Vaccine Presentation and Packaging Advisory Group (VPPAG)

DCVMN, Hanoi 8 October 2012

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Outline

A. Programme Context
B. History
C. Role in WHO advisory structures
D. Composition
E. Workplan
F. DCVMN participation and inputs
In spite of our technical advances (including space travel)
The world is not on track to achieve its MDG 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...
New vaccines offer hope against the two leading child killers – pneumonia and diarrhoea
But vaccines are not reaching those most in need
New technologies can help us...and this includes the presentation & packaging of vaccines
More and more vaccines to deliver
New vaccines: more money & space

- A refrigerator full of 4,100 doses of traditional vaccine valued at US$635.50 compared to a refrigerator full of 625 doses of a new vaccine valued at US$4,687.50.
- The value of vaccines in the refrigerator on the right is worth more than the refrigerator itself.


**Based on US$0.155 per dose for polio and measles and US$7.50/dose for Rotarix.
History

• Established by GAVI in 2007
  • “How many doses per vial?”
• WHO convened from 2008
  • No formal standing
  • Link to policy through WHO Immunization Practices Advisory Committee (IPAC)
• History of VPPAG described in January 2013 edition of the WHO Bulletin: www.who.int/bulletin/volumes/91/1/12-110700.pdf
• Impact of work described in Sep 2013 Optimize newsletter available at http://www.path.org/projects/project-optimize-newsletter
Composition

• Industry
  • DCVMN
  • IFPMA
• Public Sector
  • CDC
  • GAVI Secretariat
  • JSI/MCHIP
  • WHO (EPI + QSS)
  • UNICEF (PD +SD)
• Donor
  • BMGF

Chair: Michel Zaffran
zaffranm@who.int

Secretary: Dmitri Davydov
ddavydov@unicef.org

Monthly calls: 2nd Tuesday

Active subgroups:
• Barcodes
• Harmonization
Role of VPPAG (TORs)

• 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.

VPPAG documents including Terms of Reference (TORs) available at http://www.who.int/immunization_delivery/systems_policy/vppag/en/index2.html
VPPAG relation to WHO advice

ADVISORY BODIES
- Strategic Advisory Group of Experts (SAGE)
- Expert Committee on Biological Standardization (ECBS)
- Immunization Practices Advisory Committee (IPAC)
- Programmatic Suitability of Prequalification (PSPQ) Standing Committee
- Vaccine Presentation and Packaging Advisory Group (VPPAG)
- Other technical advisory groups

WHO ORGANIZATIONAL UNITS
- World Health Organization
  - Family, Women, and Children's Health
    - Immunization, Vaccines, and Biologicals
    - Vaccines Prequalification
  - Manufacturers, Purchasers, Regulators
  - Manufacturing country regulatory authorities

EXTERNAL RESOURCES

Recommendations and guidance
Discussion and guidance
Vial label: VPPAG advice

New recommendations being presented to WHO ECBS this year, based on VPPAG advice (through IPAC):

- Generic names for vaccines
- Standard expiry date format (mm-yyyy).
- Minimum font size and type.
- Minimum viewing area.
- Consistent layout
- (barcode)
Workplan 2013

Continuation of 2012 work:
- Barcode
- Updating the gPPP
- Harmonization
- Responding to requests
Barcode Group

• Multiple partners – work in Tanzania
• Opportunity to join group for all DCVM members
• Recent survey of industry.
• GS1 supporting this group

Sanofi Pasteur vaccine with GS1 2D DataMatrix bar code.

Photo credit: CNW Group/SANOFI PASTEUR.
Updating Generic Preferred Product Profile for Vaccines

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
Harmonization Group

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

• Group includes packaging experts from several companies (more welcome!)

• Led by Andrew Garnett who did comprehensive review of current vial and pack sizes
### Volume utilization: RCW 25 cold box with five vaccines

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Mfr</th>
<th>Presentation (doses)</th>
<th>Doses per carton</th>
<th>Carton orientation</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>Japan BCG</td>
<td>20</td>
<td>2000</td>
<td>Z: 42% YZ: 49% XYZ: 63%</td>
</tr>
<tr>
<td>BOPV</td>
<td>GSK</td>
<td>20</td>
<td>2000</td>
<td>Z: 47% YZ: 66% XYZ: 75%</td>
</tr>
<tr>
<td>Penta</td>
<td>Crucell</td>
<td>1</td>
<td>50</td>
<td>Z: 50% YZ: 76% XYZ: 78%</td>
</tr>
<tr>
<td>Measles</td>
<td>SII</td>
<td>10</td>
<td>500</td>
<td>Z: 61% YZ: 82% XYZ: 87%</td>
</tr>
<tr>
<td>TT</td>
<td>Biofarma</td>
<td>10</td>
<td>100</td>
<td>Z: 82% YZ: 82% XYZ: 82%</td>
</tr>
</tbody>
</table>

<table>
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<th>Min</th>
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<td>87%</td>
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</table>

**BCG**

**bOPV**

**Penta**

**TT**

**Measles**

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Five secondary cartons from five manufacturers.

*No common dimensions!*
**Problem:** Secondary cartons too *small* an SKU

**Result:** Stock control failures

**Solution:** Tertiary cartons the correct SKU at this level

**But:** Not universally offered
**Problem:** Secondary cartons often too large an SKU

**Consequences:**
- Loose vials
- No package insert

**Problem:** Loose vials leading to damaged labels and discarded vials
Interrelationships driving packaging choices

KEY
- Manufacturer choices
- Standards and regulatory landscape
- Public sector preferences
- Future preferences

Public sector carton preferences
- Number of secondary cartons
- Secondary carton layers

WHO 'Shipping Guidelines'
- Transport route profile
- Insulation type/thickness
- Coolant requirements
- Secondary/tertiary carton layers
- Number of secondary/tertiary cartons

Regulatory requirements

Public sector gPPP preferences
- Presentation
  - Dose size
  - Number of doses
  - Overfill
  - Headspace

TERTIARY CARTON
- Carton height
- Carton footprint

Shipping carton
- Carton height
- Carton footprint

PRIMARY CONTAINER
- Primary container height
- Primary container diameter

SECONDARY CARTON
- Carton height
- Carton footprint

PALLET
- Pallet dimensions

Container standards (ISO 8362, 9187)
- Container supplier choice

Public sector labelling preferences

Container supplier standards

Packaging line constraints

Primary container array arrangement (90°/60°)
- Primary containers per carton
- Primary container layers per carton

Customer preferences

Manufacturer's warehouse standard

Customer preferences

Pallet standards

Air container standards
DCVMN participation

• DCVMN members encouraged to join VPPAG dialogue and groups through their representatives:
  • Inderjit Sharma nderjit.sharma@seruminstitute.com or
  • Gisele Corrêa Miranda Gisa@bio.fiocruz.br

• The public-sector members of the VPPAG are available for consultations with industry about product profile issues.

• Contact Chair zaffranm@who.int, Secretary ddavydov@unicef.org, or me omansoor@unicef.org