UNICEF Vaccine Procurement - the role and opportunities for DCVMN manufacturers

A UNICEF Perspective

DCVMN 2010
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unite for children

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UNICEF procures immunization supplies on behalf of 80-100 countries annually

2009: Immunization Supplies: US$ 848m (vaccines: US$ 806m) | 2.99 billion doses | 1,997 shipments

Source UNICEF Supply Division

Immunization Supplies

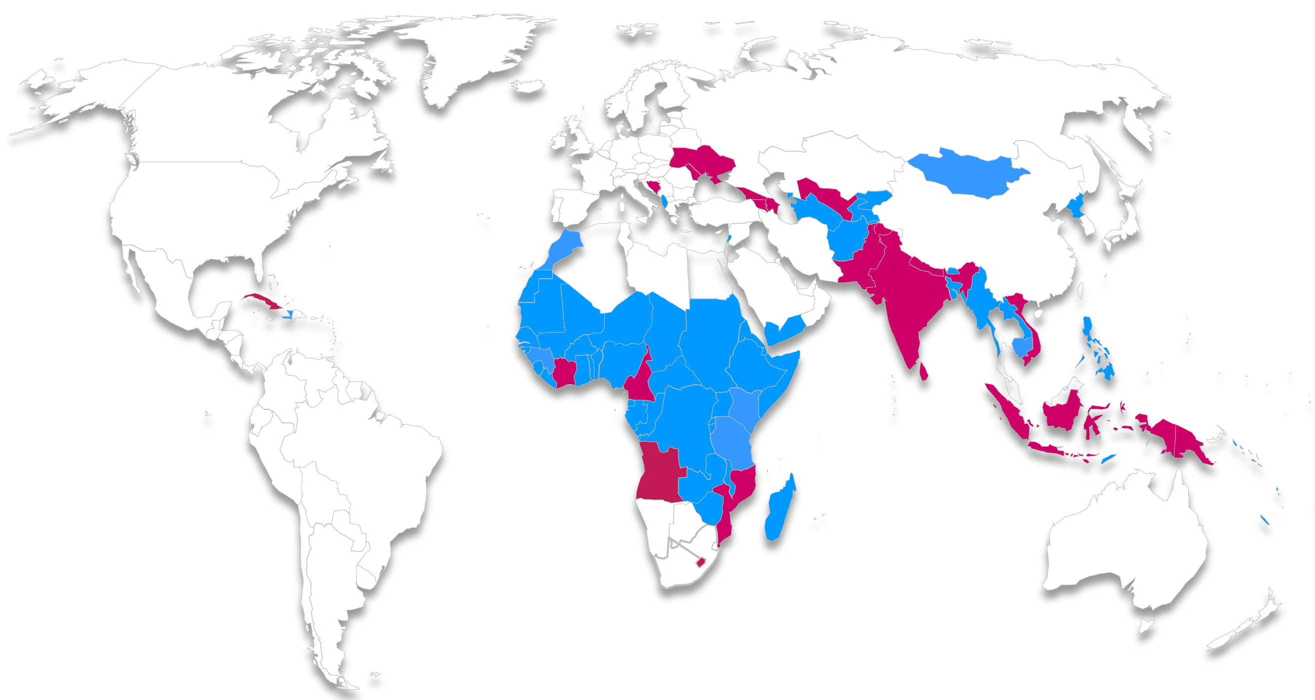
Vaccines
BCG , DTP, TT/Td/DT, Measles containing, OPV, HepB, YF, DTP-HepB, DTP-HepB/Hib, DTP/Hib, Hib, MR, Meningitis, MMR, IPV, etc.

Safe Injection equipment

Cold Chain Equipment

Countries UNICEF procures on behalf of

- All Vaccines
- Part of the Vaccines



Source: 2009 forecasts received by UNIICEF

Focusing on supporting the needs of the most vulnerable and poorest nations

2009

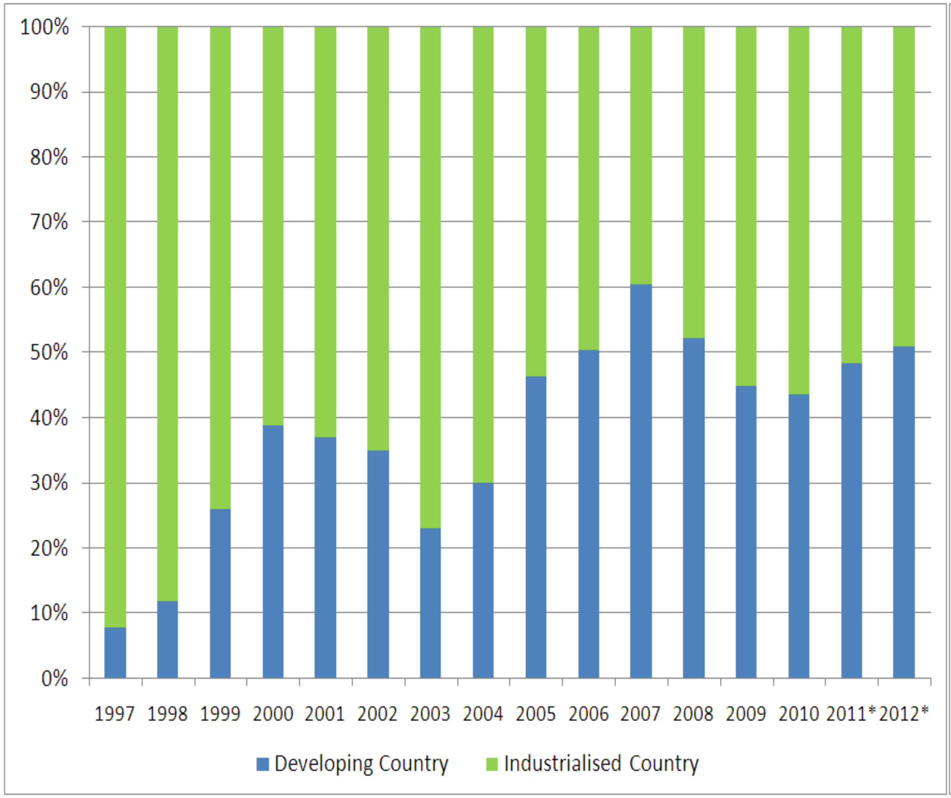
WB Income classification July 2009	Total Births 2007	% of Birth Cohort covered by UNICEF Procurement excl China India and Indonesia
High income: OECD	10,741,000	0%
High income: nonOECD	1,143,000	2%
Upper middle income	16,317,000	1%
Lower middle income	26,280,000	47%
Low income	32,263,000	92%
Grand Total	**86,744,000**	**48%**

Data Sources:
Population Data: 'The State of the Worlds Children 2008'; The State of the Worlds Children 2006
Procurement Coverage Data: UNICEF Vaccine Forecast 2009, UNICEF Vaccine Forecast 2007
Income Classification: World Bank Website 2009, World Bank Website 2007

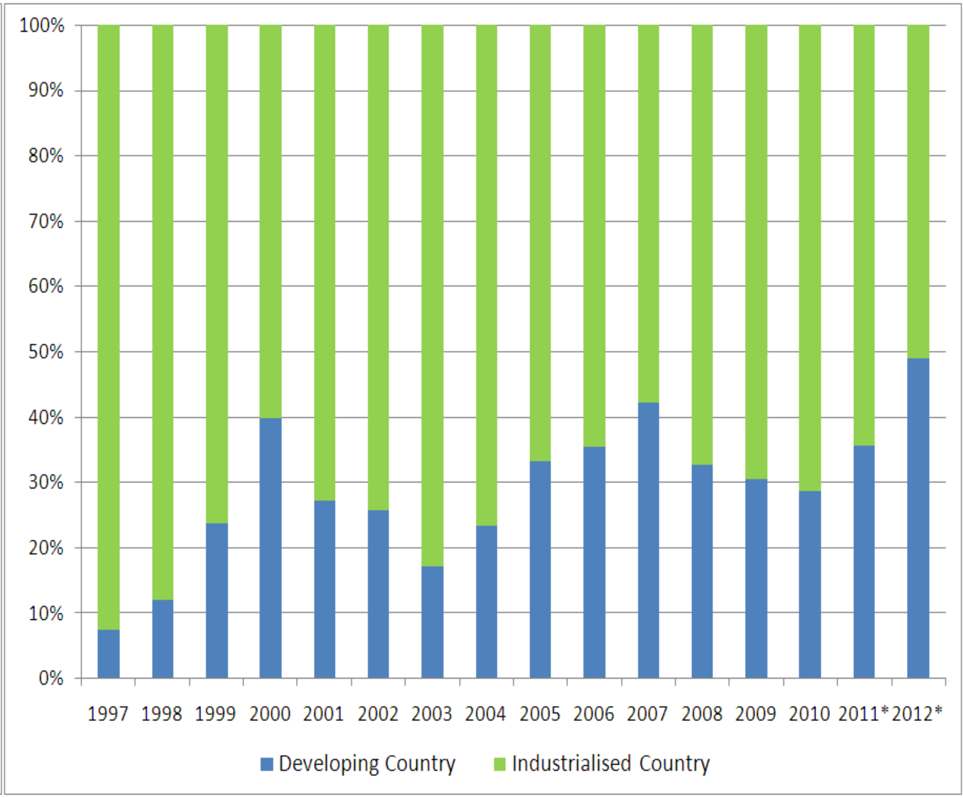
A growing portion of vaccines procured by UNICEF come from Developing Country Manufacturers

2009: 1.3 billion doses with a value of ~ $250 million

Share by Volume

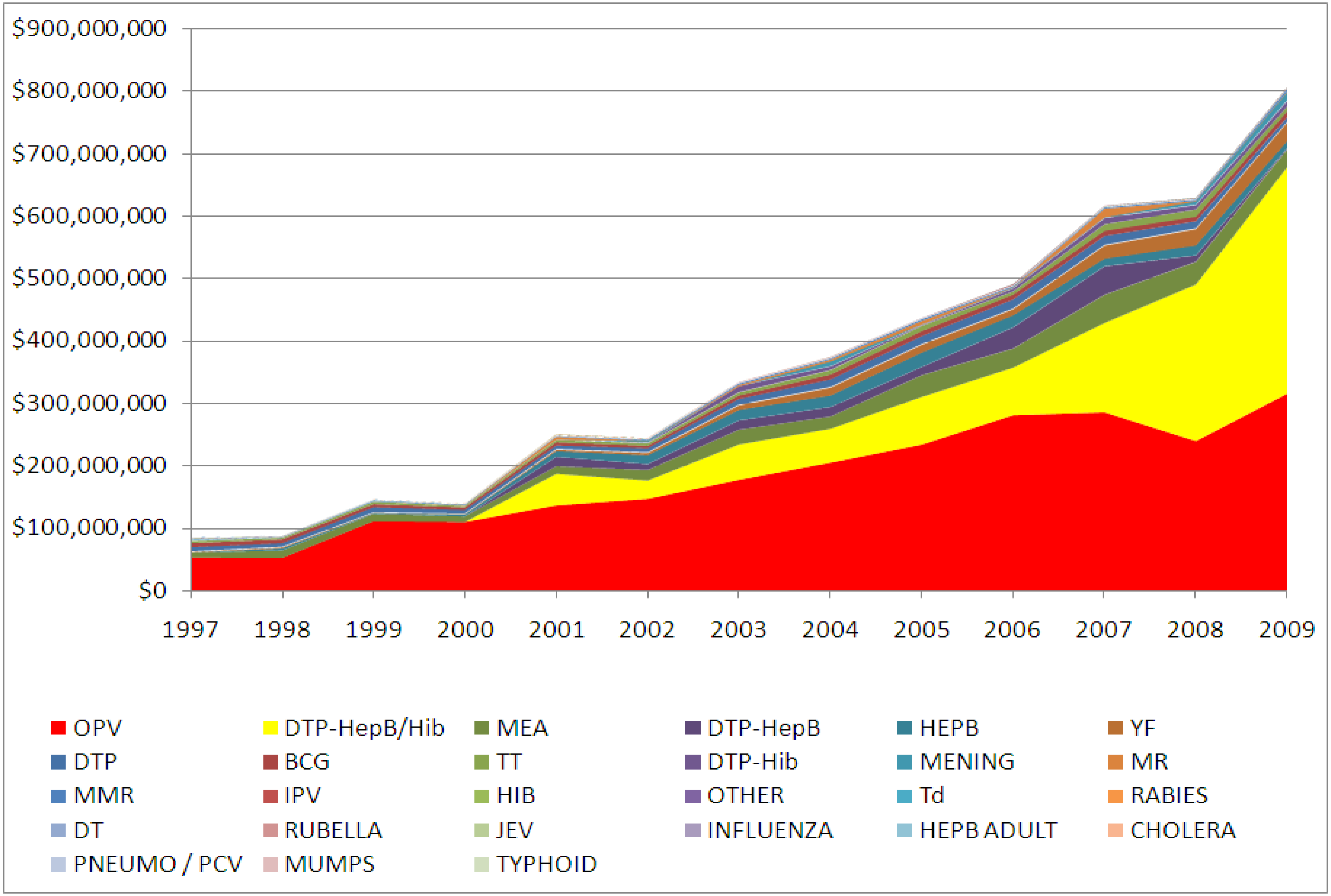


Share by Value

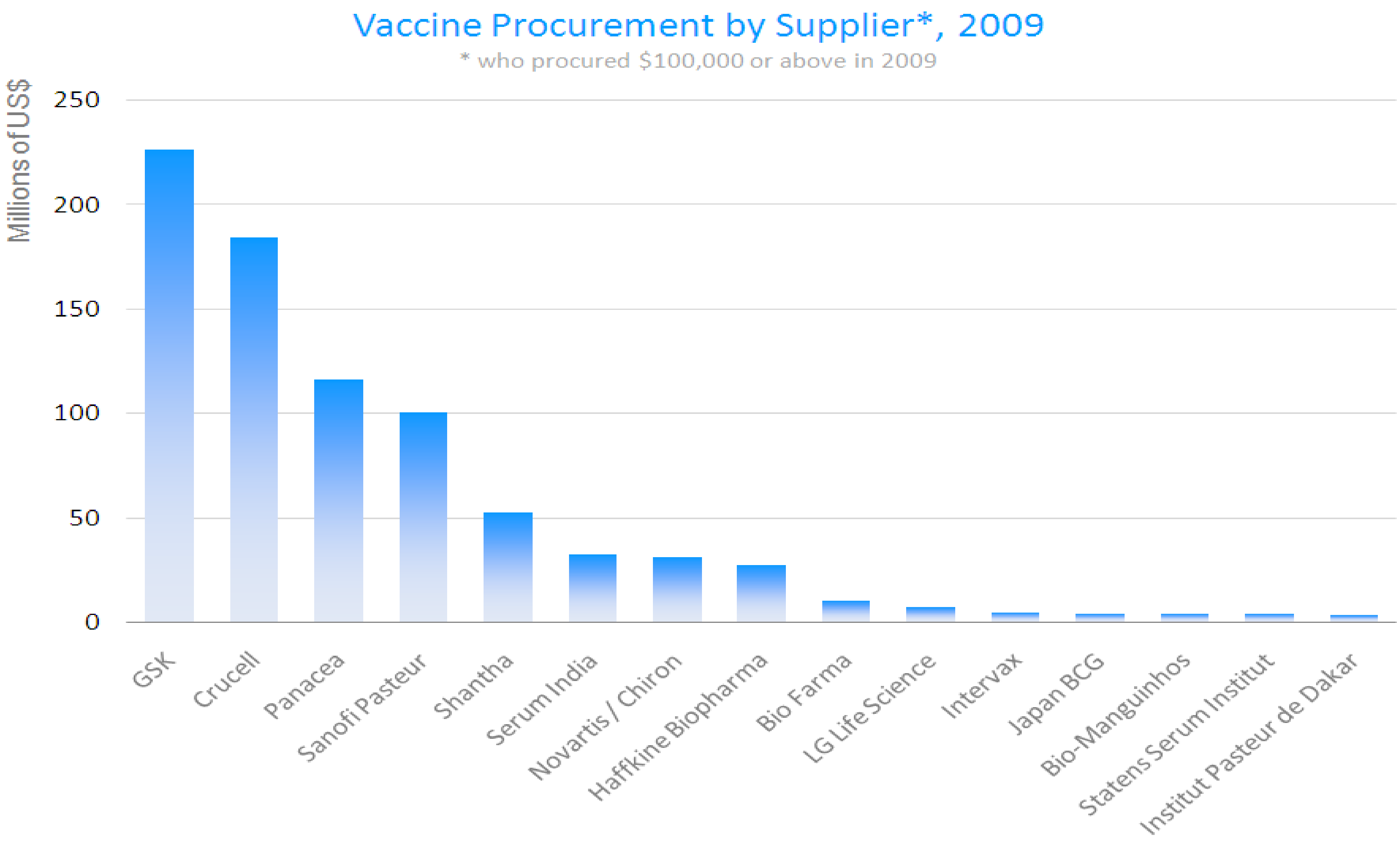


**2010 – 2012 Data based on awards already made*

UNICEF Vaccine procurement 1997 - 2009

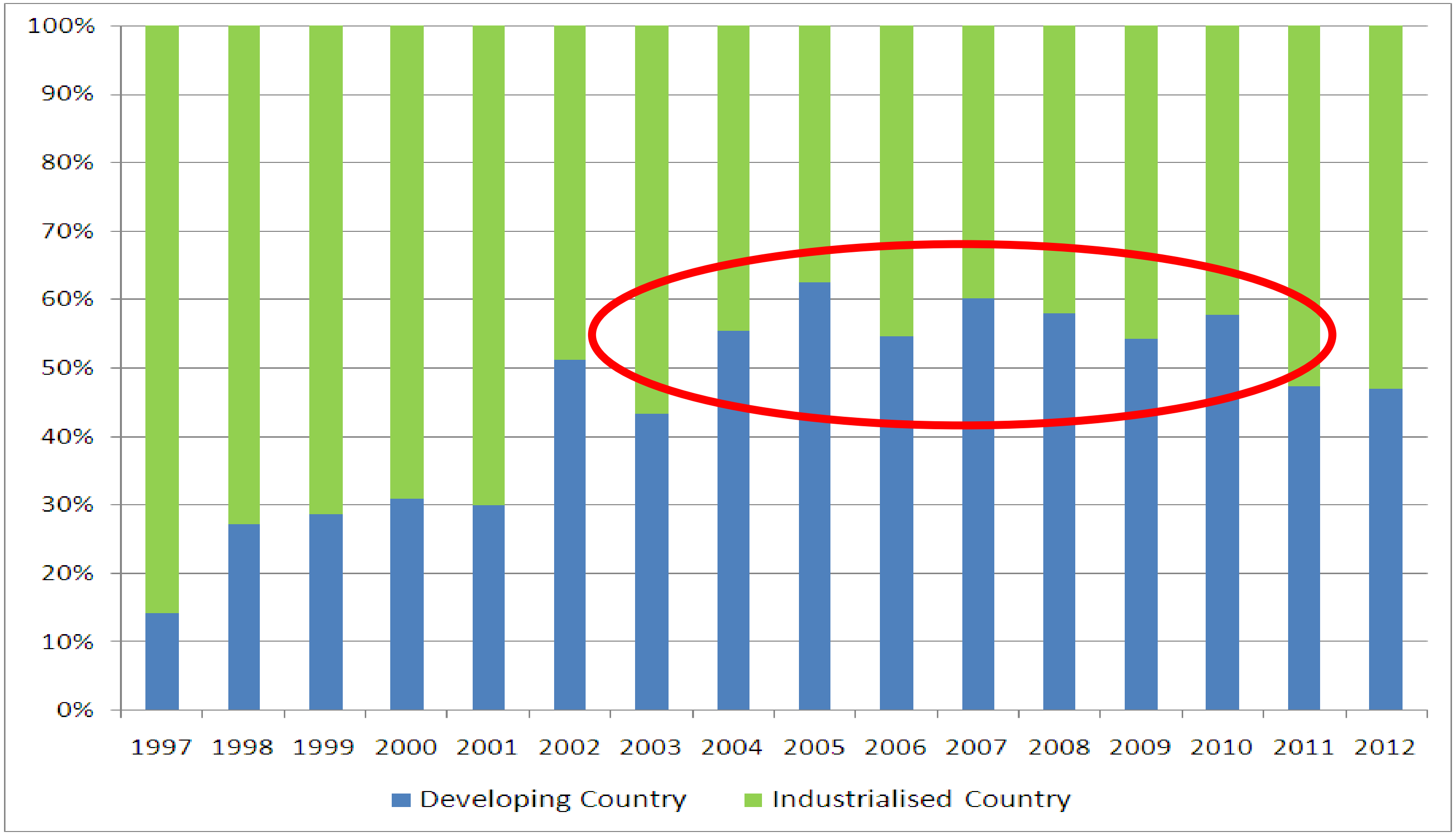


Principal drivers of the procurement volumes and value are polio and pentavalent vaccines



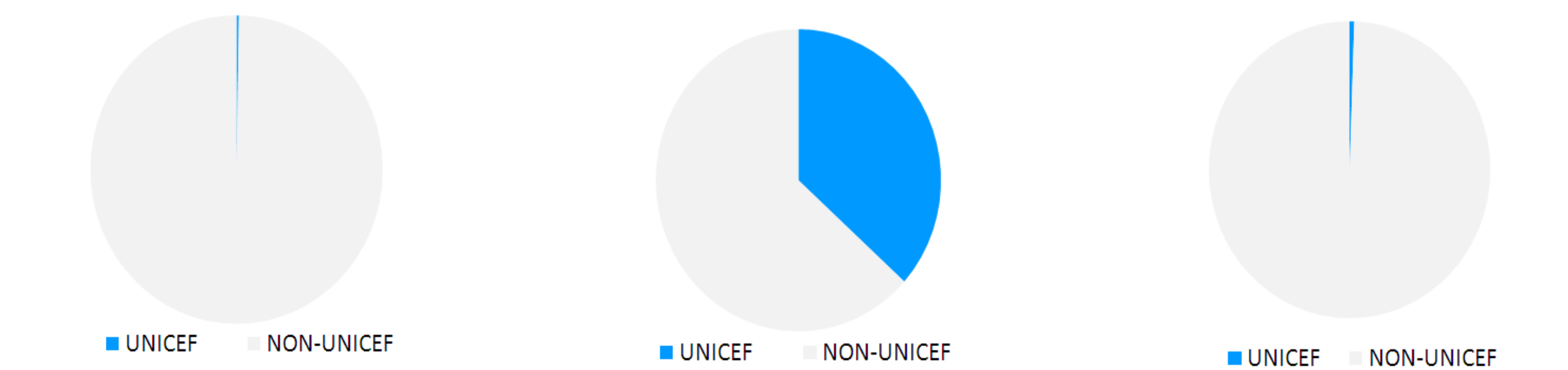
In the ‘traditional EPI vaccines’ for routine activities DCVM’s have supplied the majority of vaccines since 2004

Percentage of the Volume of BCG, DTP, Measles, HepB, TT, OPV (routine) procured by UNICEF

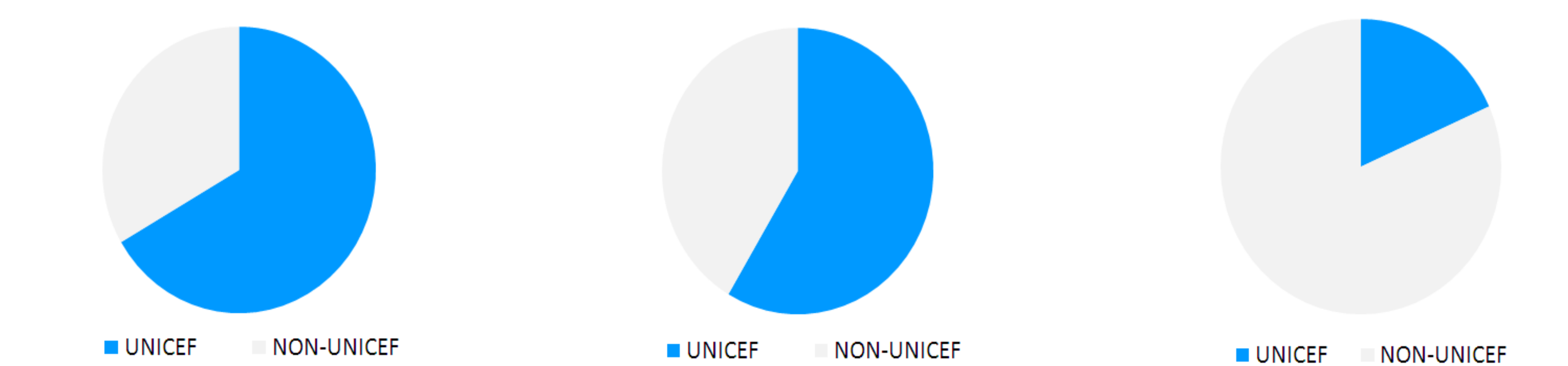


UNICEF vaccine spend as a portion of supplier's total sales 2009

Share of UNICEF procurement in the 3 largest suppliers' total sales* (multi-nationals)



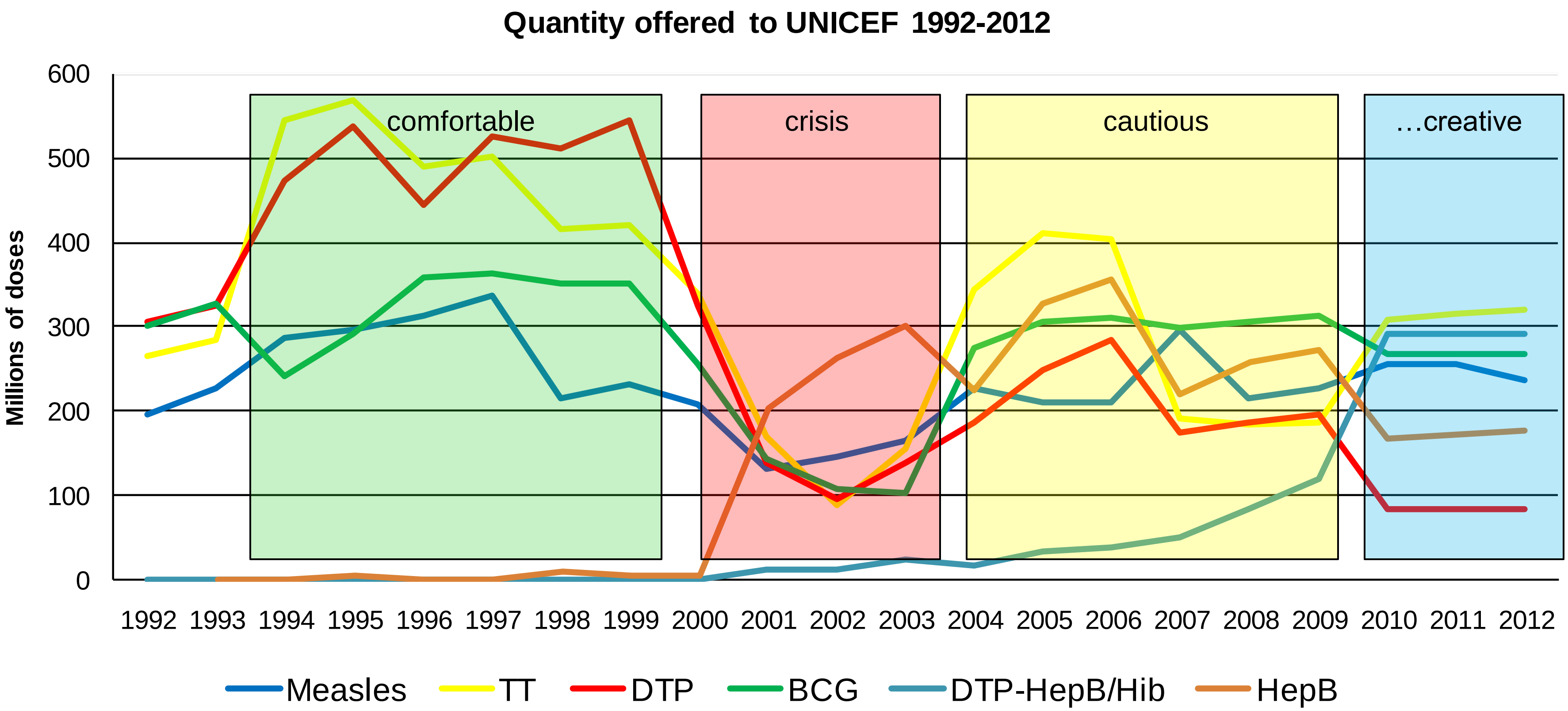
Share of UNICEF procurement in the 3 largest suppliers total sales* (emerging markets)



* Total sales in 2009 , 2006 for one supplier

Sources: UNICEF, SD, Suppliers' Annual Reports 2009 / 2006

Evolving vaccine market for lower income countries, as seen by UNICEF



crisis

Establishment of Vaccine Security: **Ensuring an uninterrupted, sustainable supply of affordable, quality vaccines**

Accurate Forecasting

Multi-year forecasts from countries and programmes. Production planning forecasts and Strategic forecasts to industry.

Funding

Understanding of funding profiles (country + aggregate); and longer term views of funding.

Appropriate Contracting

Multi-year arrangements; Multiple sources; Firm contracting (& funding) as relevant

Specific Vaccine Procurement Principles

Seeking to achieve and maintain Healthy Markets to meet the needs of Developing Countries

Historical mapping of tender periods & strategies, reflecting differing market dynamics

<table>
<tr><th>Products / Timeline</th><th>2001</th><th>2002</th><th>2003</th><th>2004</th><th>2005</th><th>2006</th><th>2007</th><th>2008</th><th>2009</th><th>2010</th><th>2011</th><th>2012</th></tr>
<tr><td>GAVI HepB/Hib containing</td><td colspan="3" rowspan="4">3 year</td><td colspan="3">3 year</td><td colspan="3">3 year</td><td colspan="3">3 year</td></tr>
<tr><td>Traditional routine (BCG, DTP, HepB, DT/Td,TT)</td><td colspan="3" rowspan="3">3 year</td><td colspan="3" rowspan="3">3 year</td><td colspan="3">3 year</td></tr>
<tr><td>Measles, MR, MMR</td><td colspan="3">3 year</td></tr>
<tr><td>YF routine</td><td colspan="3" rowspan="2">3 year</td></tr>
<tr><td>YF stockpile</td><td colspan="2"></td><td>1 yr</td><td>1 yr</td><td>1 yr</td><td>1 yr</td><td colspan="3">3 year</td></tr>
<tr><td rowspan="4">Polio tOPV</td><td colspan="5">5 year</td><td colspan="3">3 year</td><td colspan="2" rowspan="9">2 years</td><td colspan="2" rowspan="10">tbd</td></tr>
<tr><td colspan="2"></td><td colspan="2">Nov03-May04</td><td colspan="3">Apr05-Feb07</td><td></td></tr>
<tr><td colspan="3"></td><td colspan="2">Jul04-May05</td><td></td><td colspan="2">May07-May08</td></tr>
<tr><td colspan="6"></td><td>Jul07-Sep07</td><td></td></tr>
<tr><td rowspan="3">Polio mOPV1</td><td colspan="4"></td><td>Apr05-Nov05</td><td colspan="2">Jul06-Jul07</td><td></td></tr>
<tr><td colspan="4"></td><td colspan="2">Jul05-May06</td><td colspan="2">May07-May08</td></tr>
<tr><td colspan="4"></td><td colspan="2">Dec05-Dec06</td><td></td><td>Jun08-Dec08</td></tr>
<tr><td rowspan="2">Polio mOPV3</td><td colspan="4"></td><td>Sep05-Dec05</td><td></td><td colspan="2">Oct07-Dec08</td></tr>
<tr><td colspan="5"></td><td colspan="2">Jul06-Jul07</td><td>Jun08-Dec08</td></tr>
<tr><td>Polio bOPV</td><td colspan="8"></td><td colspan="2">Nov09-Dec10</td></tr>
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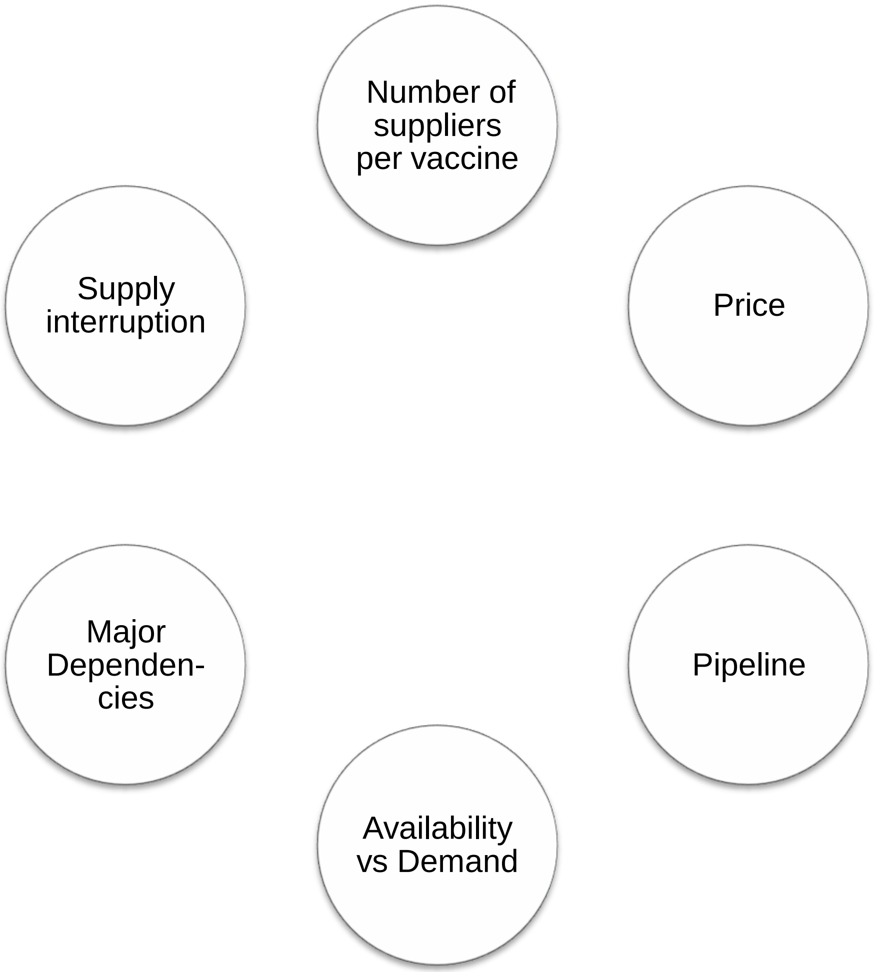
Different views of assessing the health of each vaccine market



Number of suppliers per vaccine

Vaccine Group	Number of Manufacturers awarded in 2001-2003	Number of Manufacturers awarded in 2004-2006	Number of Manufacturers awarded in 2007-2009	Number of Manufacturers awarded in 2010-2012
DTP-HepB+Hib	1	1 => 2	2 => 4	4 => 3 => 4
DTP+Hib	0	0	1	1
DTP-HepB	1	1 => 2	3	2 => 1
YF	3	3 => 2	3	4
Measles	5	5 => 4	3	3
MMR	3	3 => 2	2	2
MR	1	1	2	2
OPV	4	5	6	6
BCG	5	4	4	4
DTP	5 => 4	4 => 3	3	3
TT	7	4	3 => 4	4 => 5
HepB	4	5	6 => 5	3
DT/Td	3	2	2/2	2/2

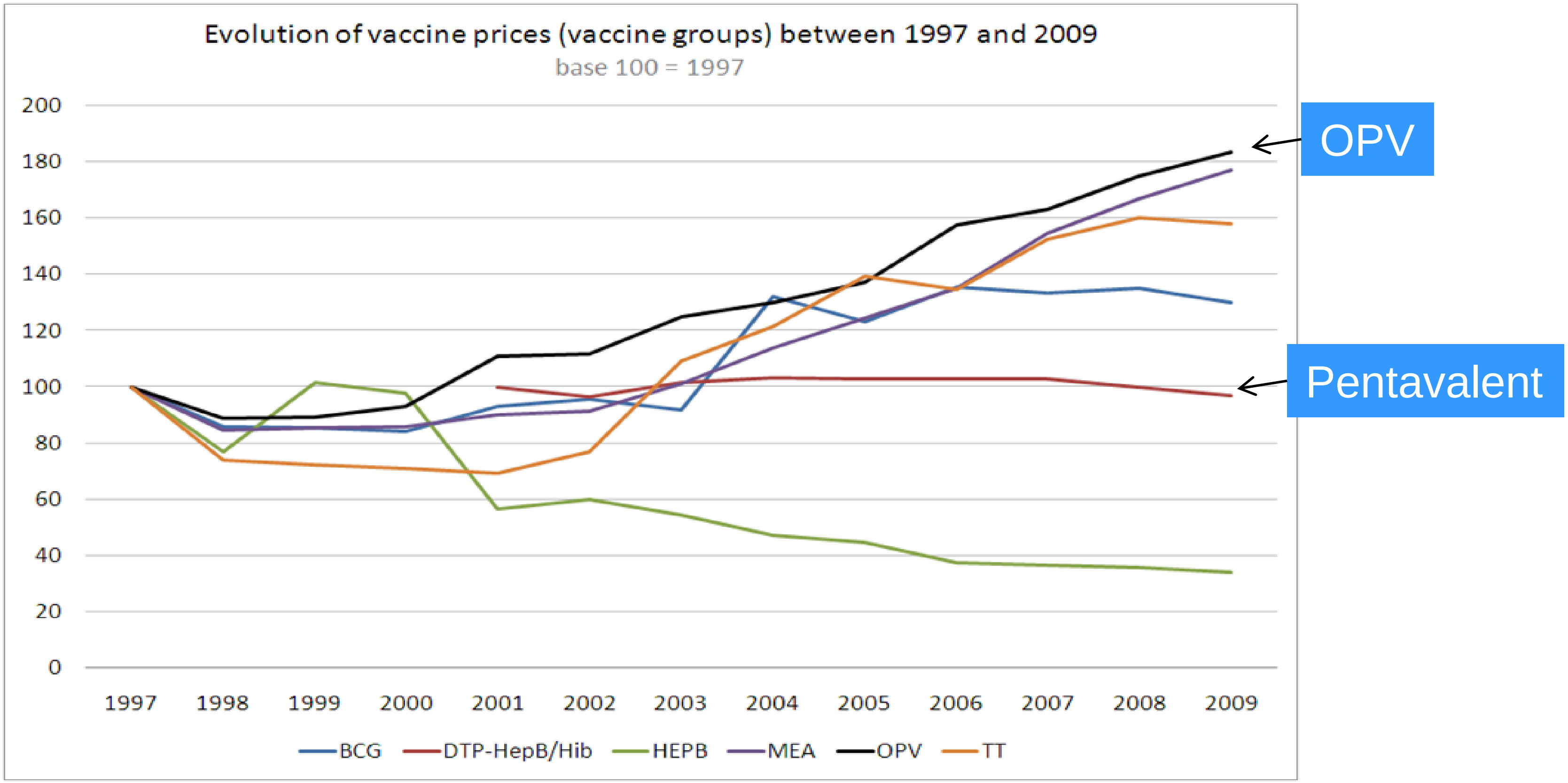
UNICEF contracted WHO pre-qualified vaccines suppliers over time, showing changes during the period

Positive trends: broadening the supply base; reducing the risk of supply interruptions; increasing competition

Pipeline

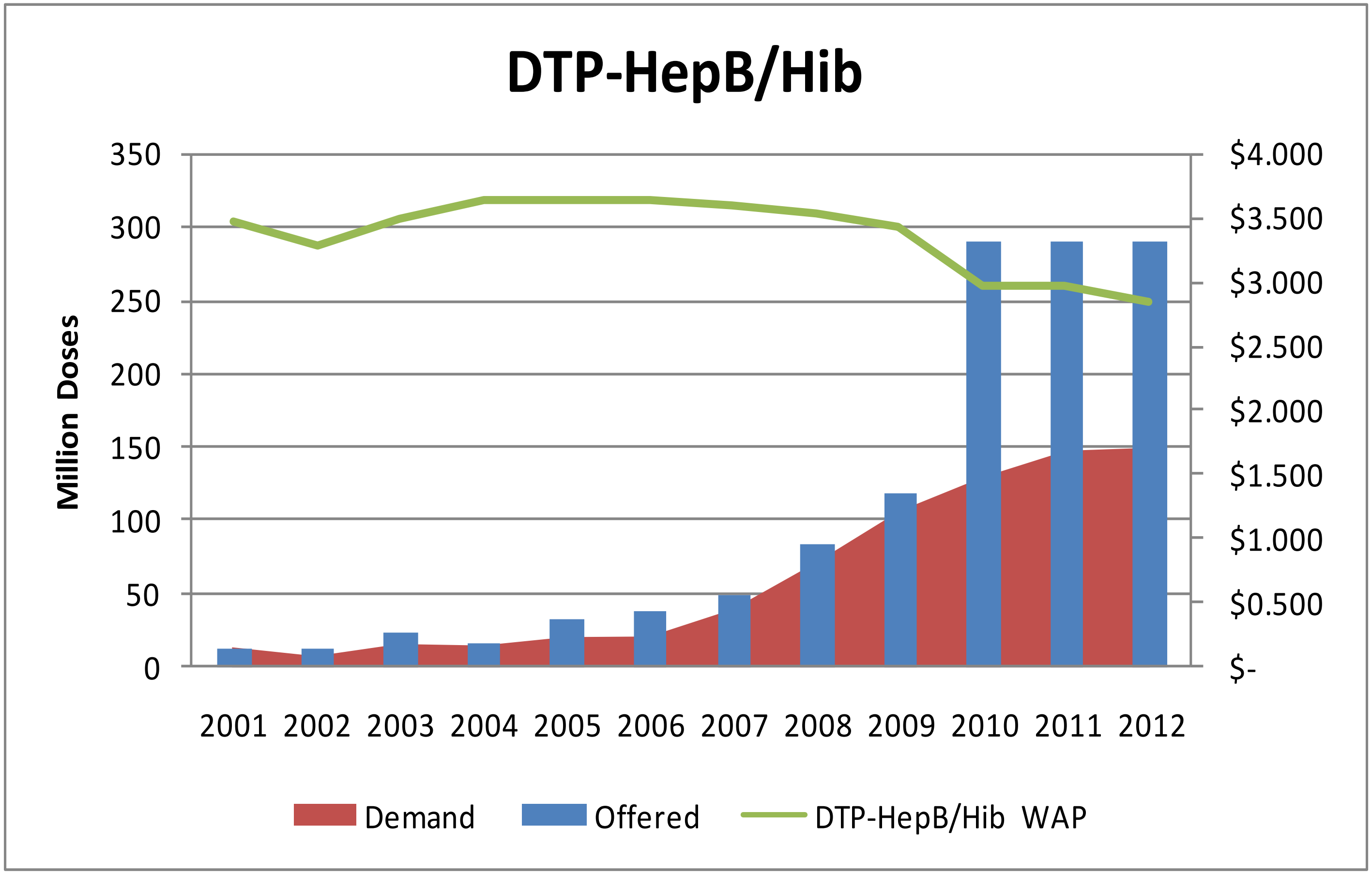
Vaccine Group	Number of Manufacturers in the pipeline in 2007-2009	Number of Manufacturers in the pipeline in 2010-2012	Number of Manufacturers in the pipeline in 2010-2012
	total	total	from Developing Countries
DTP-HepB+Hib	6	5	5
DTP+Hib	3	1	0
DTP-HepB	9	2	1
YF	1	0	0
Measles	6	5	2
MMR	1	2	1
MR	1	2	0
BCG	0	0	0
DTP	4	2	2
TT	6	2	2
HepB	4	1	1
DT	4	1	1
Td	2	2	2

Price



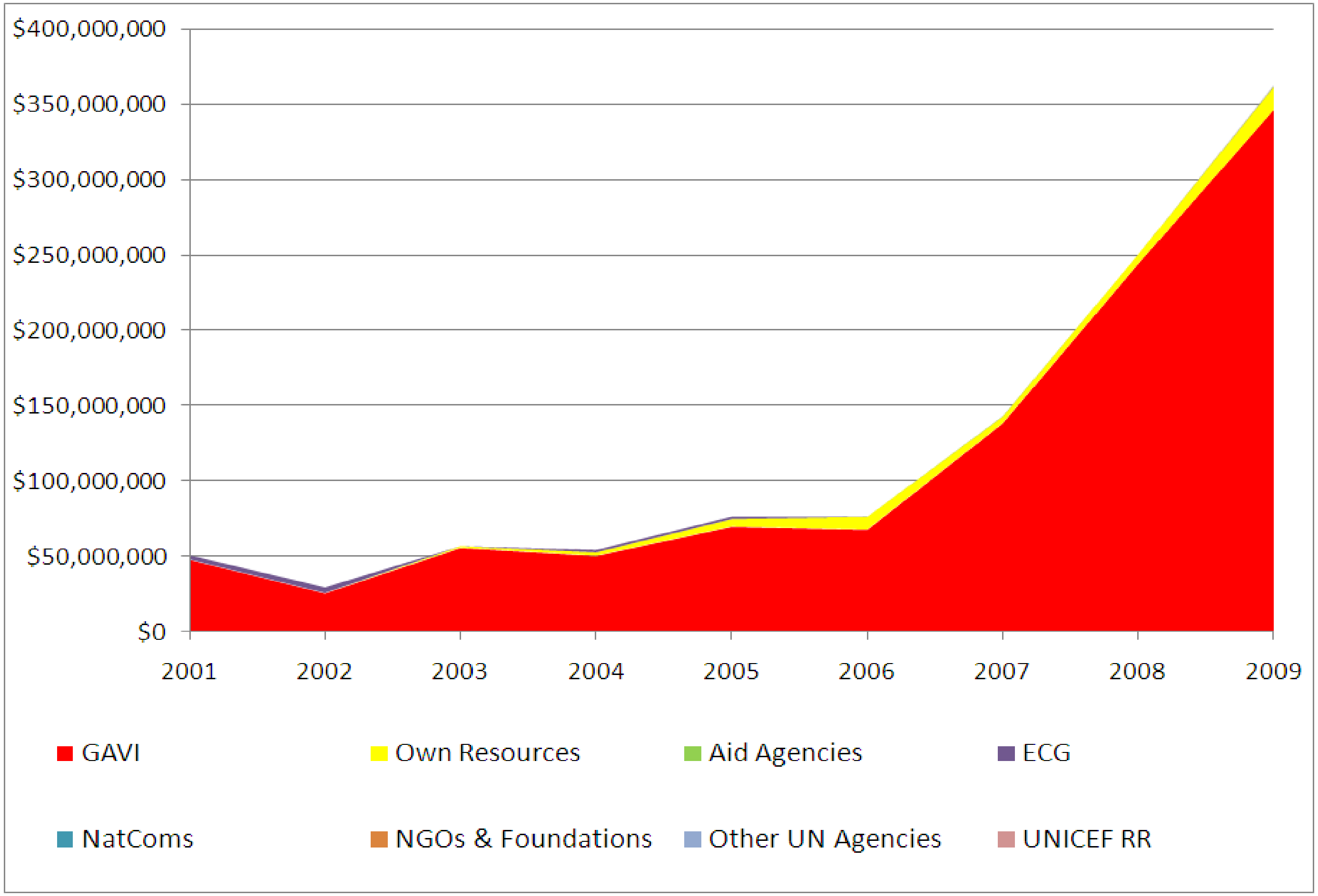
Evolution of vaccine prices (vaccine groups) between 1997 and 2009
base 100 = 1997
200
180
160
140
120
100
80
60
40
20
0
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
BCG
DTP-HepB/Hib
HEPB
MEA
OPV
TT
OPV
Pentavalent

GAVI funded support of Hib containing vaccines has enabled the 120m - 130m dose pentavalent market to be established, with 4 pre-qualified suppliers, more in the pipeline and supply now outweighing demand



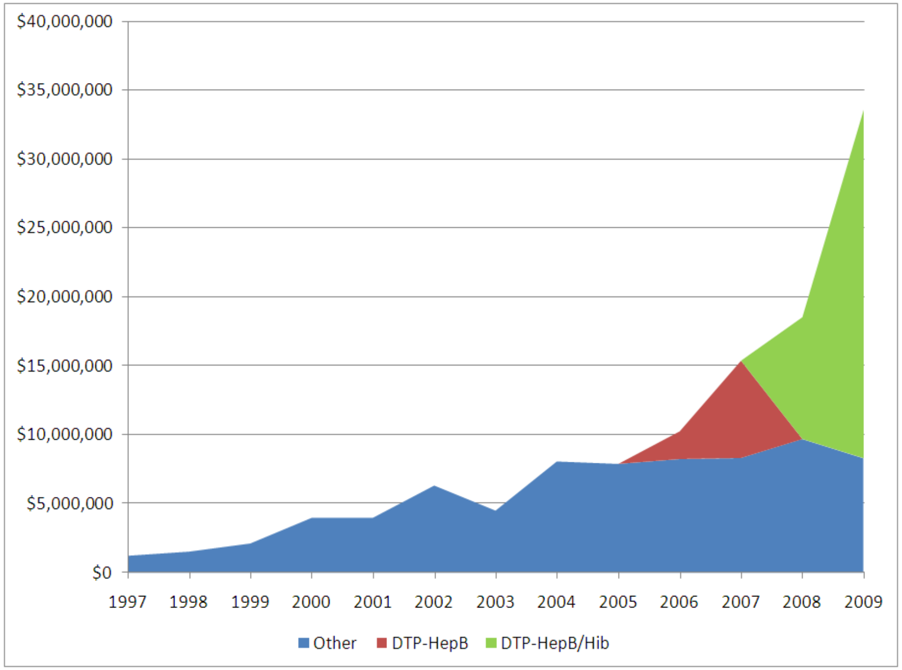
With GAVI funding over 95% of the procured quantities of pentavalent in 2009, highlighting the extreme dependency this market has on GAVI funding support

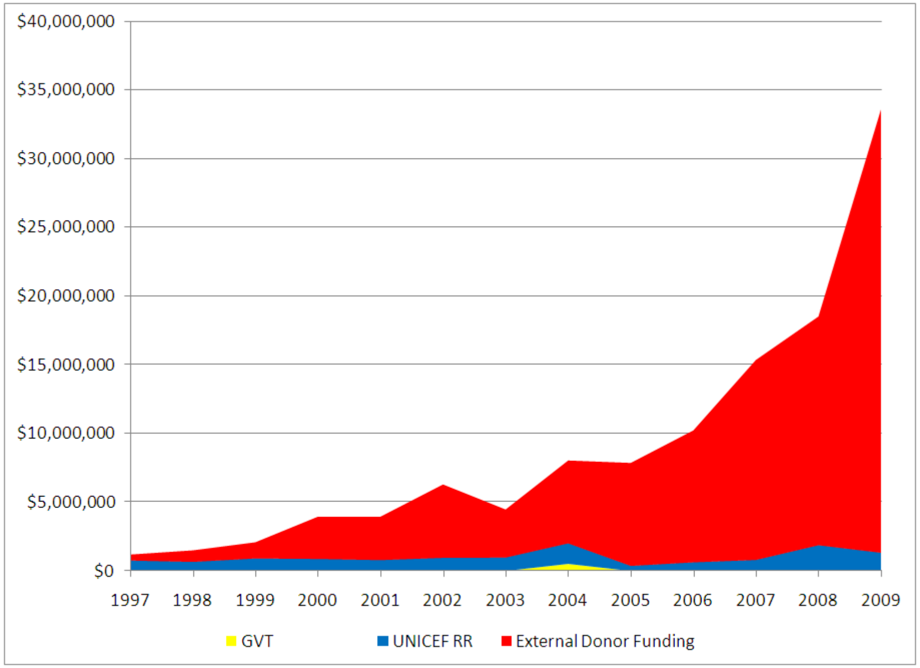
DTP-HepB/Hib Funding Profile



With 15 countries already graduating from GAVI support in 2011 and no longer be supported for vaccine procurement after 2015, Affordability needs to be prioritised in pentavalent procurement strategies in order for this to be sustainable

Country sample Product Profile & Funding Profile



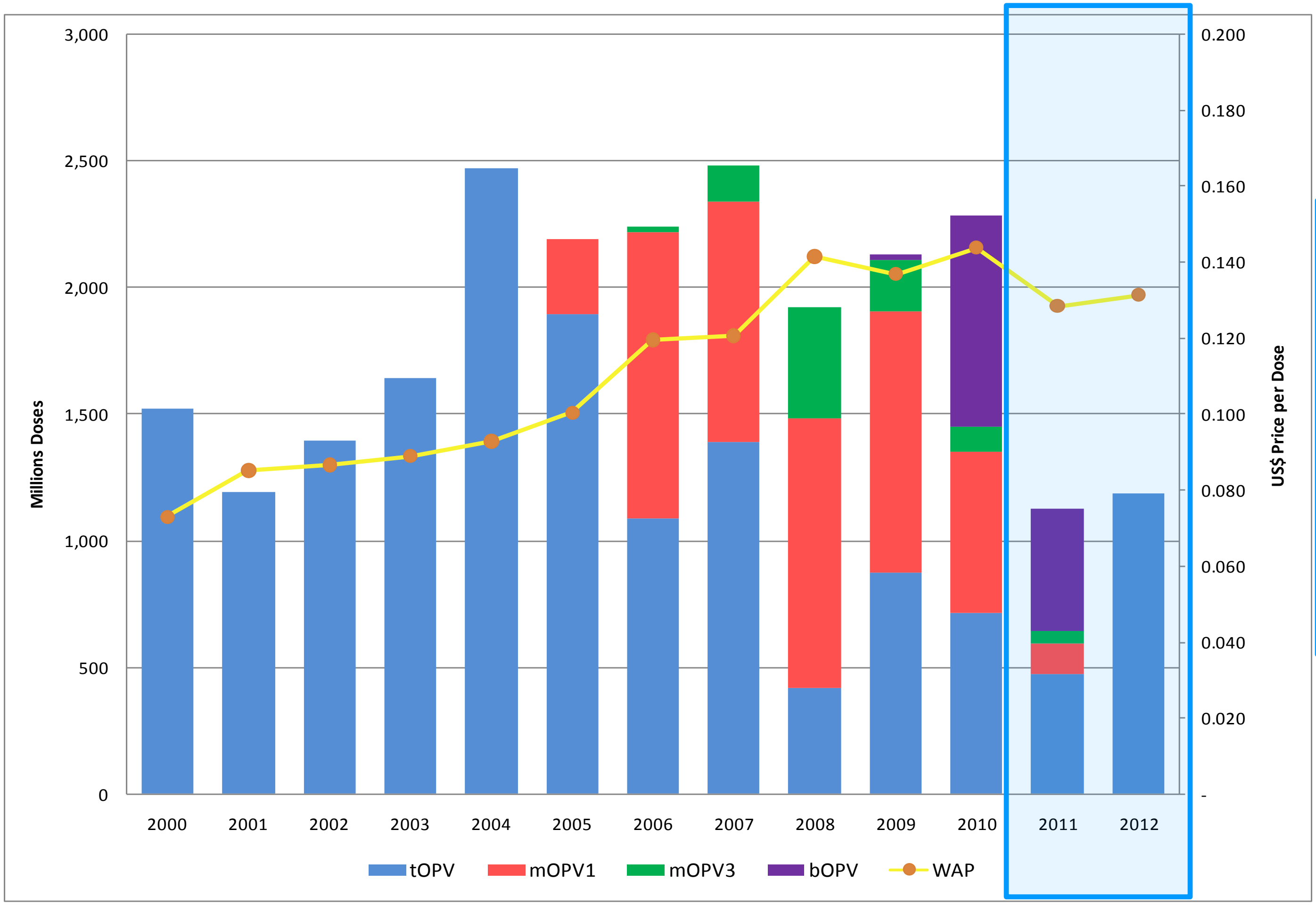


…creative

Given the diversified market situations, it’s a good time to re-think strategies to achieve healthy market objectives

- Introduction of higher priced vaccines
- Increasing complexity within procurement as new products become available
- Competition with high-income markets for production allocation
- Demand reacting to changes and developments in immunization programmes, vaccine development and funding speculation
- Country preferences on presentation and formulation
- Requires balancing with financial sustainability
- Need for increased flexibility on tendering strategies, maintaining long time horizons and providing for market flexibility

OPV tender concluded, securing supply and reduction in WAP for 2011-2012



No. of PQ/recommended products:

bOPV – 4 suppliers

mOPV3 – 3 suppliers

mOPV1 – 6 suppliers

tOPV – 5 suppliers

WAP/dose	2010	2011	% Reduction
tOPV - 20	0.147	0.1294	12.0%
bOPV	0.151	0.1316	12.8%
mOPV1	0.132	0.1134	14.1%
mOPV3	0.133	0.1252	5.9%
Total OPV	0.144	0.1284	10.8%

Lower WAPs contribute to a savings to the programme over the two year period

Upcoming Opportunities

Pentavalent

- 2011: Demand estimate 127 million doses. UNICEF has 77 million doses on LTA . Currently working on securing 50Mds due to changes in the supply base.
  - Expect and will pursue that the WAP continue the downward trend.
- 2012: At this point only 50Mds is covered by awards from pre-qualified sources. Demand projected at 127Mds.
  - Award decisions by mid year next year.

Yellow Fever

- 2011: additional 20 million doses for preventive campaigns

Potential additional awards for Measles & TT for 2011 and 2012

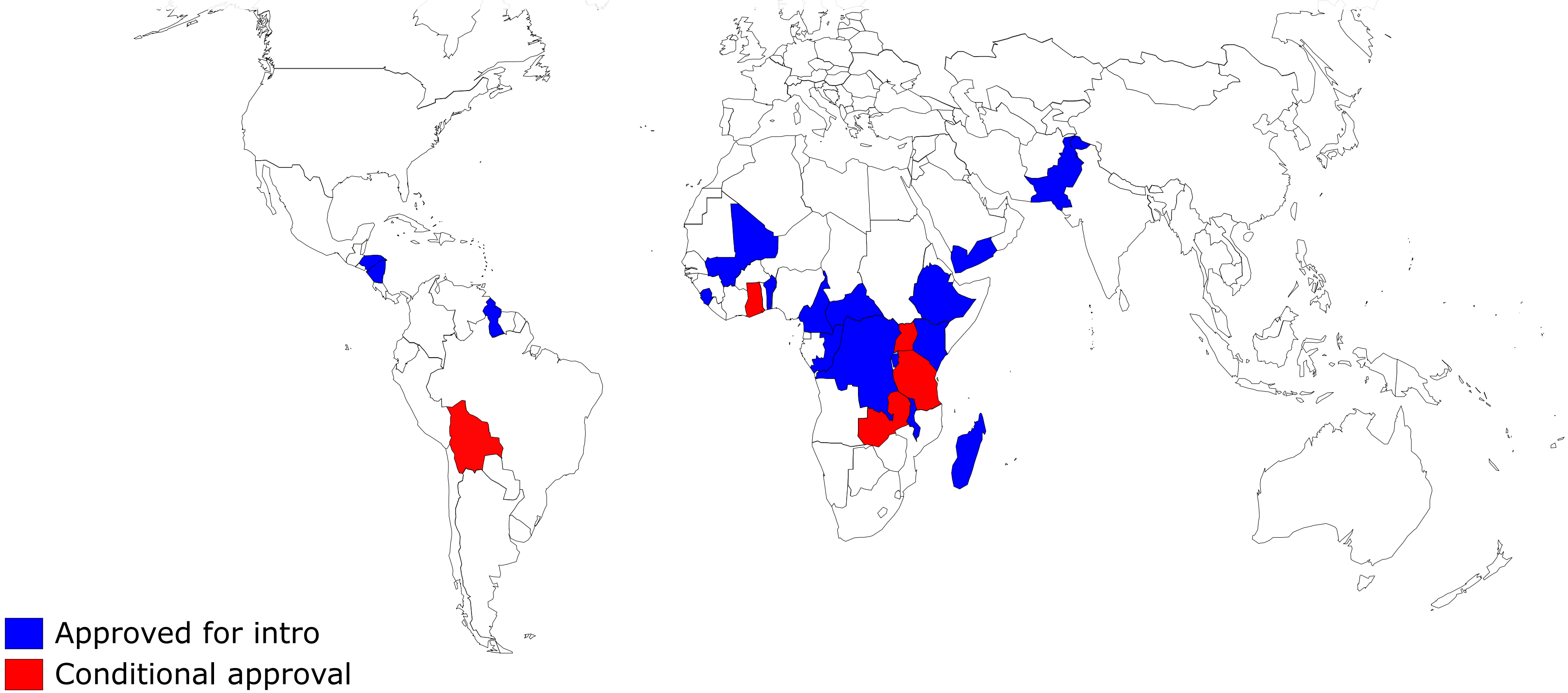
- Dependant on the outcome of the current country forecasting exercise

Pneumococcal Vaccine being procured under the Advance Market Commitment T&Cs

- 2 countries have introduced PCV7 in 2009, to switch in 2011
- 17 additional countries approved to introduce in 2010-12

Birth cohort of 18.5M to benefit

- 5 countries conditional approval Birth cohort of 5M

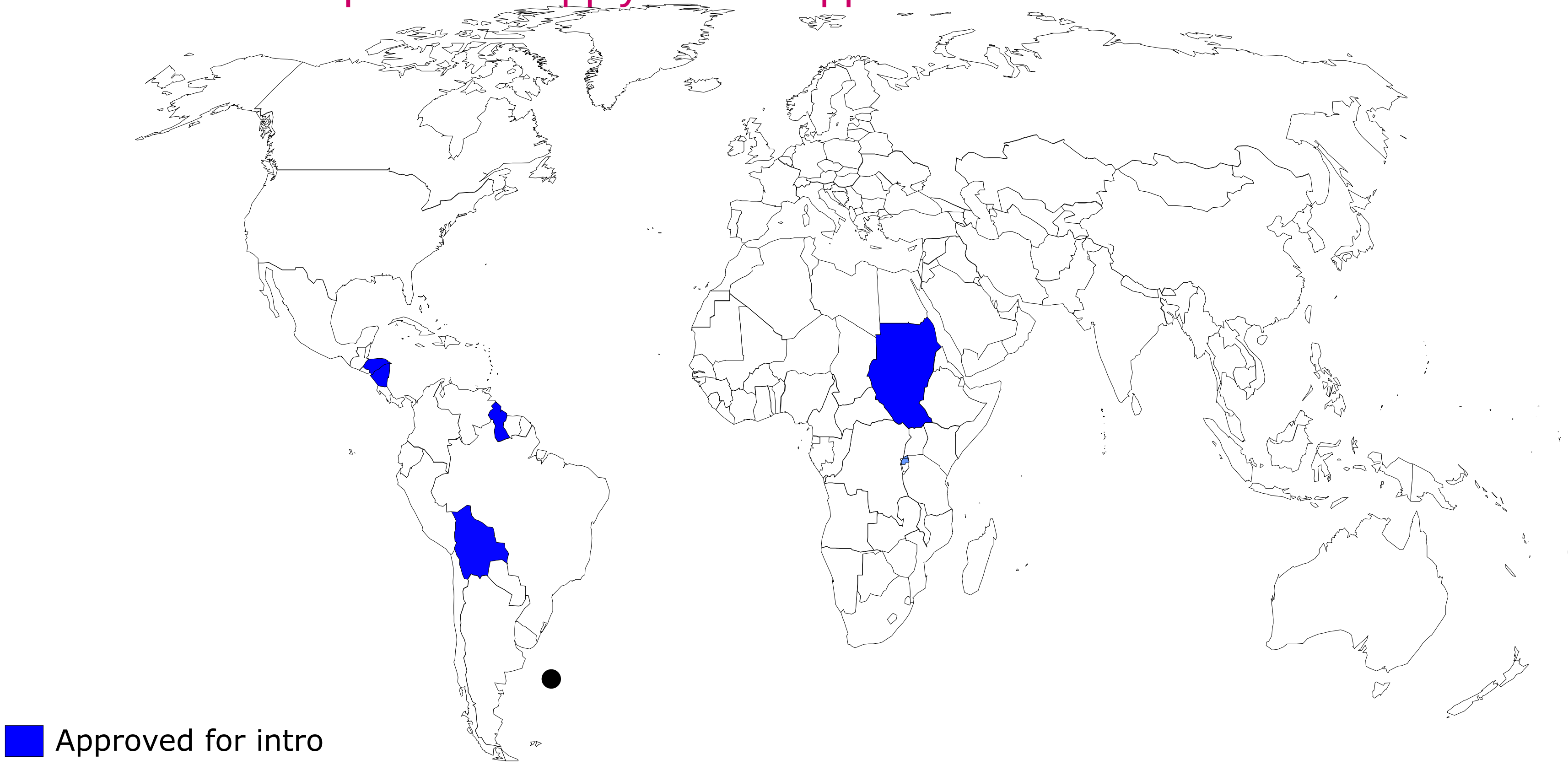


Outcome of first tender under the AMC

- Supply agreements signed with two vaccine manufacturers for 30M doses each annually from 2012 and 2013 (total of 600M doses)
- First supply to countries has started this month as vaccines have been prequalified and approved by the Independent Assessment Committee
- Out of $1.5B of AMC subsidy $1.05B remains unallocated with the purpose to incentivize new manufacturers to accelerate development of suitable vaccines
- Currently reviewing in consultation with GAVI if based on updated Strategic Demand Forecast a new tender should be issued

Countries supported by GAVI for Rotavirus vaccine

- 4 countries in PAHO region introduced Rotavirus vaccine
- 1 country to procure through UNICEF approved for introduction 2011~ 2.7M doses
- 7 countries expected to apply in next application round



Rotavirus - Procurement activities initiated to meet demand and accelerate access…

- Currently in the process of establishing a Procurement Reference Group to discuss procurement objectives and strategy
- Pre-tender meeting likely to take place late October/early November
- Tender planned to be issued November
- Aim to have vaccines with countries late Q1 to allow introduction during Q2 2011
- Strong focus on low and affordable prices – alternative offers to secure access to low prices will be considered

In Summary

Positive developments in the supplier base and encouraging DCVMN manufacturer interest in developing new products

Need to introduce new vaccines to achieve the MDGs

Increased focus on Affordability and to reduce price to ensure sustainability

Moving forward, we are going to be more creative in our tender strategies to achieve lower/affordable prices in addition to ensuring continued supply

Look forward to continuing the valuable partnership we have with the DCVMN members

Thank You!

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