



Divergence of products for public sector immunization programmes

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Data from UNICEF, PAHO RF



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 - Demand
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Basis for Study

Goal

- The goal of the public sector is to ensure that high quality vaccines are developed in adequate capacity and supplied at reasonable prices to meet the priority needs of developing countries

Current Hypothesis

- There is a divergence in product lines available to developing and developed countries
- This study should help us to see
 - What is the extent of this divergence
 - What are its implications, both good and bad
 - How can public and private sectors work together in this situation to meet the goal



Vaccine Manufacturers are changing their product lines

Tailored Products: Serving Different Markets

Tailored to the Developing Market	Disease	Tailored to the Industrial Market
Measles	Measles	MMR
DTwP	Pertussis	DTaP
OPV	Polio	IPV
Monovalent, DTwP-Hep B	Hepatitis B	Monovalent, DTaP-Hep B, DTaP-Hep B-IPV-Hib, Hep B-Hib, Hep A-Hep B
Monovalent, DTwP-Hib, DTwP-Hep B-Hib	Hemophilus Influenzae type b	Monovalent, DTaP-HepB-IPV-Hib, Hep B-Hib
Mening A/C polysaccharide	Meningitis	Meningitis C conjugate, (Meningitis BC conjugate)



A Changing Product Mix: Wyeth-Lederle

Decreasing supply and number of "traditional" products
 Increasing supply of newer products serving the industrialized world.

Product List 2001	
Influenza Virus	
Hib (conjugate)	
Meningitis C conjugate	
Pneumo 7 valent (conjugate)	
Pneumo 23 valent polysaccharide for adults	
Rotavirus	
Vaccines no longer produced	
DTPw (Triimunol)	
DTaP	
DTP-Hib	
Cholera	
Typhoid	
OPV	
small pox	
Tetanus	
DT	



A Changing Product Mix: Biofarma

Since 1990, Biofarma has been steadily adding to its portfolio of "traditional" vaccines. For the future, Biofarma has plans to expand into combinations and other new products which serve global markets.

current
 future

	Pre 1990	1990-1995	2001		Future Plans ¹
BCG					
DTP					
Rabies (mice)					
Cholera					
Typhoid (old)					
OPV					
Measles					
Hep B (filling)					
Uniject TT, hep B					
Typhoid (new)					
DTwP-Hep B					
DTwP-Hep B-Hib					
IPV combos					
Rotavirus					

Note: 1 Assumes production of current vaccines continues.

Source: Biofarma

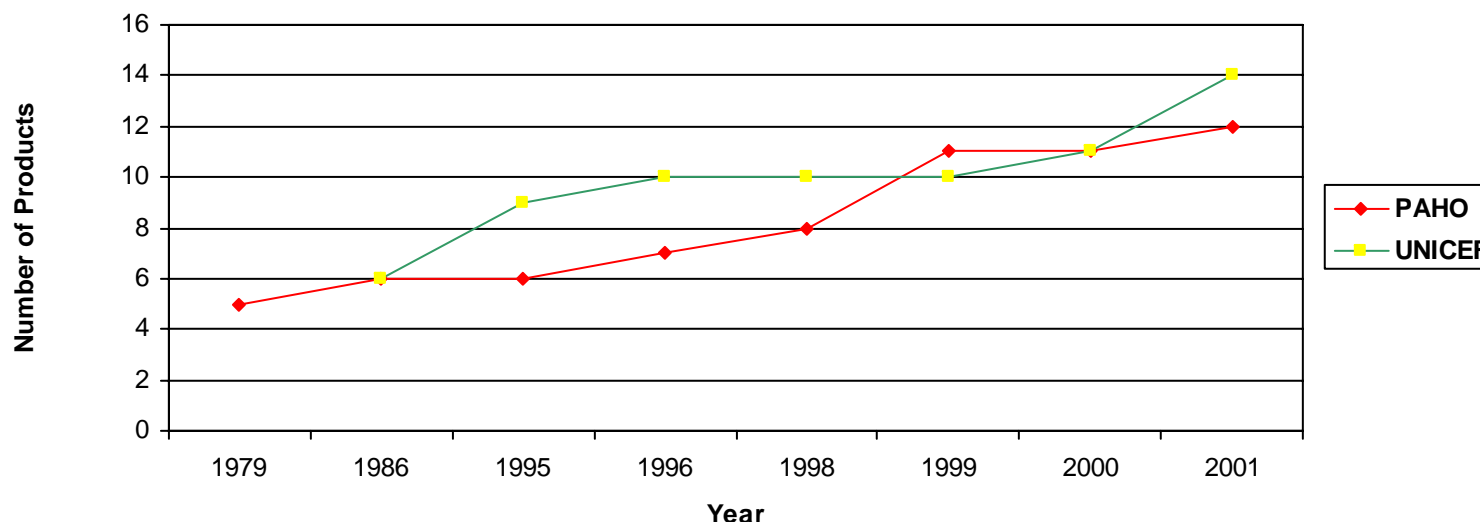
Country Spotlights: Japan, UK, US, Canada

Industrialized countries have changed their vaccine demands. The changes may reflect epidemiology or fear of adverse reactions.

Japan		UK		USA		Canada	
1985-1990	1995-2000	1985-1990	1995-2000	1985-1990	1995-2000	1985-1990	1998-2000
Diphtheria, Pertussis	DTaP	DTwP	DTwP-Hib	DTwP	DTaP + Hib	DTwP or DTwP-IPV	DTwP-IPV+Hib ↓ DTwP-IPV//Hib ↓ DTaP-IPV//Hib
OPV	OPV	OPV	OPV	OPV	IPV	OPV or IPV	IPV
MMR	Measles, Rubella	Measles	MMR	MMR	MMR	MMR	MMR
BCG	BCG	BCG	BCG high risk	-	-	-	-
JE Emergency use	JE	-	Meningitis C conj.	-	Varicella, Hep B, Hep A in selected areas	-	Hep B (infants or adolescents)

UN agency demand: Products

PAHO and UNICEF have changed their vaccine demands.
 Number of Products Requested, UNICEF and PAHO



PAHO: 1979 baseline and vaccines added

- BCG
- Measles
- Polio
- DTP
- TT
- DT (Pediatric)
- MMR
- Hep B
- Yellow Fever
- Hib
- DTP-Hep B-Hib
- DTP-Hib

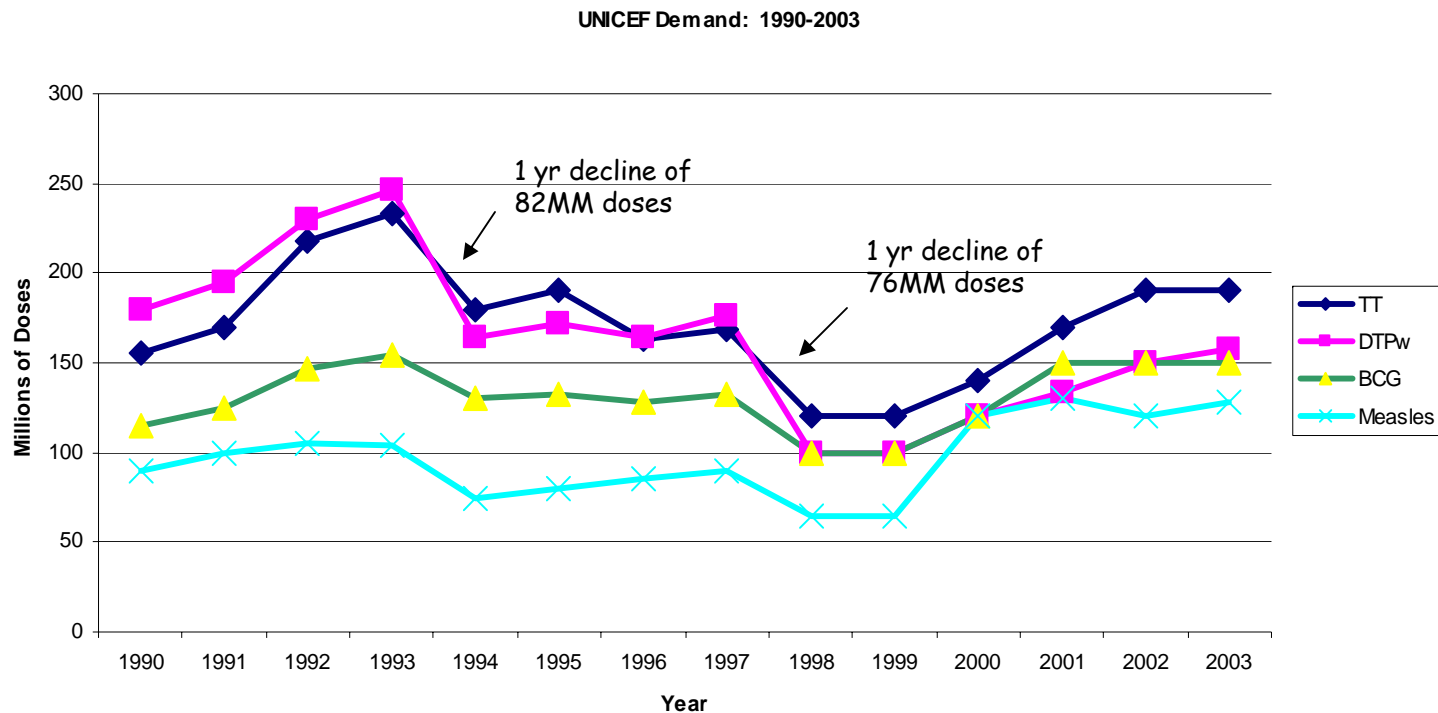
UNICEF: 1986 baseline and vaccines added

- BCG
- TT
- DT
- DTP
- Measles
- OPV
- Yellow Fever
- Hep B
- Td
- Men AC
- MMR
- Hib
- DTP-Hep B
- DTP-Hep B-Hib



UN agency demand: Volume

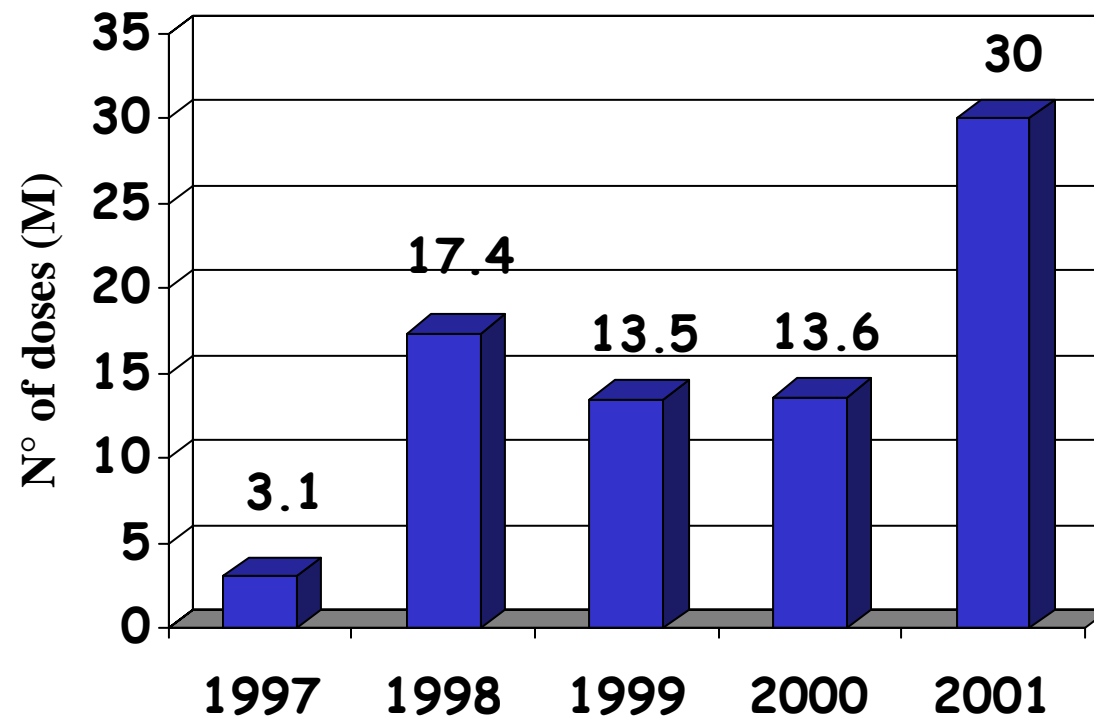
UNICEF demands large numbers of doses of traditional vaccines. However, the demand is fluctuating and at times unpredictable.



UN agency demand: Volume

For newer vaccines, demand is increasing.

PAHO demand 1997-2001 MMR vaccine



Source: PAHO



UN agency mix of suppliers

Over the past 20 years, PAHO and UNICEF have changed supplier base to a mix of industrialized and developing country/emerging economy (DC/EE)¹ manufacturers

DC/EE manufacturers

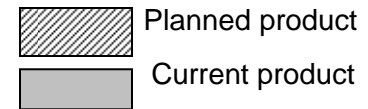
Vaccine	1986	1996	2001
Measles	Institut Merieux SKB Sclavo Evans Connaught	PMC Biocine Il Zagreb SKB Biken Evans Serum India	Aventis Biken Serum India
Polio	Inst Merieux SKB Sclavo Connaught	PMC Biocine SKB Chiron Behring	Aventis Chiron Vaccines GSK Biofarma
DTP	Inst Merieux Connaught Swiss Serum Behring	PMC Serum India Swiss Serum CSL Biocine Chiron Behring	Aventis Biofarma CSL Serum India
TT	Inst Merieux Connaught Swiss Serum Behring	PMC Human Serum India Swiss Serum CSL Biocine	Serum India Biofarma CSL Human
Hep B	--	SKB Cheil LG Green Cross	LG Green Cross Cheil (recomb)* Bharat* Shantha*
Hib combos	--	--	Aventis Chiron GSK

Note: 1 DC = Developing country, EE = Emergng economy. * = not yet WHO-prequalified

Source: PAHO, WHO



Product Targeting



	Tailored to the DC Market			Tailored to the Industrial Market				New		Future	
	Measles	DTwP	OPV	MMR	DTaP	IPV	Mening C conjugate	DTwP-Hep B or Hib	Pneumo	Rotavirus	Multivalent meningitis conjugates
DC Mfgs											
BioFarma								Planned product		Planned product	
Vacsera											
Razi/Pasteur											
Butantan/Biomanguinhos								Planned product			
India Private Sector											
Cuba								Planned product			Planned product
China											Planned product
Industrialized Mfgs											
Aventis											Planned product
Chiron											Planned product
CSL											Planned product
GSK											Planned product
Merck											Planned product
Wyeth-Lederle											Planned product

DC manufacturers traditionally have concentrated on the developing country market. In the future, they plan to focus on the newer and future vaccines which may have global applicability

Some industrialized country manufacturers are continuing to supply all types of vaccines



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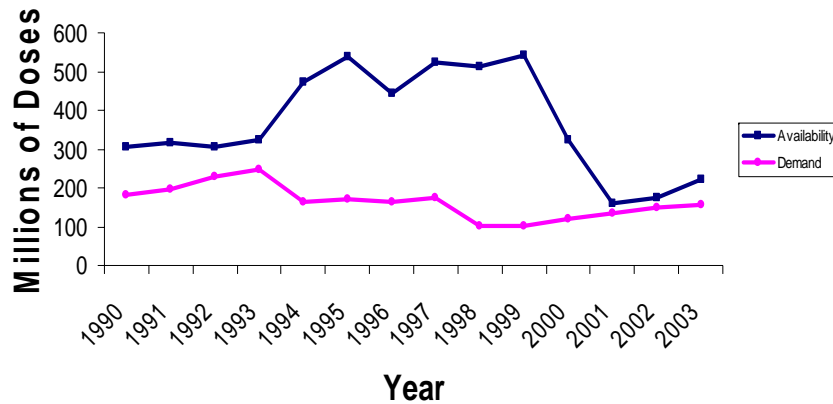
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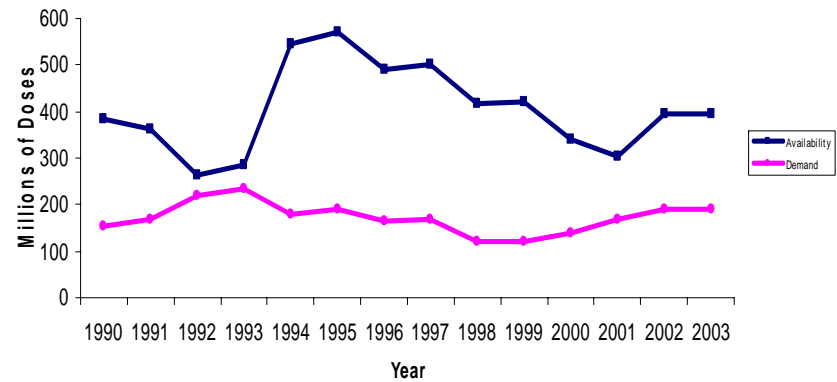
Supply: UNICEF Demand and Availability 1990-2003

Demand and availability are converging for UNICEF-supplied traditional vaccines. This demand is largely being met by DC/EE manufacturers as the market diverges. Thus divergence makes supply more tenuous

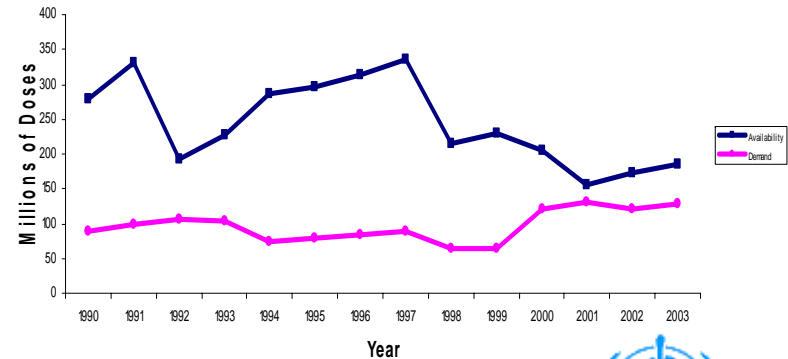
DTwP



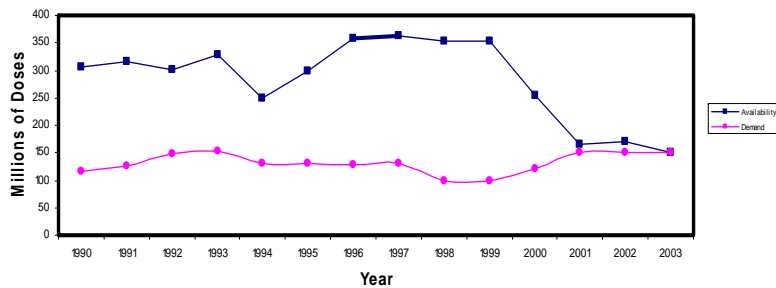
TT



Measles



BCG

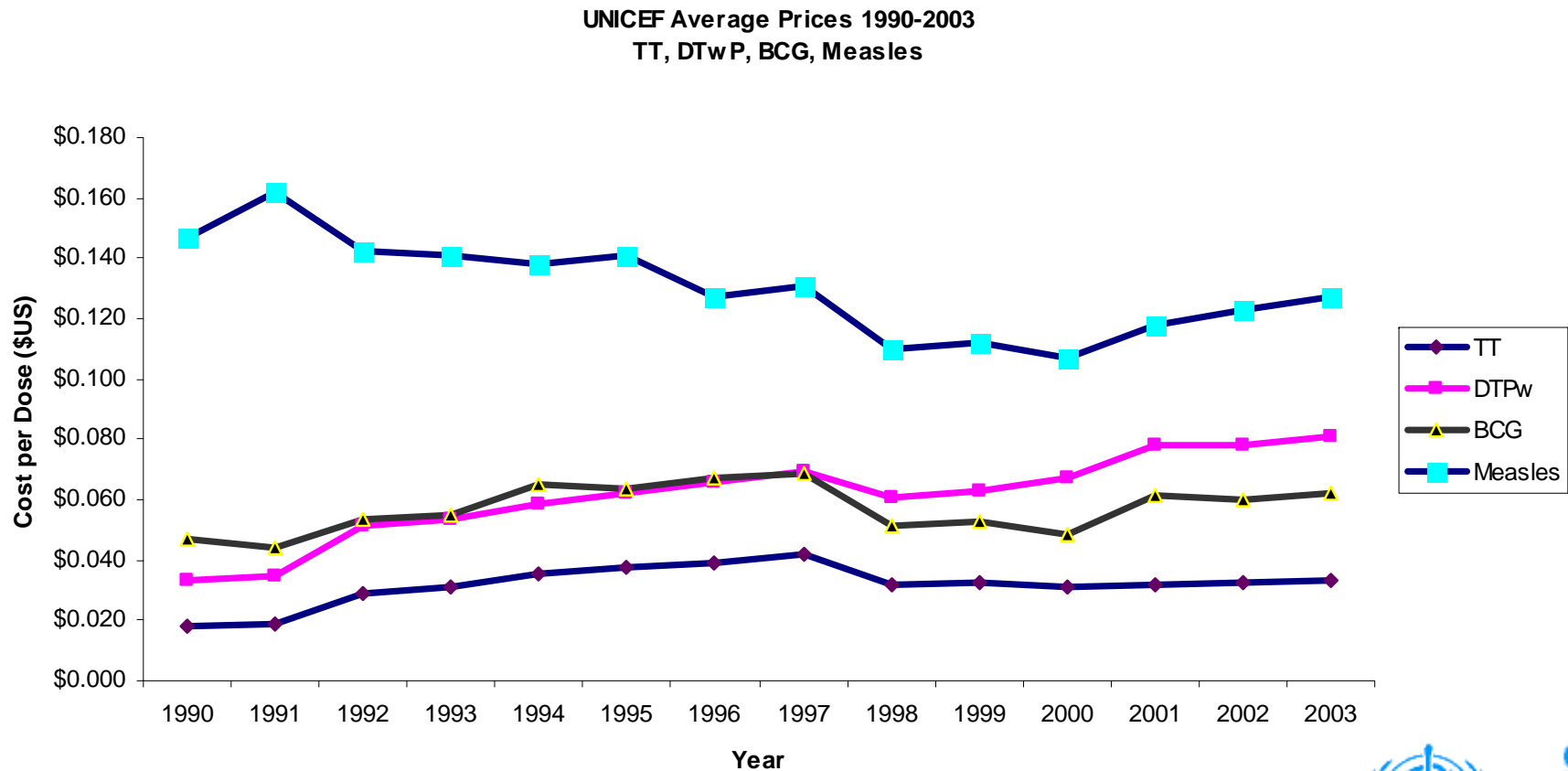


Source: UNICEF



Pricing: UNICEF Average Prices

Prices have remained extremely static for traditional vaccines, however...

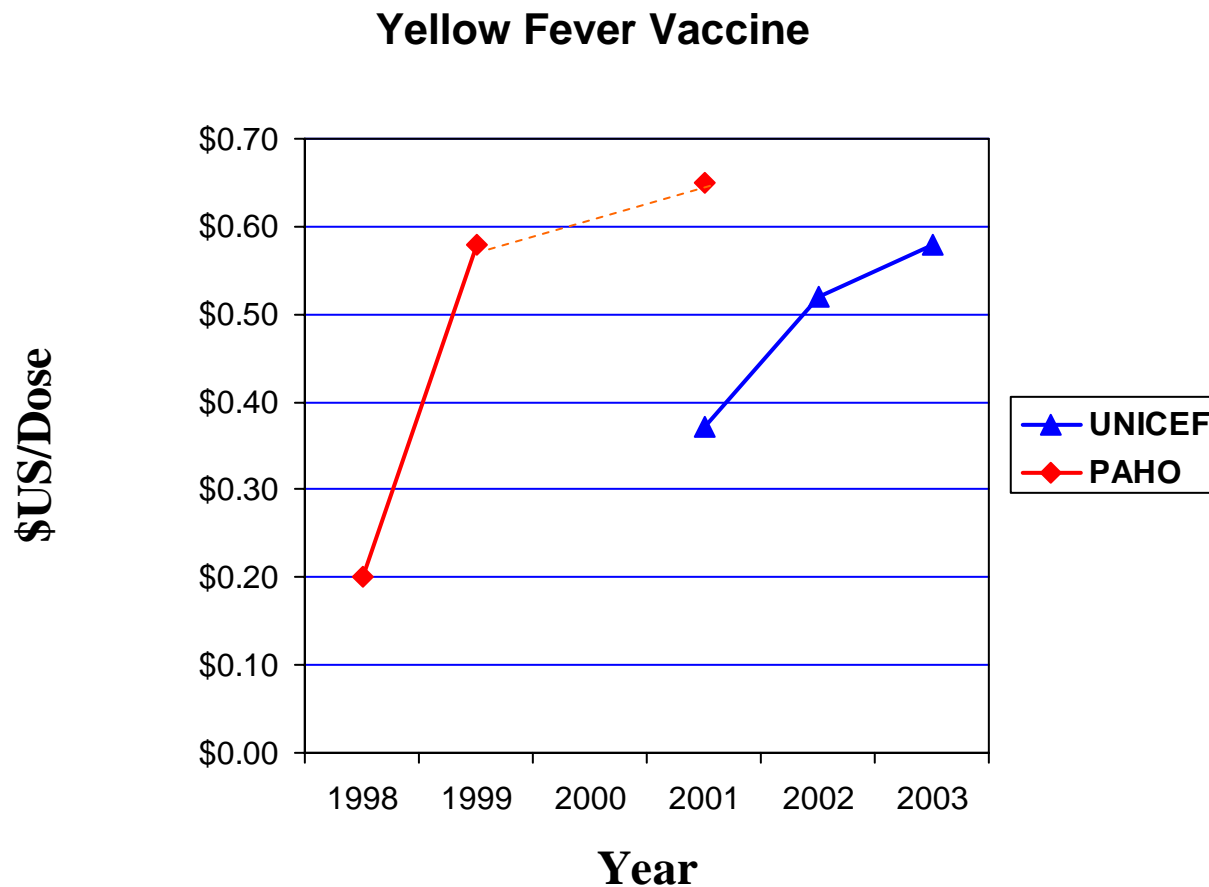


Source: UNICEF



Pricing: UN agency average prices

For older traditional vaccines without excess capacity, prices are rising.



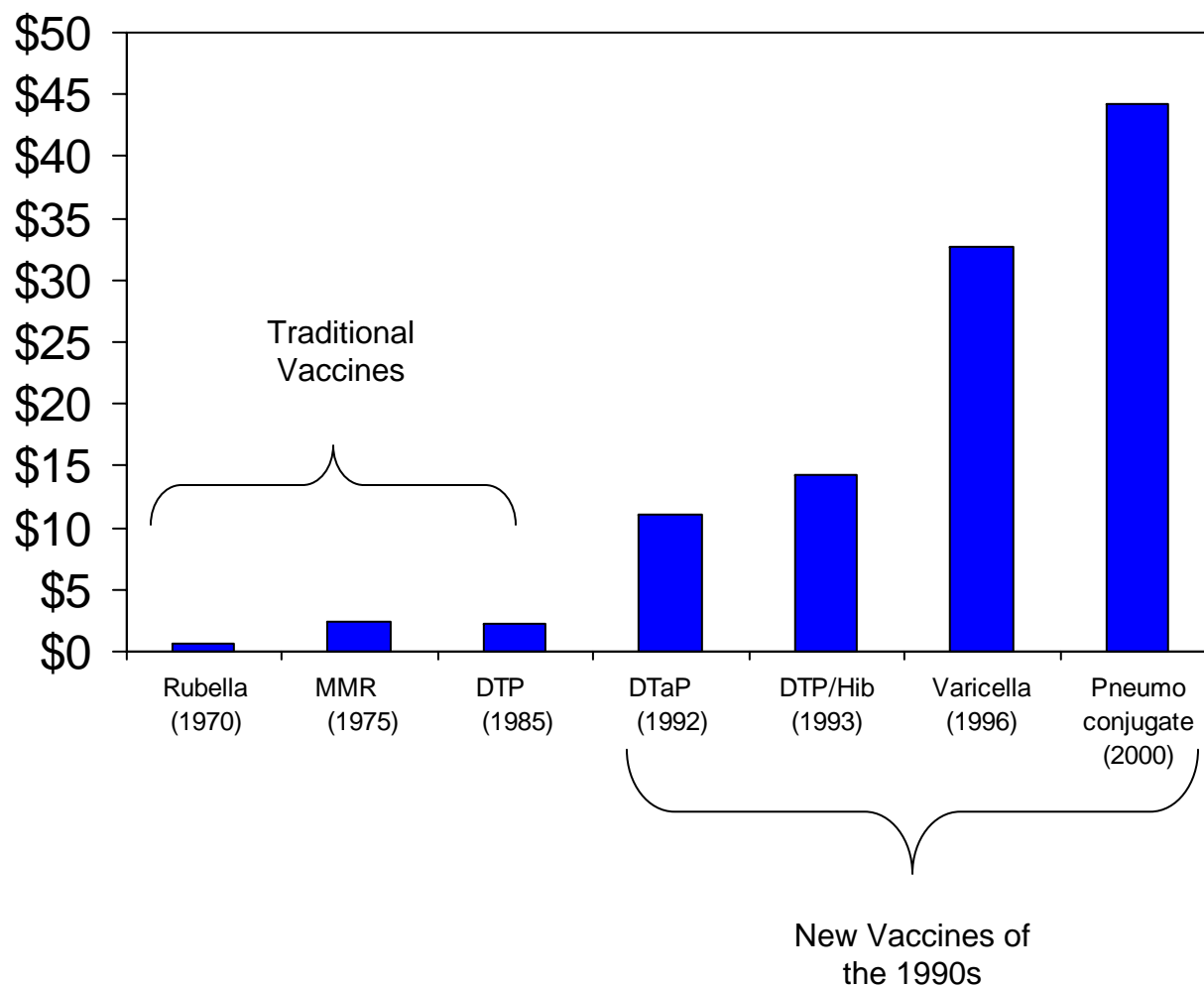
Note: PAHO did not receive any response to its tender in 2000

Source: PAHO, UNICEF



Pricing: Traditional vs. "New" Vaccines

Prices for newer vaccines are orders of magnitude larger than prices for the traditional vaccines.



Source: CDC contract prices, 1970-2000



Regulatory Issues:

- Regulatory requirements are increasing for all products
 - ❑ One manufacturer estimates cost/sq m has risen 3 fold in past 5 years because of this
- NRAs in developing countries have been weak historically
 - ❑ NRAs in 32/51 producing countries are achieving required six regulatory functions
 - ❑ Only 73% of DTwP vaccine supply is of assured quality
- Regulation requirements in industrialized countries are changing
 - ❑ EU only licensing products used within EU



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Summary Points

Vaccine products are diverging. This is unlikely to change in the near term.

❑ On the demand side

- UN agencies demand large but unpredictable volumes of traditional vaccines
- UN agencies are demanding new combination products tailored for the developing market
- Industrialized countries are changing their vaccine usage reflecting epidemiology and fear of adverse reactions

❑ On the supply side

- Some industrialized manufacturers tailoring new vaccines to industrial markets in lieu of traditional vaccines
- Developing country manufacturers are increasing capacity for supply of traditional vaccines and future products are tailored to developing market



Implications for: Availability, Pricing, Regulation

- ❑ Sudden changes in demand or supply (e.g manufacturing failures of any supplier) may threaten public sector immunization programmes
- ❑ Investment in capacity will be necessary to meet demand for new vaccines
- ❑ Although traditional vaccines have had very steady and low prices, new vaccines are orders of magnitude more expensive requiring a fundamental change in public sector willingness to pay
- ❑ The supplier base of UN agencies increasingly includes developing country manufacturers
- ❑ Regulatory requirements are impacting prices and capacity



Goal

The goal of the public sector is to ensure that high quality vaccines are developed in adequate capacity and supplied at reasonable prices to meet the priority needs of developing countries

Recommendations

- Develop and communicate strong positions on product selection to minimize issues related to perceived safety and quality of developing market products
- Keep key manufacturers in the market through incentives, including clear communication of demand
- Ensure that appropriate systems exist for licensing and regulatory oversight of these products

