

# UNICEF's perspective

WHO Informal Consultation to develop  
further guidance on vaccines for the  
UNEP-convened INC4  
Geneva, 3-4 April 2012

# UNICEF procures immunization supplies on behalf of around 100 countries annually



**2011 Vaccines Supplies:** US\$ 1, 030 million

2.49  
billion doses

2,105  
shipments

*Source UNICEF Supply Division*

## Immunization Supplies

### Vaccines

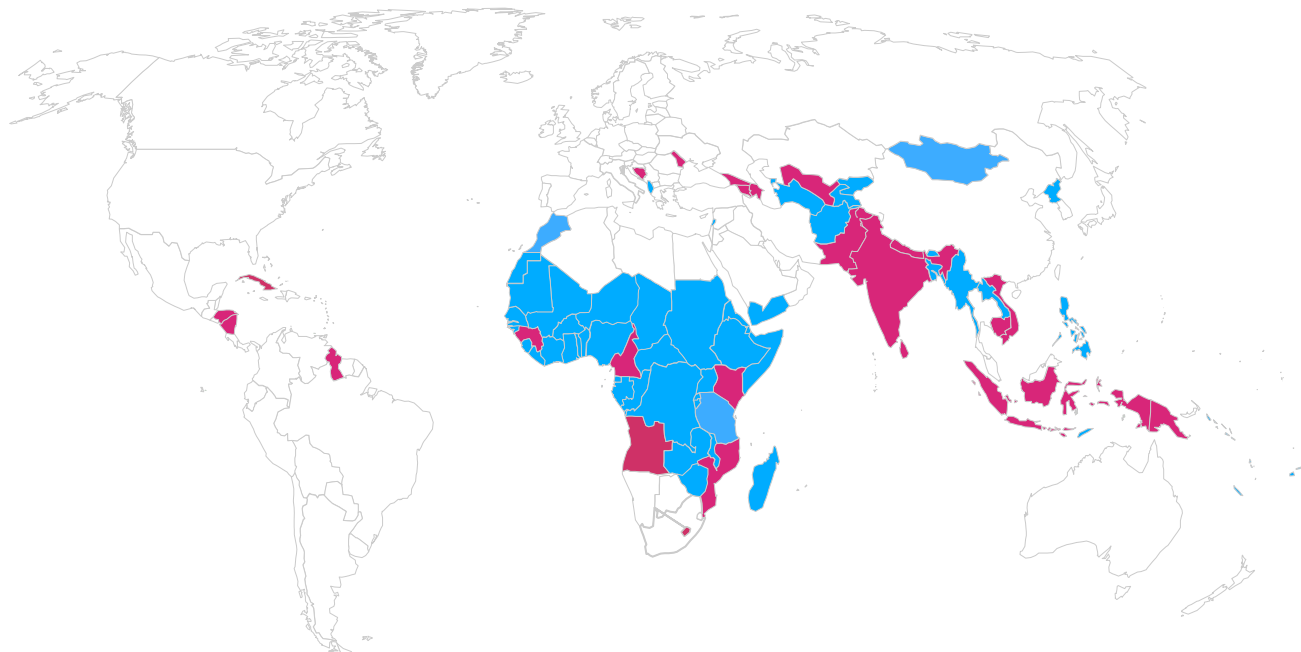
BCG , DTP, TT/Td/DT, Measles containing, OPV, HepB, YF, DTP-HepB, DTP-HepB/Hib, DTP/Hib, Hib, MR, Meningitis, MMR, PCV, RV IPV, etc.

Safe Injection equipment

Cold Chain Equipment

## Countries UNICEF procures on behalf of

- Full schedule
- Partial schedule



*Source: 2012 country forecasts received by UNICEF*

# UNICEF procurement focuses on serving the poorest children

## Developing Country Routine Vaccine Needs

| WB Income classification | Estimated % of Birth Cohort covered by UNICEF Procurement |
|--------------------------|---|
| High income: OECD        | 0%  |
| High income: nonOECD     | 2%  |
| Upper middle income      | 1%  |
| Lower middle income      | 18%   |
| Low income               | 95%   |
| <b>Grand Total</b>       | <b>32%</b>  |

| WB Income classification | Estimated % of Birth Cohort covered by UNICEF Procurement excluding China, India and Indonesia |
|--------------------------|--|
| High income: OECD        | 0%   |
| High income: nonOECD     | 2%   |
| Upper middle income      | 1%   |
| Lower middle income      | 50%  |
| Low income               | 95%  |
| <b>Grand Total</b>       | <b>50%</b>   |

### *Data Sources:*

*Population Data: 'The State of the Worlds Children 2008'*

*Procurement Coverage Data: UNICEF Vaccine Forecast 2010*

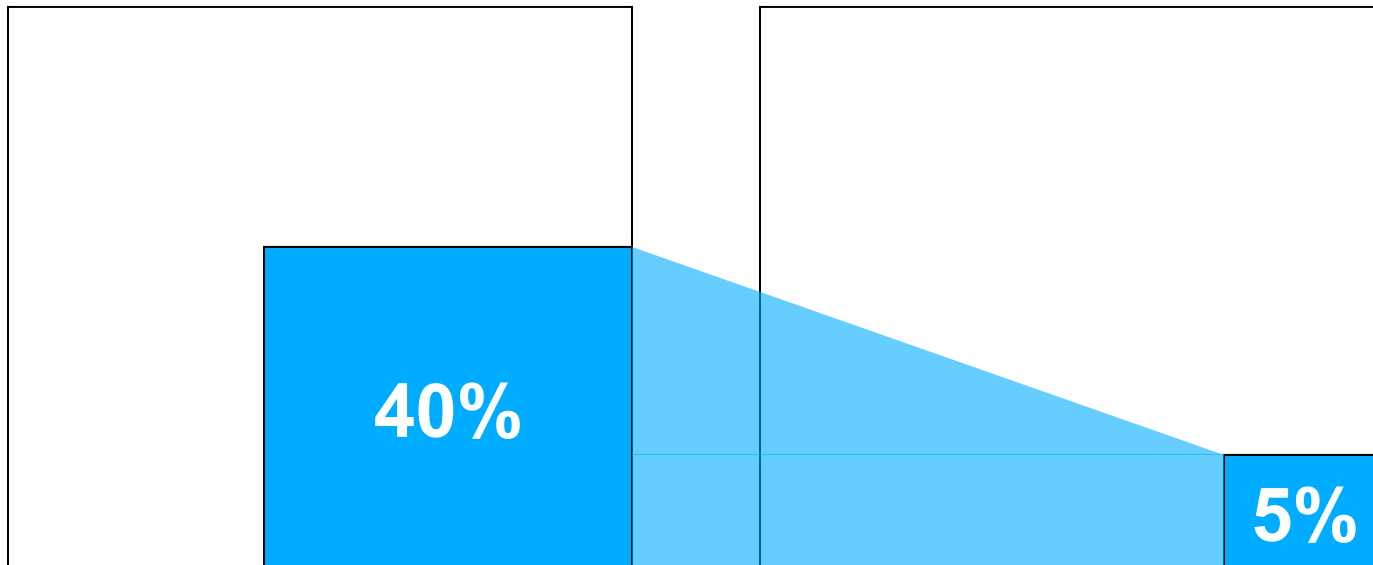
*Income Classification: World Bank , July 2009*

*\* Based on UNICEF Vaccine forecast 2010*

UNICEF's procures 40% of the global volume of vaccines doses, but only 5% of market value

**Global Volume of Doses**

**Global Value of Doses**



**Vaccine Security – Ensuring the uninterrupted, sustainable supply of affordable vaccines of assured quality**

# The global supply situation is constrained for most vaccines

due to the nature of the products, the limited level of competition within the market and the limited supplier base

## Vaccine Product Profile



### High Product Sensitivity

- Biological products requiring constant temperature control ⇔ Cold Chain from Manufacturer to Child
- Significant risks of production failures
- Quality is the OVER-RIDING criterion
- Highly regulated production environment
- Dependency on well functioning NRA
- Limited shelf life



### Limited Supply

- 1-5 suppliers per product
- High entry cost to manufacturers
- No 'generics'



### Long lead times for vaccine production

- Production of a dose: 6-24 months
- Capacity Increase: 2-3 years
- New Plant: 5-7 years
- New regulatory requirements can cause interruptions, therefore careful planning required

UNICEF relies on WHO's advice on standards for vaccines including for quality and safety, procuring WHO pre-qualified vaccines

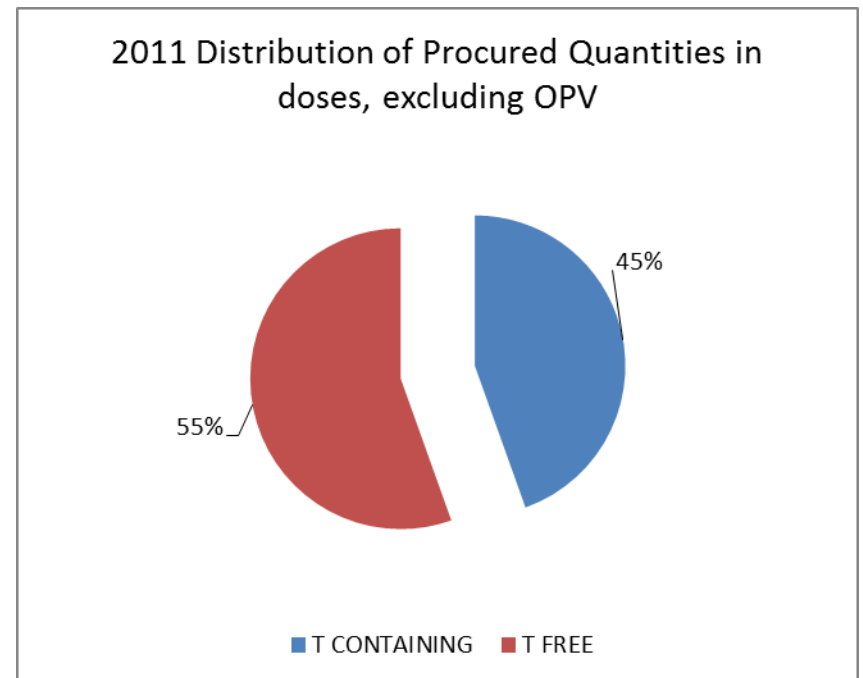
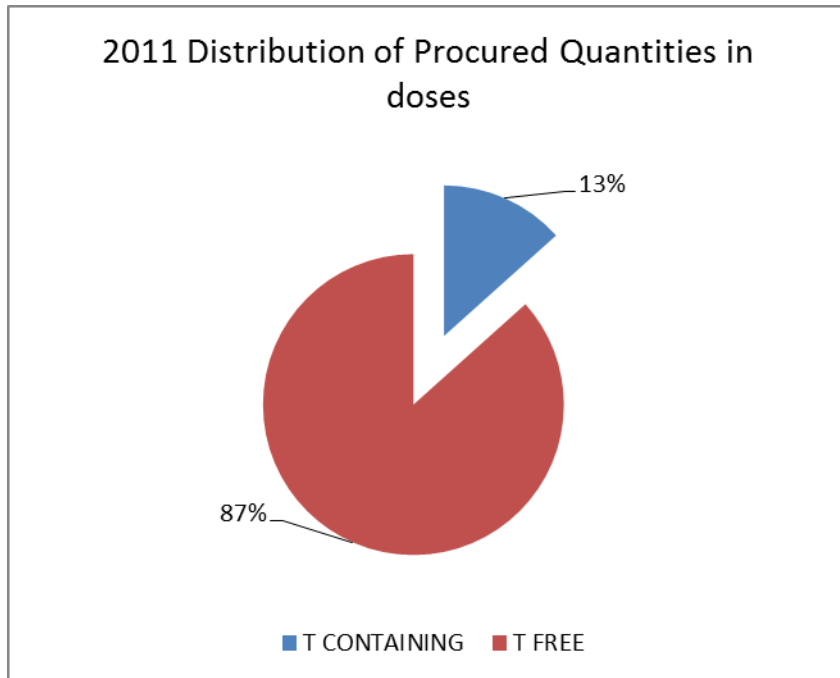
...and the number of manufacturers per vaccine continues to be of concern for most vaccines...

## Number of manufacturers 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 |
|---------------|--|--|--|--|
| BCG           | 5  | 4  | 4  | 4  |
| DTP           | 5  | 4  | 3  | 3  |
| Measles       | 5  | 5  | 3  | 3  |
| TT            | 7  | 4  | 4  | 4  |
| OPV           | 4  | 5  | 6  | 6  |
| DTP+Hib       | 0  | 0  | 1  | 1  |
| DTP-HepB/Hib  | 1  | 1  | 4  | 4 (6)  |
| DTP-HepB      | 1  | 1  | 3  | 3  |
| HepB          | 4  | 5  | 6  | 3  |
| YF            | 3  | 3  | 3  | 4  |
| MMR           | 3  | 3  | 2  | 2  |
| MR            | 1  | 1  | 2  | 2  |
| DT/Td         | 3  | 2  | 2/2  | 2/2  |
| PCV           | -  | -  | -  | 2  |
| Rota          | -  | -  | -  | 2  |

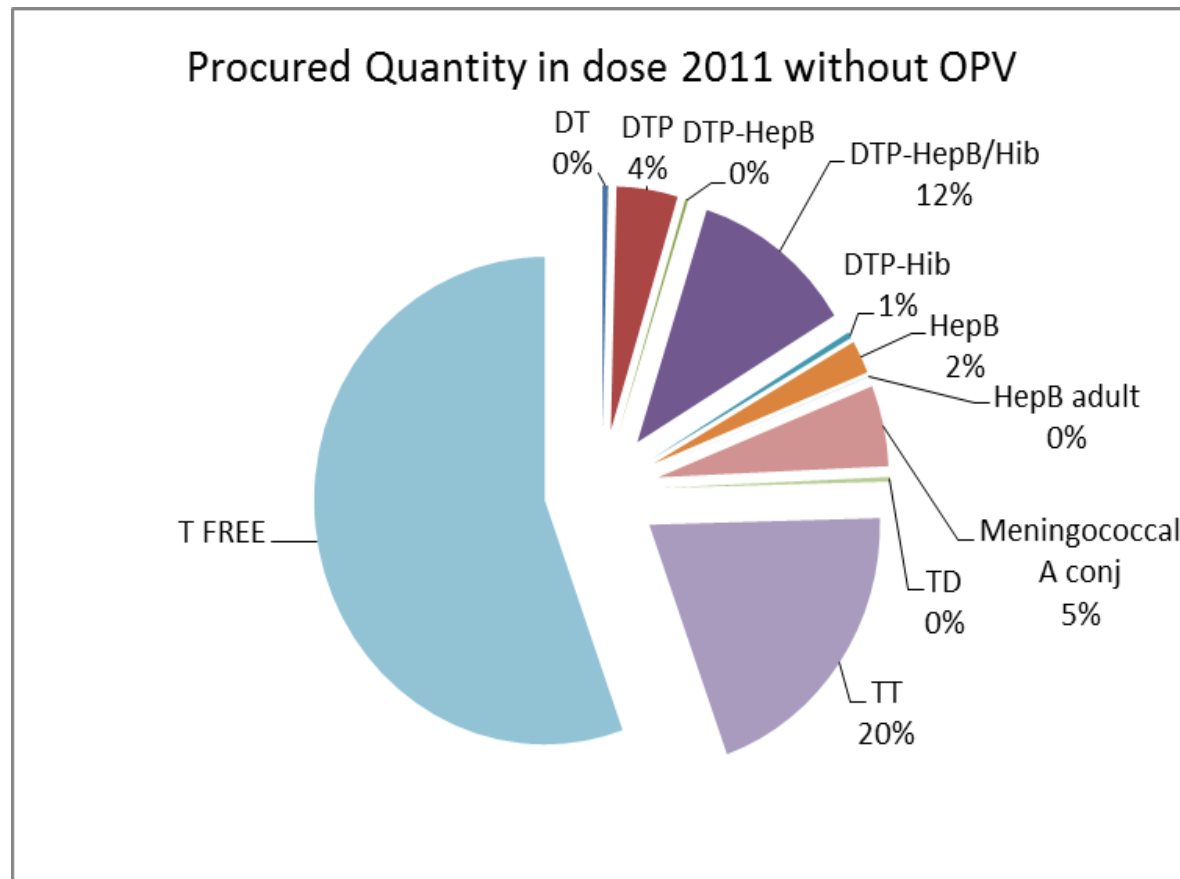
UNICEF procures from multiple suppliers to mitigate risks of supply interruptions – currently shortages in YF, PCV, RV, DTP

Out of 2.49b doses procured by UNICEF in 2011, only a small percentage contained thiomersal....



..however, when excluding OPV, almost half of the doses procured contained thiomersal.

# Most DTP containing, Mening, and T vaccines supplied to UNICEF contain thiomersal

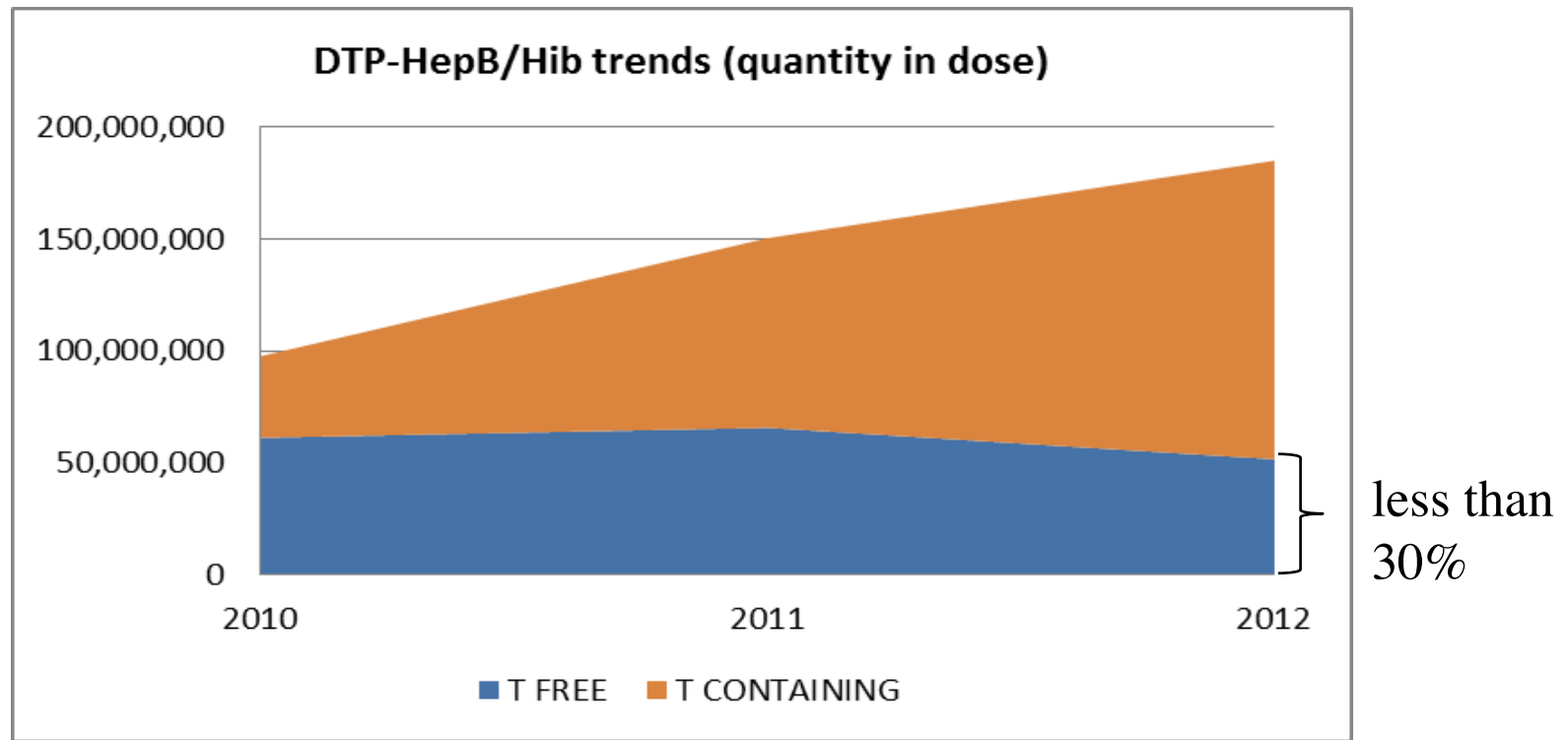


330 mio. doses supplied in 2011, assuming full utilisation:

- 49 mio. women of childbearing age protected from tetanus
- 40 mio. children immunized against DTP+
- 40 mio. immunized against meningitis caused by Men A



DTP-HepB/Hib is the preferred vaccine and an increasing share contains thiomersal...



Data source : UNICEF

Note : 2012 data (estimate)

- 6 pre-qualified vaccines awarded in past three years, all except one containing thiomersal in all presentations
- Strong country product preferences for 10 dose vial due to reduced cold chain requirement, freeing up capacity for introduction of other new vaccines (price driver?)

## Immediate implications on supply, should the INC4 decide that thiomersal in vaccines should be banned...

Based on projections for 2012, a total of 380 mio. doses of thiomersal containing vaccines will be delivered

No WHO pre-qualified vaccines available to protect against DTP, hepatitis B, meningococcal A meningitis, or tetanus

One WHO pre-qualified DTP-HepB-Hib vaccine in 1 dose vial, to ensure the sustainable supply to more than 60 countries

- Fragile market with risks of interruption to programmes due to single source, insufficient supply capacity and time required to scale up capacity
- Up to a four fold increase in capacity requirements for air freight, cold chain and in-country distribution systems – potentially necessitating a delay in planned introductions or a temporary interruption of the roll out of new life saving vaccines

## Current suppliers of thiomersal containing vaccines would need to develop new products to be considered for supply to UNICEF

- Formulation of new vaccines - without preservatives or adding an alternative preservative:
  - Technical feasibility? Potential future issues with alternatives?
  - Requirements for clinical documentation and licensing strategies to be mapped out between suppliers and regulators (lead times + 2-5 years?)
- In case of recommendation of preservative free vaccines to be supplied in single dose presentations:
  - Scaling up of filling and packaging capacity with suppliers (lead times + 2 years?)
  - Expansion of cold chain and logistics from supplier to health facility
- Development costs and increased production costs to be reflected in prices – therefore, no guidance from current UNICEF prices

## In summary

### UNICEF

- Strives for the survival, health and well-being of children – contributing to global immunization is an important measure towards this end
- Fully supports continued efforts to ensure quality and safety of vaccines and rely on WHO's guidance
- Expects that any guidance provided will be evidence driven, balancing the relative risks and benefits of alternative options, factoring in disease burden and supply implications
- Cautions that should evidence lead to a ban on thiomersal, a transition plan should consider the best solution for children, both short and long term – and ensure and encourage a supply market to enable continued access to immunization under a new framework
- Irrespective of the outcome of this process, communication strategies and messages require careful consideration

Thank you