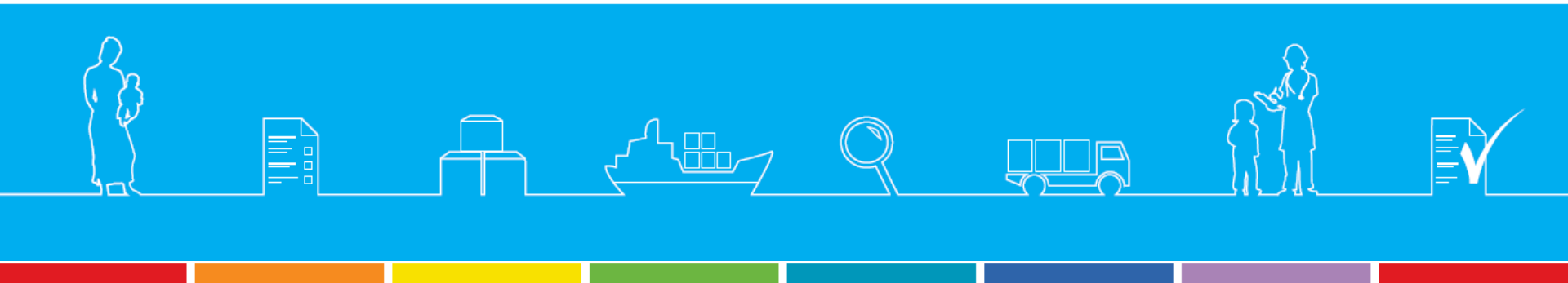




Supply Chains for Children

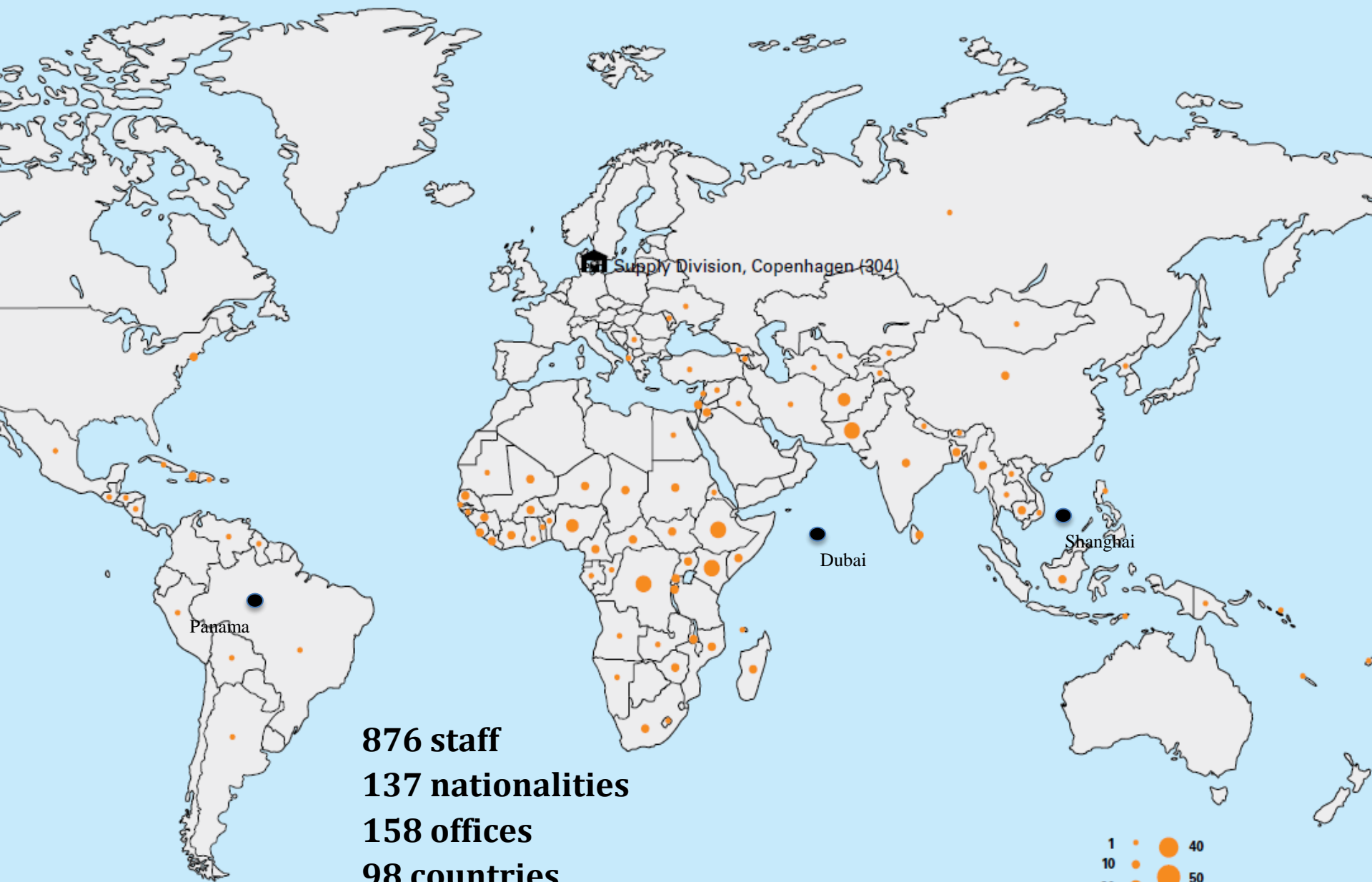


UNICEF Procurement Update

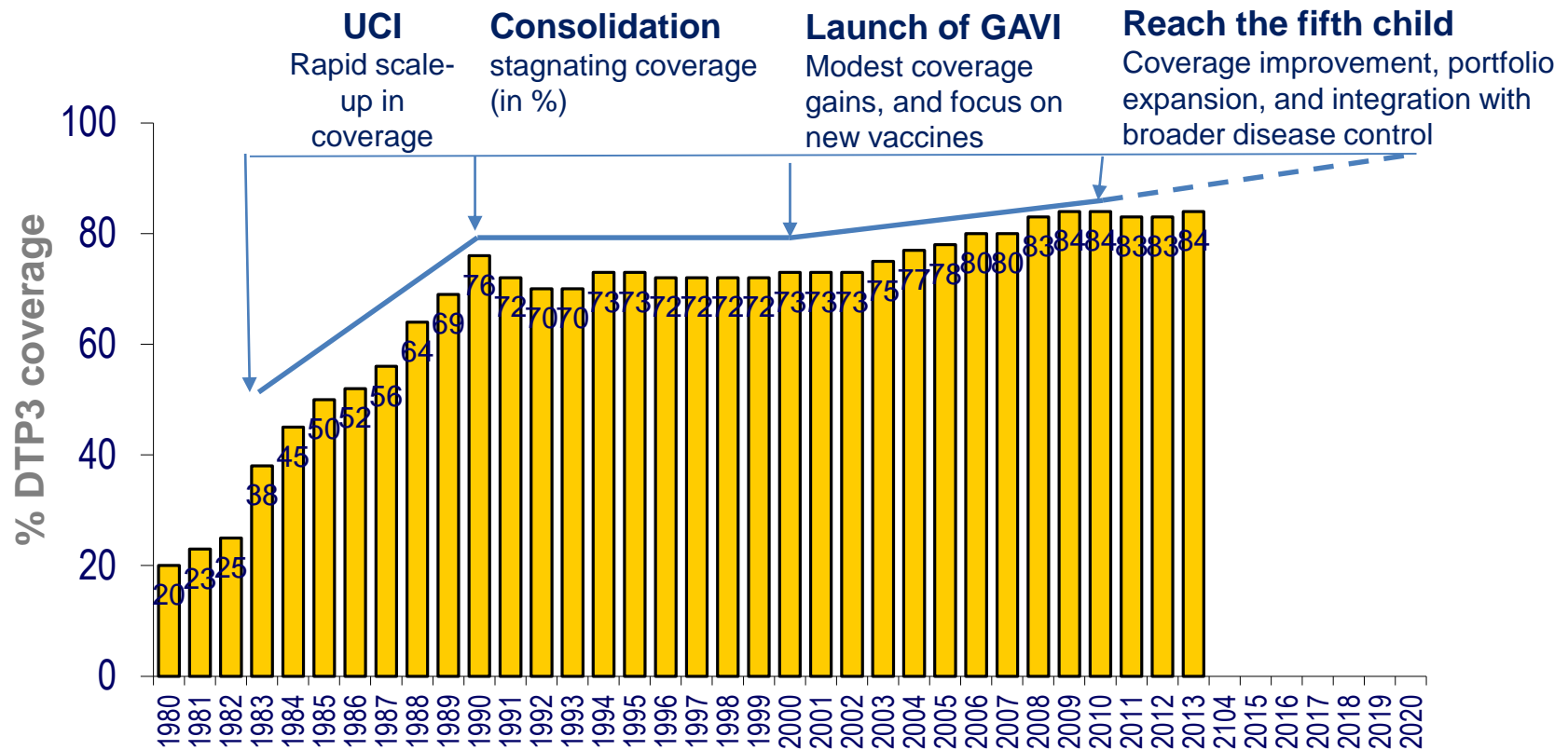
DCVMN Annual Meeting

India

28 October 2014



The expansion of vaccination coverage



Adapted from: L. Brearley et al. Vaccine 31S(2013) B103-B107

UNICEF has a key role in vaccine procurement, procuring immunization supplies on behalf of **around 100 countries** annually



2013 Vaccines Supplies: US\$ 1, 285 million

2.79
billion doses

2,185
shipments

Source UNICEF Supply Division

Immunization Supplies



Vaccines

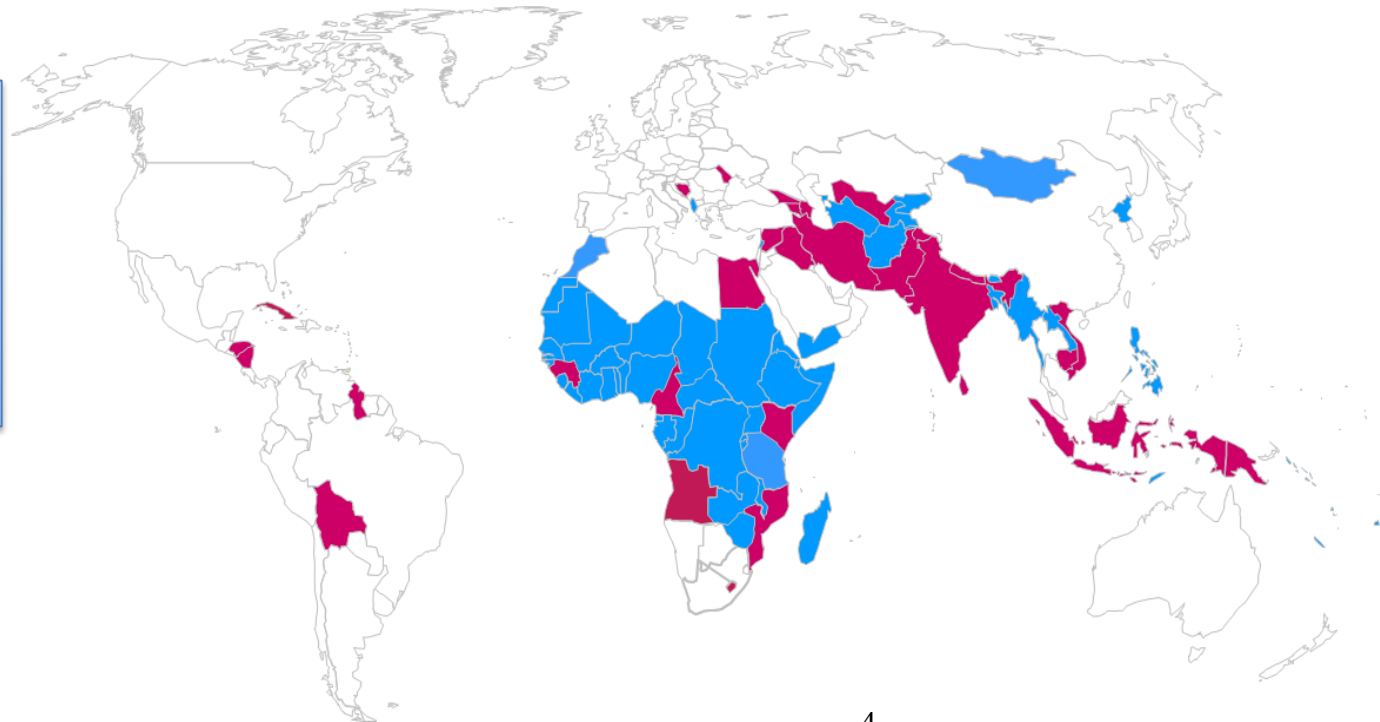
BCG , DTP, TT/Td/DT, Measles containing, OPV, HepB, YF, DTP-HepB, DTP-HepB/Hib, DTP/Hib, Hib, MR, Meningitis, MMR, PCV, RV IPV, HPV etc.

Safe Injection equipment

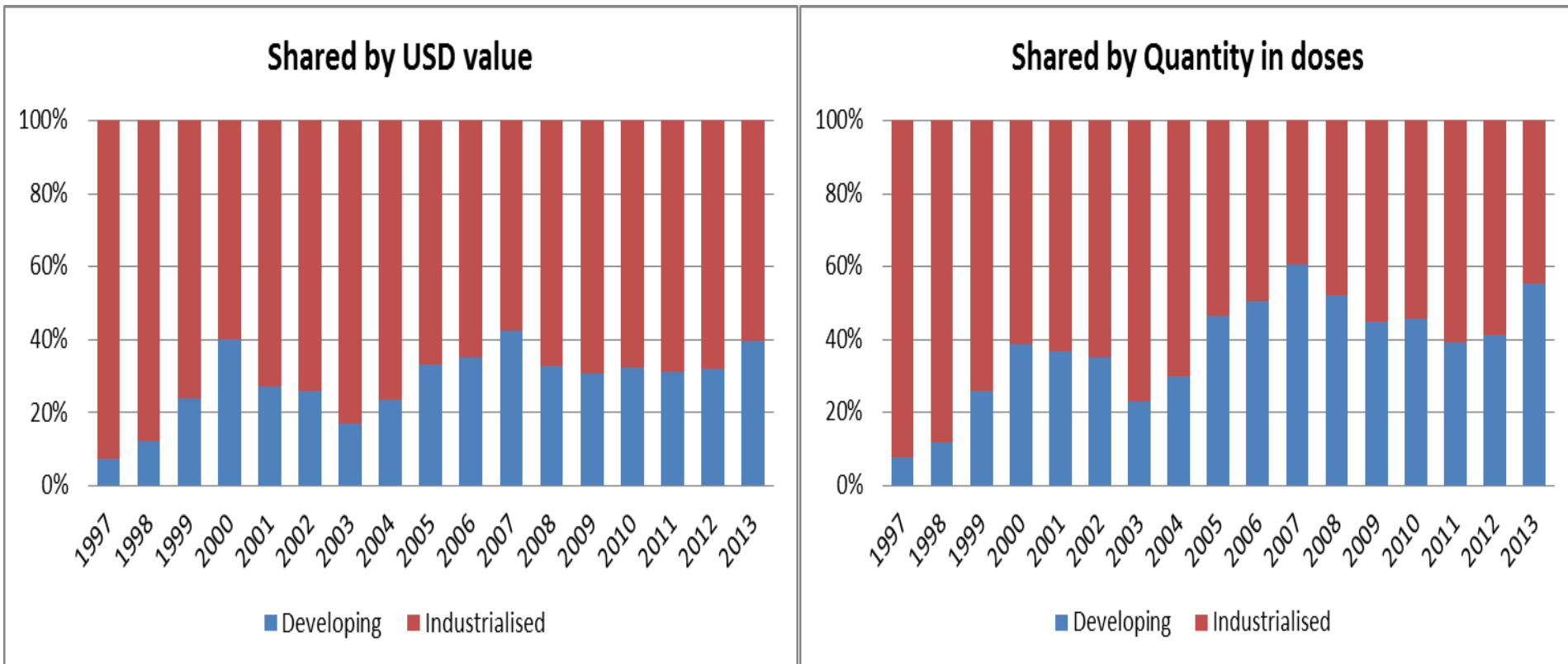
Cold Chain Equipment

Countries UNICEF
procures on behalf of

-  Full schedule
-  Partial schedule



A considerable portion of vaccines procured by UNICEF come from **emerging market** country manufacturers
 2013: 1.55 billion doses with a value of \$507 million



9 emerging market country manufacturers for 15 different vaccines in 2013

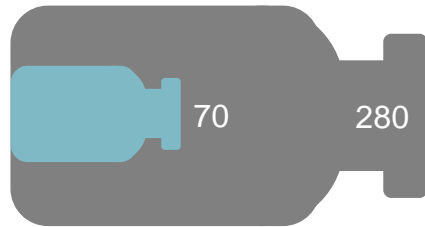
Vaccine introduction status and tentative plan for Eastern & Southern Africa region: 2014-2020

Updated date: Aug 2014		Tentative year of vaccine introduction									Number of vaccine introduction plan 2014-2018
Country	Penta	Pneumo	Rota	MSD	MR/MMR	HepB birth	HPV	IPV	YF	MenA	
Angola	2006	2013	2014	2017		2017	2017	2015	1999		4
Burundi	2005	2011	2013	2013	2017	2017	2015	2015	2017	2016	6
Botswana	2009			2011		2000		2015			1
Comoros	2009	2016	2016	2015	2018	2018	2016	2015			7
Eritrea	2008	2015	2014	2012	2015	2020	2018	2015	2020	2018	5
Ethiopia	2007	2011	2013	2018		2018	2016	2015		2018	5
Kenya	2001	2011	2013	2013	2015	2017	2014	2015	2000	2017	5
Lesotho	2008	2014	2015	2013		2015	2011	2015			4
Madagascar	2008	2012	2014	2018		2018	2018	2015			5
Mozambique	2009	2013	2015	2015	2018	2018	2017	2015			6
Malawi	2002	2011	2012	2015	2016	2021	2015	2015			4
Namibia	2009	2014	2014	2015		2012		2015			4
Rwanda	2002	2009	2012	2014	2014	2018	2014	2015	2016	2017	7
Somalia	2013	2016	2018					2015			3
Mozambique	2009	2013	2015	2015	2018	2018	2017	2015			3
South Sudan	2014	2016	2018	2018				2015	2016		6
Swaziland	2010			2008				2015			1
U R of Tanzania	2009	2013	2013	2014	2014	2018	2014	2015			5
Uganda	2002	2013	2016	2016		2017	2015	2015	2020	2016	6
Zambia	2004	2013	2012	2013	2015	2019	2015	2015			3
Zimbabwe	2008	2012	2014	2015	2015	2019	2014	2015			5
Total											95

Immunisation supply chain risk will increase due to higher volumes, doses and vaccine cost

Supply chain requirements 2010 2020

Growing volume (cm³) to vaccinate per child¹



Increasing number of doses²



~4x

~6x

~5x

~2x

\$0.8

\$4.1

2010
Vx mix³

2020
Vx mix
(price 2013)³

Introduction of more expensive vaccines³

Increase in stock keeping units per year for GAVI vaccines⁴



Note: All figures relate to GAVI-funded vaccines

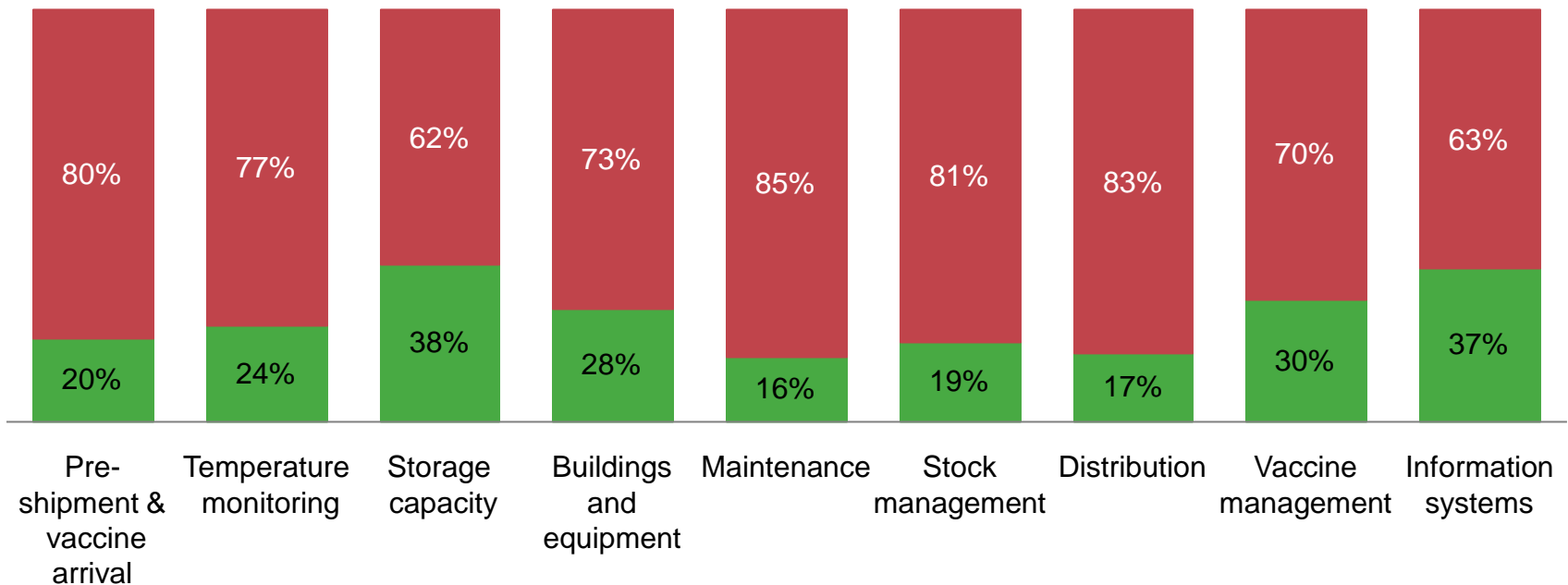
1. UNICEF Supply 2012 Financial report, WHO data for Pneumo and Rota vaccines, and HPV (only for girls);
2. 2010: GAVI Shipment Data; 2020: GAVI SDF Forecast; Including volume for GAVI future graduated countries;
3. Comparison based on 2013 Price; 2020 Vaccines include: Rota, Pneumo; HPV; 2010' vaccines include: YF, Measles, DPT, OPV (UNICEF SD);
4. GAVI Background SDF Information; 2010*: estimates based on 2009 data; 2020: estimates based on 2013 forecast

On average country immunisation supply chains do not meet WHO standards today



% of countries that reach 80% target on relevant supply chain WHO standards¹

■ Not reaching standard
■ Reaching standard



1. EVM (Effective Vaccine Management) Assessments – Average score of Principal, Sub-National, Local District and Service Point Level;
Source: EVM assessment for 57 GAVI countries, WHO

Vaccine Market Updates and Developments



UNICEF's procurement is focused on achieving **Vaccine Security** – the sustained, uninterrupted supply of affordable, vaccines of assured quality.

Vaccine Security



UNICEF **Vaccine Procurement Principles**, implemented following the supply crisis in the traditional vaccine markets, are considered relevant for all vaccines to ensure a healthy market

Forecasts are at the foundation

Forecast Type	Main purpose	Example	Vaccines	Duration	Methodology	Tendency	Public
Programmatic	Projected programme targets / achievements	GAVI SDF	Penta, PCV, Rota, HPV, etc	20 years	Global aggregate; informed guestimates on country decisions and readiness	Tends to be aspirational	Yes
		GPEI	Polio	5 - 10 years			
		Measles Partnership	Measles	5 years			
Financial	Provides targets for fundraising and financial planning	GAVI SDF	Penta, PCV, Rota, HPV, etc	20 years	Aggregate	Tends to be conservative	Yes
		GPEI	Polio	5 - 10 years			
Country	Projects 1-5 year need for UNICEF procurement	Government / UNICEF	Routine and Supplemental	5 years	Country based	Tends to be aspirational	No
Procurement	Projects what will be procured during the tender period	UNICEF	All Vaccines	1 - 10 year	Provided on aggregate level and by country	Tends to be conservative	Yes
Production Planning forecasts	Projects monthly deliveries to LTA suppliers	UNICEF	All Vaccines	12 month (rolling)	Provided on aggregate level and by country	Tends to be conservative	No

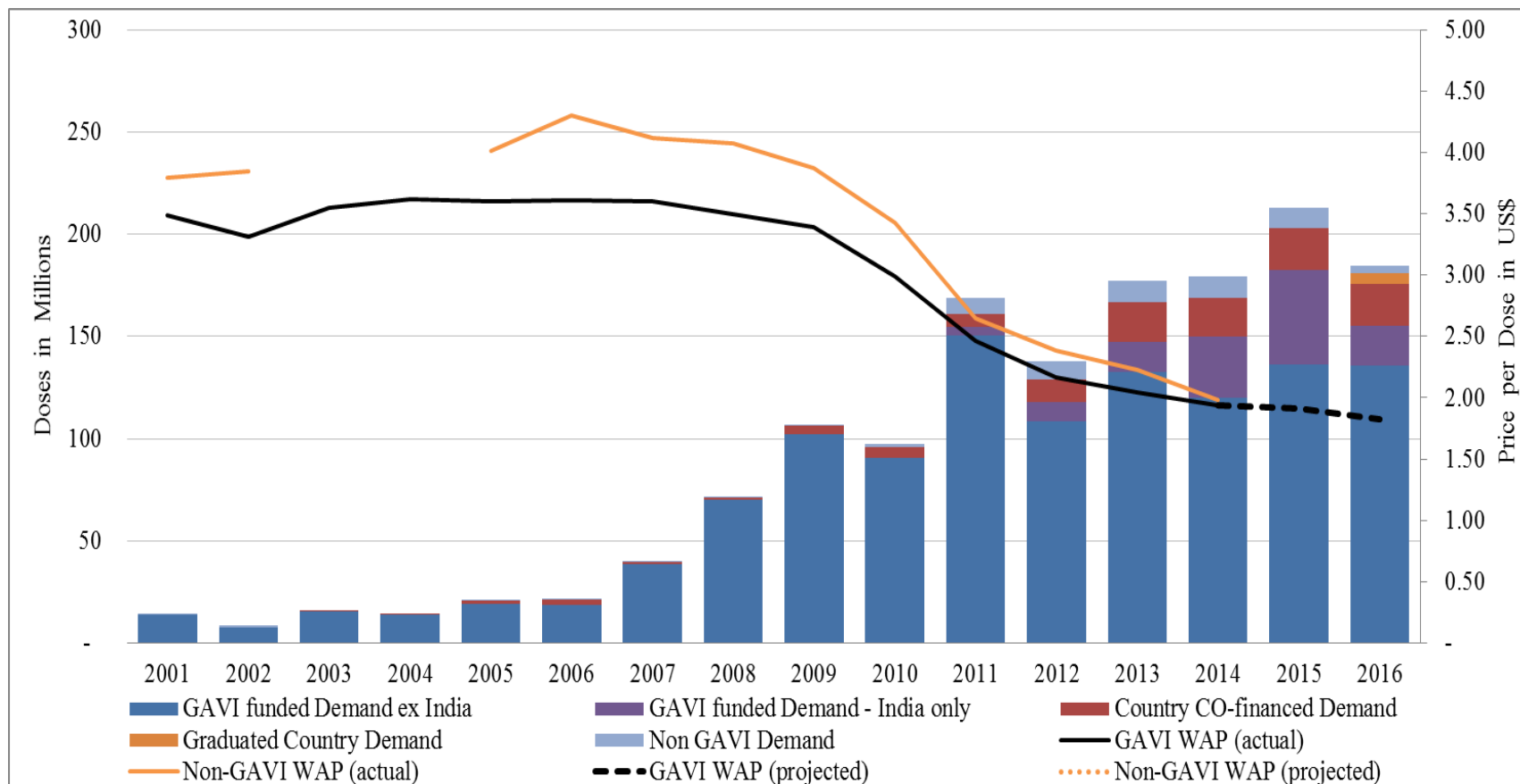
UNICEF's tender and contracting approach

- Individual product procurement strategies, based on analysis and experience
- Informed by industry and partner consultations and objectives alignment
- RFPs for strategic products – flexibility for manufacturers to shape the offer to highlight how they can bring best value
- Multi-year Tender & award period – providing planning horizon and more certainty to manufacturers
- Wide invitee-list. All manufacturers are able to participate (including pipeline) invited
- Awards; LTA – ‘good faith’ framework agreements.
 - Based on good will from accurate forecasts, but ‘treated’ as contracts
- Multiple suppliers awarded per product
- Pipeline assessed in award recommendation, and inform award strategy to incentivize continued market development

Market Updates: Pentavalent

- Current tender covered period 2013-2016.
- Presentation preferences have evolved: now preference for liquid, 10 dose vials
- 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
- 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

Market Updates: Pentavalent – different demand tranches



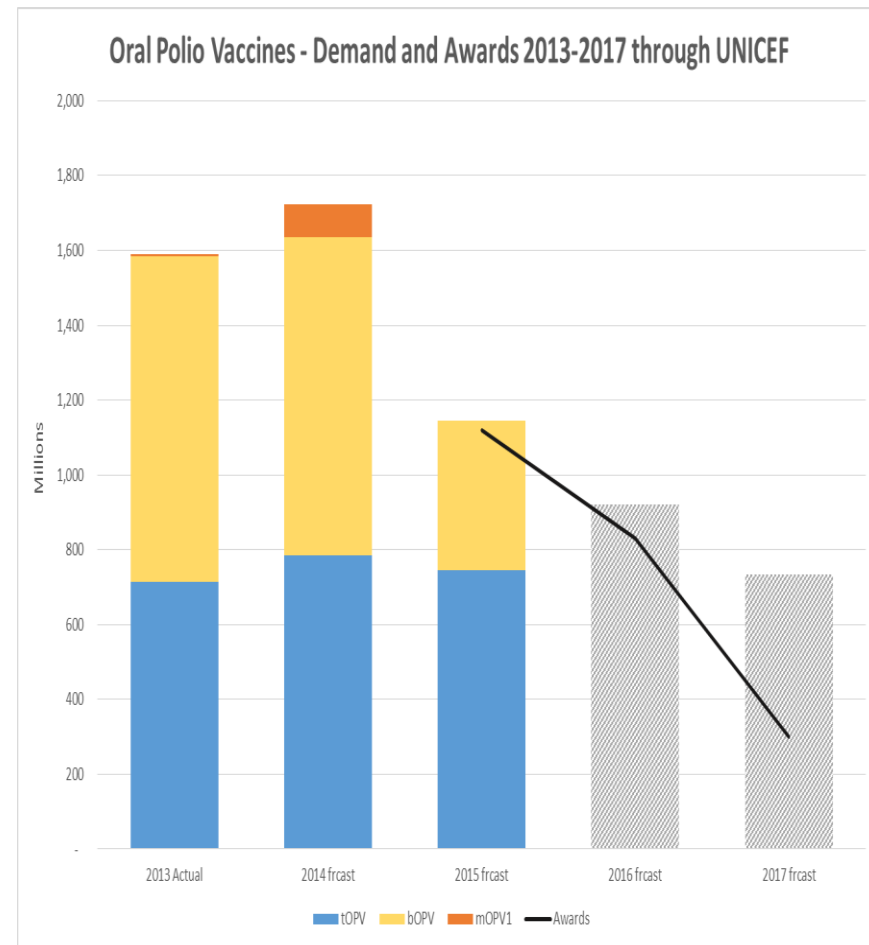
Market Updates: OPV

Current status

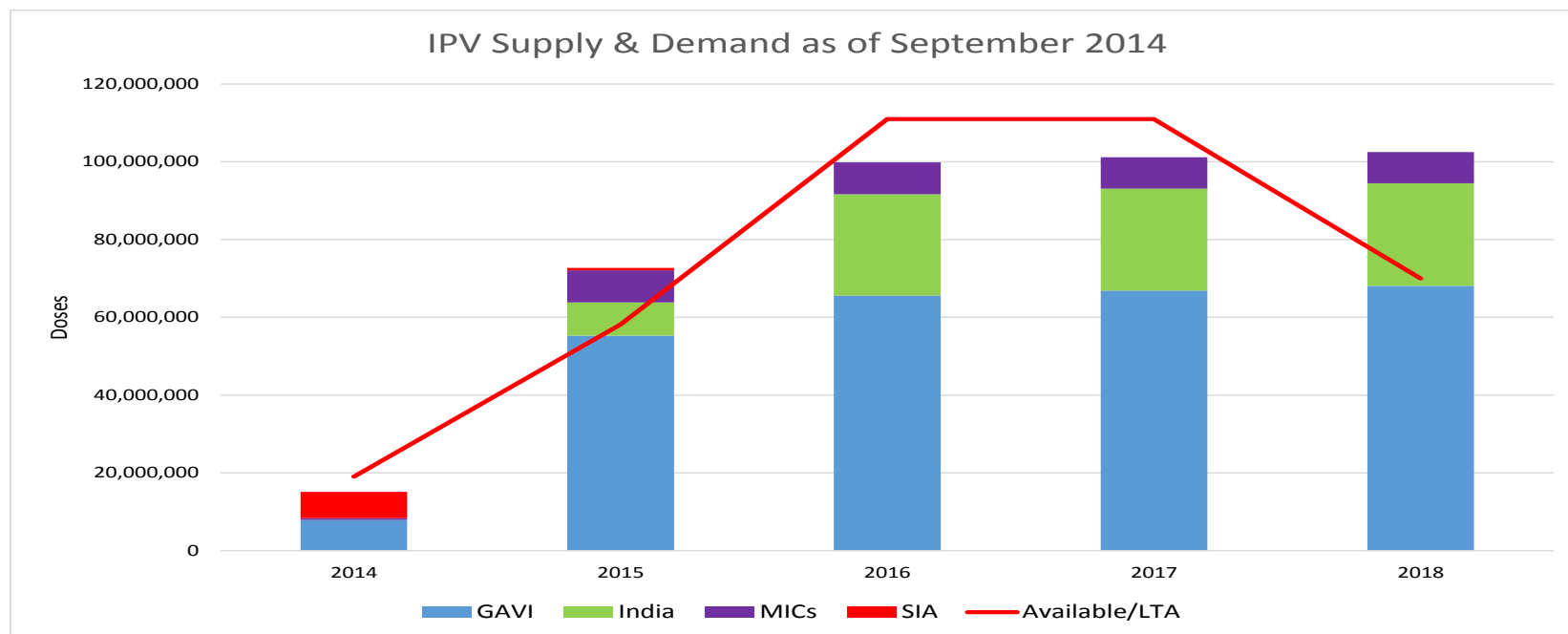
- Contracts in place for 2013-2016/2017
- Additional awards required for 2016-2017 – and potentially for 2H of 2015

Demand outlook

- 2011-2014 average annual requirement around 1.5 billion doses
- Continued high demand for endemic countries and outbreak response adding to routine requirements
- Programmatic requirements moving towards using only bOPV in line with Endgame Strategic Plan 2013-2018



Market Updates: IPV



- Supply gap for 2015 of at **least 10 million doses**
 - Reduced availability due to scaling up of production
 - Delays in national licensure = late WHO pre-qualification
 - UNICEF has requested all manufacturers with prequalified products for additional quantities
- Demand firming up and increasing due to new requirements
 - 66 GAVI supported countries have already submitted application to GAVI (including India)
 - 15 to 20 MICs are expected to procure through UNICEF
 - Requirements for 8-9 million doses for SIAs in endemic countries

Market Updates: Pneumococcal Vaccine

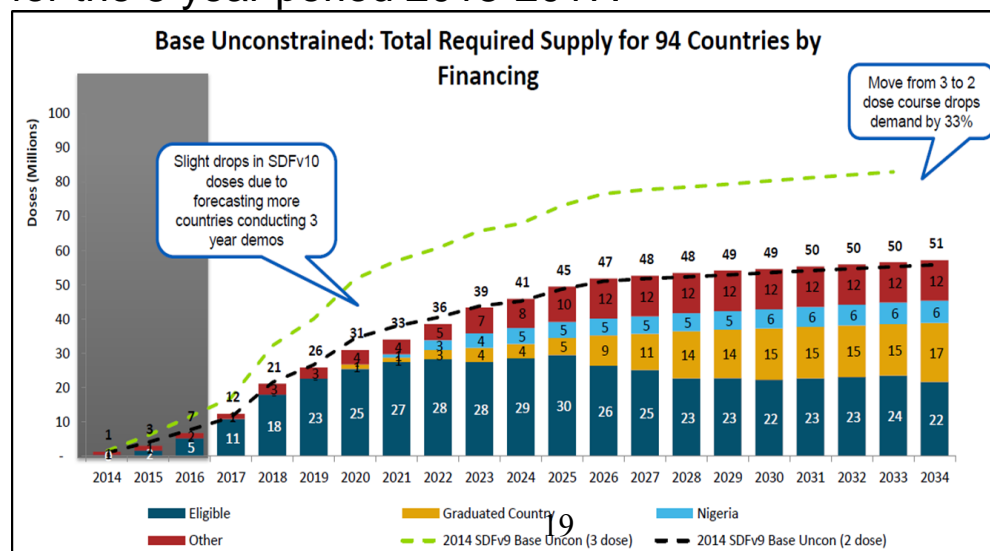
- 3rd Call for Offer concluded July 2013, securing 50 million doses annually from 2016, increasing **total supply to 146 million doses from 2016**
- New long term prices (Tail Prices) reduced to \$3.40-\$3.30 per dose from 2014
- \$405 million out of \$1.5 billion of Advance Market Commitment donor funds available for future awards to contribute to the AMC objective to create **a healthy vaccine market including multiple manufacturers**
- Manufacturers with pneumococcal vaccines in development should **register to the AMC** to have supply offers assessed, if supply within 5 years
- **Timing of next tender** to be discussed between GAVI and UNICEF based on supply and new requirements from AMC eligible countries

Market Updates: Rotavirus Vaccine

- UNICEF tendered for 88 million courses of Rotavirus Vaccine for 2012-2016
- 71 million courses have been awarded to two suppliers with prequalified vaccines
- Demand higher than supply (34 countries approved with GAVI support , 33 more eligible countries can apply)
- 90% of demand for one vaccine using a two dose schedule; scaling up of supply requiring countries to delay introductions
- Prices per course reduced to \$10.50-\$5.00
- A need to rapidly expand the supply base of prequalified vaccines to continue accelerated introductions and to meet projected future demand

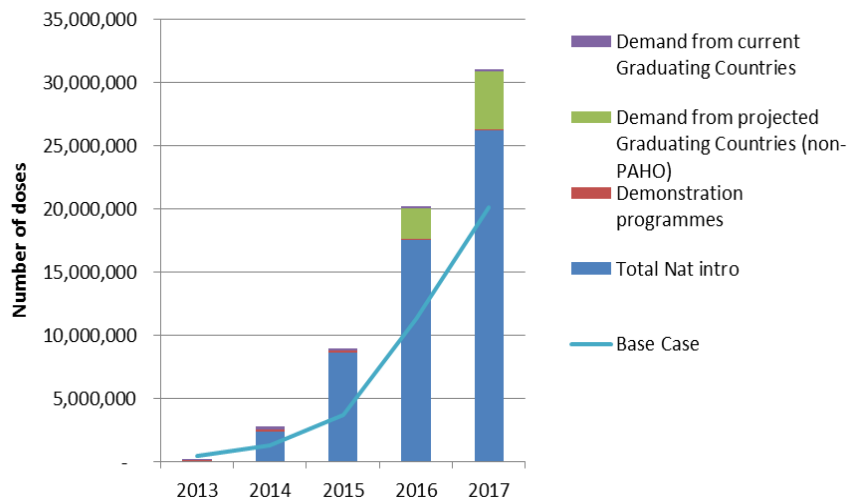
Market Updates: HPV

- Tender covered 2013-2017
- New programme, the support window opened in 2012, the first countries started in 2013
- 21 countries have been approved for demonstration programme – almost 50% of the eligible countries have applied
- Changes to forecasts due to:
- Challenges in predicting country starts, particular for national introduction.
- More countries projected for 3 year demo programmes
- Change from 3 dose to 2 dose schedule recommendation
- Programme design; different from the other childhood vaccines
- The RFP high scenario totaled 62 Mds for the 5 year period 2013-2017.
- Current prices: \$4.60-4.50 per dose

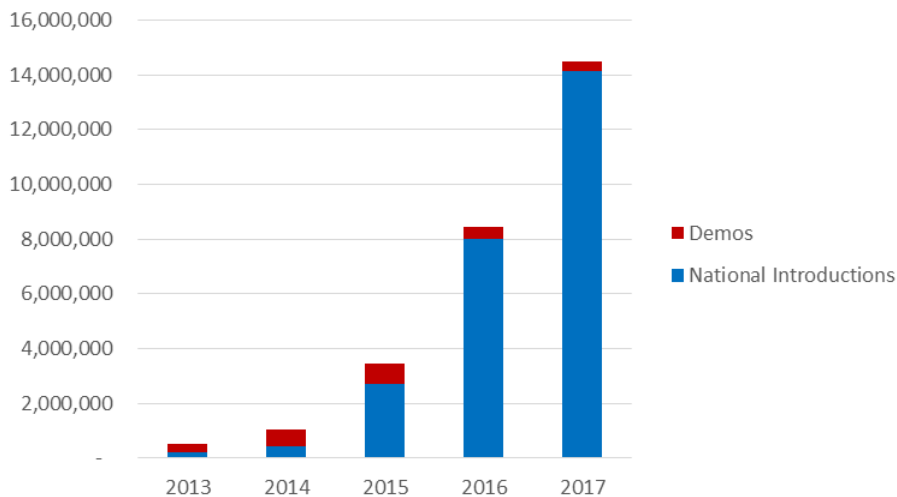


Market Updates: HPV

HPV Projected Demand 2013-2017

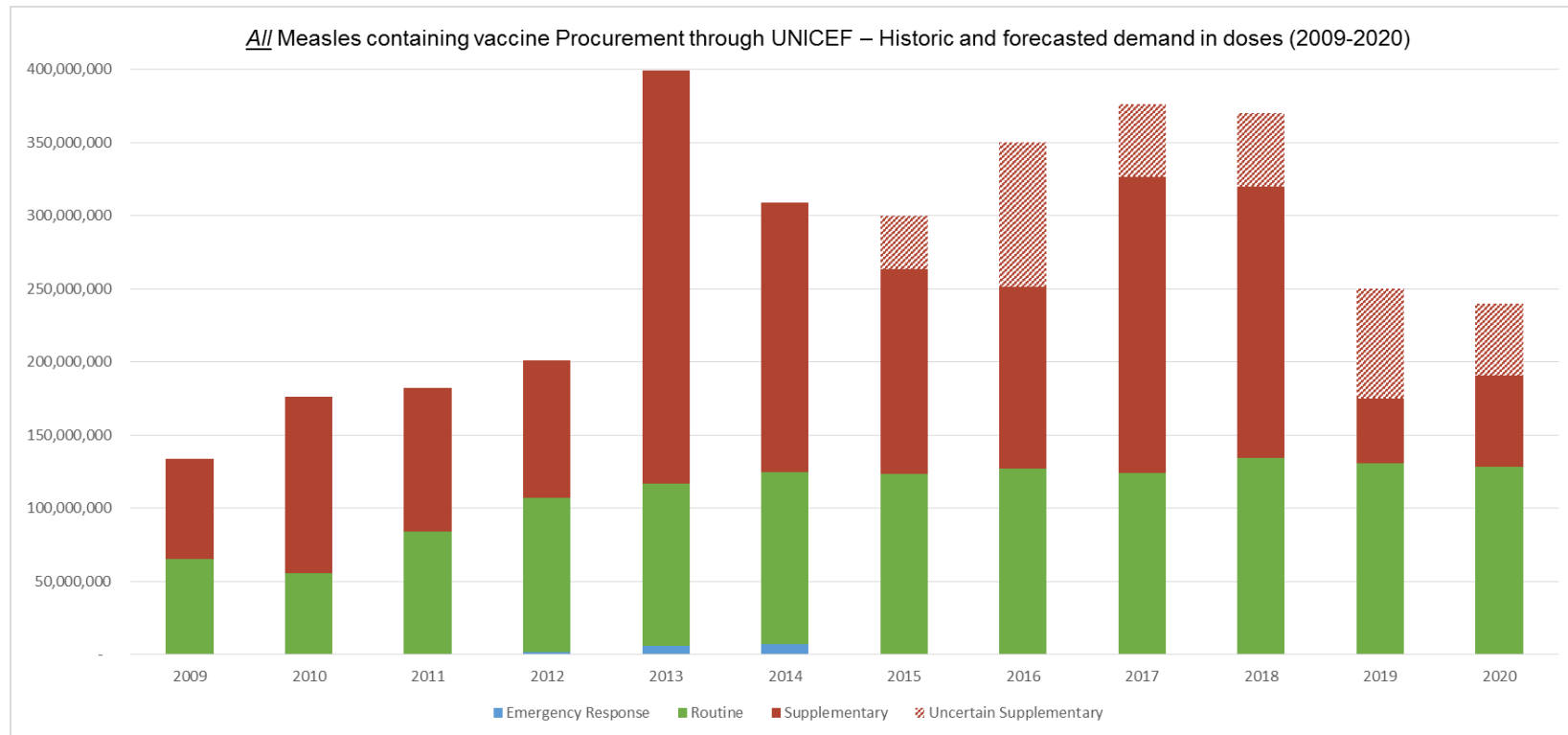


ADF v 10 forecast 2013-2017



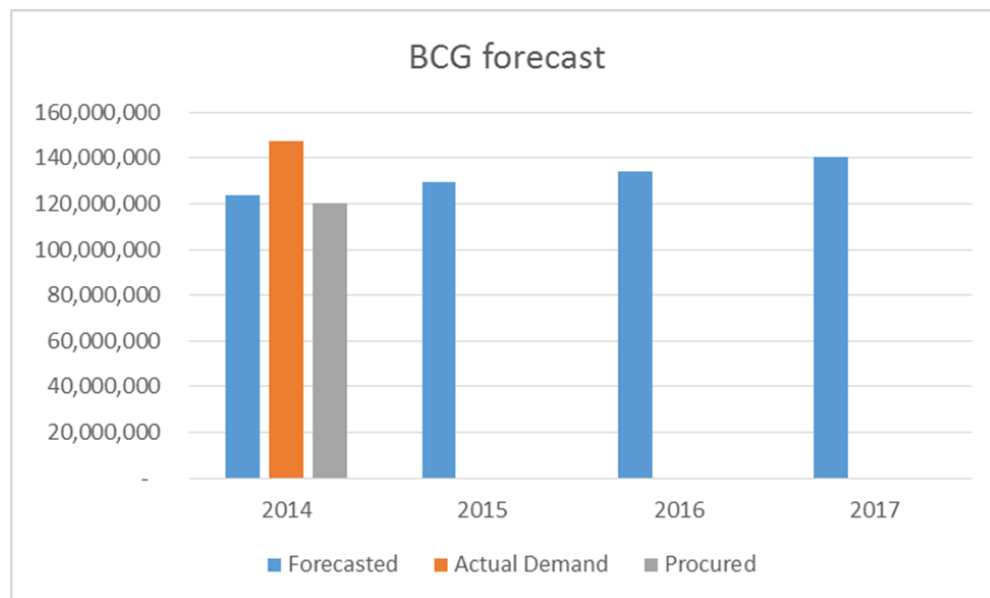
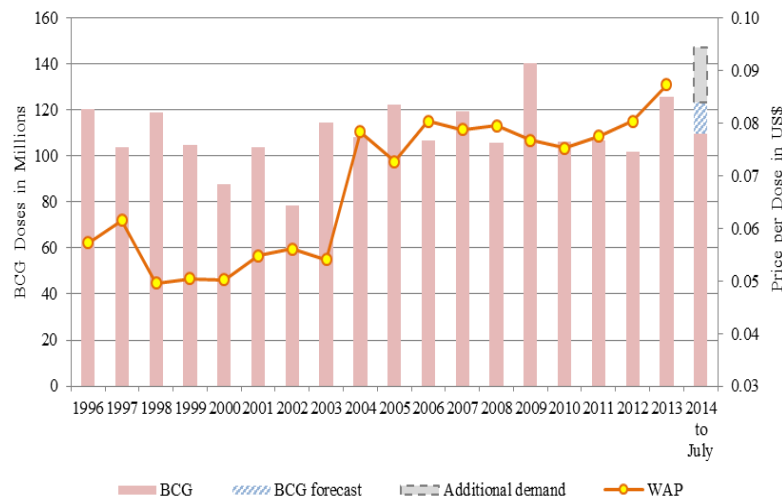
- We intend to share an HPV Market note before year end
- Expect to issue a new tender for GAVI supported countries in 2016 to cover requirements from 2018 onwards
- Demand from non-GAVI countries will also be encouraged and supported.
 - Procured with reference to our Middle Income Country (MIC) tender or ad hoc tenders
- 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 increase

Market Updates: Measles / MR



- Current high demand due to wide-age range MR catch-up and Measles follow-up campaigns taking place at regular intervals.
- Due to continuing outbreaks of measles and changing epidemiology, the uncertainty remains in Measles vaccine uptake. High probability that the Measles demand remains high.
- Peak demand for MR is forecasted to occur in 2017-2018.
- Programmatic and supply interdependence with the programme strategies and development.
- High reliance on single supplier for both vaccines. New entrants are expected after 2017. 21

Market Updates: BCG



- Historically: 100-120 million doses annual demand
- Supply 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
- Forecasted increased demand 2015-2018 as new countries may come through UNICEF
- Tender for supply 2016 and beyond will be issued in early 2015.
- All current and future WHO pre-qualified manufacturers are encouraged to engage with UNICEF and respond to the tender.

Market Updates: Japanese Encephalitis Vaccine

- Following the pre-qualification of the first suitable JE vaccine for use in children, GAVI opened a window for a first round of Applications to invite eligible countries to apply for support to introduce this vaccine.
- The first GAVI-supported JE vaccine campaigns are expected to start in 2015.
- The conditions of this support are:
 - 1- Support to JE catch-up campaigns for a single dose course; and
 - 2- with the condition that countries will self-finance JE vaccine introduction in their routine immunization programs after the conclusion of the catch-up campaign.
- UNICEF conducted a Tender in 2014 for quantities needed for the first introduction (Lao PDR in 2015). Cambodia is expected to introduce in 2016.
- Currently there are 3 WHO pre-qualified vaccines, with different regimes and big price differences.

Overview of main 2014-2015 tender activities* for vaccines

Vaccine	2014	2015				2016
	Q4	Q1	Q2	Q3	Q4	
Pentavalent (non-GAVI)	Tender issuance	2015				
Influenza, seasonal (NH)		Tender issuance		2015		
BCG		Tender issuance		2015-2017		
DTP, DT, HepB			Tender issuance		2015-2016/17	
Pentavalent (GAVI)					Tender issuance (TBD)	
Rotavirus			Tender issuance		2015-2016	
Cholera (for emergency stockpile)			Tender issuance			2016-18
IPV containing combination	Expression of interest					

*Estimated timelines, may be adjusted

Supporting Middle Income Countries to Access New Vaccines

Working with governments, donors, and suppliers to support MICs' purchase of **affordable vaccines**

Tender issued in December 2012 for HPV, Rotavirus and Pneumococcal vaccines, based on indicative country interest from 24 MICs

- Negotiations on-going
- Initial pricing from some manufacturers being communicated to countries
- Soliciting additional country interest in procuring these vaccines

In addition,

- Separate annual tender for Pentavalent vaccines for MICs
- MIC demand included in IPV tender

For additional information on UNICEF's MIC New Vaccine Procurement Initiative see http://www.unicef.org/supply/index_67101.html

UNICEF is experiencing an increase in countries requiring national licensure

- By using WHO prequalified vaccines, countries are ensured that vaccines meet international standards of quality, safety and efficacy
- The NRA of importing country need to undertake – as a minimum - an oversight role:
 - Marketing Authorisation and licensing activities
 - Post Marketing Surveillance, including monitoring of adverse events
- To ensure supply security, avoid delays in introductions or rejection at port of entry, UNICEF is working towards establishing an overview of countries requiring licensure to share with manufacturers
- An increasing number of countries also accept a 'light' process – WHO's Procedure for Expedited Review of Imported Prequalified Vaccines for Use in National Immunisation Programmes -
http://whqlibdoc.who.int/hq/2007/WHO_IVB_07.08_eng.pdf

In conclusion

- Vaccine Security – the sustainable uninterrupted supply of affordable vaccines of assured quality – remains the focus
- A high number of the vaccine markets are characterized by a limited supplier base, putting programs at risk
- Opportunities for new manufacturers to supply to countries through UNICEF provided pre-qualification of vaccines

The Supply Chain Ends Here



THANK YOU



unicef 
unite for children