Vaccine Supply in the CEE/CIS Region

Kiev, Ukraine
May, 2004

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Vaccine Security

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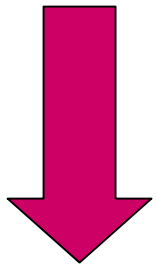
UNICEF experienced vaccine shortages and developed strategy to address them:



VACCINE SECURITY: Ensuring an uninterrupted sustainable supply of affordable vaccines of assured quality

ELEMENTS OF VACCINE SECURITY

CONTRACTING OF AFFORDABLE VACCINES

- Forward commitments
- Healthy vaccine industry - variety of manufacturers from both industrialized and developing countries

SURE FUTURE FUNDING

- Donors, Countries
- Working with Finance Ministries

ACCURATE, LONG-TERM FORECASTING OF DEMAND

- UNICEF forecasts to manufacturers: 10-year Forecast for OPV; 3-year rolling forecasts for EPI vaccines
- UNICEF forecast accuracy in 2002/2003 was ~80% (aggregate, all vaccines);
- Manufacturers need to give accurate forecasts as well

The Vaccine Market

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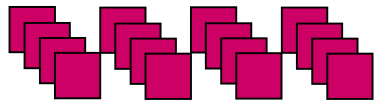
Vaccine manufacturing shifted from being Governmental to Private Sector; which shifted production objectives from national sufficiency to business drivers.

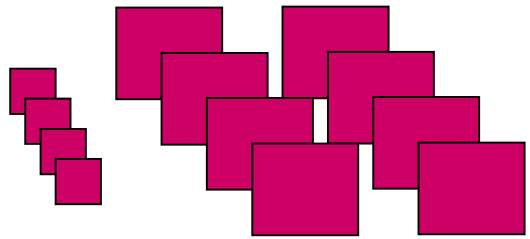
1940's – 1980's:

Many vaccine manufacturers
Government owned
Focus was on national sufficiency to protect population.



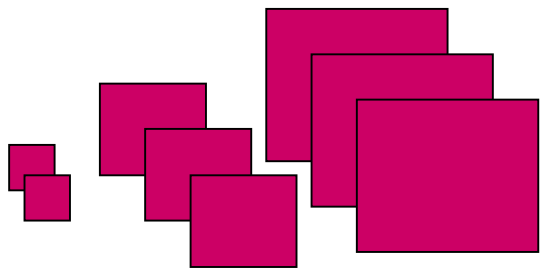
1970's - 1990's:

Privatization
Shift to privatize vaccine production
Business assessments of costs, prices, competition, new drivers for R&D.



1990's - 2000's:

Mergers
Consolidation of manufacturers
Business drivers compared with pharma-products, loss of "excess capacity", reduction of manufacturing sights.



Each market type has different drivers
The evolution of the vaccine market is similar to the evolution of most other markets globally.

Procurement for Developing countries in a diverging vaccine market:
For DTP the divergence is between wP and aP

INCOME	Measles	DTP	TB	HepB	Hib	Polio
LOW	MONO	Wholecell	BCG	Mono & in combo with DTwP	in combo with DTwP	OPV
MIDDLE	MMR	Wholecell in combo	BCG	in combo with DTwP	in combo with DTwP	OPV
HIGH	MMR	Acellular in combo		in combo with DTaP	Not usually unless with IPV and/or in aP combo	IPV in combo

Greatest profitability is seen in the high income market

INCOME	Measles	DTP	TB	HepB	Hib	Polio
LOW	12¢	7¢	7¢	32-90¢	$3.10	10¢
MIDDLE	MMR	Wholecell in combo	BCG	in combo with DTPw	in combo with DTPw	OPV
HIGH	$15.50	$10.65		$9.00	$21.38	$8.25

Vaccine production is complex and require long lead-times to change

Timelines for vaccine production

Production of a dose: 7-24 months

Capacity Increase: 2-3 years

New Plant: 5-7 years

Changes in regulatory requirements or cGMP standards can also cause production interruptions

Buyers need to understand timelines because:

Vaccine is no longer available "off the shelf"

Explains the need for longer term planning and forecasting with industry to influence availability

UNICEF in the Vaccine Market

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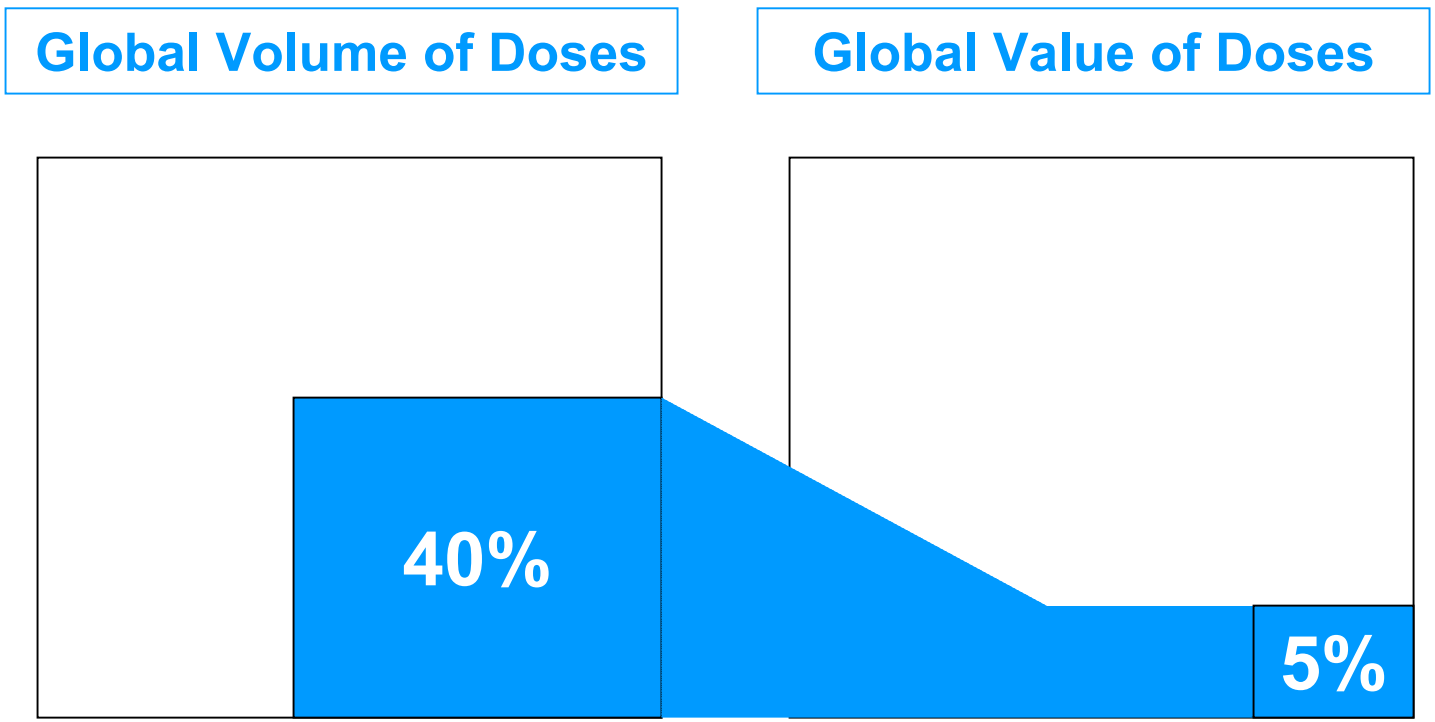
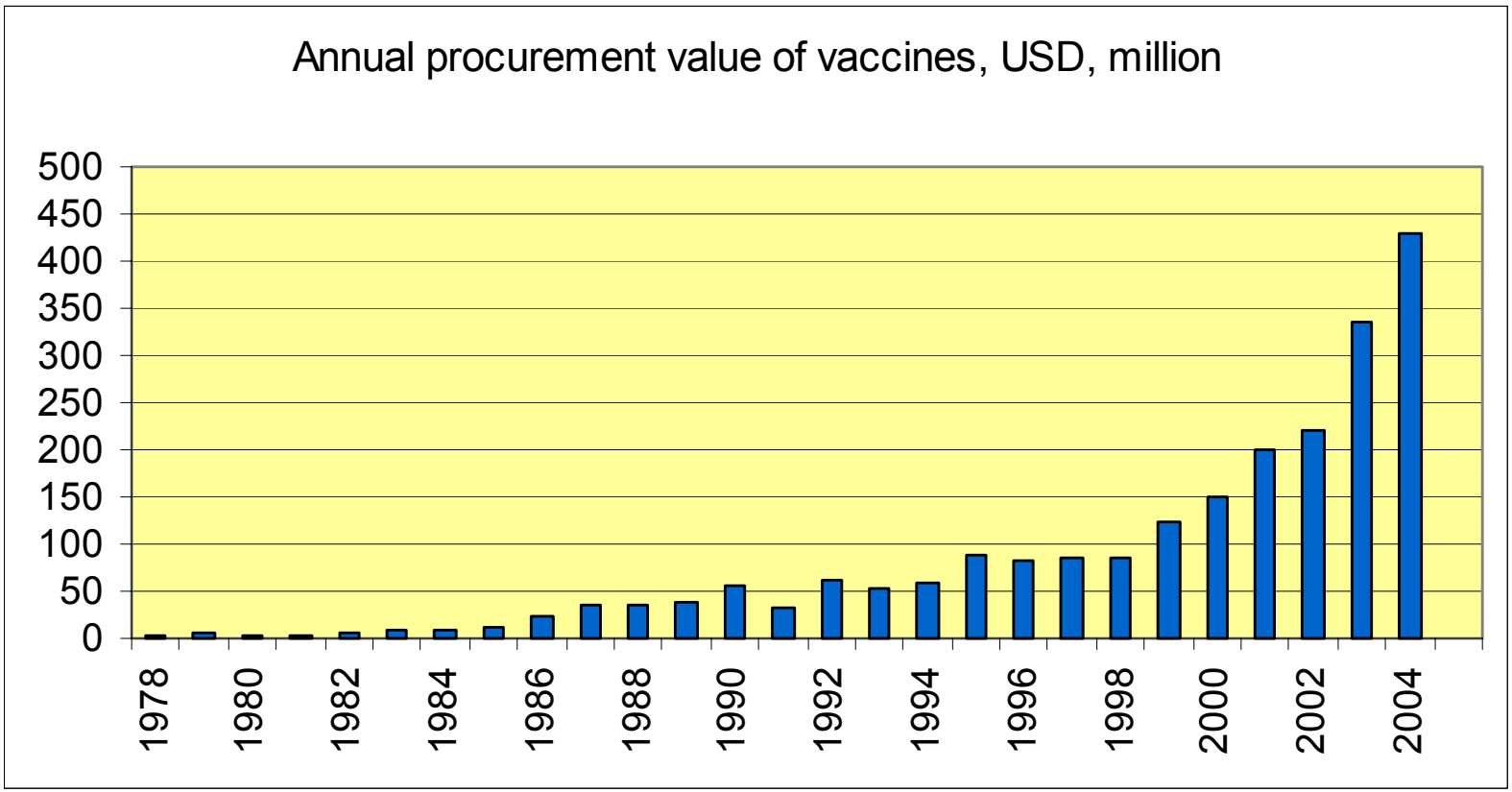
The unique position of UNICEF is it buys 40% of the global volume of vaccine doses, mainly basic vaccines, but represents only 5% of market value



Rough estimates of the regional vaccine needs that met via UNICEF procurement

Income Grouping (excl. India, China & Indonesia)	Percentage of Income Group's Population covered by UNICEF Procurement
Low Income	84%
Lower Middle Income	18%
Upper Middle Income	1%
High Income	0%

UNICEF annual procurement value continues to increase; From 2000 to 2003, procurement value more than doubled.



Causes for increase in procurement value:

- Supplemental activities has increased demand for OPV, Measles, TT (~240M in 2004)
- New vaccines funded by VF/GAVI (~110M in 2004)
- Procuring for new countries (eg, Nigeria, ~10M in 2004)
- Slight increases in demand for routine
- Price increases (5-20% for EPI vaccines)

Vaccine Supply Overview

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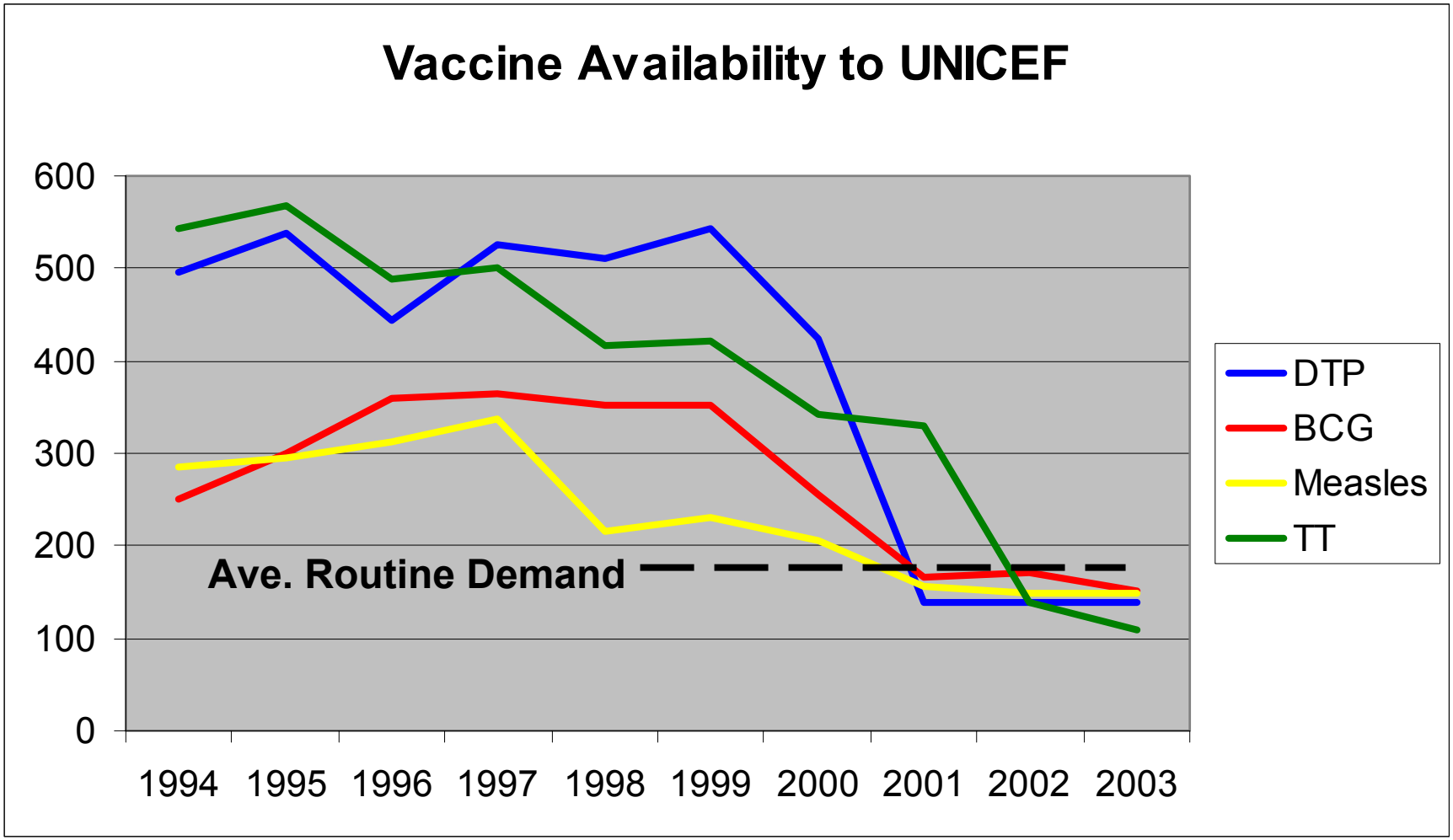
The effect of the market changes, divergence in products was a reduction of availability of basic vaccines to UNICEF



- The 2001-2003 period was very tight and with periodic shortages for some vaccines.

Changes made by UNICEF in order to contribute to increases in availability

- Shift from Buyer/Trader to Strategic Partner in Immunization
- Increase of capacities and competencies within Supply Division
- New Forecasting Approach
- Continuous Analysis of Vaccine Market
- Benchmarking with other buyers (CDC, PAHO, NIH-UK)
- Emphasis on Vaccine Management at Country level
- “Vaccine Security” strategy accepted by UNICEF Executive Board January, 2002

UNICEF Vaccine Procurement Overview

- Establish 3-year supply arrangements with multiple suppliers.

  Majority of vaccine is supplied via mutual “good-faith” arrangements between UNICEF and Manufacturer.

  In 2002, UNICEF started establishing firm commitments to secure quantities of scarce EPI products that otherwise may not be produced, backed by UNICEF resources.

  In 2003, firm commitment for combination vaccines in order to secure quantities and obtain price concession is pending.

  Firm commitment requires firm financial backing. UNICEF considers this type of contracting to be a response in order to ensure vaccine availability and price during a changing/developing market.

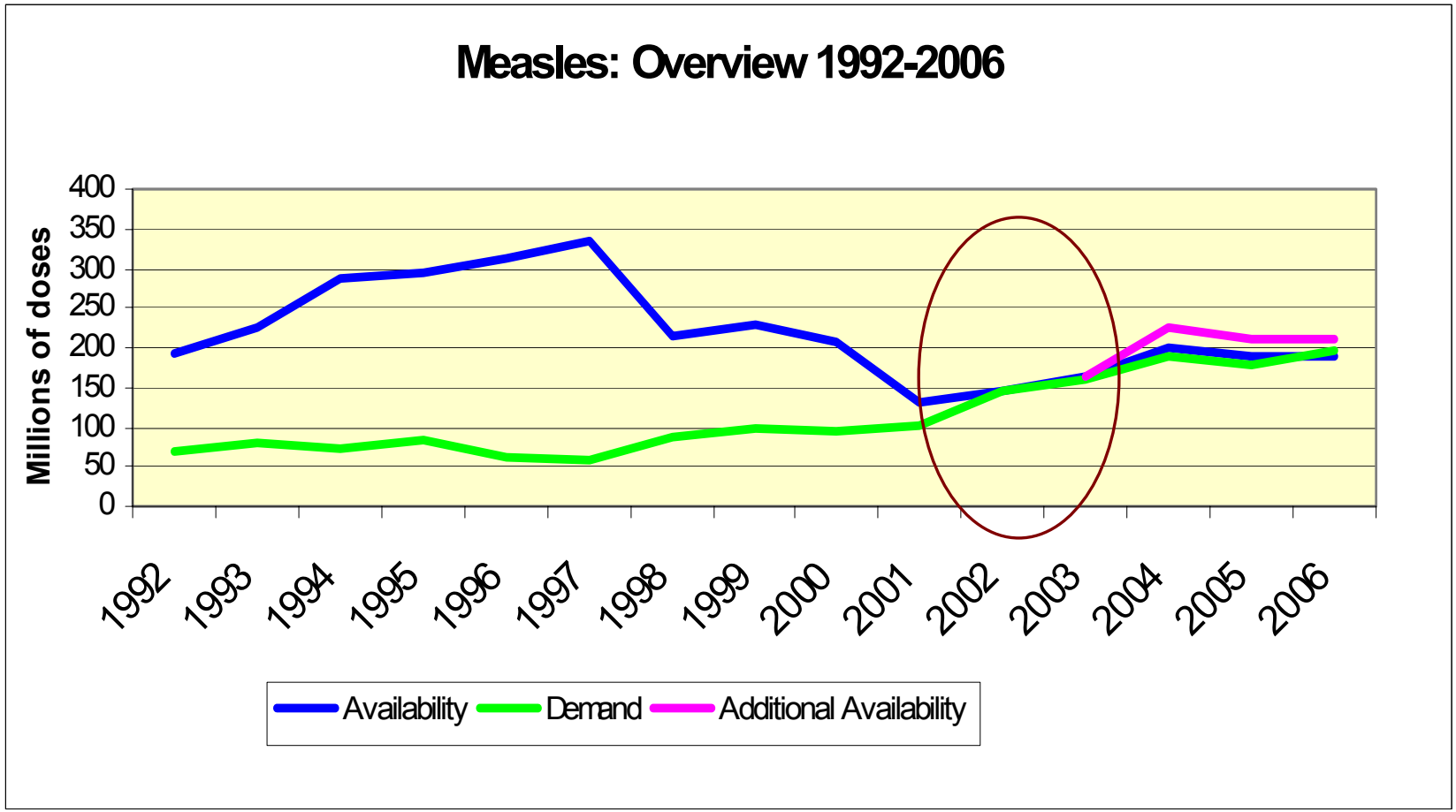
UNICEF provides 12-month rolling forecasts to manufactures, updated each month in order to plan production and deliveries.

Summary Update on the market:

UNICEF considers the market to be responsive and becoming healthier

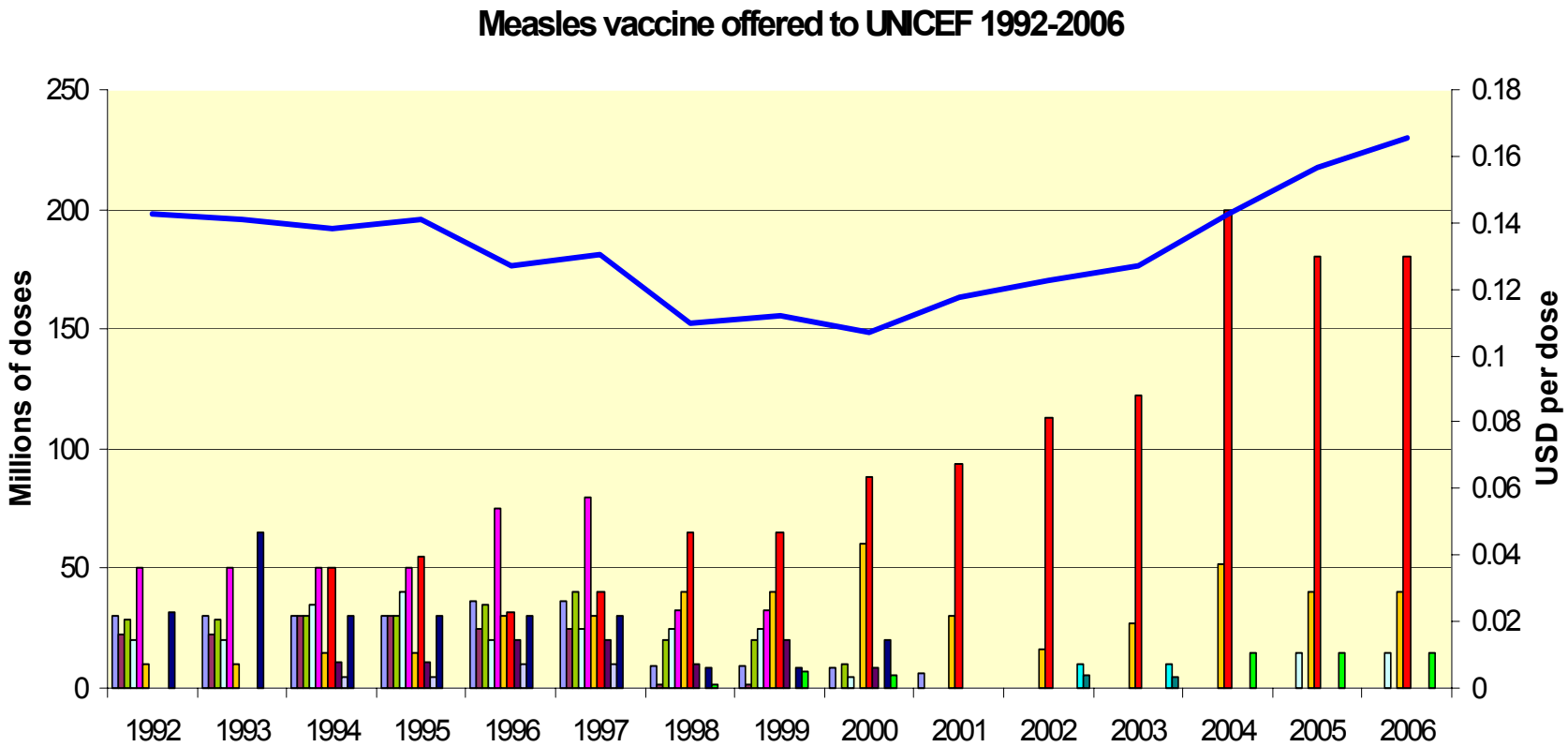
- **Result of the 2004-2006 tender:**
  - **Greater availability and more suppliers of all vaccines**
  - **Average of 2-4 suppliers for all vaccines (except HepB/Hib-combinations)**
  - **Vaccine prices vary significantly among manufacturers – large price spread within one vaccine type**
  - **We are experiencing price increases on traditional 'penny' vaccines including DTP, BCG, Measles, TT, OPV, Yellow Fever, due to:**
    - the costs of obtaining increases in production
    - the costs of upgrading manufacturing plants to ensure compliance to cGMP and WHO standards
    - the fact that manufacturers that previously had stopped production have re-entered production and there is a cost to re-entry
    - normal market factors in a constrained market

Sample vaccine: UNICEF SD Demand and Availability for Measles vaccine



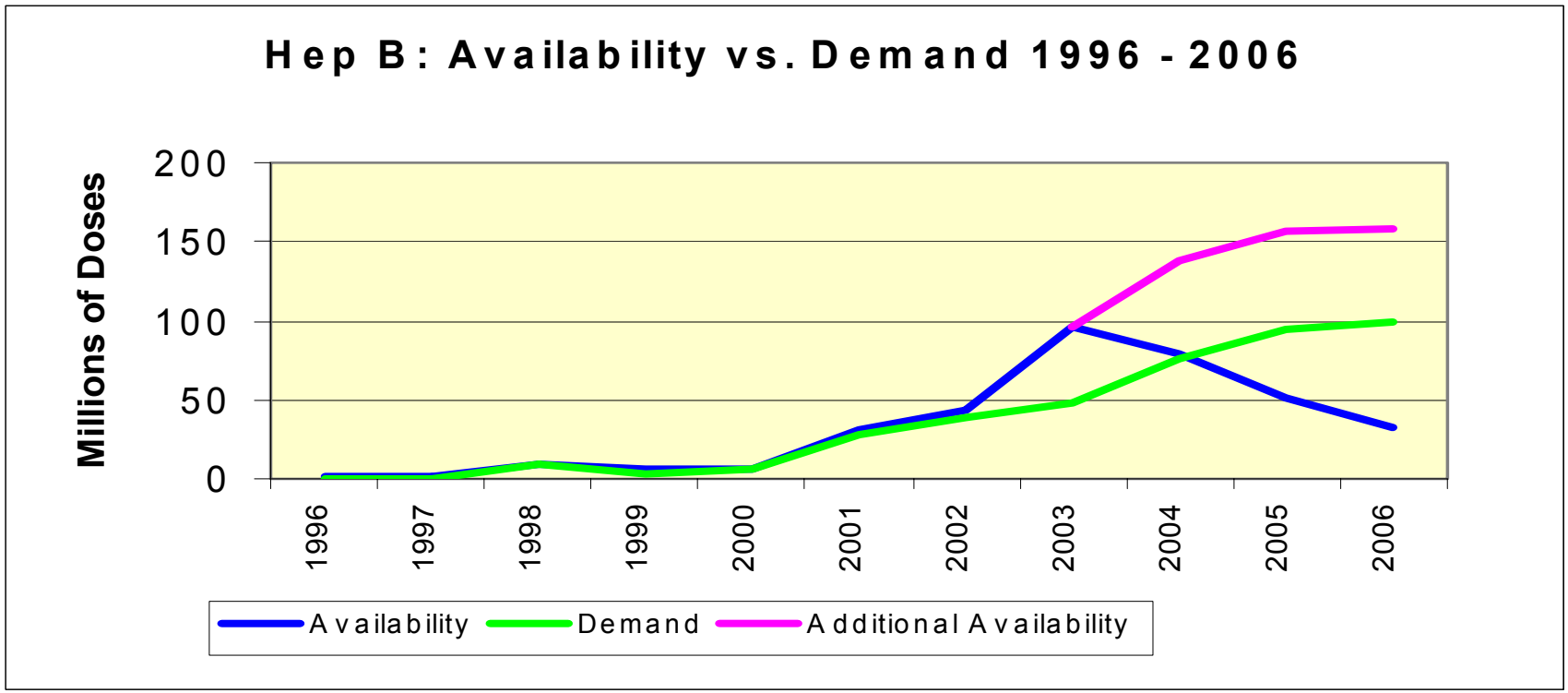
- Additional availability from WHO pre-qualified suppliers, but not necessarily at same price
- 6 month lead-time for an increase of up to a 20% of the yearly awarded quantity
- 9 month lead-time for an increase of up to 40% of the yearly awarded quantity

Measles vaccine - increased availability of measles vaccine, but at an increased weighted average price



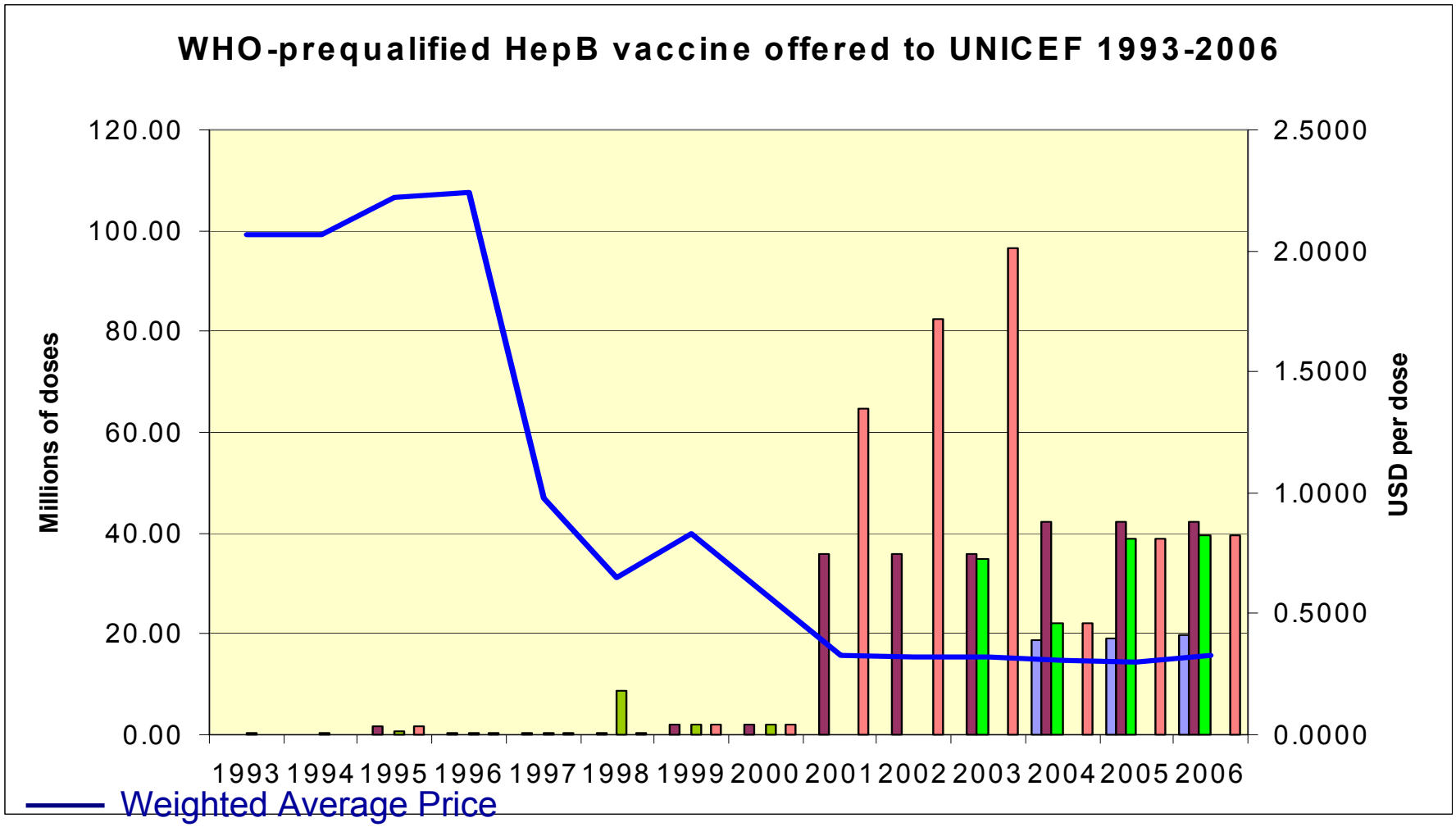
- Blue line – Average weighted price
- Each bar represent a manufacturer
- 2001-2003 were tight years, the current situation is improved with more manufacturers offering to UNICEF

Sample vaccine: UNICEF SD Demand and Availability for Hepatitis B vaccine

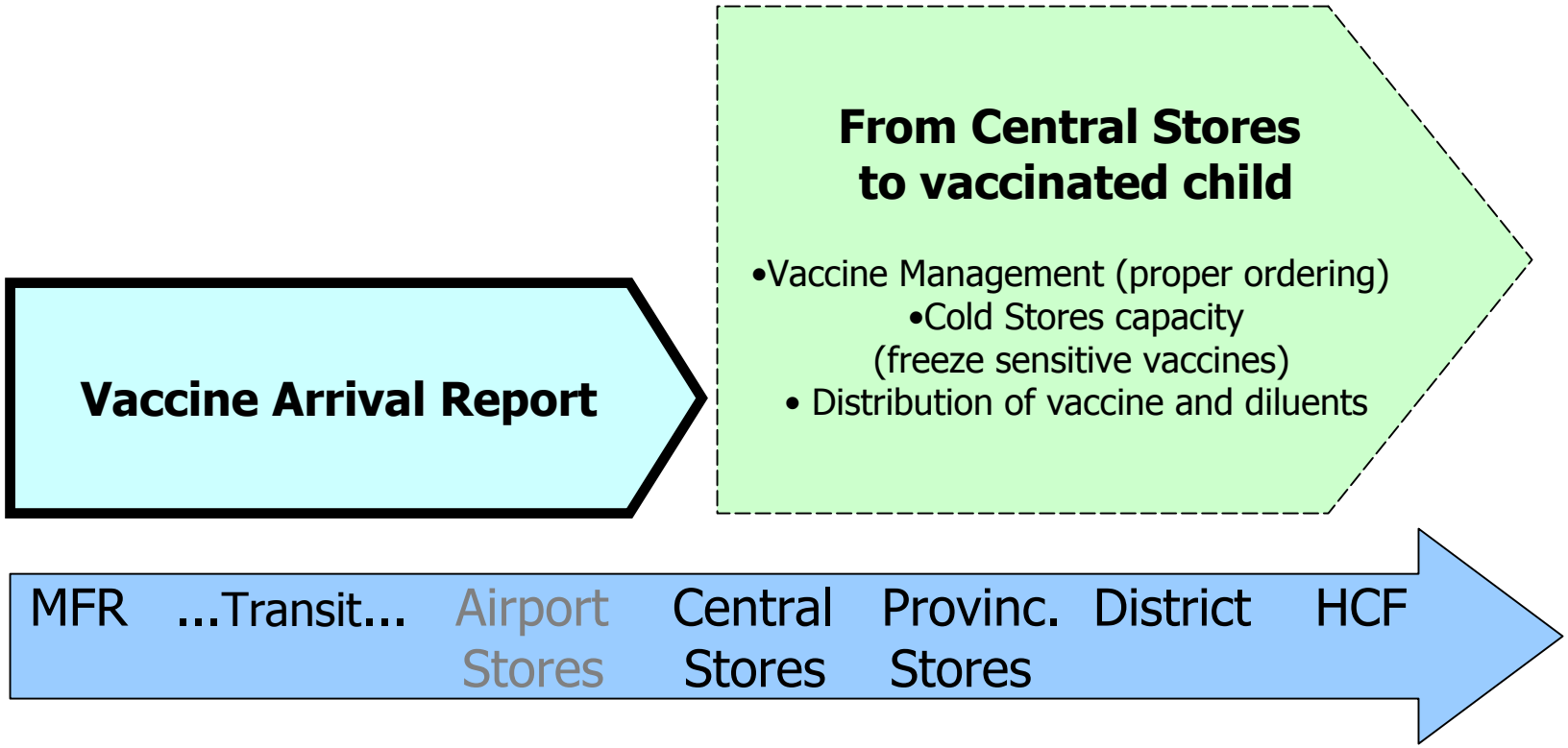


- HepB LTAs will be revised by mid-2004 if need be.
- Additional availability from WHO pre-qualified suppliers.
- 6 month lead-time for an increase of up to a 20% of the yearly awarded quantity
- 9 month lead-time for an increase of up to 40% of the yearly awarded quantity
- 12/15 month lead-time for an increase above 40% of the yearly awarded quantity

With $1 billion in advance funding from the Vaccine Fund (GAVI) for newer vaccines for low income countries, large quantities of HepB vaccine are available at decreasing prices



Vaccine Safe Arrival

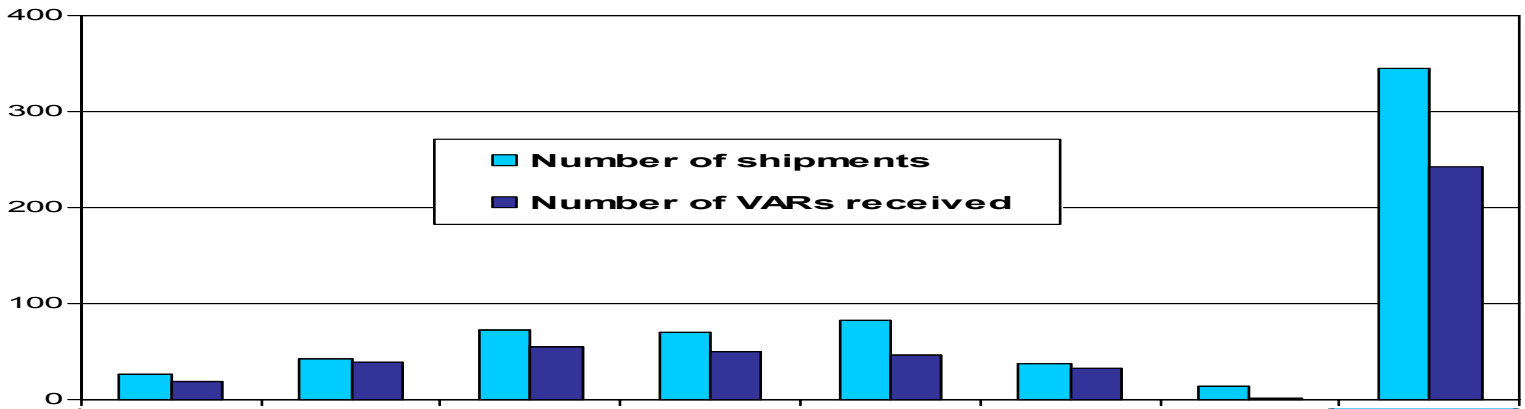


- Every shipment should be inspected by the UNICEF/CO utilizing a "Vaccine Arrival Report" to ensure that delivery problems (e.g. heat exposure) are detected and determined early in the process and that delivery practices are improved constantly

Introduced 1 May, 2003 for all UNICEF vaccine shipments - average 7 shipments/day

ABOUT VARs

VARs RECEIVED BY REGION



Region	CEE/CIS	EAPRO	ESARO	ROSA	WCARO	MENA	TACRO	Total
% VAR received	73%	93%	75%	71%	55%	89%	7%	70.5%
Average no. of days to receive VARs	14	6	18	10	12	16	3	12

UNICEF Vaccine Supply in the CEE/CIS Region

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Procurement through UNICEF in the CEE/CIS region

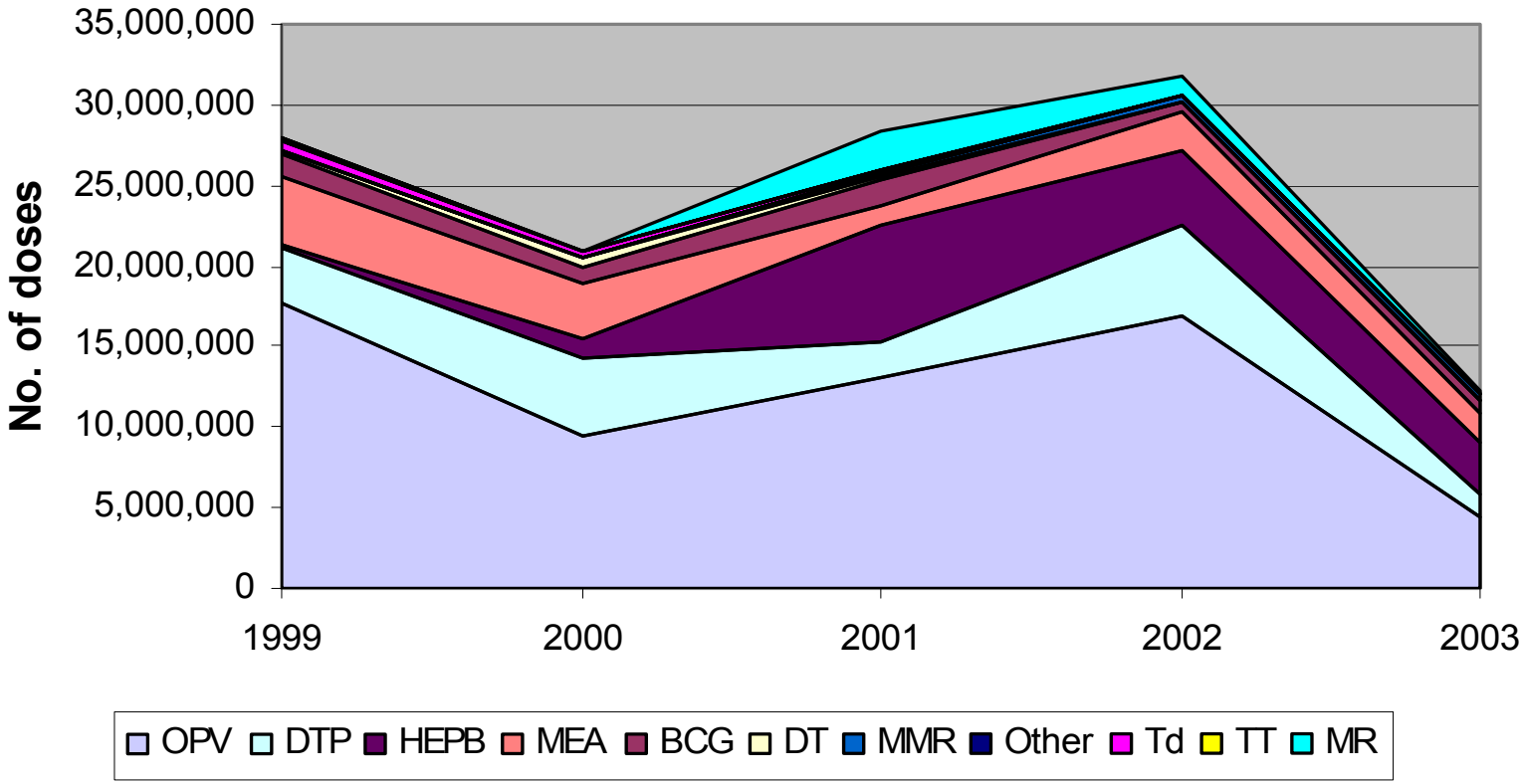
Region (excl. India, China & Indonesia)	Percentage of Region's Population covered by UNICEF Procurement
CEE/CIS	8.35%
EAPRO	28.78%
ESARO	79.17%
MENA	31.57%
ROSA	92.32%
TACRO	0.90%
WCARO	93.58%

Countries in UNICEF CEE/CIS region

Albania
Armenia
Azerbaijan
Belarus
Bosnia & Herzegovina
Bulgaria
Croatia
Georgia
Kazakhstan
Kyrgyzstan
Latvia
Lithuania
Macedonia
Moldova
Romania
Russia
Serbia and Montenegro
Tajikistan
Turkey
Turkmenistan
Ukraine
Uzbekistan

- UNICEF SD has been involved in Vaccine procurement in all countries except Latvia and Lithuania, but play a role in the routine vaccine supply only for about 25% of the countries
- 6 of the countries are Low Income Countries

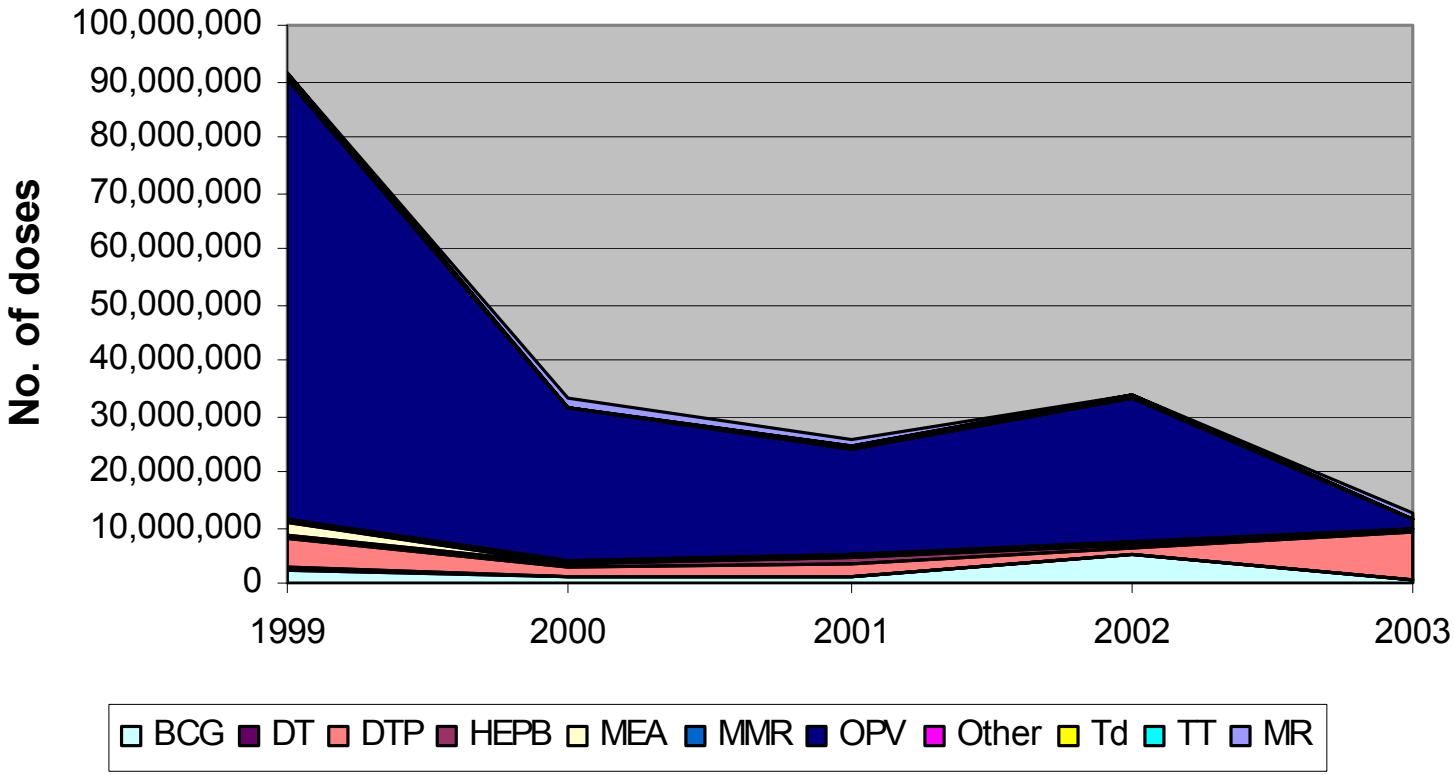
Procurement through UNICEF for the **Low Income Countries** in the CEE/CIS region In Doses



•Annual procurement between 20-30 million doses. Polio elimination caused the decrease in 2003 figures

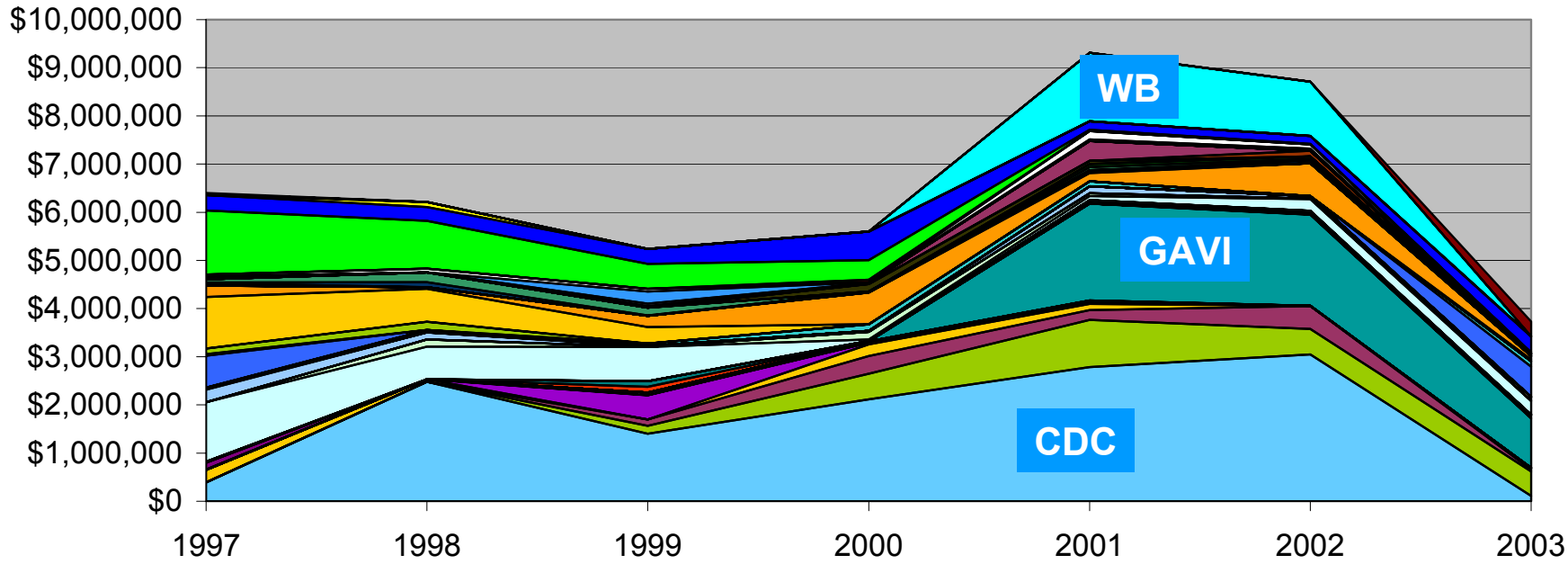
•**Low income countries (as per WB Aug 2003 indicators):**
ARMENIA, AZERBAIJAN, GEORGIA, KYRGYZSTAN, MOLDOVA, TAJIKISTAN, UKRAINE, UZBEKISTAN

Procurement through UNICEF for the **Lower Middle Income Countries (LMIC)** in the CEE/CIS region In Doses



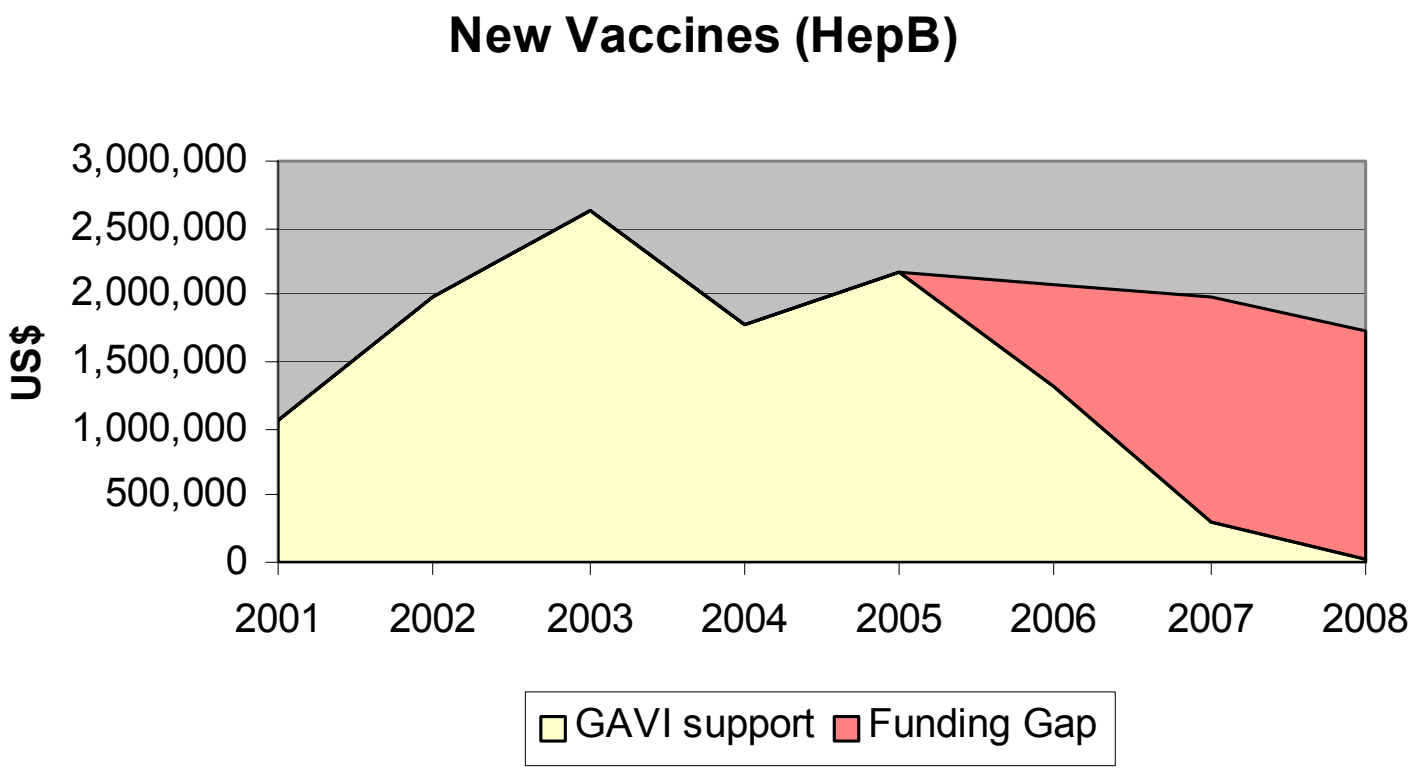
LMIC (as per WB Aug 2003 indicators): ALBANIA, MACEDONIA, YUGOSLAVIA FR, BOSNIA-HERZEGOVINA, BELARUS, BULGARIA, KAZAKHSTAN, ROMANIA, RUSSIAN FEDERATION, TURKEY, TURKMENISTAN

Funding Sources within the Region



- US Center for Disease Control & Prevention
- JICA
- CIDA
- USAID
- ECHO
- BPRM (Bureau for Population, Refugees and Migration)
- SIDA
- Consolidated Funds from NatComs
- DIK - Merck
- GAVI
- GVT Albania
- GVT Armenia
- GVT Canada
- GVT Denmark
- GVT Finland
- GVT Ireland
- GVT Italy
- GVT Japan
- GVT Kazakhstan
- GVT Kyrgyzstan
- GVT Netherlands
- GVT Norway
- GVT Sweden
- GVT Switzerland
- GVT Turkey
- GVT Turkmenistan
- GVT UK
- GVT USA
- GVT Uzbekistan
- National Committee AUSTRIA
- National Committee BELGIUM
- National Committee CANADA
- National Committee FRANCE
- National Committee GERMANY
- National Committee ITALY
- National Committee JAPAN
- National Committee LUXEMBOURG
- National Committee NETHERLANDS
- National Committee PORTUGAL
- National Committee SPAIN
- National Committee UK
- National Committee USA
- PATH
- Rotary International
- UNICEF RR
- Unknown
- UNOCHA
- World Bank
- World Health Organization

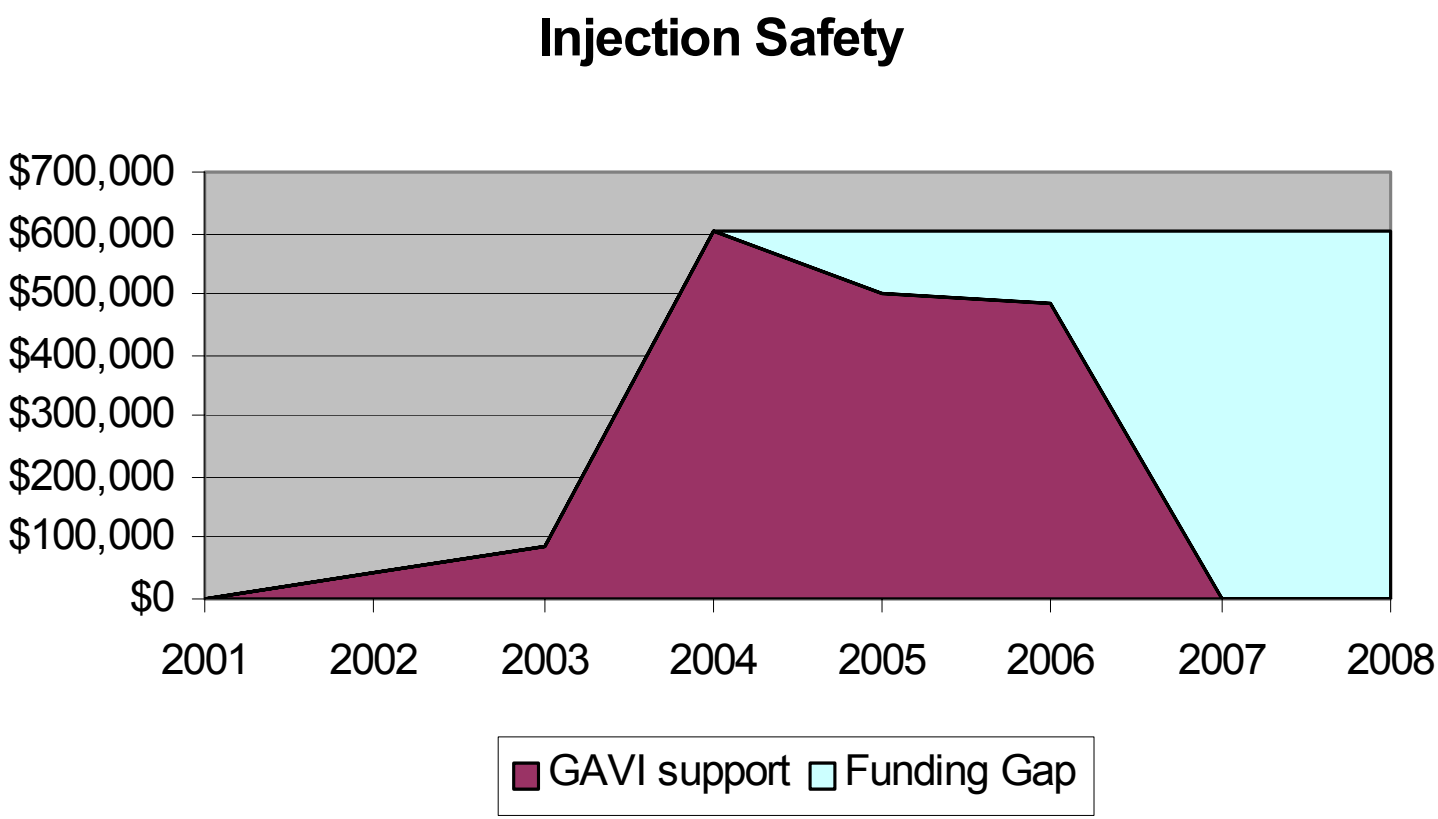
GAVI funded vaccines in the region (value)



Approx USD value of vaccine support (incl. syringes and safety boxes for these vaccines)

GAVI funded injection safety in the region – Value

(AD syringes, safety boxes and reconstitution syringes)



Procurement Options

Options:

- Self-procurement
- Pooled procurement (PAHO model)
- UNICEF Procurement Services may be an option for some countries
- (Own production)

Each procurement channel has pros and cons and the right solution depends on the characteristics and possibilities in each country

The overall goal of for each country should strengthen Vaccine Security in the country: The Sustainable, Uninterrupted supply of Affordable Quality Vaccines

Independent of the procurement method the success still depends on the elements of Vaccine Security: good forecasting, adequate and timely funding, wound and timely contracting.

Procurement options

Factors to consider when reviewing potential procurement channels:

- Procurement capacity
- Procurement legislation
- Funding availability
- Budget cycles
- Size of procurement (country)
- NRA capacity to ensure vaccine quality and set standards
- Particular requirements (presentation, language, vaccine types)

UNICEF procures primarily on behalf of the poorest countries, and believe in tiered pricing.

UNICEF will not take over procurement for cost saving reasons alone, but may assist with Vaccine Security Missions to help identify the ways to strengthen a country's Vaccine Security.

Procurement Services

- Requires an MOU to be signed with the government outlining the nature of the agreement
- Requires UNICEF presence in the country
- Requires transfer of funding up front (no LCs)
- UNICEF charges a handling fee for the service (6%)
- UNICEF procures WHO pre-qualified vaccine and appropriate shipment.
- Follow up in case of vaccine quality issues, including AEFIs
- Gives access to UNICEF long term agreements for vaccines and decreases risk of stock outs due to delivery delays.
- Requires diligent forecasting
- Country will be monitored and followed up on their procurement plan.

Vaccine Security missions: SD and CO review and help countries with their Funding, Forecasting and Procurement of vaccines and devices

Funding:

- accurate budgeting based on forecast
- timely release of funds
- consumption of budget

Procurement

- effective, public procurement
- new market conditions
- Arrival/Inspections (VAR)

Forecasting:

- accurate forecast
- methodology: targets vs. utilization
- central, provincial, district levels

Cold Chain

- proper storage conditions at national, provincial, district levels

Distribution

- arrival/inspections
- stock management
- central, provincial, district

Vaccine Security Missions

Countries in 2003**:** Pakistan, Bangladesh, Nigeria, Iran, Philippines, Turkey, (Tunisia)

Objective: On invitation from the country we assess the forecasting, planning, budgeting, funding and procurement in light of the current Vaccine market.

Mission goals:

- Inform counter-parts of the Current Vaccine Market and Vaccine Security, including requirements for forward planning and funding
- Review current processes, including procurement options and budgeting, depending on the country profile.
- Review forecast for current and next years and start to identify areas that need action

Common issues:

- Stock outs due to interrupted supply
- The need to consume budget will conflict with planned consumption
- Price increases draws criticism from other gov't partners and halts procurement process
- Legislation counters effective procurement (no prepayment, gov't controlled pricing, laws on tender processes etc.)
- Limited/sporadic communication between MOH, MOF, suppliers and programme makes it difficult to anticipate shortages/problems
- Limited capacity to perform rigorous procurement and to keep in touch with the market.

thank you

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