

Vaccine Presentation and Packaging Advisory Group (VPPAG)

Barcoding Subgroup
Rich Hollander (co-chair)





In spite of our technical advances – (including space travel)



**The world is not on track to achieve its
commitment to a 67% reduction in child
mortality by 2015**



In many communities, more than one in ten children die before their fifth birthday, from preventable diseases



Simple interventions can shift the balance from death to life for millions of children each year like...



Clean water



Adequate Nutrition



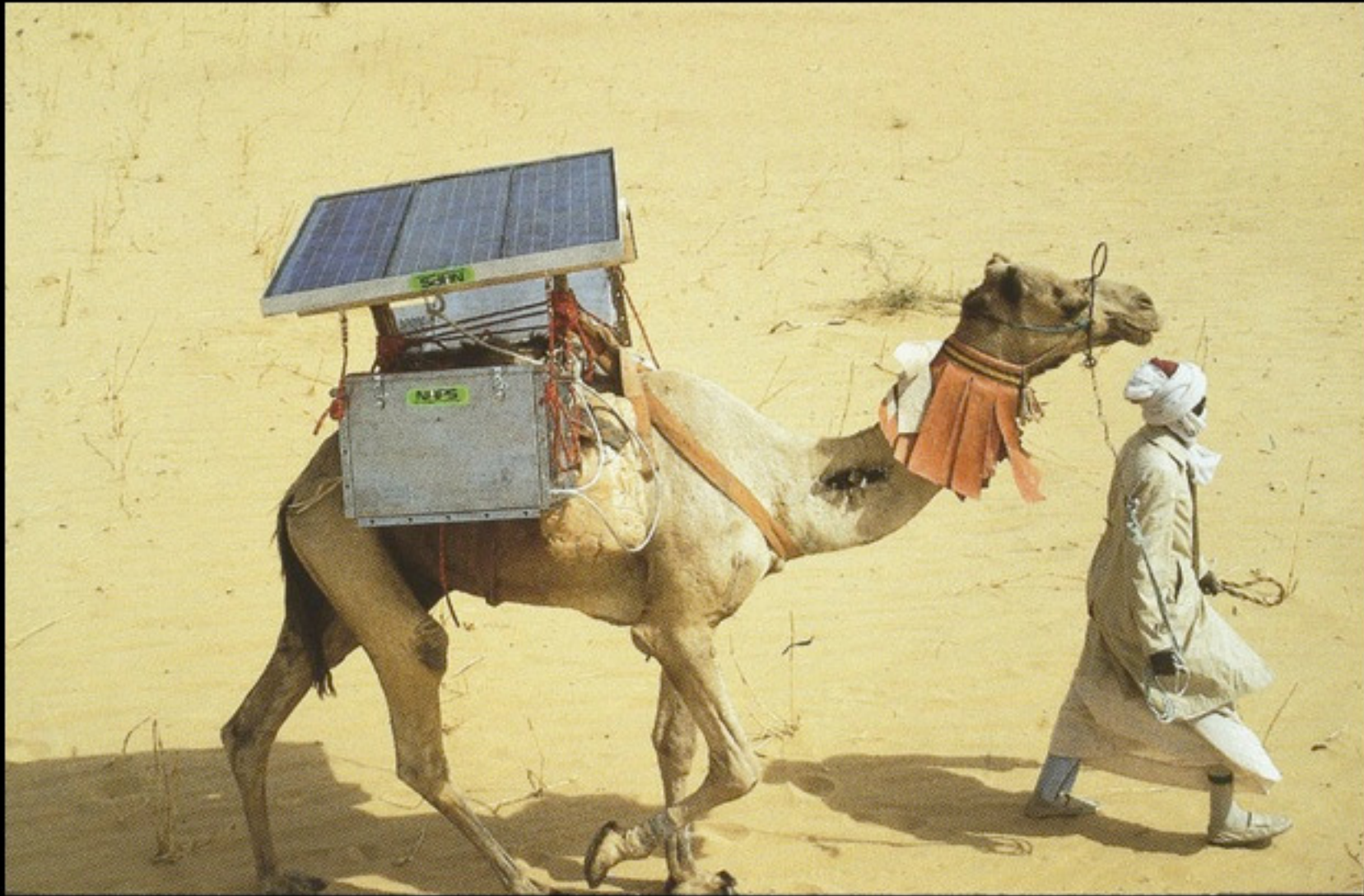
Immunization

New vaccines offer hope against the two leading child killers – pneumonia and diarrhea





But vaccines are not reaching those most in need



New technologies can help us...and this includes the presentation & packaging of vaccines

Vaccine Presentation and Packaging Advisory Group



- Background
 - Established in 2007 by the GAVI Alliance to aid with questions from industry on rotavirus and pneumococcal vaccine product attributes
 - WHO and UNICEF assumed responsibility in 2008 and expanded scope to all vaccines
- Purpose
 - Serves as a forum for industry and public-sector dialogue and consensus-building on presentation and packaging of vaccine products.
 - Responds to industry requests for guidance on specific product presentation issues.
 - Facilitates improvements in presentation and packaging of vaccine products through development of preferred product profiles.

Representative Organizations



International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

The United Nations Children's Fund (UNICEF) Programme Division

John Snow, Inc.

World Health Organization (WHO), Expanded Programme on Immunization (EPI); Immunization, Vaccines and Biologicals (IVB)

PATH

WHO Quality, Safety, and Standards (WHO/QSS)

Developing Countries Vaccine Manufacturers Network (DCVMN)

UNICEF Supply Division

Bill & Melinda Gates Foundation

United States Centers for Disease Control and Prevention

GAVI Secretariat

Updating Generic Preferred Product Profile Product Profile for Vaccines

Pfizer GLOBAL SUPPLY

Topics include:

- Vaccine container dimensions and volumes
- Bundling multicomponent vaccines
- Doses per container
- Labeling for higher-temperature storage

Update will cover:

- Pack volumes and harmonization
- Bundling of multi-component containers
- Environmental packaging
- Compact, prefilled auto-disable syringes
- Labeling for higher temperature storage



Work Area – Label Standardization

Pfizer GLOBAL SUPPLY

Potential new guidelines for vaccine product labels based on VPPAG recommendations.*

Focus on:

- Expiry date format (mm-yyyy)
- Standard generic names for vaccines
- Minimum font size and type
- Minimum viewing area
- Consistent layout

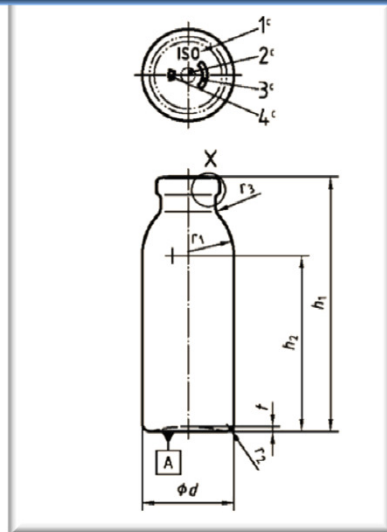


*Recommendations will be endorsed by WHO's Immunization Practices Advisory Committee and Expert Committee on Biological Standardization (Target Q2 2015)

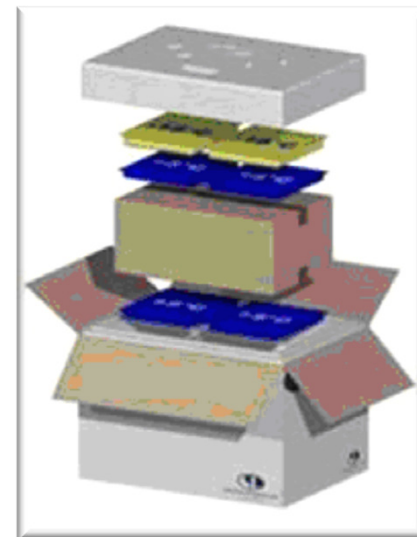
Harmonization Working Group

- To make best use of the limited storage space by having harmonized packs & appropriate pack sizes for different levels of supply chain

Vaccine Container Dimensions



Insulated Shipping Containers



VPPAG Barcode Working Group

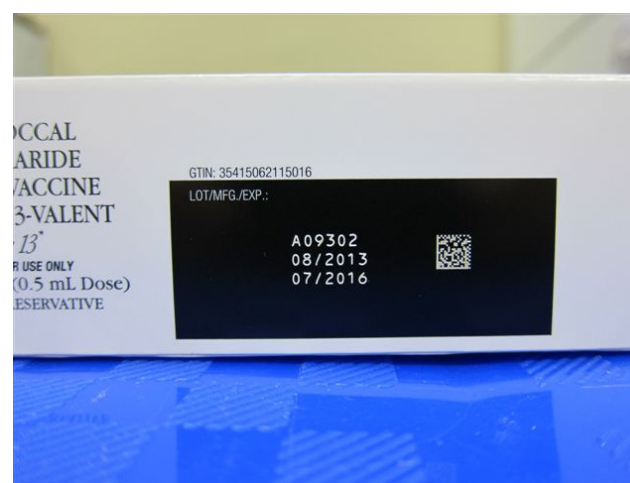
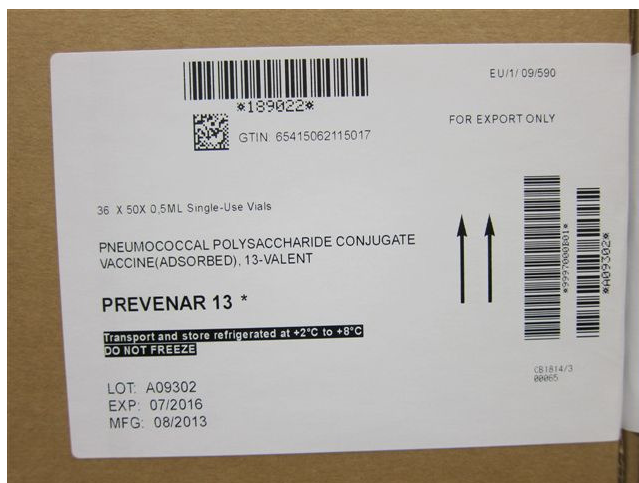


- Established 2011
- Barcoding becoming prevalent for medicinal products to improve Inventory Visibility and patient safety in developed markets
- How to leverage for vaccines in Developing Markets
- Challenges – Data Definition, Structures, symbologies; Investment into Marking Technologies; Integration into existing systems in the field
- Alignment to Global Standards Critical
 - Lead Healthcare Need in Developing Markets
 - Key to Meeting Future Needs driven by Future Health Authority Policies



Barcode Working Group Recommendations

- Bar codes are recommended on all packaging levels used by manufacturers, with the exception of the primary packaging level, and should conform to GS1 standards and associated specifications.
- Bar code data should include the Global Trade Item Number (GTIN), lot number, and expiry date.



Barcode Working Group

Next Steps



- With Markings Agreed, Support Proof of Principal Project in Tanzania
 - Pfizer, Serum Institute of India, GSK, Sanofi-Pasteur
- Develop Implementation Guideline
 - “How to” Direction for details
 - Data, Data Structures and Symbologies
 - Print Quality Requirements
 - Human Readable Information
- Scale to other Regions/Markets