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

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<th>Organization</th>
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<tr>
<td>International Federation of Pharmaceutical Manufacturers &amp; Associations (IFPMA)</td>
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<td>The United Nations Children's Fund (UNICEF) Programme Division</td>
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<td>John Snow, Inc.</td>
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<td>World Health Organization (WHO), Expanded Programme on Immunization (EPI); Immunization, Vaccines and Biologicals (IVB)</td>
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<td>PATH</td>
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<td>WHO Quality, Safety, and Standards (WHO/QSS)</td>
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<td>Developing Countries Vaccine Manufacturers Network (DCVMN)</td>
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<td>UNICEF Supply Division</td>
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<td>Bill &amp; Melinda Gates Foundation</td>
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<td>United States Centers for Disease Control and Prevention</td>
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<td>GAVI Secretariat</td>
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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
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
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 Heath Authority Policies
• 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