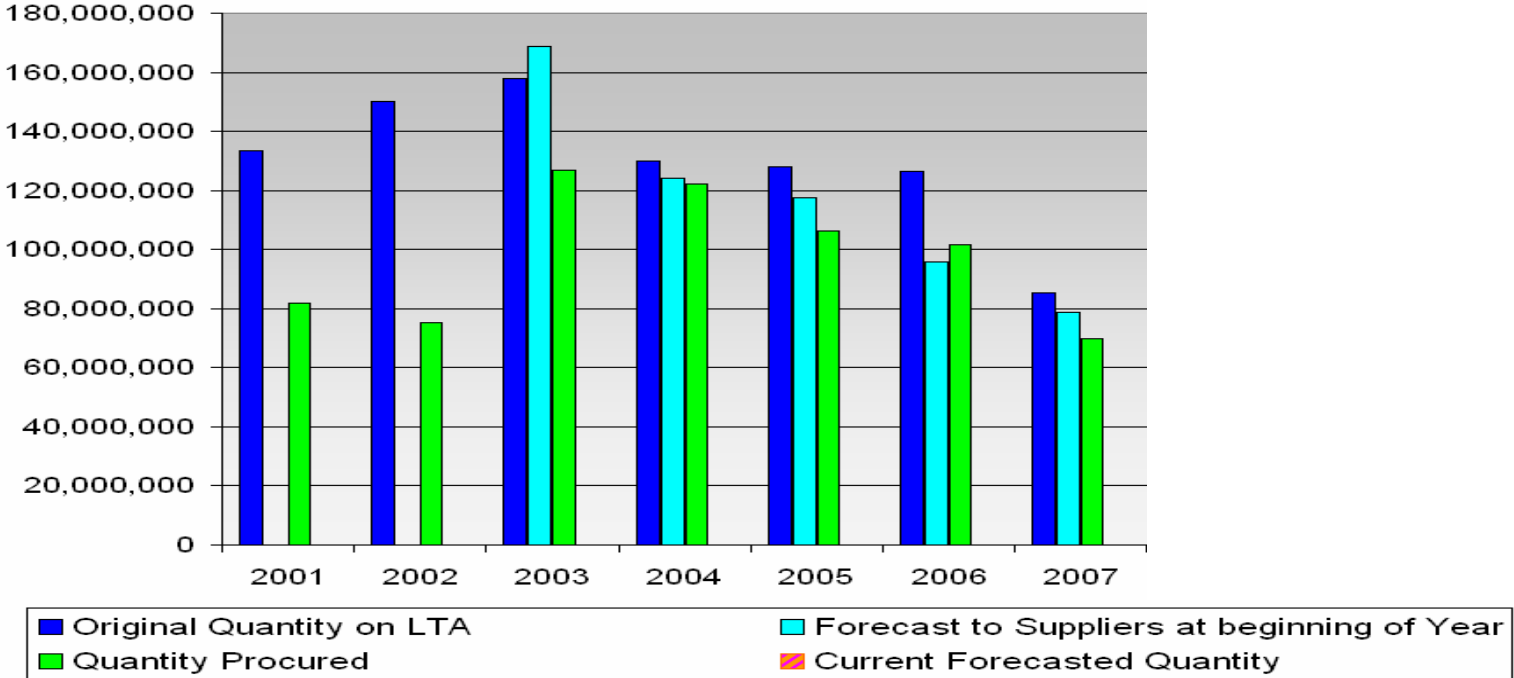
DTP – Quantities offered to UNICEF



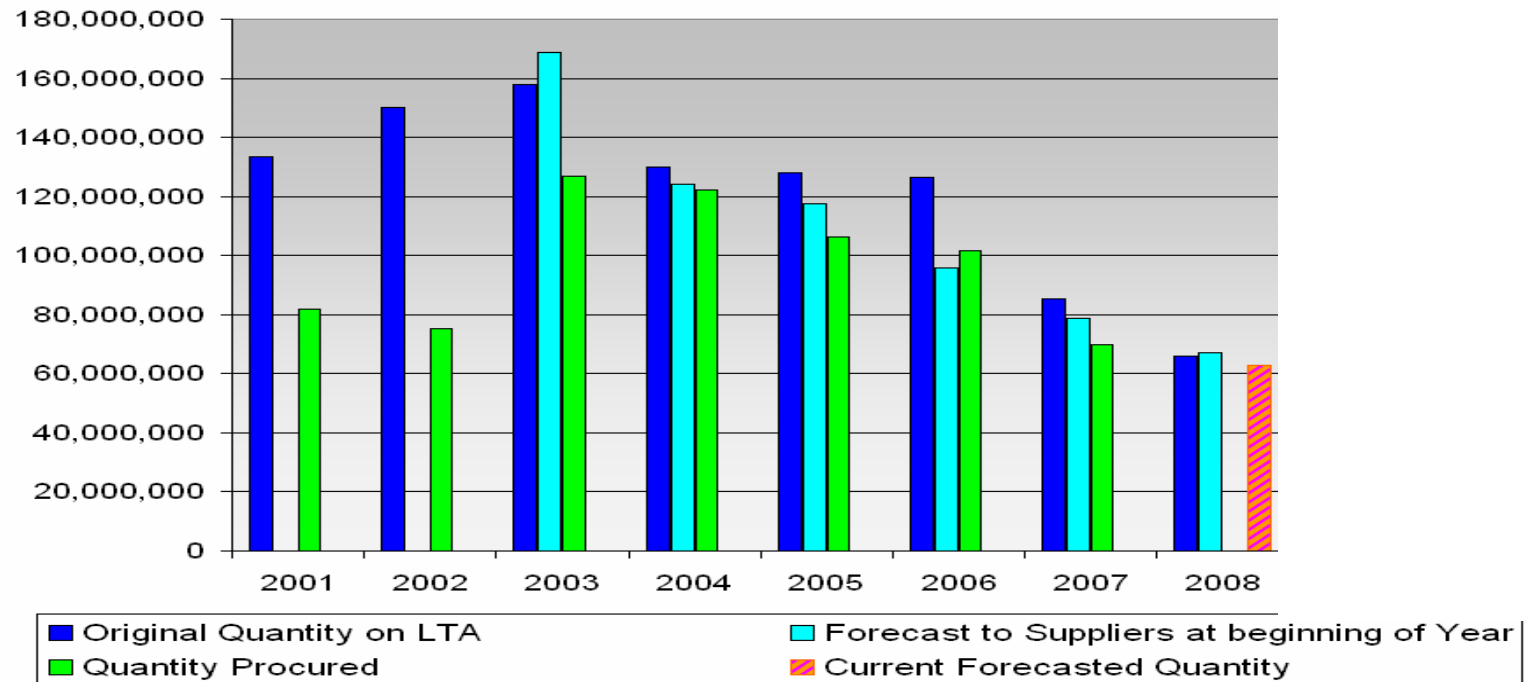
Awards were made to multiple suppliers to ensure vaccine security, **but** awards below the forecasted demand due to expected switches to combination vaccines

3 Suppliers have LTAs currently

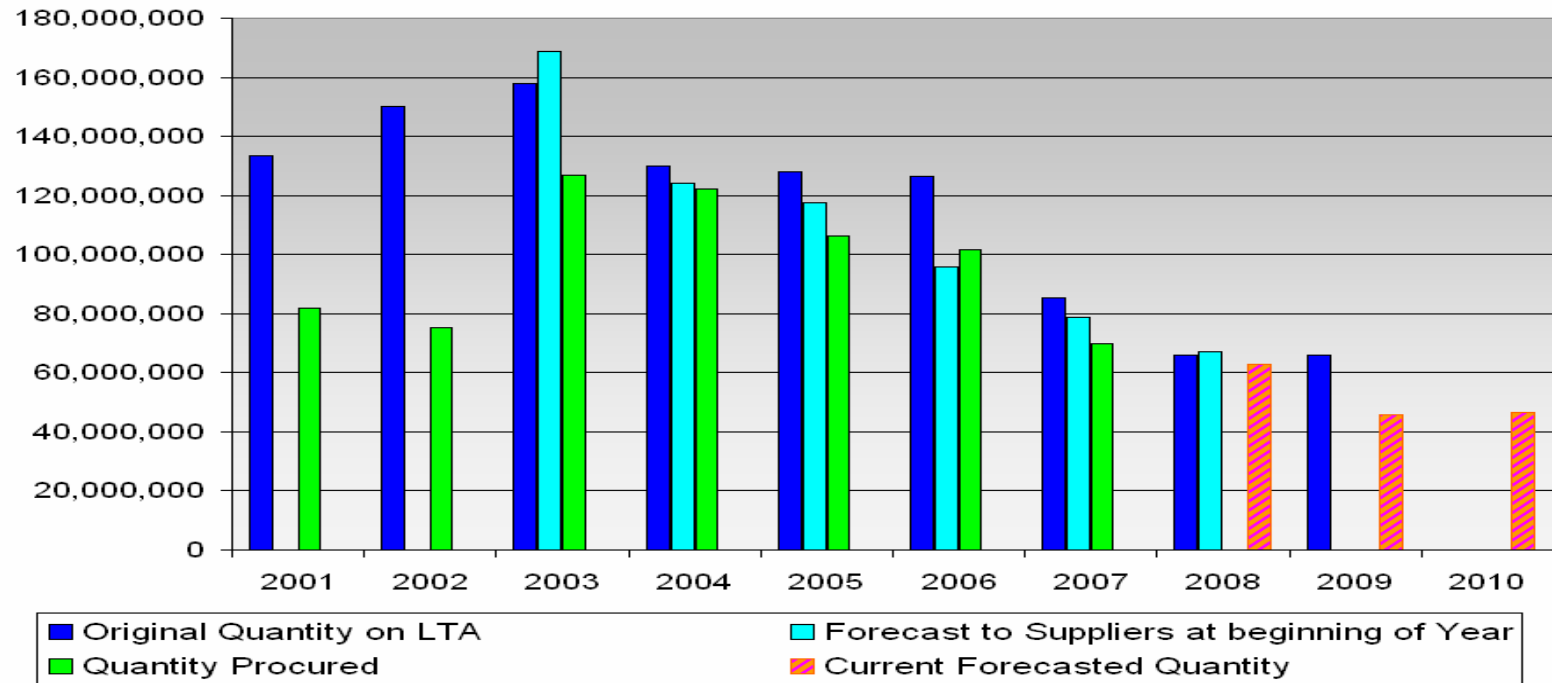
DTP – Procurement Overview - Historical



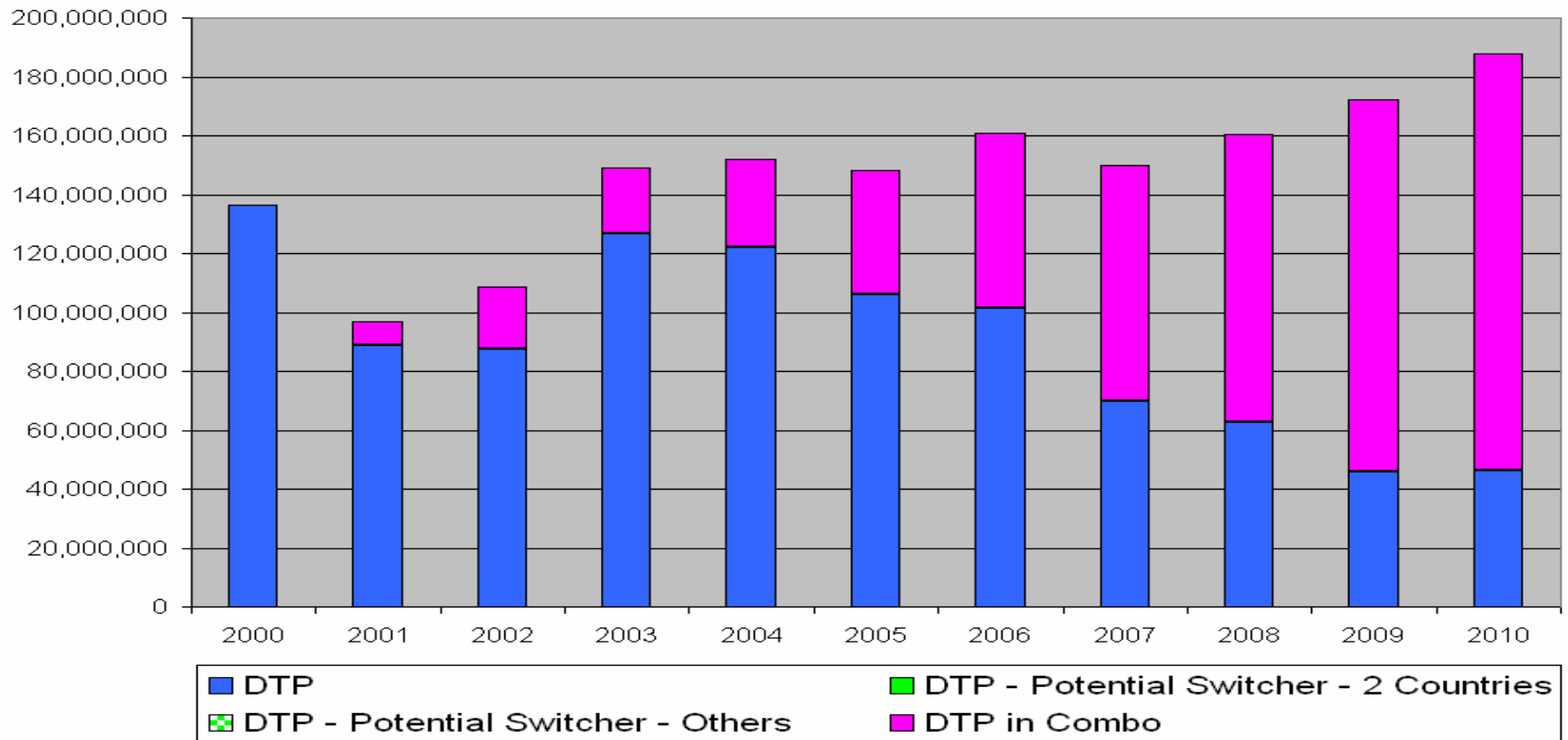
DTP – Procurement Overview - Current



DTP – Procurement Overview - Future



Transition of DTP demand –



Based on the current estimates the trend is towards the substantial potential to switch during the Tender Period

DTP-HepB

Briefing Sheet: DTP-HepB

Criteria

Status

Demand Profile

Presentation	2 & 10 dose vials
Quantity	~30 million (2008)
Activity Split: Routine, Campaign	100% Routine
Demand Volatility: Urgency of Need, Reliability of Demand	Stable, planned demand for 15 countries in 2008 (14 GAVI/1 Non-GAVI)
Anticipated duration of Demand	Limited
Trends	Decreasing as countries move to DTP-HepB/Hib vaccine; limited demand outside of GAVI-supported countries

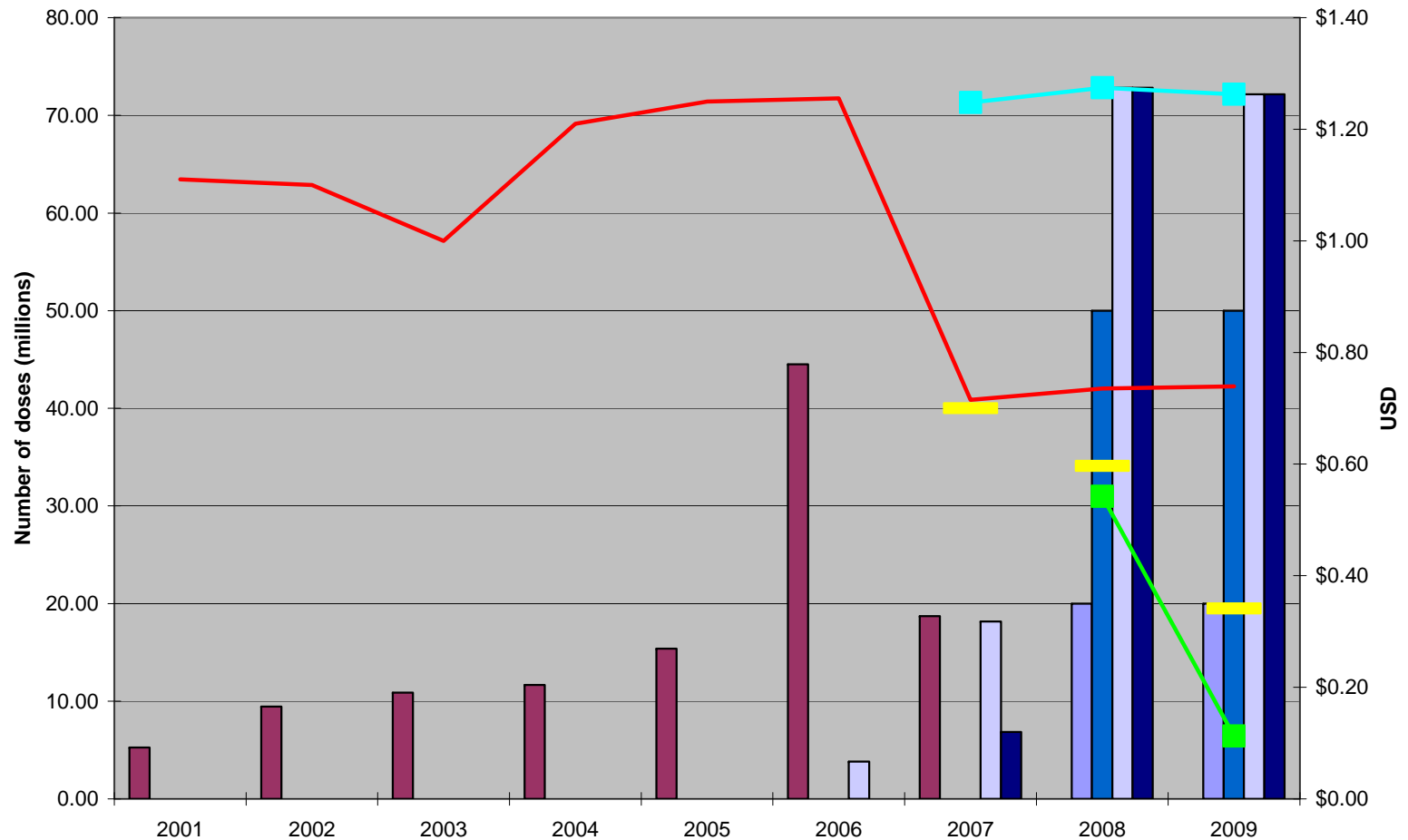
Market Profile

Development Stage	Mature
Market Status	6 WHO PQ vaccines (from 5 manufacturers)
Trends	Stable
Forecast Accuracy	Variable
Funding Profile	Primarily GAVI and some country co-financing
Contracting	LTA following RFP
Supply Status	Good

Comments:

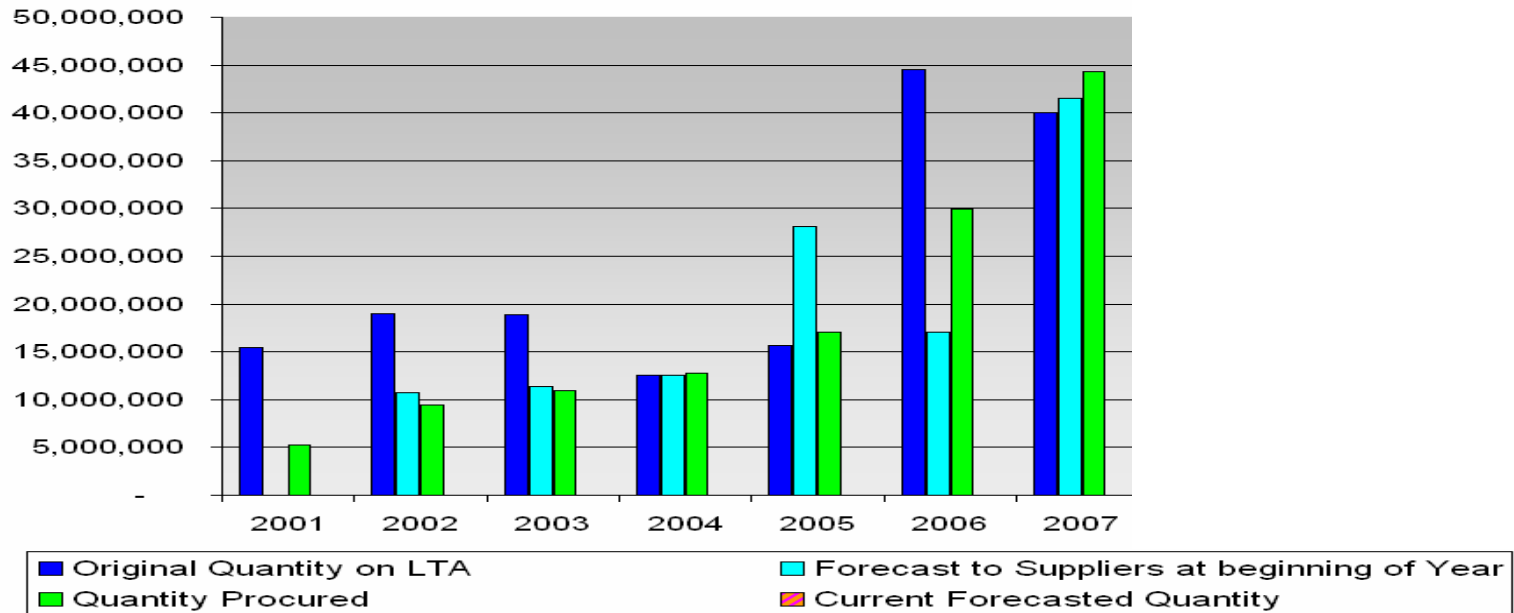
DTP-HepB: Significant developments in the market with multiple vaccines now pre-qualified, but demand is decreasing as countries switch to pentavalent vaccines

DTP-HepB: Procured (2001-2007) & PQ offers (2008-2009)

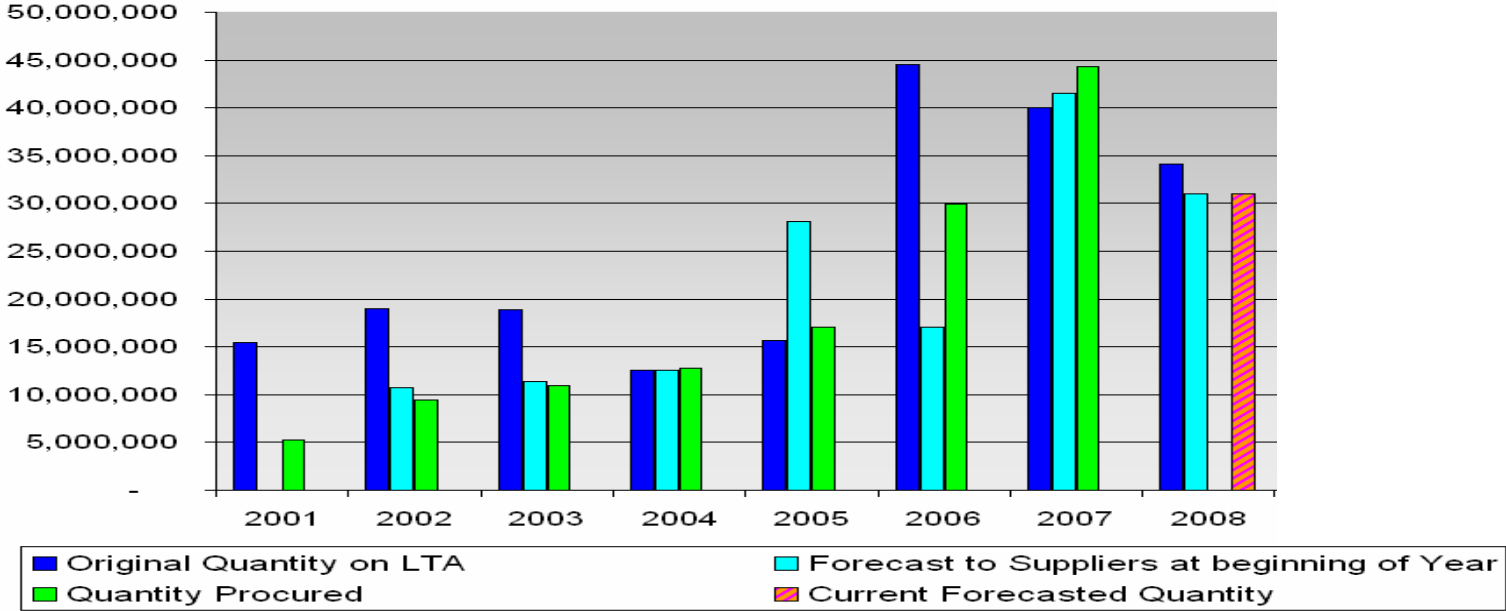


— Weighted average price
 — Maximum demand (RFP)
 — Actual demand
 — Awards

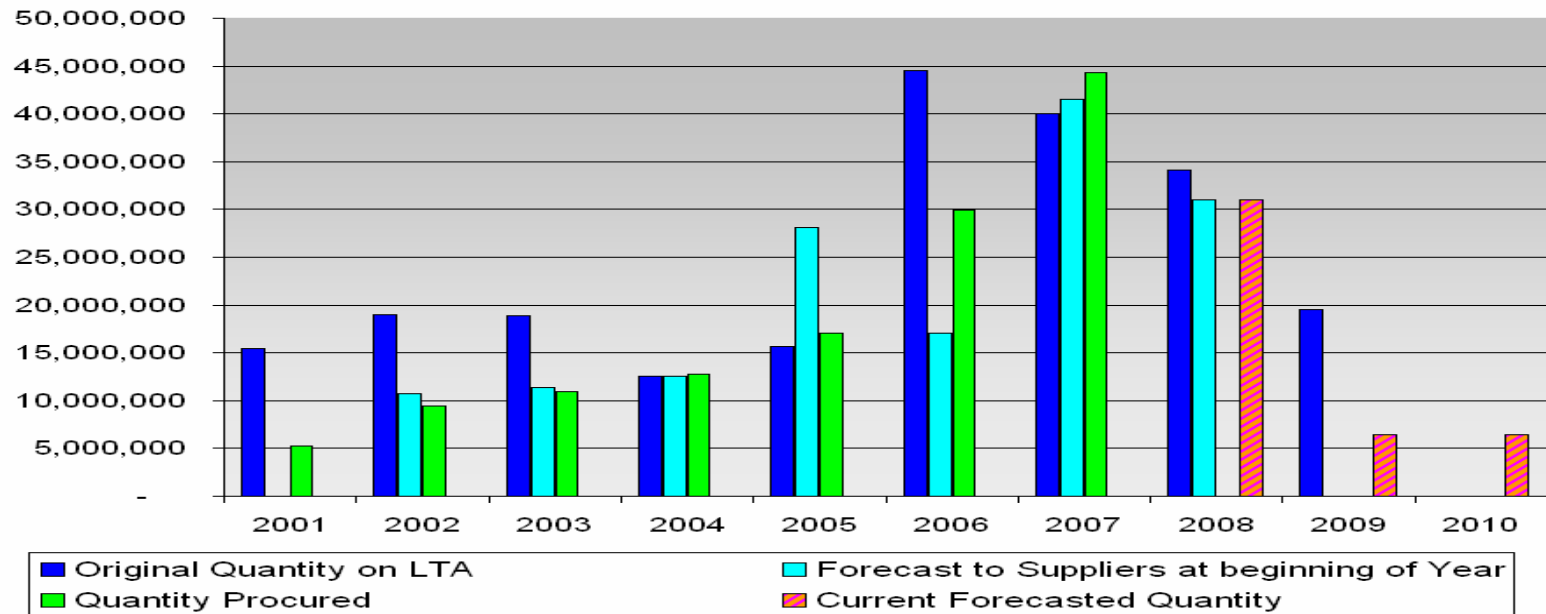
DTP-HepB – Overview - Historical



DTP-HepB – Overview - Current



DTP-HepB – Overview - Future



DTP-HepB/Hib

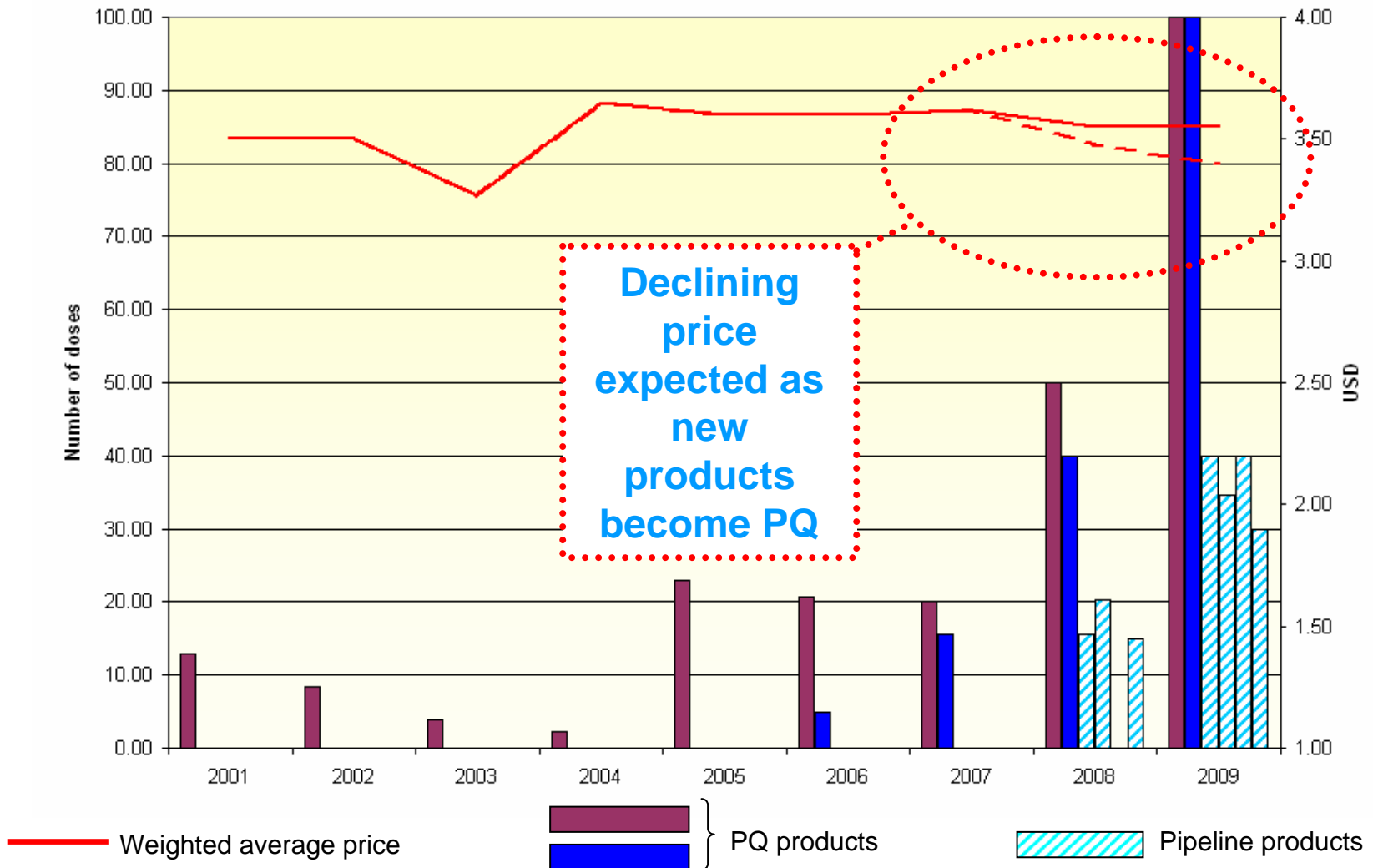
Briefing Sheet: DTP-HepB/Hib

Criteria	Status
Demand Profile	
Presentation	1 & 2 dose vials
Quantity	~66 million doses (2008 current approvals)
Activity Split: Routine, Campaign	100% Routine
Demand Volatility: Urgency of Need, Reliability of Demand	Stable, planned demand for 40 countries in 2008 (38 GAVI/2 Non-GAVI). Some delays with country first introductions.
Anticipated duration of Demand	Continuous
Trends	Significant increases as countries continue to introduce. Limited demand to date in non-GAVI-supported countries.
Market Profile	
Development Stage	Maturing
Market Status	3 WHO PQ vaccines (liquid & lyophilized) (from 2 manufacturers)
Trends	Strong pipeline for PQ vaccines
Forecast Accuracy	Good
Funding Profile	Primarily GAVI and country co-financing
Contracting	LTA following RFP (GAVI); PO placement following RFP (non-GAVI)
Supply Status	Good
Comments: Preference emerging for fully liquid vaccines. Optimal vial sizes for country programmes to be determined.	

Positive trends in the pentavalent market...

- on the threshold of healthy market (increased availability & developing pipeline)
- declining prices
- more significant price decrease expected in next tender round (2010-2012)

DTP-HepB/Hib: Actuals (2001-2007) and Pipeline (2008-2009)

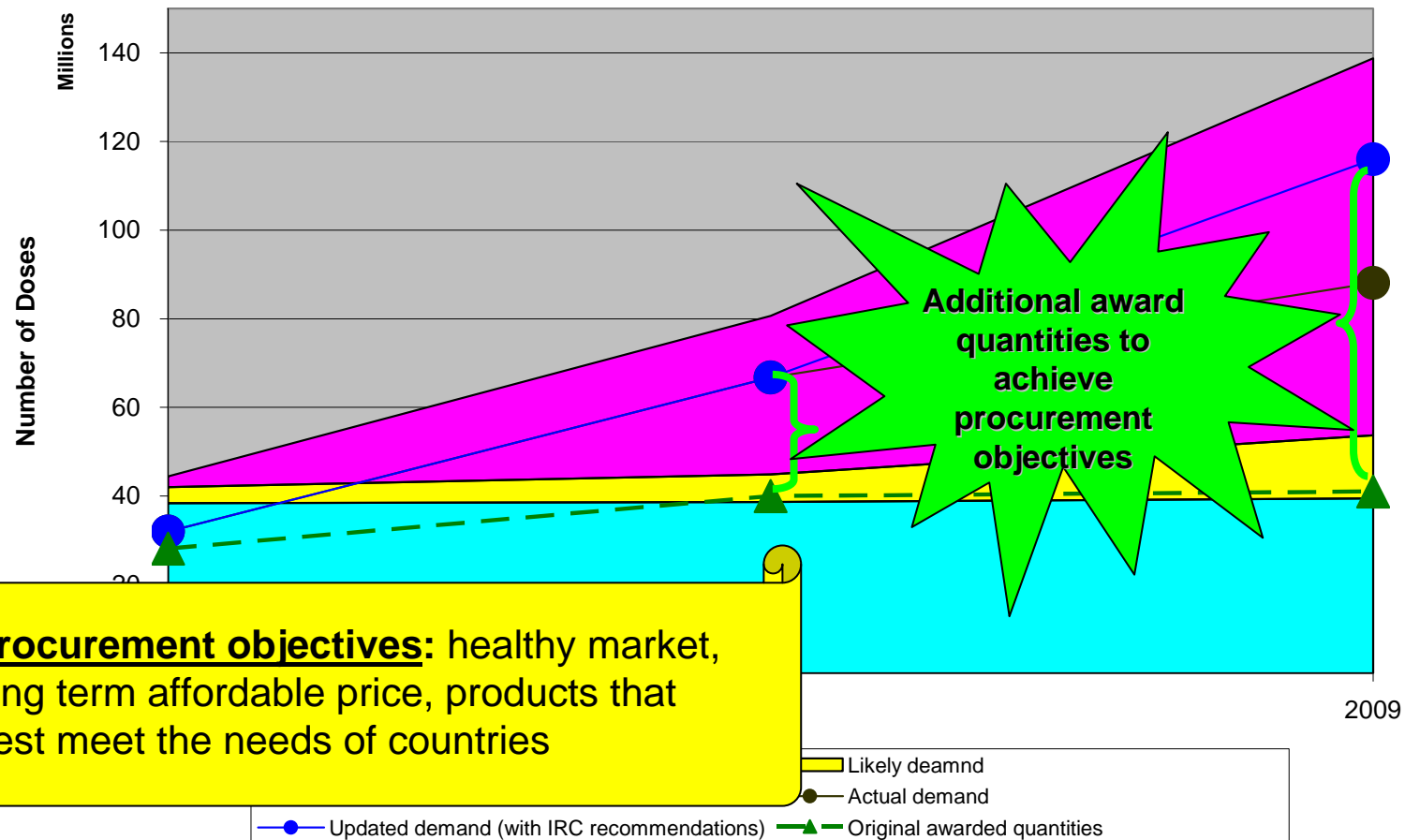


...and significant increases in demand

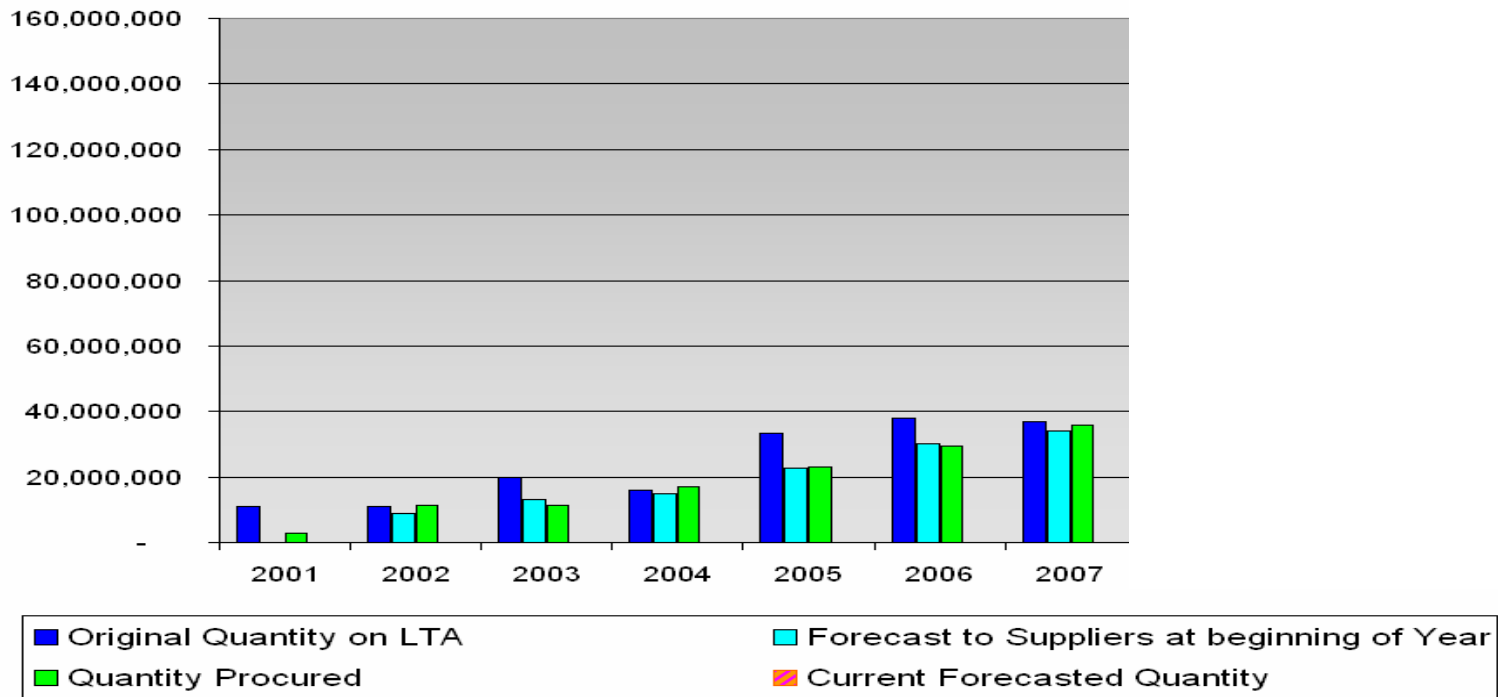
GAVI-supported country demand:

- 35 million doses in 2007
- 38 countries currently using or approved to introduce (~66 m doses in 2008 & ~88 m doses in 2009)
- 5 more countries recommended for approval for introduction in 2009 (~25m additional doses)
- Additional countries expected to apply
- Country preference for liquid vaccine emerging

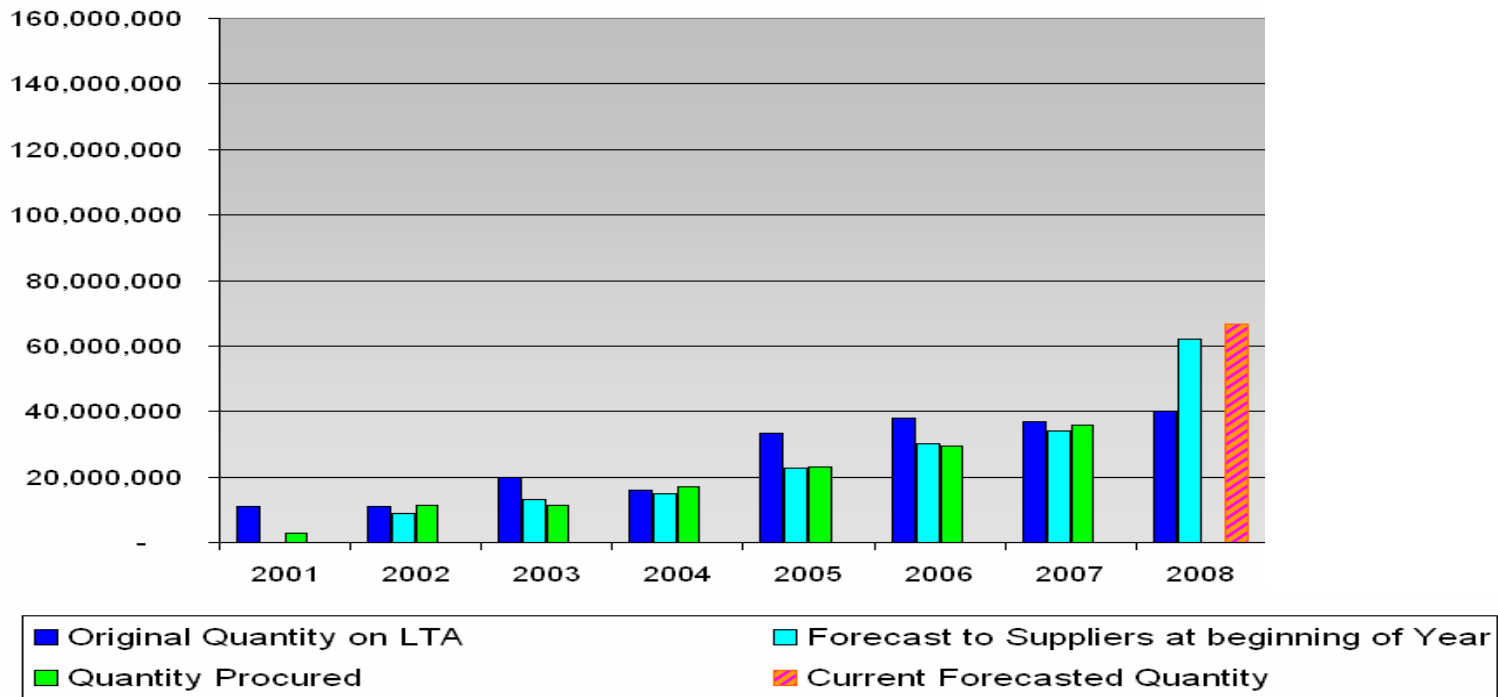
DTP-HepB/Hib: RFP forecast, demand & awards



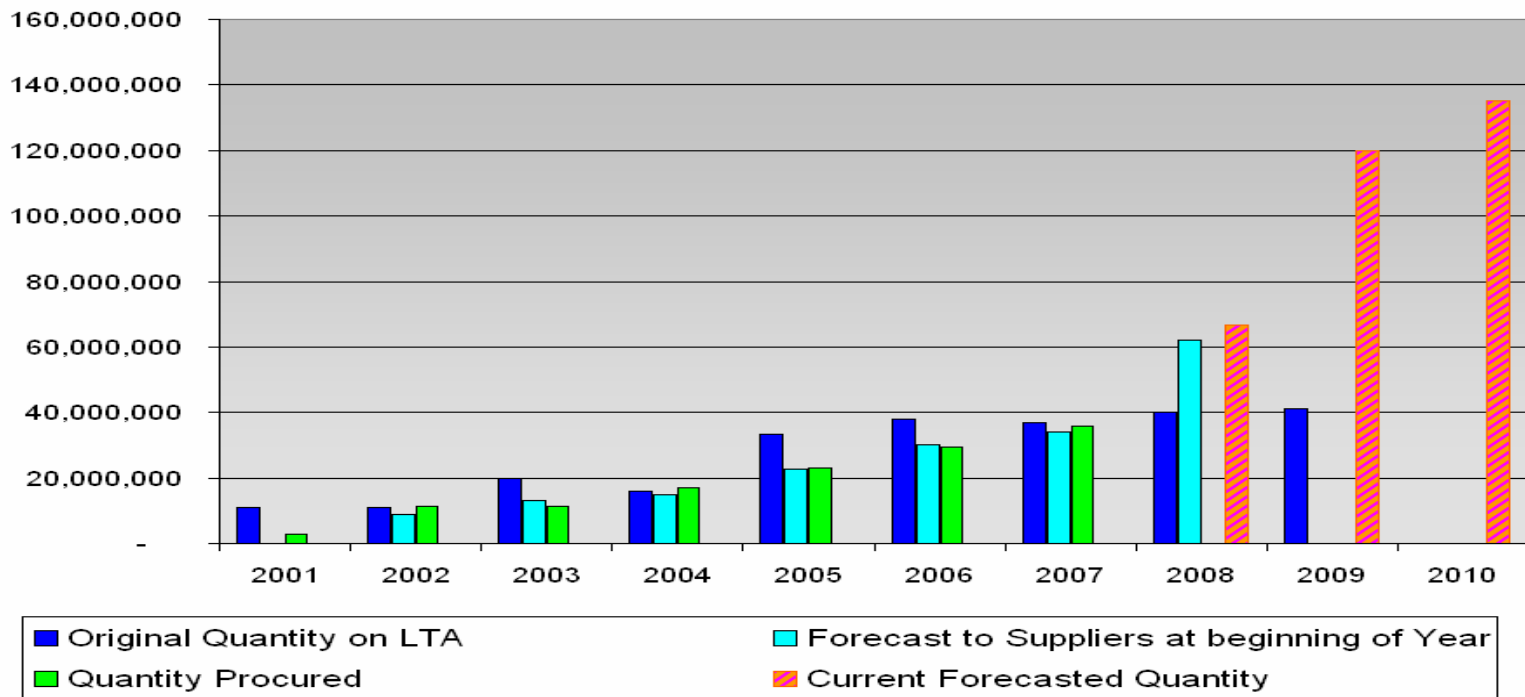
DTP-HepB/Hib – Overview - Historical



DTP-HepB/Hib – Overview - Current



DTP-HepB/Hib – Overview - Future



Lessons learned from DTP-HepB/Hib introduction... It takes time for new markets to mature

- Healthy market:
 - The more complex the product, the longer it takes for the market to mature (availability and number of PQ products)
 - With only one or two manufacturers in the market, supply interruptions are a real risk that need to be managed while the market is developing
- Demand :
 - 7-8 years from first vaccine introductions to scale up to significant global levels
 - More manufacturers are attracted by the demand stimulation
- Affordable prices:
 - Healthy market (competition) needed before significant decreases in price occur

DTP/Hib & Hib

DTP/Hib

Criteria

Status

Demand Profile

Presentation

1 & 10 dose vials

Quantity

~3 million doses/year

Activity Split: Routine, Campaign

100% Routine

Demand Volatility: Urgency of Need,
Reliability of Demand

Relatively stable, planned demand for 8 countries in 2008 (3 GAVI/5 Non-GAVI)

Anticipated duration of Demand

Continuous

Trends

Decrease from GAVI-supported countries.
Stable for non-GAVI countries.

Market Profile

Development Stage

Limited (due to limited demand)

Market Status

3 WHO PQ vaccines (liquid & lyophilized)

Trends

Stable

Forecast Accuracy

Good

Funding Profile

Multiple sources (GAVI and countries)

Contracting

LTA following RFP (GAVI); PO placement following RFP (non-GAVI)

Supply Status

Fair

Comments:

Hib

Criteria

Status

Demand Profile

Presentation	1 dose vials
Quantity	<300,000/year
Activity Split: Routine, Campaign	100% Routine
Demand Volatility: Urgency of Need, Reliability of Demand	Relatively stable, planned demand for 4 countries in 2008 (2 GAVI/2 Non-GAVI)
Anticipated duration of Demand	Continuous
Trends	Stable but very limited quantities

Market Profile

Development Stage	Limited (due to limited demand)
Market Status	4 WHO PQ vaccines (liquid & lyophilized)
Trends	Stable
Forecast Accuracy	Good
Funding Profile	Multiple sources (GAVI & countries)
Contracting	LTA following RFP (GAVI); PO placement following RFP (non-GAVI)
Supply Status	Fair

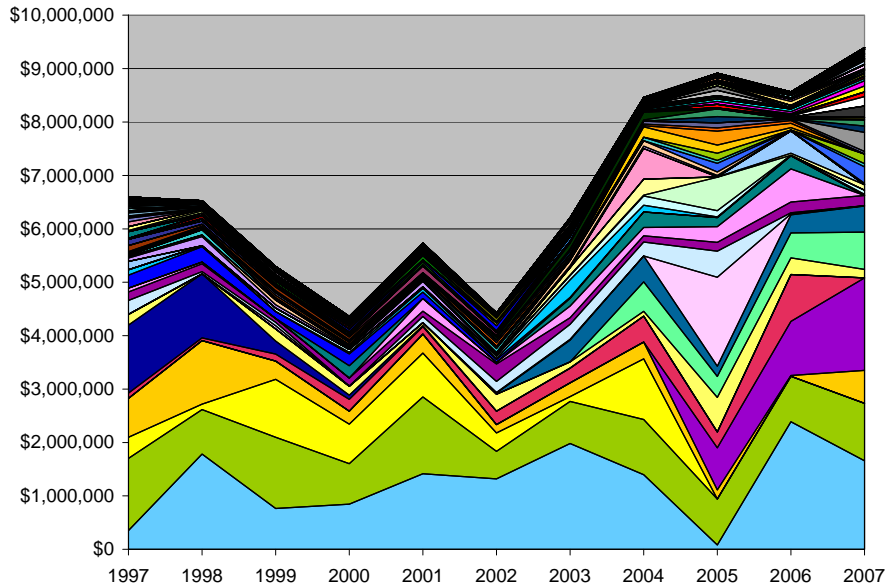
Comments:

EPI vaccines: funding streams

Traditional EPI vaccines: BCG & DTP

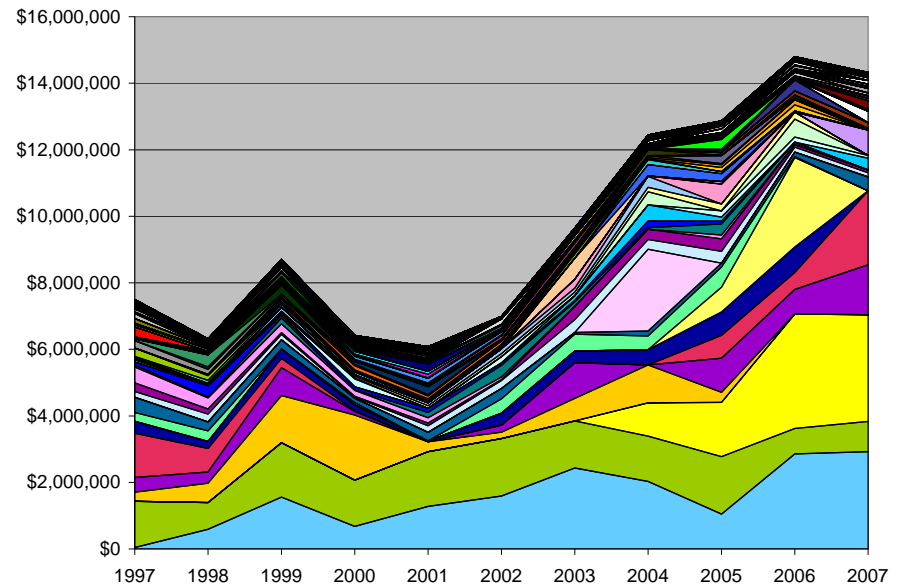
As a result of having multiple types of sources, funding for routine vaccines is complex to manage but has a high degree of reliability & sustainability (> 20 years)

BCG



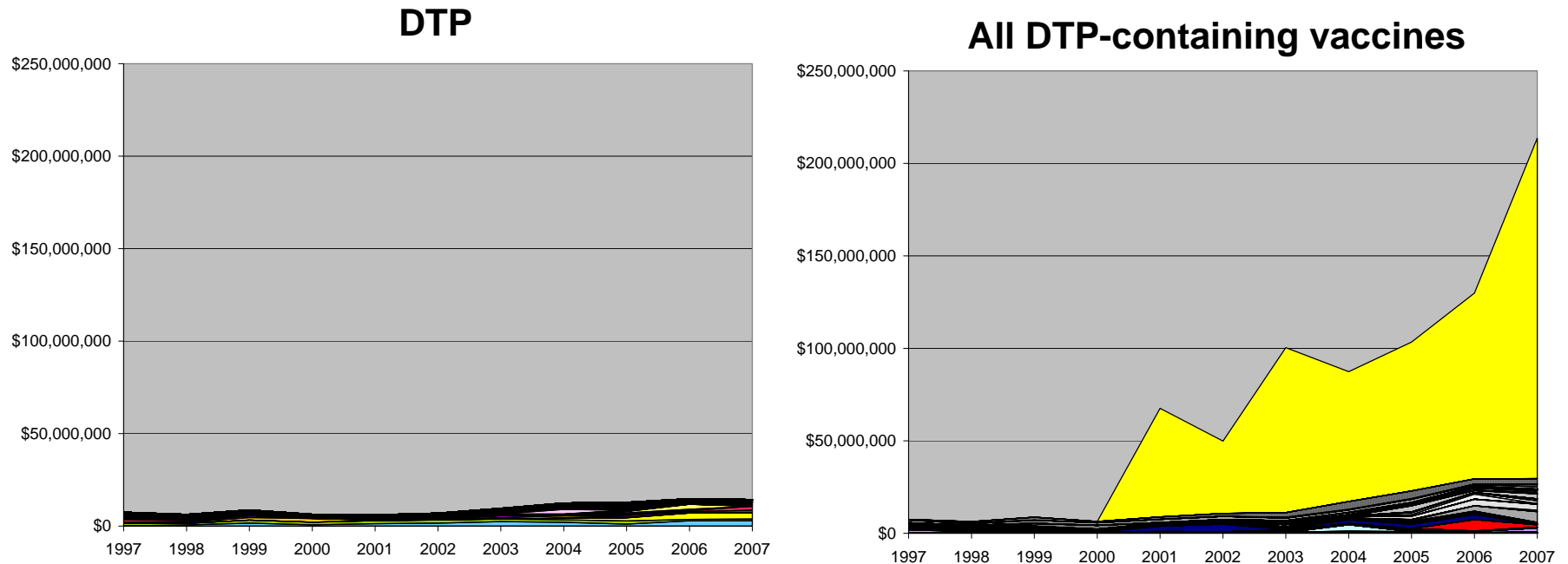
- Low value (~ \$9m per year)
- Each country sourcing own funding
- Large funding sources: WB (blue) & UNICEF (green); however individual countries needed to apply independently to obtain this funding.

DTP



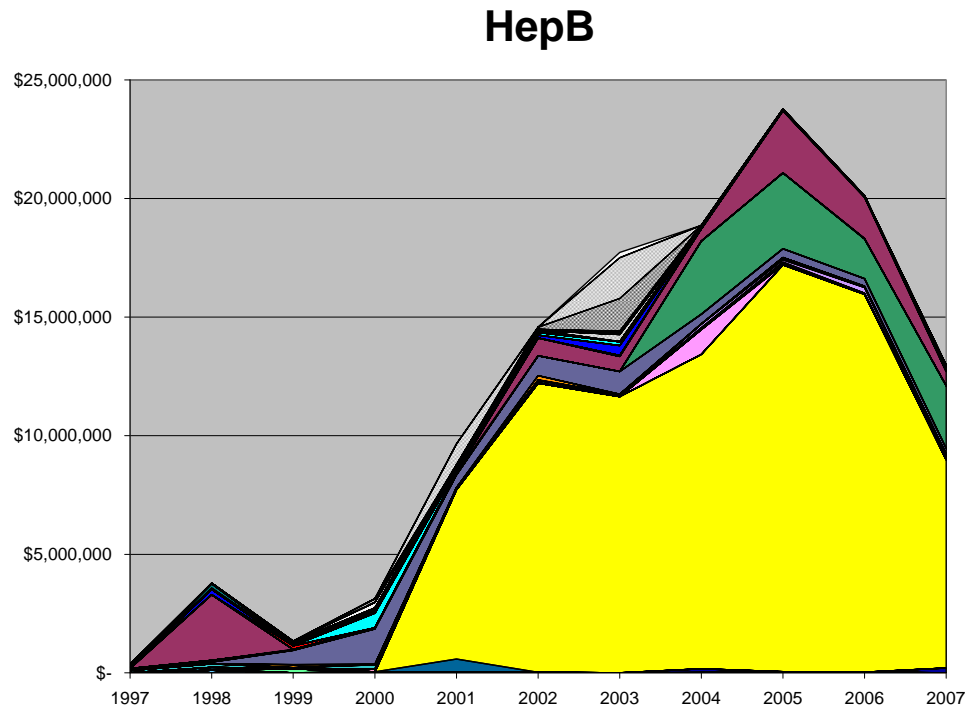
- Low value (~\$15m per year)
- 3 large countries (self-funding) made up 50% of funding in 2007
- Routine Vaccine demand in transition
- Bangladesh (red) likely to switch combination vaccine in 2009.

In perspective of the introduction of combination vaccines, the funding profile is dominated by GAVI support introduced in 2001, scaling up as new countries introduce these vaccines.



- With the introduction of the DTP combination vaccines the scale of funding requirements was significantly increased
- GAVI support for these vaccines sets out to absorb the costs of introducing the new combination vaccines
- Countries will gradually take over the funding of these vaccines through co-financing as the price becomes more competitive
- The overall funding requirements are anticipated to decrease over time making it affordable to countries

HepB funding has been dominated by GAVI and a few large countries. However, overall value is expected to decrease and funding to become more diversified as GAVI support ends and/or countries introduce combination vaccines.



Thank You