



Supply Chains for Children



Managing constrained vaccine supply: prevention and remediation

Lessons learned and ways forward

DVCMN Annual Meeting

October 5-7 2015

Bangkok, Thailand

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



2014 Vaccines Supplies: US\$ 1,474 million



2.771
billion doses



2,556
shipments

Immunization Supplies

Vaccines

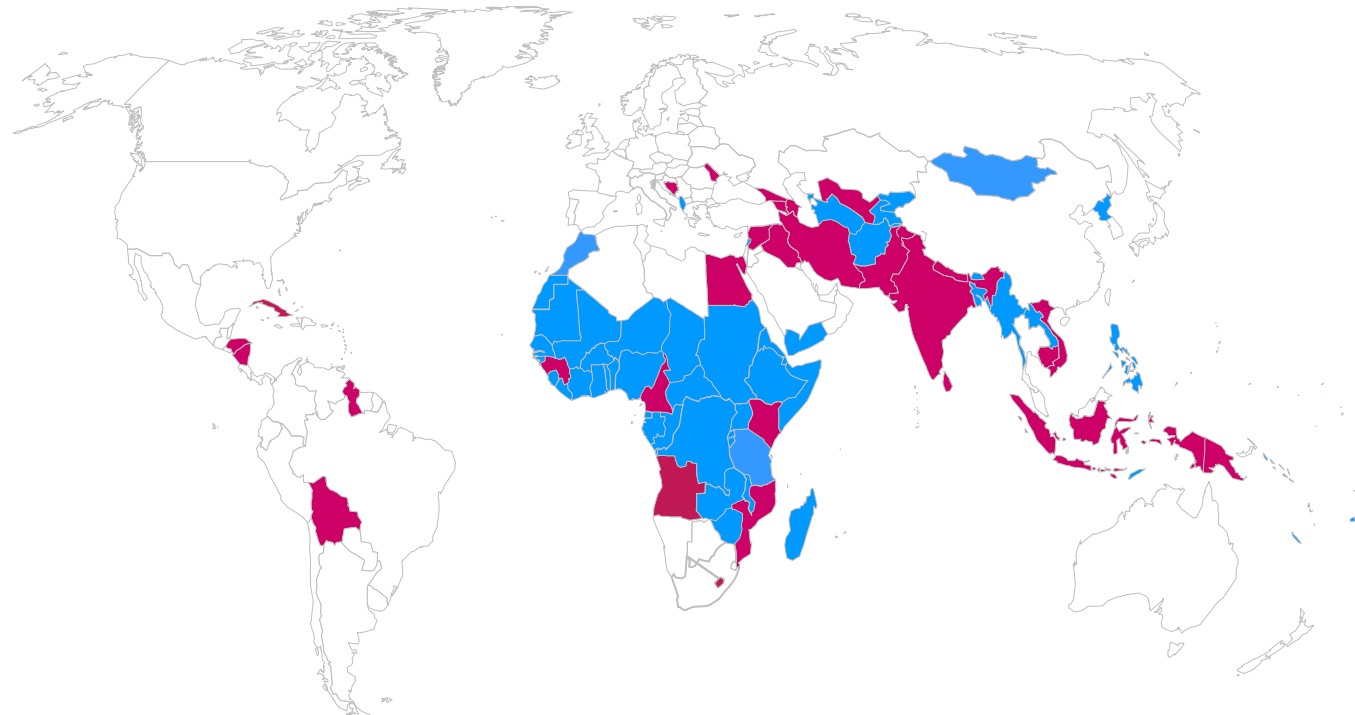
BCG, DTP, TT/Td/DT, Measles containing, OPV, HepB, YF, DTP-HepB, DTP-HepB/Hib, DTP/Hib, Hib, MR, Meningitis, MMR, PCV, RV IPV, HPV, etc.

Safe Injection equipment

Cold Chain Equipment

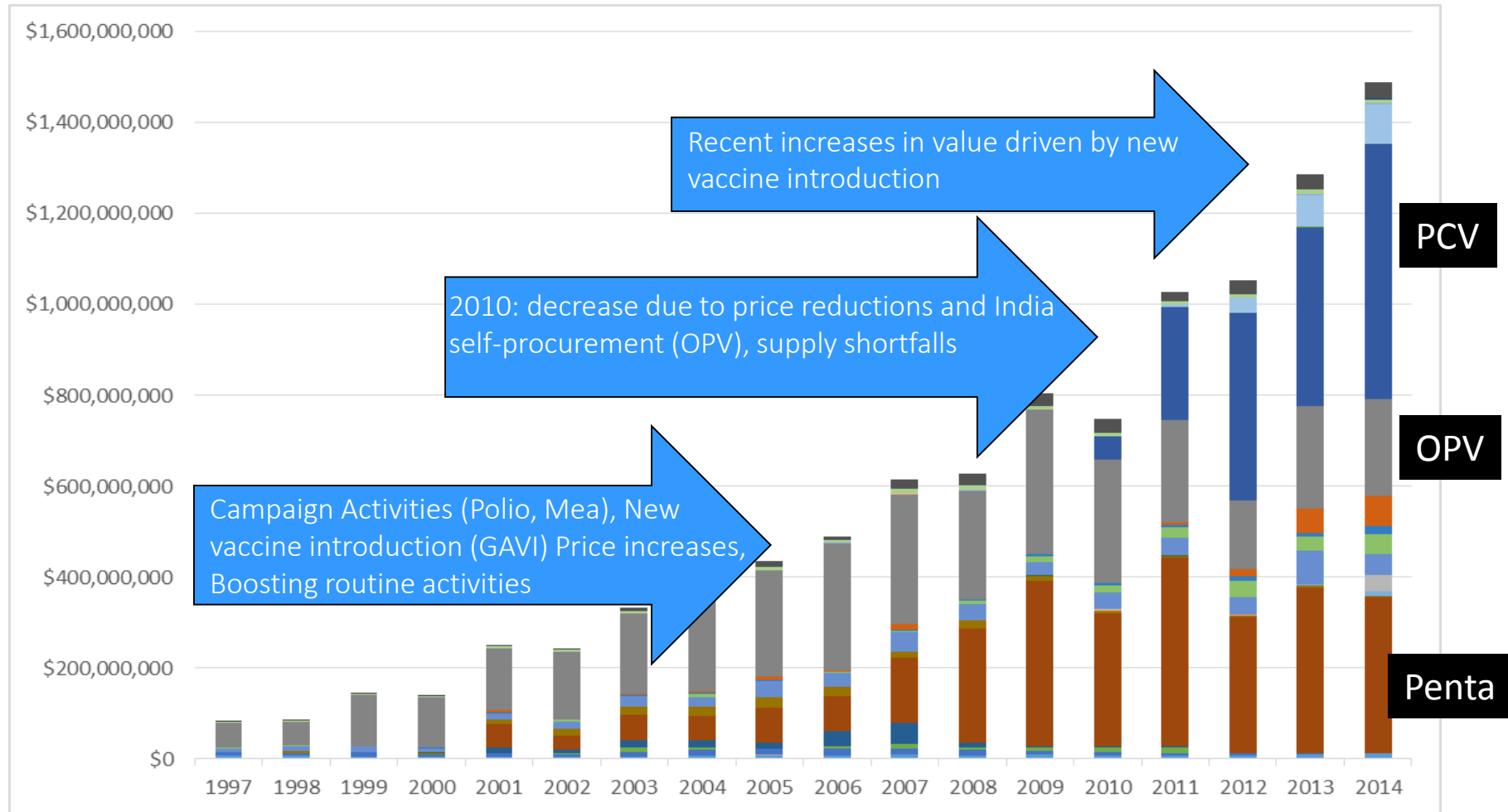
Countries UNICEF procures on behalf of

- Full schedule
- Partial schedule



Source: UNICEF Supply Division

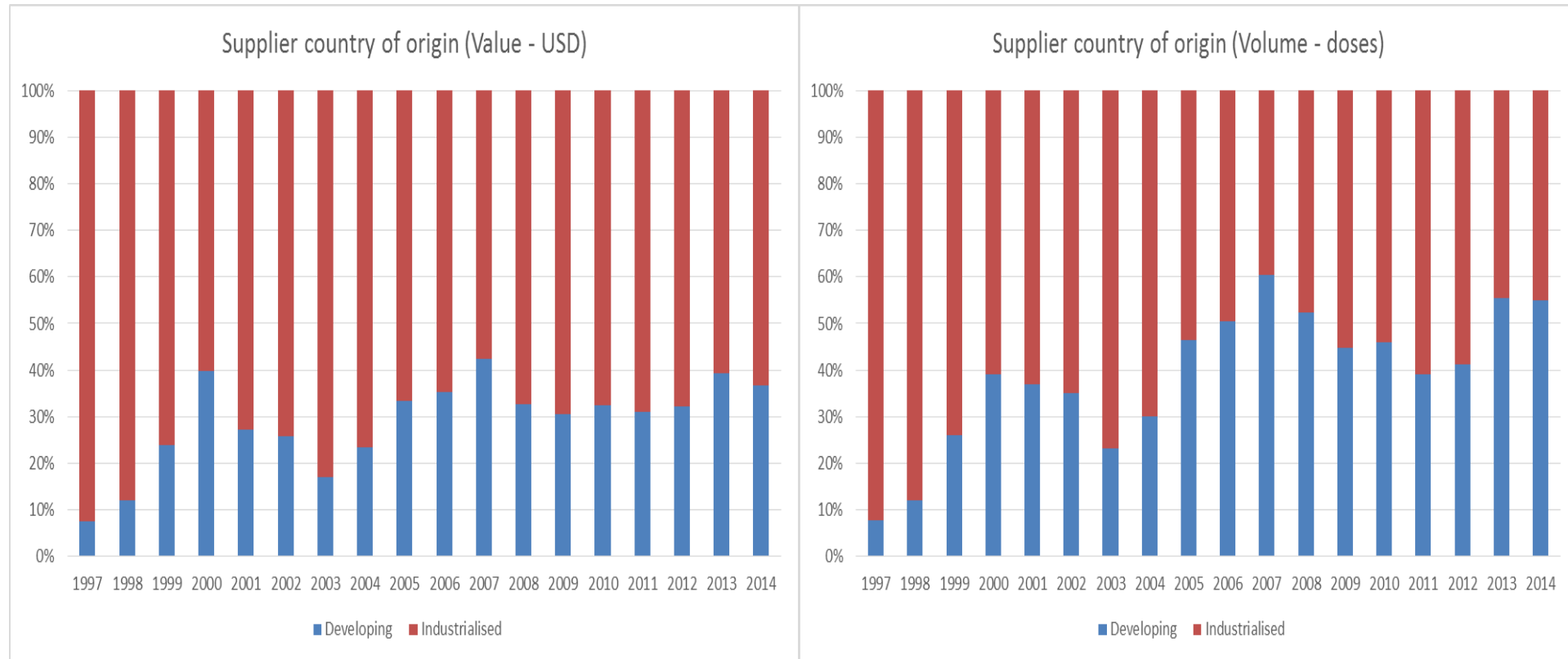
UNICEF annual vaccine procurement has increased significantly



The arrows indicate the main programme drivers for the increased procurement value.

Source UNICEF Supply Division

A considerable portion of vaccines procured by UNICEF come from emerging market country manufacturers



Vaccine Security

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

- **Influencing markets** - to achieve value for money and access to vaccines for children in need
- Achieving **healthy markets** through the Vaccine Security approach (forecasting, funding and appropriate contracting) and specific vaccine procurement principles
- Vaccines as biological products – requiring a specific approach for vaccine procurement



UNICEF Vaccine Procurement Principles

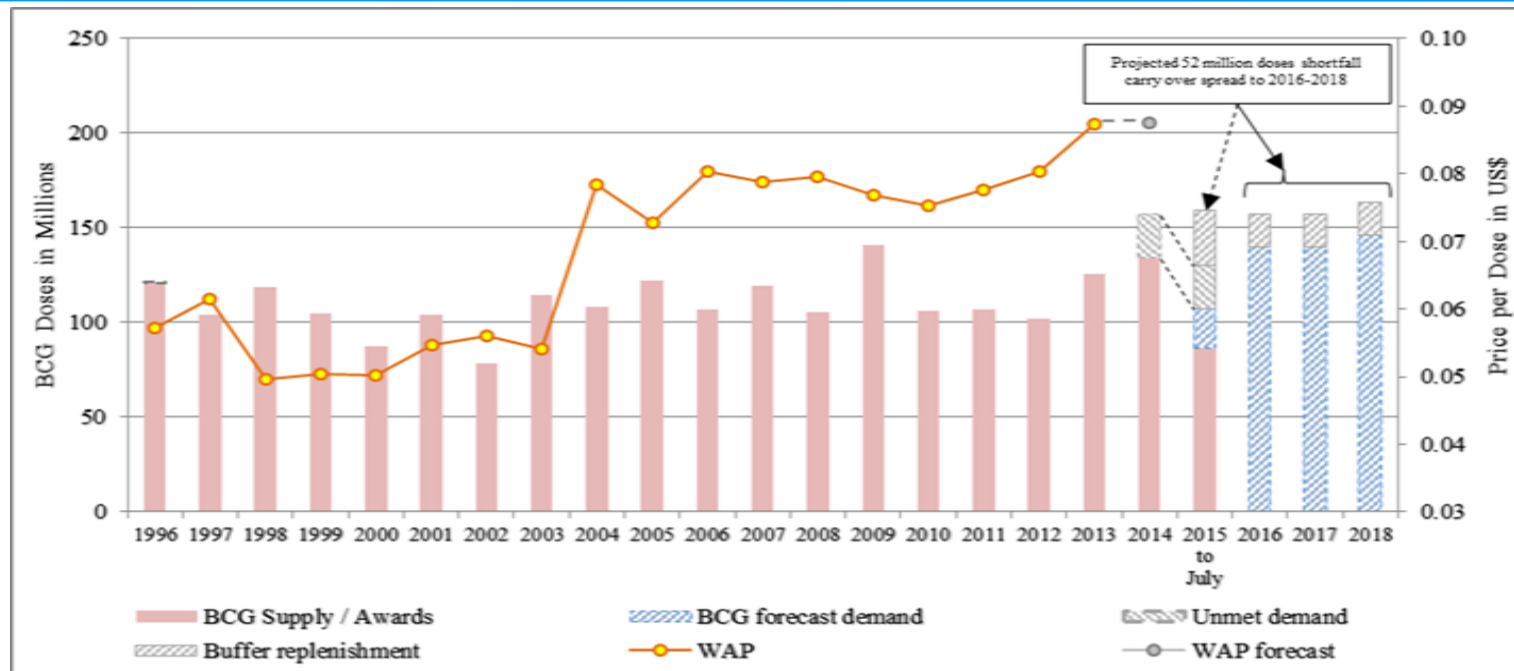
1. A **healthy industry** is vital to ensure uninterrupted and sustainable supply of vaccines
2. Procurement from **multiple suppliers** for each vaccine presentation
3. Procurement from manufacturers in **developing countries and industrialized countries**
4. Paying a price that is **affordable** to Governments and Donors and a price that reasonably covers manufacturers minimum requirements
5. UNICEF should provide manufacturers with **accurate and long-term forecasts**;
Manufactures should provide UNICEF with accurate and long-term production plans
6. As a public buyer, providing grants to manufacturers is not the most effective method of obtaining capacity increases
7. The option to quote **tiered pricing** should be given to manufacturers.

Recent supply-constrained markets affecting vaccine security principles and programs

- Supply constraints or global shortages with a number of products
 - Traditional vaccines: BCG, Yellow Fever
 - Supply to support program introductions: IPV, PCV, Rota
 - Country product preference: MMR, DTaP
 - Emergency/Outbreak response: Meningococcal C and W containing vaccines
- Types of supply constraints
 - Acute shortage
 - Short and medium term supply constraints
 - Chronic
- Mitigation options vary by product, depending on:
 - Health of existing market, options for alternative supply,
 - Causes for the supply shortage
 - Tools available for mitigating



Case study - BCG



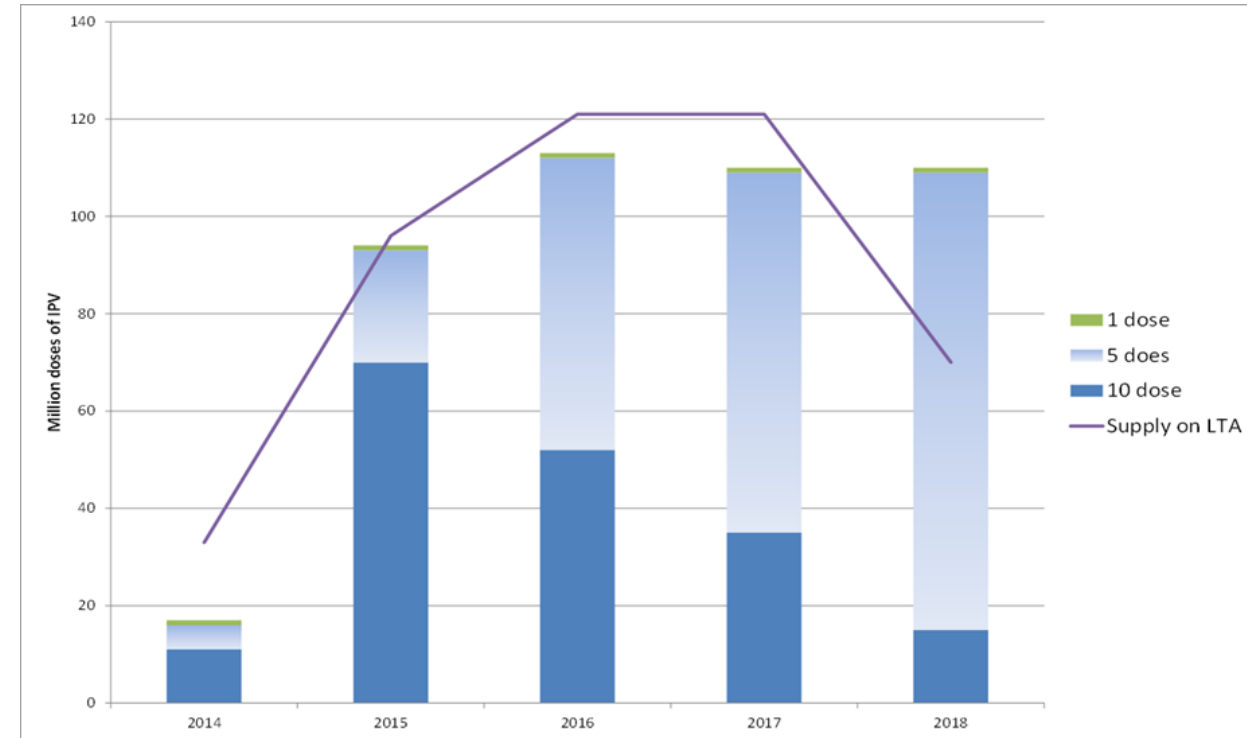
- For the last decade, demand through UNICEF has been stable at around 120mds per year; four suppliers each year
- In 2013; production interruption caused loss of supply until early 2014. Mitigation through additional awards
- In 2014, UNICEF experienced further loss: Production stoppage, technical difficulties
 - 2 suppliers reduced availability by 50-95%
 - Insufficient capacity from other suppliers to make up for this loss
 - Decrease in global availability created increased demand through UNICEF
- By January 2015, demand exceeded supply through UNICEF by 71 mds

Case study - BCG (2): Mitigating steps to minimize risk of program interruption

- Since beginning of shortfall, managed supply through the use of existing data sources and supply management tools, regular monitoring of country stock levels, close coordination with countries
- Coordination with WHO and other partners to establish criteria for supply allocation and with regions and countries to minimize stock outs
 - Allocating available vaccine to WHO predefined priority countries and based on guidance from WHO, Global STOP TB.
 - Making partial shipments to some countries in order to maximise the global buffer with suppliers rather than at country levels
 - Extensive dialogue with countries, regional offices, suppliers, freight forwarders to plan shipments to arrive just in time to avoid stock out.
- Communication
 - Market update on UNICEF Website
 - Updates to partners (EPI Managers, PAHO, BMGF, WHO, CHAI...)
- Secured additional quantities:
 - Two of the awarded manufacturers ([Total additional 37MDS secured in 2015](#))
 - Expected pipeline manufacturers achieving WHO PQ
 - Currently, demand is about 152.2MDS. Supply is 135.7 MDS, with a shortfall of 16.5MDS
- New tender has been issued for requirements 2016+

Case Study – IPV

- Ambitious agenda to introduce IPV in 126 OPV-using countries within 1.5 years in time for the global OPV2 withdrawal
- At time of IPV planning, about 68 high and middle-income countries were using IPV
- 2014 UNICEF issued a tender for stand-alone IPV in line with Endgame Strategy
- Procurement objective to ensure sufficient supply for 1 dose of IPV at an affordable price to meet demand
- 2 manufacturers awarded, 1 pipeline
- Awarded quantities and near term bulk and filled product manufacturing capacity anticipated to be sufficient to meet planned and some unplanned demand



- Demand for India and 20 L/MICs included

Case study – IPV (2)

- Expected scale up of IPV unprecedented compared to other new vaccine introduction programs
- Since awards major changes in supply availability
 - 2014-2015 supply reduced from 129 mds to 63 mds
 - 2016 supply reduced from awarded 121 mds to expected 77 mds
- At same time, significant increases in demand
 - India requiring 28 million doses for 12 month catalytic support from GPEI
 - Catalytic support to 25 countries as approved by POB
 - Increased demand for routine immunization (to date 1.2 million doses – more required?)
 - SIA requirements of 8.7 million doses of IPV delivered, global stocks of 1.2 million doses set aside for SIAs - more required for post switch outbreak response

Case Study – IPV (3): Mitigating actions

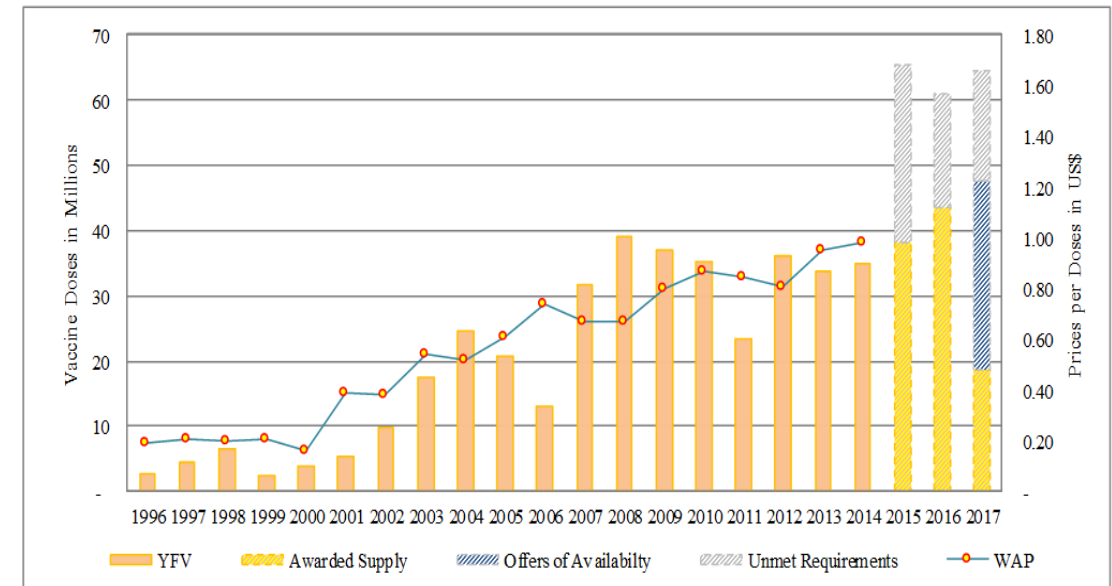
- Consultations to establish criteria for allocation of constrained supply
- No other suppliers in pipeline in near term, therefore, mitigating actions focused on managing supply that was available in line with programmatic priorities
 - Close and ongoing coordination with WHO and GPEI partners to establish supply prioritization criteria
 - Depending on prioritization of country, a number of countries required to delay introductions
 - Effort by WHO and PQT to approve MDVP to IPV to increase doses available
 - Tight management of supply including delivery of buffer stocks, daily monitoring of stock levels and preparation of supply and demand scenarios

Case Study: Yellow Fever

- Chronically constrained supply market over last several years due to multiple manufacturing challenges
- Programmatic demand based on routine needs, outbreak response requirements, and new YF vaccine introductions through a preventive catch up campaign
- ~ 34 million doses a year from 2007 to 2014, with UNICEF procuring all WHO prequalified vaccine available
- Demand increasing due to spread of disease outside of West Africa to Central and East Africa regions, and re-emergence in Latin America.
- 4 manufacturers, enough capacity to meet overall **routine** demand but insufficient to meet SIAs + routine and outbreak response
 - Limited interest to expand capacity as demand will not be sustained
- Increasing WAP

Manufacturer	WHO PQ	Presentation	Shelf life	WHO PQ Status
Bio-Manguinhos (Brazil)	2001	5 ds	24 months	Suspended
	2007	10 ds	24 months	
	2001	50 ds	24 months	
Institut Pasteur de Dakar (Senegal)	2001	5 ds	36 months	Active
	2001	10 ds	36 months	
	2001	20 ds	36 months	
FSUE Chumakov (Russia)	2009	2 ds	24 months	Active
	2009	5 ds	24 months	
	2009	10 ds	24 months	
Sanofi Pasteur (France)	1987	10 ds	36 months	Active

Source: UNICEF Supply Division, Yellow Fever Vaccine: Current Outlook, February 2015

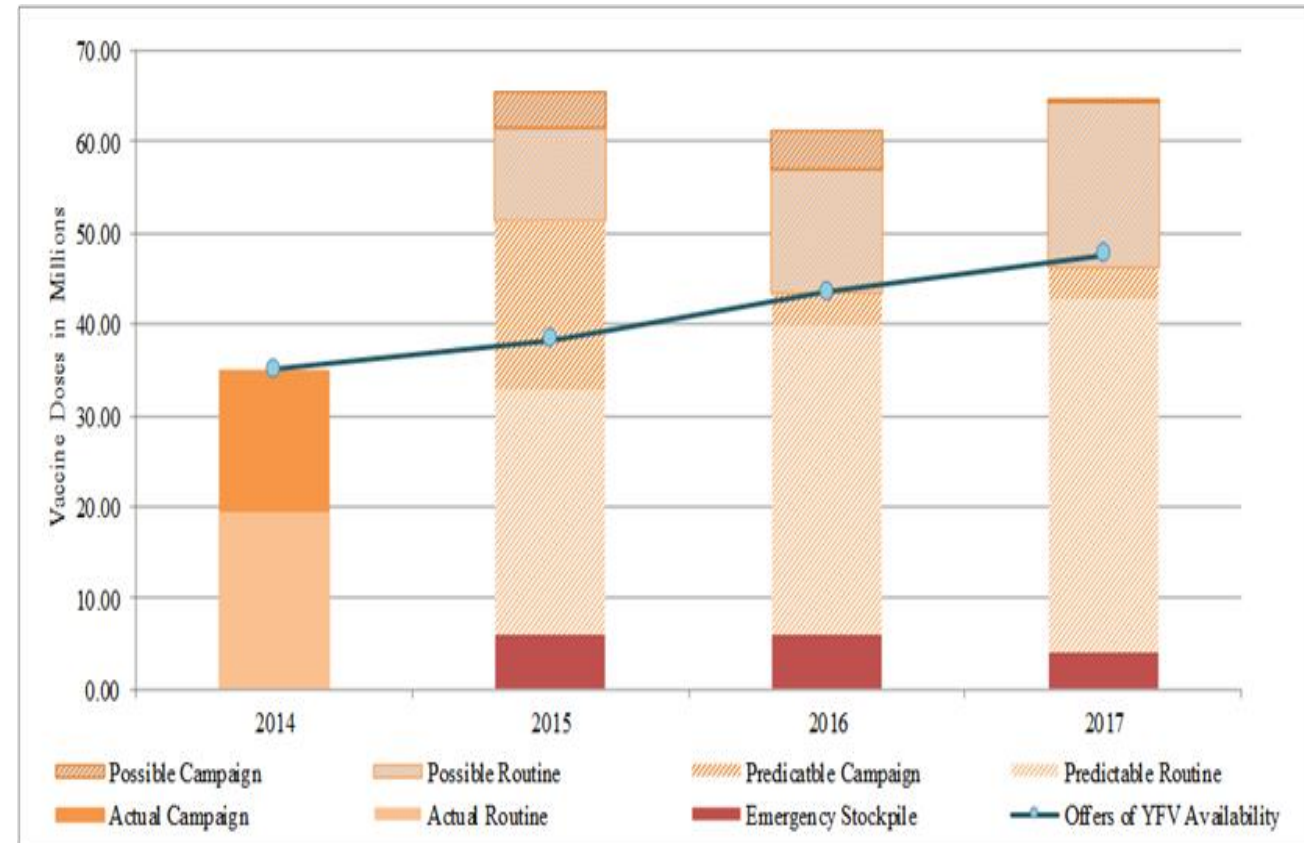


Source: UNICEF Supply Division / GAVI SDF v.10.

Case study – Yellow Fever (2) Impact

- Coordination with ICG to establish supply prioritization criteria
 - Outbreak response
 - Routine vaccine needs
 - Preventive catch up campaigns for new introduction
- New YF introductions delayed in several countries
 - Delayed catch up campaigns resulted in outbreaks, requiring outbreak response in country
- Pressure and dependence on remaining manufacturers to supply
- Timing of supply availability not in line with timing of campaigns

YFV Unconstrained Demand Forecast and Supply Offers per Activity for 2014-2017



Source: UNICEF Supply Division / GAVI SDF v.10.

Case Study – Yellow Fever (3) Mitigation actions

- Close coordination with Partners and program to allocate supply
- Working with manufacturers to improve the timing of the availability of the supply to meet programmatic requirements
- Establishment of a stockpile to ensure reliable supply for outbreak response as the 1st priority for supply allocations
- A WHO revolving fund was created in order to support YF outbreak response and YFV supply.
- Improved forecasts for industry to provide greater visibility
- Continued work with manufacturers to increase production capacity and/or encourage production through new entrants

Causes of supply-constrained markets experienced by UNICEF

Supply-related:

- Market exits; limited investment to expand or change manufacturing technologies
- No alternative suppliers in the immediate or near term
- Antigens used in traditional vaccine products used in new product presentations
- Production failures: Failure in production technologies, batch releases, quality control, etc.
- Regulatory: NRA of the country of manufacturer declared non-functional; product suspended or removed from the WHO PQ list
- Long production lead times due to demand uncertainties

Demand related:

- Poor planning of medium- to long-term vaccine requirements and programmatic direction
 - Significant demand increases due to new programs or intensified activities
 - Uncertain demand and/or funding for new vaccine introductions for new country programs, leading to changes in production timelines
 - Country ability to finance immunization programs including existing and new vaccine introductions
- 

Lessons learned to manage constrained supply and ways forward

- Early and transparent communication from manufacturers on any potential supply constraint and causes critical to ensure mitigations can be implemented on time
 - Contractual obligation to notify UNICEF and WHO if there are any issues that may impact availability of awarded supply
- Early consultations with program partners on considerations for future vaccine demand and strategies being considered (outbreak/emergency response demand, market exits, production changes, etc)
- Reviewing stock levels from country have been essential for managing supply constraints with countries to minimize risk of stock outs
- Close coordination and communication with partners, countries and regions required to delay or prioritize program implementation
- Closer coordination with WHO and Program partners on programmatic directions essential for providing long- and medium term forecasts to industry



UNICEF markets dashboard & product notes

The Markets Dashboard

Taking inspiration from UNITAID's Market Dynamics Dashboard, UNICEF developed and began publishing its own Markets Dashboard during 2013. The Dashboard monitors the market dynamics of more than 50 essential commodities for women and children. It provides a qualitative assessment of the determinants of a healthy market, including:

- Availability
- Affordability
- Competition
- Quality
- Acceptability
- Delivery
- Funding security

This qualitative assessment helps to identify elements that contribute to gaps between supply and demand of particular products and suggests opportunities to catalyse frameworks and interventions that will achieve a more balanced market.

For example, some market shortcomings may call for engagement on a traditional procurement strategy basis where UNICEF may pool demand to achieve improved scale purchasing and better visibility for manufacturers.

Other contexts may suggest that UNICEF should support Country Offices in developing a quality local supplier base from which it can source the commodity. Where there are gaps in quality standard-setting, UNICEF may be well positioned to positively influence market dynamics by collaborating with partners and publishing the normative guidelines that it follows.

The Markets Dashboard is updated and published twice a year. Placing the analysis in the public domain informs debates amongst stakeholders who include governments, international procurement agencies and manufacturers. The outcome of these discussions and ideas can underpin UNICEF's policies, and approaches to make products more available and affordable for children. Additionally, these new insights provide UNICEF with an opportunity to challenge the assumptions underlying its own procurement decisions and strategies.

UNICEF is increasingly disclosing high-level strategies within this

Dashboard context to continue to spur debate and build on transparency initiatives. Feedback is welcome and can be provided via the links at the UNICEF Supply website.

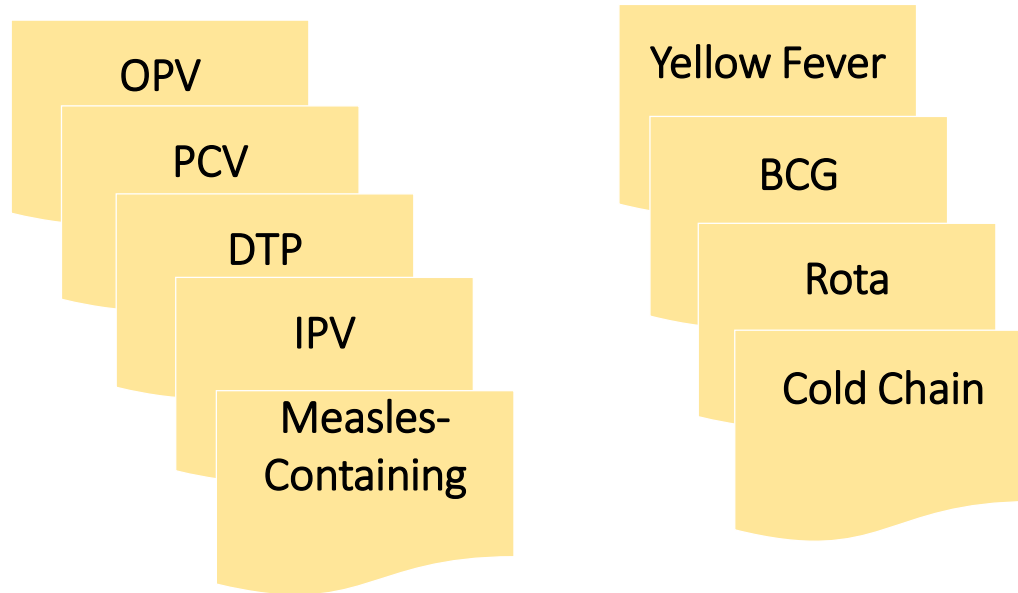
See the latest UNICEF Markets Dashboard at:
http://www.unicef.org/supply/index_70578.html

The image shows a close-up of the UNICEF Markets Dashboard, which is a large, multi-page spreadsheet. The top of the page features the UNICEF logo and the title 'UNICEF Supply Division'. Below this, there are several columns and rows of data. The columns include 'Commodity', 'Quantity', 'Availability', 'Affordability', 'Quality', 'Acceptability', 'Delivery', and 'Funding security'. The rows are organized into sections for different product categories, such as 'Maternal and Child Health', 'Immunization', and 'Family Planning'. The data is presented in a grid format, with various cells containing numerical values and text descriptions. The overall layout is professional and detailed, reflecting the complexity of the market data being tracked.

Publications on Products & Markets for key vaccine supplies for children

Communication pieces issued on various market situations of vaccine products including to support Government knowledge

http://www.unicef.org/supply/index_54214.html



Information available on the UNICEF website

Address



http://www.unicef.org/supply/index_immunization.html

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Immunization



© UNICEF/Lao DPR/2007/Hartman

Lao DPR: A girl smiles as she receives a measles injection at Don Sa Souk primary school in a suburb of Vientiane.

Vaccines and micronutrient supplementation save millions of lives each year. Almost every child can be reached with vaccines and supplements, even under the most difficult circumstances. UNICEF is the leading agency for vaccine procurement. In 2011 UNICEF procured vaccines worth \$1.03 billion. For more information please click [here](#).

UNICEF Supply Division is responsible for buying all vaccines and related items for global campaigns to eradicate polio, eliminate neonatal and maternal tetanus, and control measles. In addition, the Division procures vaccines for UNICEF-supported programmes, and for [GAVI](#).

Procuring vaccines is complex. In recent years the market has changed, owing to a growing divergence between the types of vaccines used in industrialized and developing countries. The unpredictability of funding is another difficulty. UNICEF promotes [vaccine security](#) by working with manufacturers to ensure there is a reliable supply of quality, affordable vaccines, and with governments to assess their vaccine requirements. And, [accurate forecasting](#) is the first step in ensuring adequate immunization supplies and is the foundation of Vaccine Security.

UNICEF is concerned about [vaccine safety](#). The

Latest

[Market update on current OTP supply status](#)

[UNICEF tender supports Middle Income Country access to affordable new vaccines](#)

[Strategy for supporting Middle Income Countries with access to new vaccines](#)

[UNICEF presents its Middle Income Country New Vaccine Procurement Strategy to SAGE](#)

[Developing Country Vaccine Manufacturers Network](#)

[Current IPV Supply and Recent Tender Results](#)

[Vaccine Suppliers Integral to Achieving Polio Free World](#)

[AD Syringes Protections](#)

[Auto-Disable \(AD\) Syringes and Safety Boxes - current price data](#)

[Vaccine Industry Consultation II June 27th 2012](#)

[Vaccine Industry Consultation 23th - 28th January 2012](#)

[AMC for Pneumococcal](#)

[Vaccine Price Data](#)

[Cold Chain Report and Volume Calculator](#)

[Historical Vaccine Procurement](#)

[Vaccine protections](#)

24 February 2011 - Vaccines to fight major childhood diseases, such as polio, Hib, meningitis, pneumonia, diarrhoea, and

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SYRIA CRISIS

The ongoing violence in Syria is taking a toll on children and their families. Donate to help UNICEF meet the urgent needs of children.

[Donate Now](#)

Vaccine Supplier Meetings

[Polio Pre-Tender Meeting 2012](#)

[AMC Pre-Tender Meeting 2012](#)

[Pre-Tender Meeting December 2012](#)

[Supplier Meeting 2-4 April 2012](#)

French and Spanish version of this page



UNICEF Supply Catalogue



Thank you



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children

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