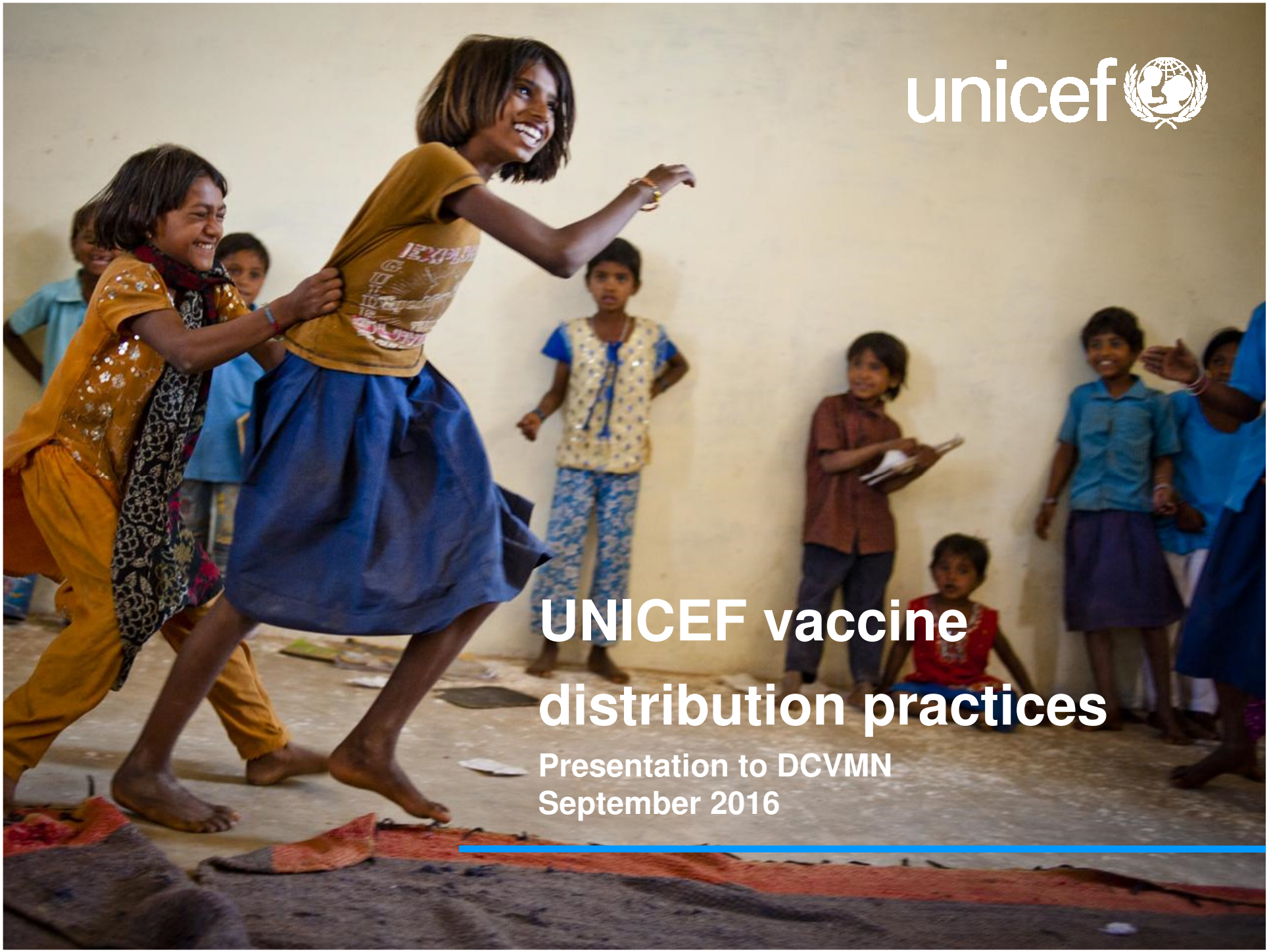


UNICEF vaccine distribution practices

Presentation to DCVMN
September 2016

Agenda

- Overview of vaccine distribution through UNICEF
- Requirements as indicated in tenders and subsequent agreements
- Ensuring quality throughout Procurement to delivery process:
  - ✓Procurement & solicitation
  - ✓Delivery
  - ✓International Shipment
  - ✓Vaccine arrival process
- Policy, guidelines and reference materials as a basis for UNICEF's requirements

Objectives of the session

- To provide an overview of UNICEF vaccine procurement
- To update vaccine manufacturers on requirements for Good Distribution practices for international shipments through UNICEF

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

2015	Vaccines Supplies: US$ 1.72 billion	2.80 billion doses	2,491 shipments

Immunization Supplies

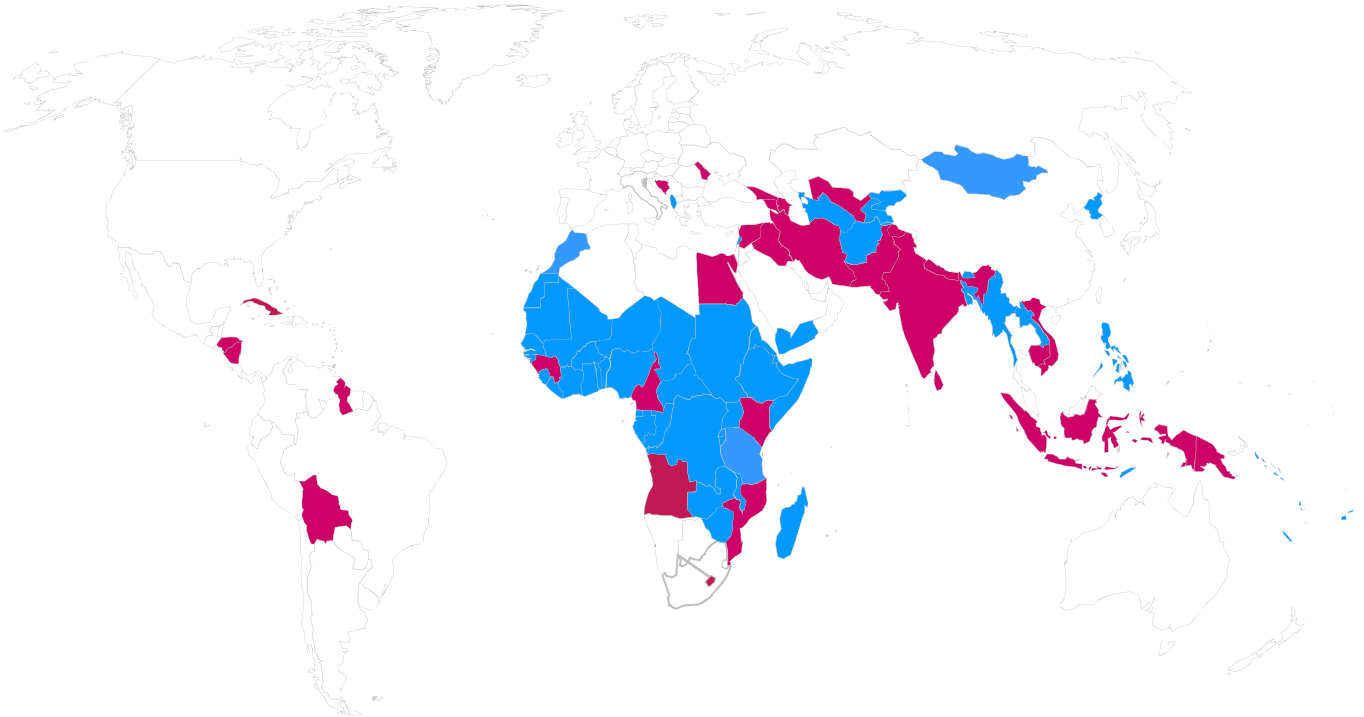
Vaccines
BCG, DTP, TT/Td/DT, Measles containing, OPV, HepB, YF, DTP-HepB, DTP-HepB/Hib, DTP/Hib, Hib, MR, Meningitis, MMR, PCV, RV, IPV, HPV, etc.

Safe Injection equipment

Cold Chain Equipment

Countries UNICEF procures on behalf of

- Full schedule
- Partial schedule

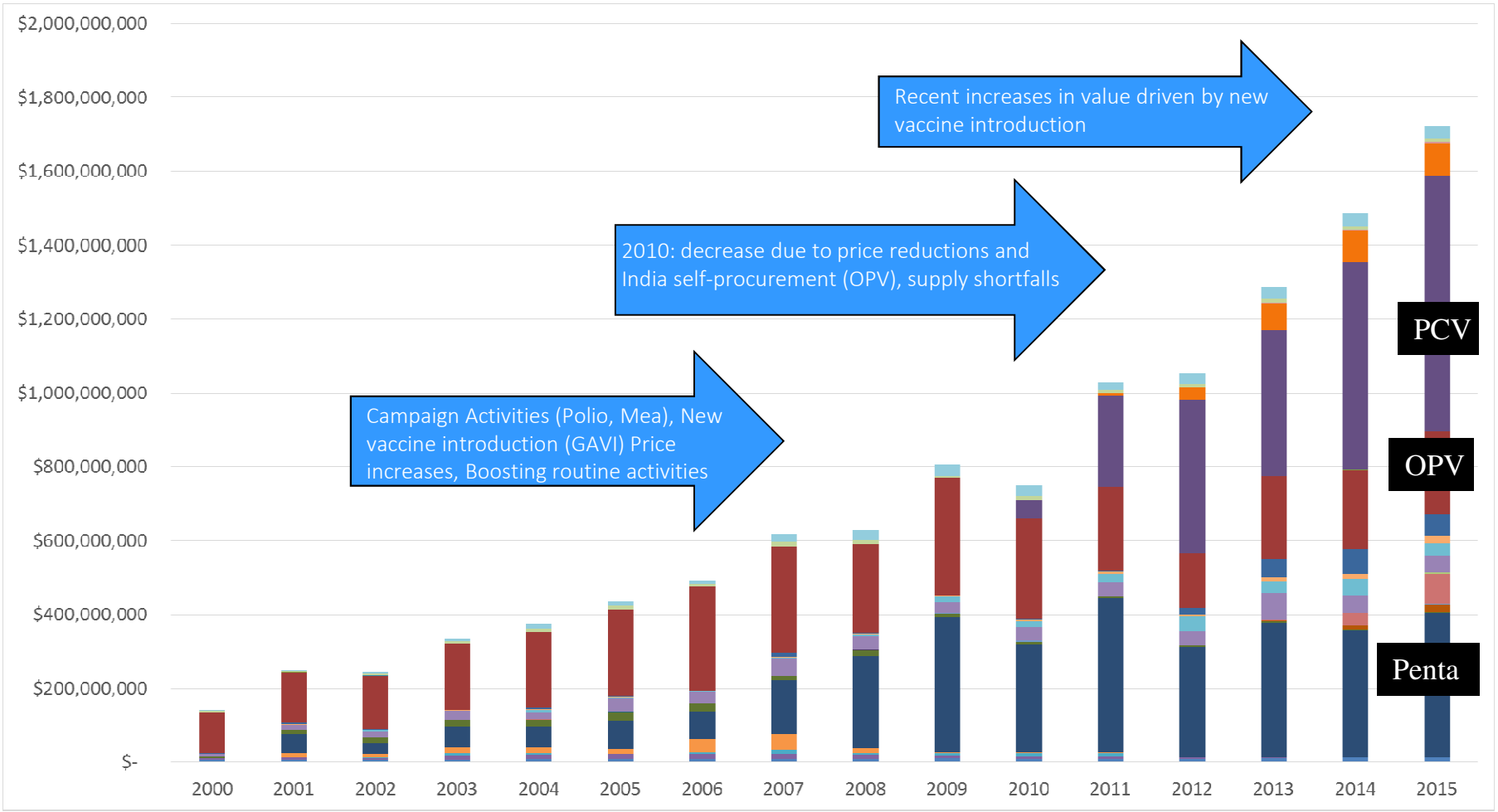


Source: UNIICEF Supply Division

Vaccine Centre: 2015 in Summary

- 2,112 purchase orders created
- 2,564 purchase order Item lines
- 2,491 shipments delivered
- 2,219 VARs received
- 2.8 billion doses shipped
- USD $1.71b procurement
- USD $34m in freight
- 6 million Kgs freight
- 24 suppliers
- 15 origin countries
- 103 recipient countries
- 2 freight forwarders

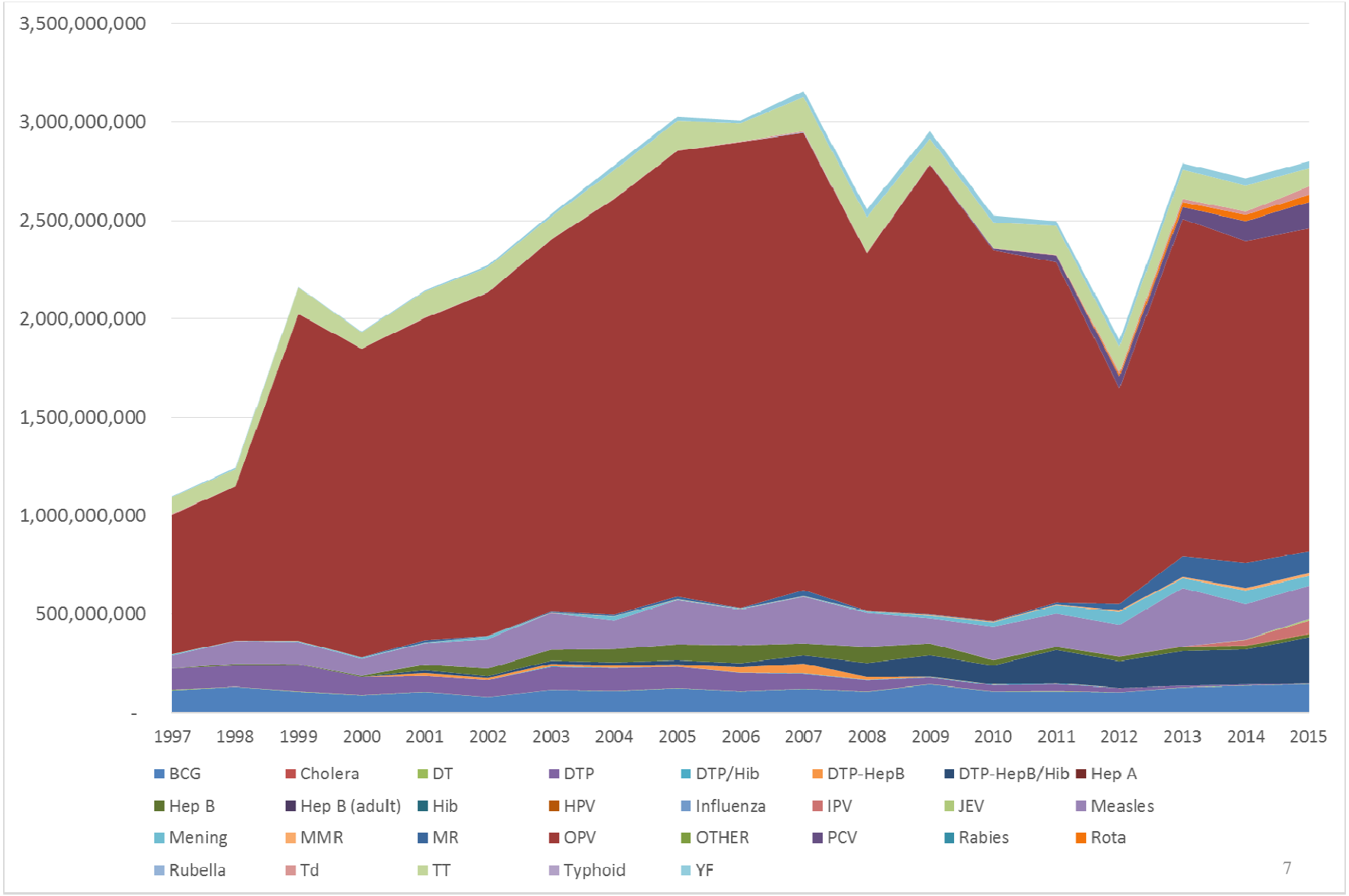
Annual vaccine procurement increased significantly since 2000 supporting UNICEF Programmes and on behalf of Partners, Global Programmes, Governments and NGO's



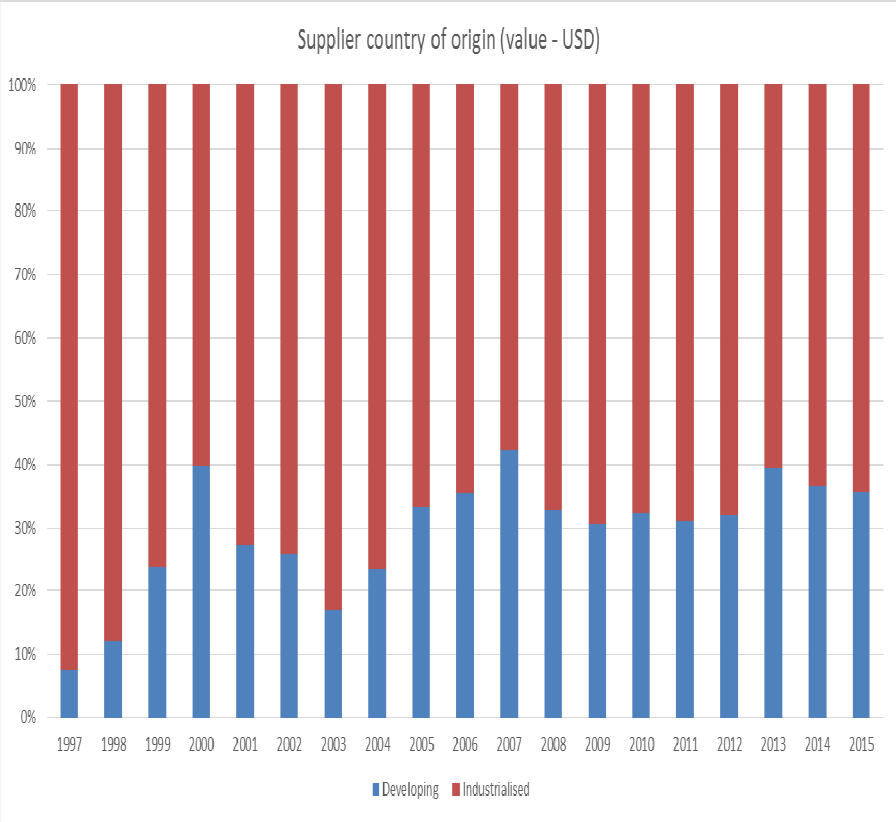
The arrows indicate the main programme drivers for the increased procurement value.

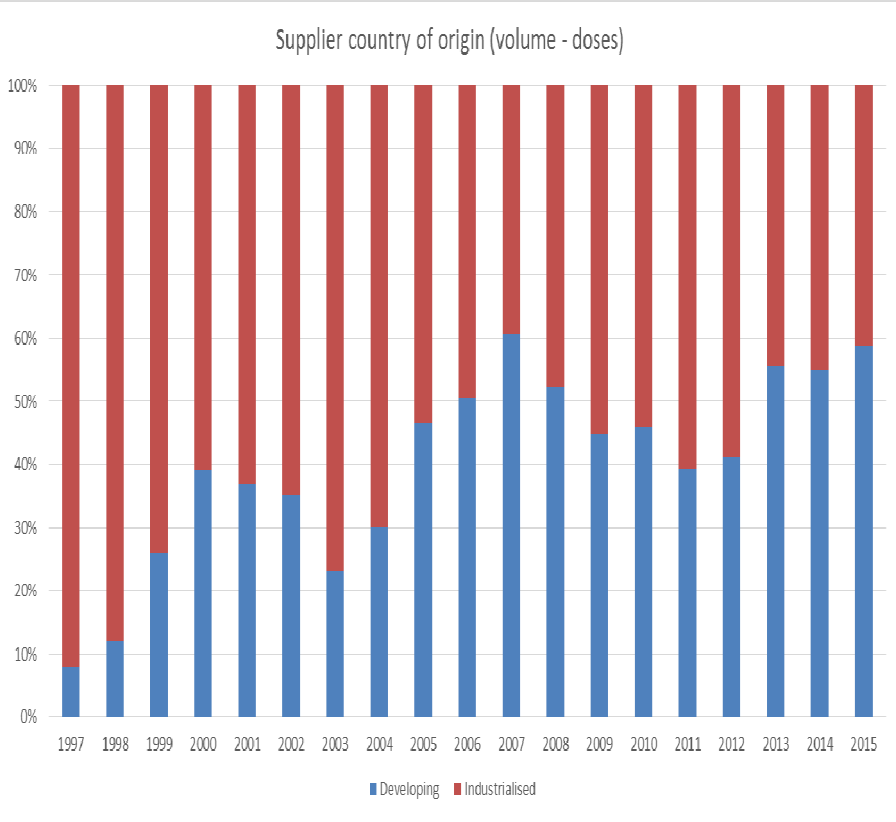
Source UNICEF Supply Division

Volumes by type of Vaccine procured through UNICEF 1997-2015



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

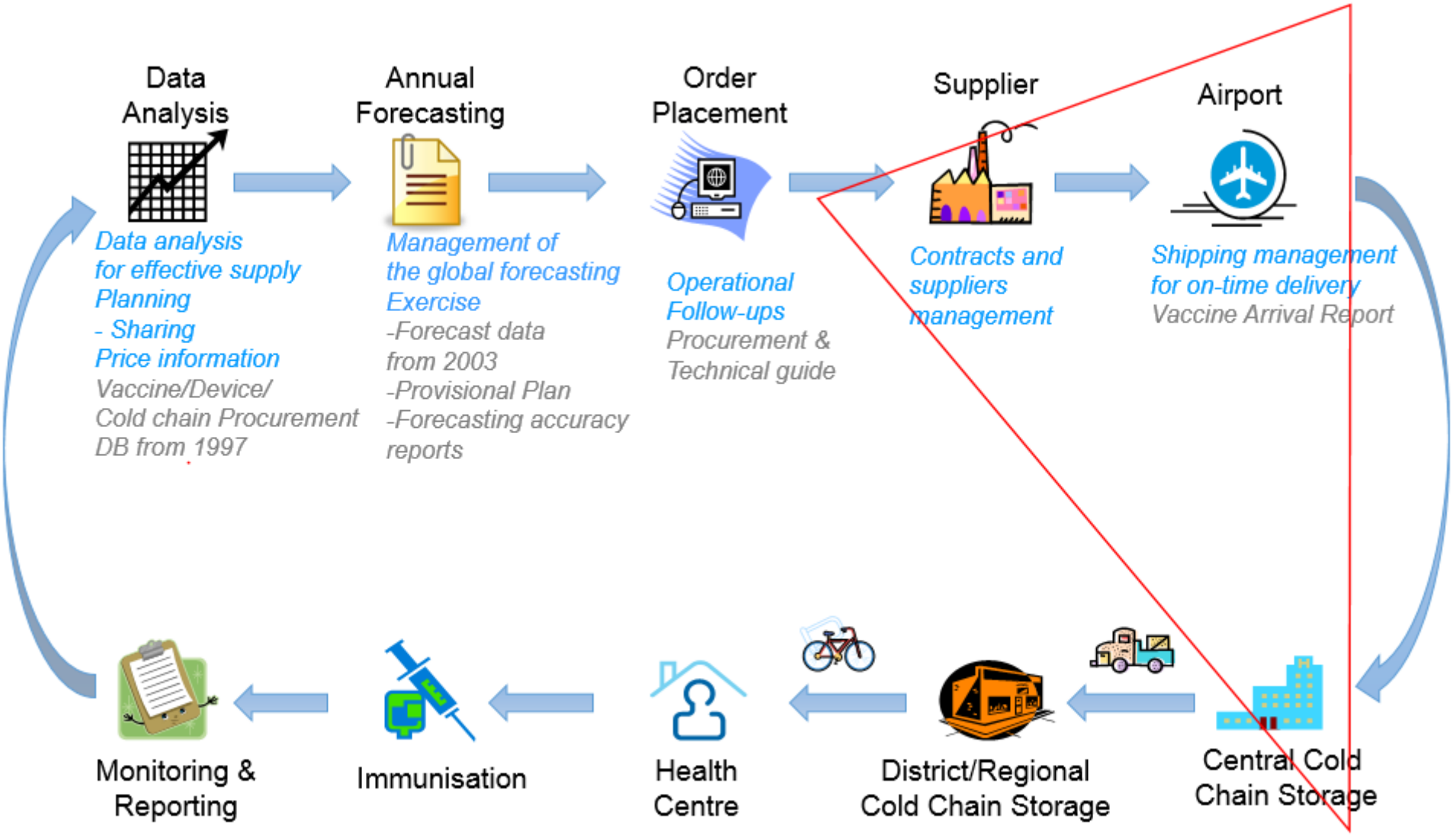




- 36% of the value being delivered by manufacturers with a production base in developing countries
- 59% of quantities delivered by manufacturers with a production base in developing countries

Source UNICEF Supply Division

UNICEF Supply Division Vaccine Center - main roles & resources in the Supply Chain



WHO Good Distribution Practice

WHO Good Distribution Practices for pharmaceutical products, Annex 5 of TRS 957, 2010

Good distribution practices (GDP)

- That part of quality assurance that ensures that the quality of a pharmaceutical product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded pharmaceutical products.

General principles

- All parties involved in the distribution of pharmaceutical products have a responsibility to ensure that the quality of pharmaceutical products and the integrity of the distribution chain is maintained throughout the distribution process from the site of the manufacturer to the entity responsible for dispensing or providing the product to the patient or his or her agent.
- The responsibility for applying and verifying GDP standards during transportation is with the wholesaler or manufacturer of the medicinal product

Ensuring the integrity of the distribution chain and quality of vaccines from supplier to port of entry

Ensuring Vaccine quality starts with the procurement process

- Registration to the United Nations Global Market place – financial assessment by UNICEF's Quality Assurance Supplier Evaluation Unit
- Procurement of WHO pre-qualified vaccines - ensuring the quality, efficacy and safety of products
- Information on country of origin of products offered, Certificate of Origin of Goods by Chamber of Commerce
- Submission of samples – vaccine vial, closure, label, insert, inner box – for WHO PQT assessment
- Where WHO GMP requirements are not detailed enough other international guidelines shall be followed – EU, PDA, USP – and justification for use, and WHO will assess against such
- Lot release certificates required for each lot by the NRA of country of manufacture/NRA of record
- Purchase orders placed directly with vaccine manufacturers – reduces risks of counterfeits
- Access to warehouse facilities to assess/reassess packaging and storage
- Long term supply agreements – ensures mutual accountability and commitment
- Vaccine Vial to be fitted with Vaccine Vial Monitors, compliant with WHO PQS Performance Specifications

Ensuring the integrity of the distribution chain and quality of vaccines from supplier to port of entry

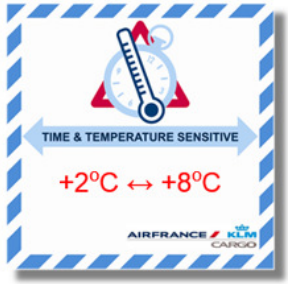
Handover from Supplier to Freight Forwarder

- FCA Origin Incoterm between Supplier & UNICEF (or designated Freight Forwarder), direct delivery reduces risks of counterfeits and assures cold chain quality
- SOP document detailing responsibilities of Supplier and Forwarder incl labelling, documents, trucking, customs clearance, agreed packaging standards
- **UNICEF LTA with Freight Forwarder**
- Requirements for use of "Prime Carriers" (Class A airlines) & airports for vaccines:
  - Reliable temperature control facilities (+2 to +8 deg C, and -15 to -25 deg C)
  - 24/7/365 customer care
  - Door to door monitoring
  - Lane & carrier risk assessment for every shipment
  - Document management
  - Ability to re-ice where necessary – Dry Ice and ice packs
- Transit must not exceed 48 hours from airport of origin to airport of unloading (unless agreed by UNICEF)
- Direct flights where possible, and trans-shipment only through airports with cold storage or with a temperature climate, where necessary
- Arrival outside of weekends / public holidays
- Documents for Import Customs clearance including NRA release certificates to be supplied to consignee at least **7 days** in advance of shipment arrival

Ensuring the integrity of the distribution chain and quality of vaccines from supplier to port of entry

Temperature Control during Air Transport

- WHO Guidelines - Electronic Time & Temperature Monitoring Devices in each individual shipping carton
- Use of 'Prime Carrier' airlines ensure onboard cargo hold cooling ensuring temperature management during air transport and at transhipment airports
- OPV Dry Ice coolant – use of Cold Chain card (battery in device does not function at -25 deg C)
- IATA regulations for temperature labelling to match AWB



Delivery at Destination – Vaccine arrival and inspection

- Vaccine Arrival Report (VAR) is required by WHO to be completed by consignee and returned to SD for every UNICEF international shipment upon arrival & inspection
- Provides a record of cold chain conditions during transport and of compliance with Shipping Instructions
- To be submitted by consignee to UNICEF CO within 72 hours
- SD are responsible or follow up with Supplier, Freight Forwarder, WHO or other party for taking appropriate action as required
- VAR Mobile App project update


HAUT
+2°C to +8°C
152 / 177
BAS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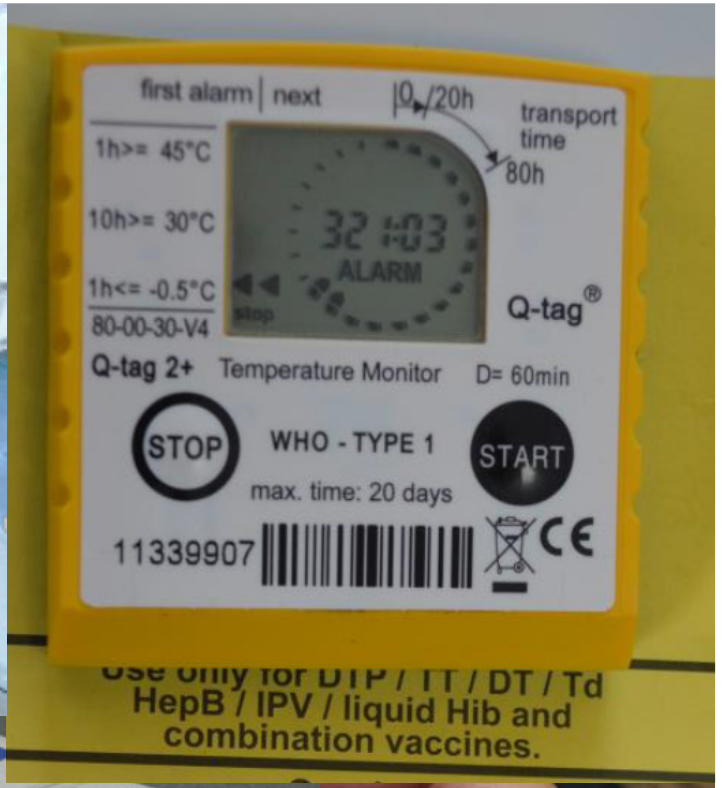
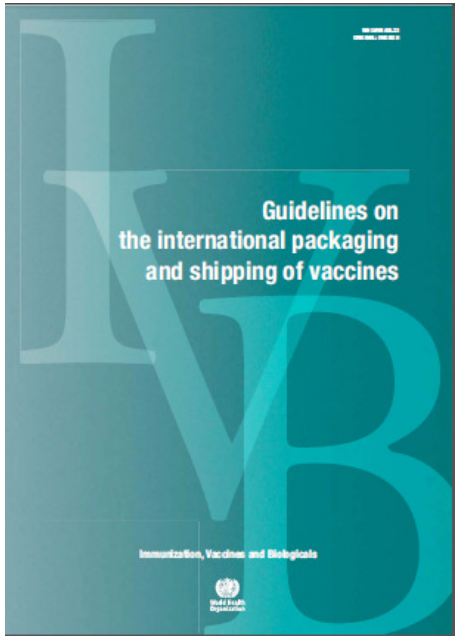

first alarm | next
0 / 20h
transport time
80h
1h>= 45°C
10h>= 30°C
1h<= -0.5°C
80-00-30-V4
32 h 03
ALARM
Q-tag®
Q-tag 2+ Temperature Monitor D= 60min
STOP
WHO - TYPE 1
START
max. time: 20 days
11339907
HepB / IPV / liquid Hib and
combination vaccines.


UP
OPEN HERE

WHO Guidelines for the International Packaging & Shipping of Vaccines (WHO/IVB/05.23)

Requirement of Manufacturers, Forwarders, consignees to adhere to guidelines listed in WHO/IVB/05.23*:

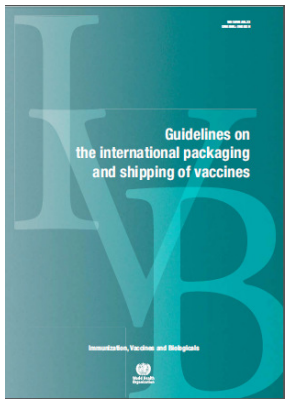
- Vaccine Packaging – validation of temperature control inside carton at defined ambient temperatures
- Temperature monitoring requirements – electronic devices
- Storage Volume Standards - vaccine volume per dose
- Labelling and Packaging – vial/ampoule, carton markings
- Shipping procedures – Routing, shipping docs, LRC, AWB
- Vaccine Arrival Report process – VAR form
- Shake Test protocol instructions for freeze sensitive vaccines



**Publication is currently under review by the Packaging Working Group led by WHO PQT including recipient country survey on shipments of vaccines packaged in Pallet Shippers*

Other standards - Vaccine shipments by Air

- WHO Vaccine Management Handbook (EVM) – Monitoring Temperatures in the Vaccine Supply Chain WHO/IVB/15.04
- IATA Perishable Cargo Regulations (PCR) Chapter 17 - Time and Temperature sensitive health care products for air transport - packaging, labelling, handling, staff training, risk mitigation, CAPA
- IATA CEIV – Centre for Independent Validators for Pharmaceutical Handling advocates GDP related globally accepted standards and regulations, provides training and certifies operators in aviation industry
- New contract for Global Freight Forwarding services effective 1 Dec 2016. Technical evaluation included compliance with GDP principles



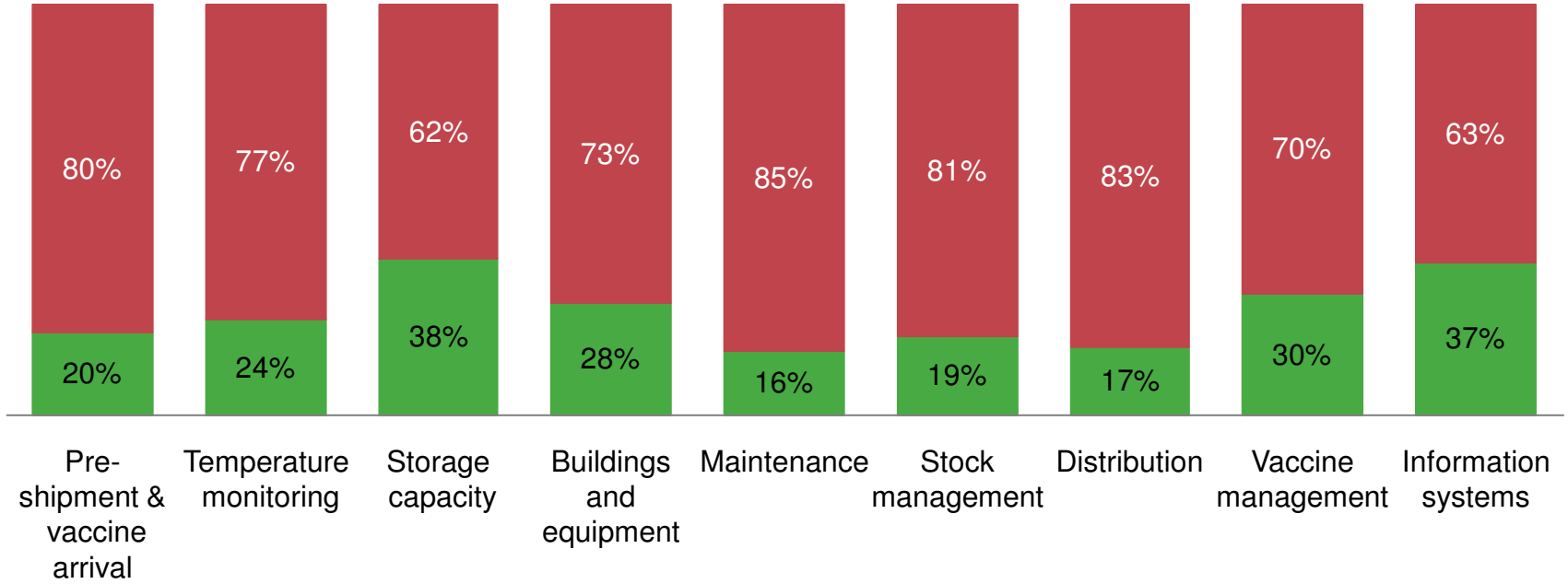
KNPharmaChain
Air GXP Compliant

AIRFRANCE KLM
Martinair CARGO

EXCELLENCE IN PHARMACEUTICAL LOGISTICS
IATA
CEIV
PHARMA

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

% of countries that reach 80% target on relevant supply chain WHO standards[1]



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

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Thank you

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