

VACCINE PRESENTATION AND PACKAGING ADVISORY GROUP (VPPAG)



UPDATE FOR TECHNET

BANGKOK, 15 MAY 2015

DEBBIE KRISTENSEN, PATH

VPPAG Mission

VPPAG provides a platform for industry and the public sector to engage in constructive dialogue on the presentation, packaging, and delivery of vaccine products in order to harness new innovation and maximize the appropriateness of immunization products for public-sector use.

The VPPAG process aims to sensitize industry to developing-country programmatic preferences and operational realities, and sensitize the public sector to industry constraints and economic realities.



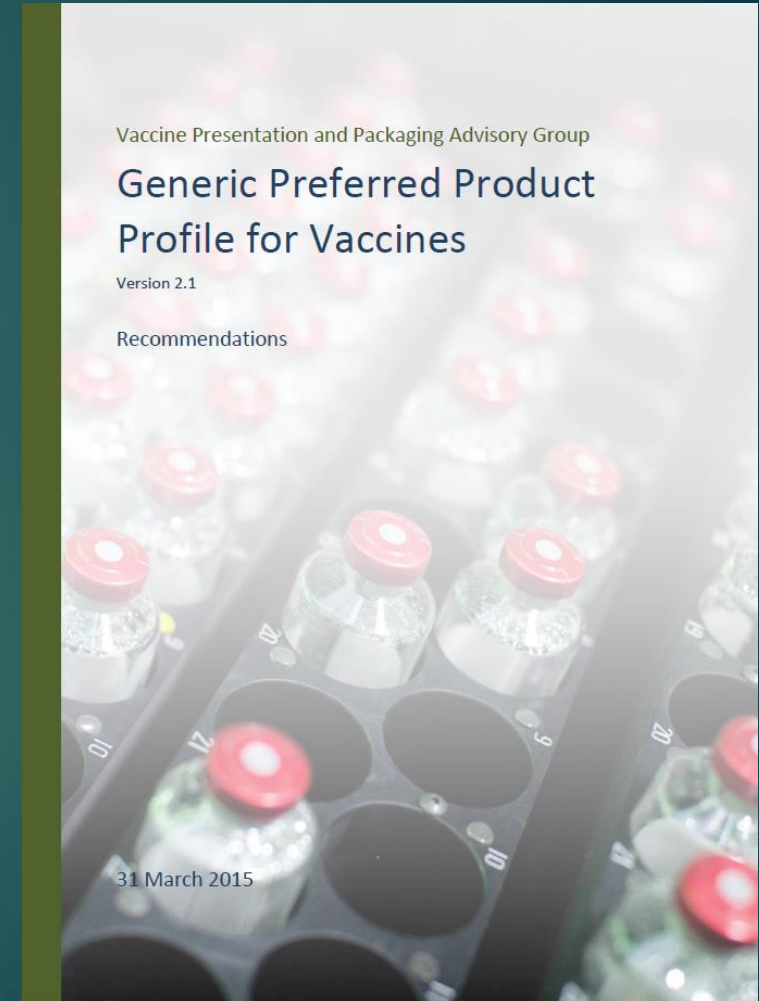
Current VPPAG Members

Organization	Main and Alternate Representatives
Bill & Melinda Gates Foundation	Kristina Lorenson, Raja Rao
Developing Countries Vaccine Manufacturers Network (DCVMN)	Inderjit Sharma (Serum Institute of India, Ltd.), Sai Prasad (Bharat Biotech), Fernando Lobos (Sinergium Biotech)
Gavi, the Vaccine Alliance, Secretariat	Lauren Franzel, Ed Baker
International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)	Sy Gebrekidan (Merck), Andrea Arancibia (Sanofi Pasteur)
John Snow, Inc.	Ousmane Dia, Robert Steinglass
Médecins Sans Frontières (MSF)	Florence Fermon
PATH	Debbie Kristensen (Chair), Darin Zehrung
UNICEF Programme Division*	Dmitri Davydov (Secretary)
UNICEF Supply Division	Ann Ottosen
US Centers for Disease Control and Prevention	Hardeep Sandhu, Carla Lee
WHO, Immunization, Vaccines and Biologicals, Expanded Programme on Immunization (WHO/IVB/EPI*)	Anna-Lea Kahn, Isaac Gobina
WHO Quality, Safety and Standards (WHO/QSS)	Drew Meek

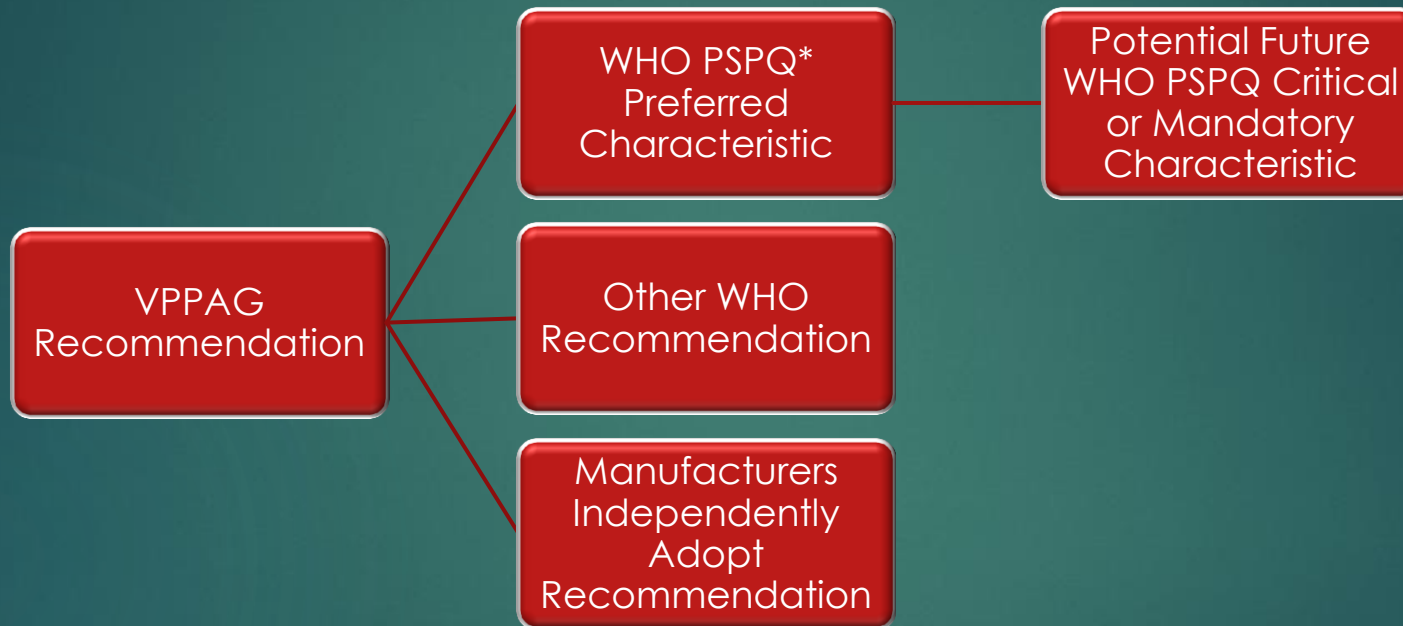
*Convening organization bearing administrative and financial responsibility.

VPPAG Mechanisms of Action

- ▶ Topic specific-working groups to generate/review evidence and advance consensus recommendations.
- ▶ Generating generic preferred product profile recommendations for vaccines.
- ▶ Responding to industry requests for guidance on specific product presentation issues.
- ▶ Serving as a standing subcommittee of the WHO Immunization Practices Advisory Committee (IPAC).

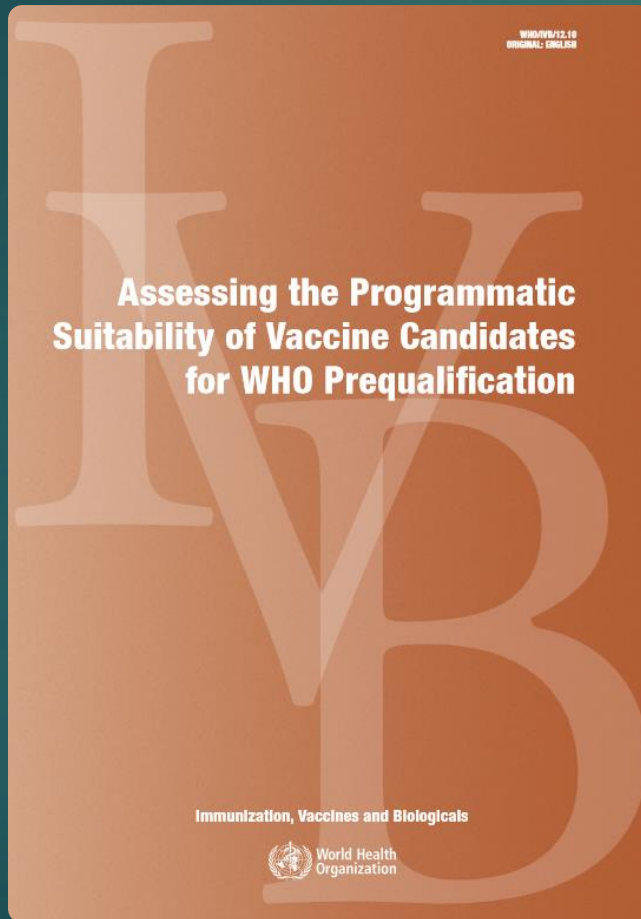


Impact of VPPAG Recommendations



* PSPQ, WHO Programmatic Suitability of Vaccine Candidates for Prequalification.

VPPAG Recommendations in WHO's Programmatic Suitability of Vaccine Candidates for Prequalification (PSPQ)



<http://tinyurl.com/WHO-IVB-12-10>

Table 4: Preferred vaccine characteristics and characteristic values

Characteristic	Applies to...	Value
Maximum packed volume	All vaccines	A smaller packed volume is preferred. Where appropriate, components should be packed/shipped together, e.g. for ready-to-use presentations: pre-filled AD syringe with needle, etc. Packaging devices should be considered, to assure components are shipped together, e.g. vial clip. (WHO EPI, VPPAG gPPP: maximum packed volume; see Guidelines on the international packaging and shipping of vaccines ¹¹ .
Dose volume	Oral vaccines	Smaller volumes and standardized volumes are preferred (WHO EPI).
Doses per primary container, non-campaign setting	All vaccines	Vials with ≤ 10 doses per vial are preferred (WHO EPI, VPPAG gPPP: optimal number of doses per primary container, work programme).
Doses per primary container, campaign setting	All vaccines	Vials with ≥ 0 doses per vial are preferred (WHO EPI).
Doses per secondary container	All vaccines	Should reflect logistics schedule and needs in order to minimize stock accumulation at the peripheral level (WHO EPI).
Process of preparation for administration	All vaccines	Single component/ready to use (e.g. liquid) formats are preferred (WHO EPI). For multi-component vaccines, vaccines with a short and simple preparation process are preferred (WHO EPI).
Thermo stability / storage	All vaccines	Vaccines and diluents that can be stored for extended periods at temperatures above $+8^{\circ}\text{C}$ are preferred (TLAC).
Freeze sensitivity	All vaccines	Vaccines that are not damaged by freezing temperatures ($<0^{\circ}\text{C}$) are preferred (TLAC).
Materials, primary and secondary packaging and injection material	All vaccines	Materials that minimize environmental impact are preferred (VPPAG gPPP: materials).
Secondary packaging, diluents and vaccines	Vaccines requiring reconstitution	Diluents and vaccines should have the same number of doses per secondary container.

Recommendations Influence WHO Guidelines for Vaccine Manufacturers

- ▶ VPPAG recommendations made on content and language requirements for primary containers:
 - ❑ Expiry date format (mm-yyyy)
 - ❑ Standard generic names for vaccines
 - ❑ Minimum font size and type
 - ❑ Minimum viewing area
 - ❑ Consistent layout
- ▶ Recommendations endorsed by WHO's Immunization Practices Advisory Committee (IPAC) and Expert Committee for Biological Standardization (ECBS).
- ▶ WHO advancing recommendations for inclusion in Technical Report Series No. 822.¹



1. See <http://tinyurl.com/pspq2-keyissues>

Recommendations Voluntarily Adopted by Industry

Crucell Quinvaxem®



2nd generation product reduced from 13.1 cm³ to 10.3 cm³ per dose.

GlaxoSmithKline Rotarix™



3rd generation product reduced from 156 cm³ to 12 cm³ per dose.

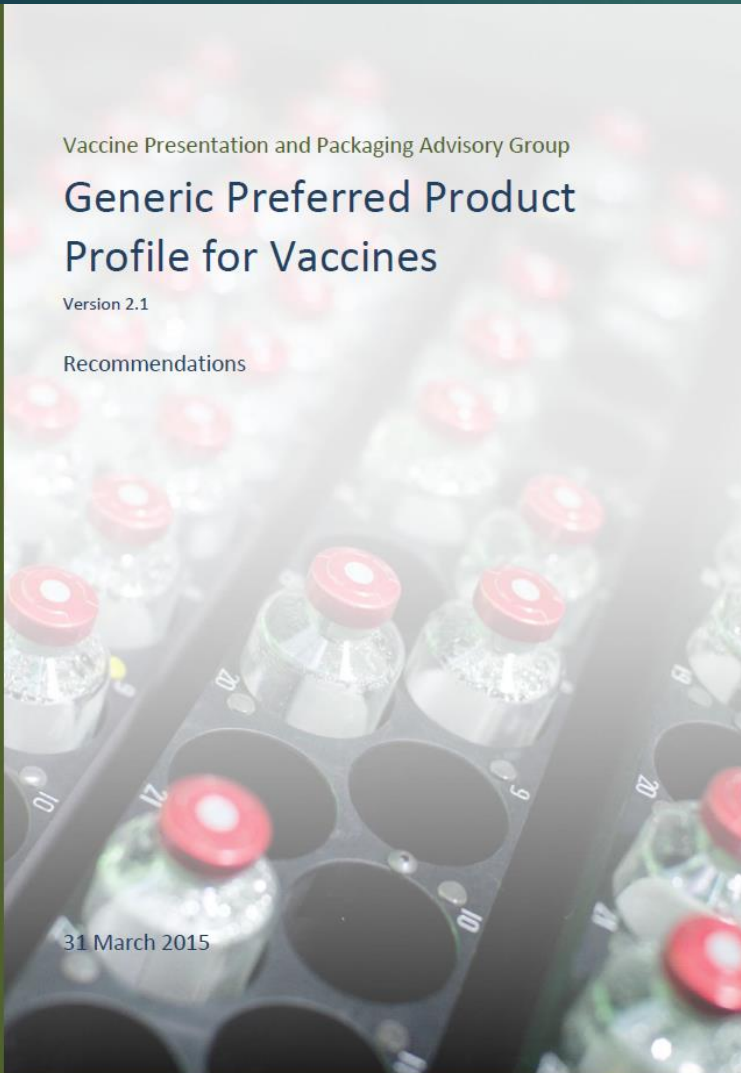
Pfizer Prevenar 13®



2nd generation product reduced from 56 cm³ to 12 cm³ per dose.

Updated Generic Preferred Product Profile

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RECOMMENDATIONS:

Formulation

- ▶ Single- versus multi-component vaccines
- ▶ Heat stability
- ▶ Freeze stability
- ▶ Antimicrobial preservatives

Presentation

- ▶ Product format
- ▶ Container type
- ▶ Prefilled injection systems
- ▶ Doses per primary container
- ▶ Primary container dimensions

Packaging

- ▶ Secondary carton dimensions
- ▶ Tertiary carton dimensions
- ▶ Materials

Labeling

- ▶ Primary container label
- ▶ Vaccine vial monitors
- ▶ Carton and packaging labels
- ▶ Bar codes
- ▶ Package inserts

New Recommendations for Future Primary, Secondary, and Tertiary Vaccine Packaging

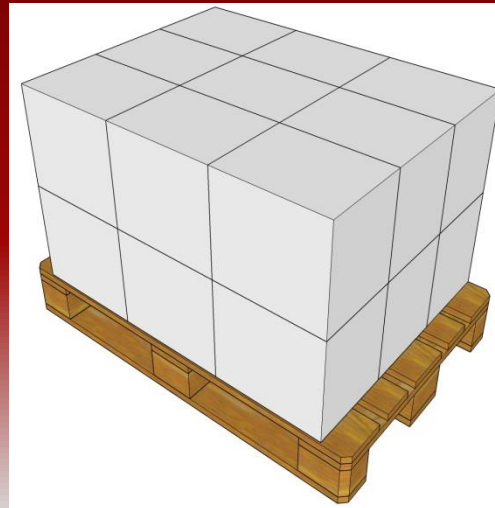
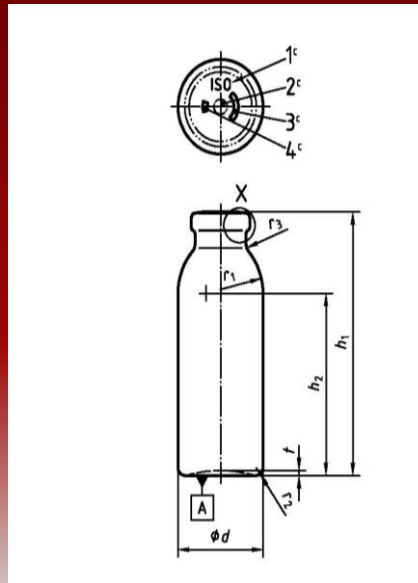
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- ▶ VPPAG working group was led by Andrew Garnett.
- ▶ Movement toward ISO (International Organization for Standardization) standards.
- ▶ Example:
 - ▶ *“For vials: Vaccines in presentations from one to five 0.5 ml doses are recommended to be filled in a ‘2R’ vial conforming to ISO 8362 dimensions. Where technically possible, and if the dose size permits, manufacturers are encouraged to reduce the height of the vial from the current standard of 3.5 cm to 3.1 cm or less, both for reasons of volume reduction and dimensional harmonization.”*



Photo: Crucell, Korea

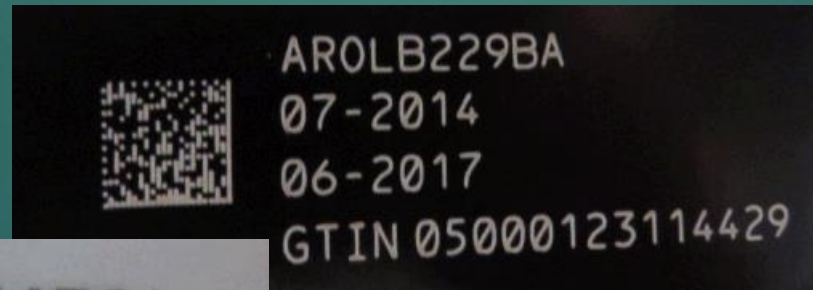
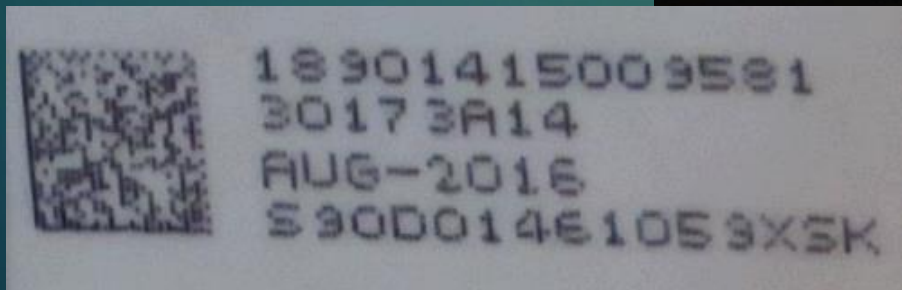
Objective: Harmonization and Reduced Cold Chain Volume Requirements



Source: PATH

Bar Coding

- ▶ VPPAG working group led by Rich Hollander (IFPMA/Pfizer) and Kaleb Brownlow (Gavi) with support from GS1.
- ▶ VPPAG recommends that bar codes should be placed on all packaging levels used by manufacturers, except primary packaging.
- ▶ The barcode should conform to GS1 standards and specifications and encode the Global Trade Item Number (GTIN), batch/lot number, and expiry date.



Ongoing Bar Code Work

- ▶ Pakistan LMIS pilot complete including GS1 bar codes for both vaccines and contraceptives.
- ▶ Majority of vaccine manufacturers included GS1 bar codes on vaccine shipments sent to Tanzania in Q4 2014.
- ▶ With Gavi support, bar code functionality being added to OpenLMIS\ eLMIS for use by Tanzania and other countries.
- ▶ Technical standards for bar codes and guidance document for implementation developed.



Current VPPAG Areas of Focus

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- ▶ **Packaging.**
 - ▶ **Analysis of bundling of multi-component vaccines.**
 - ▶ **Pallet shipping containers**—Look at programmatic and environmental impact, UNICEF surveying countries as first step...
 - ▶ Novel packaging solutions/environmental impact reduction.
 - ▶ Dimensional standards for containers other than vials.
 - ▶ **Package inserts.**
- ▶ **Bar coding.**
- ▶ **Delivery devices and technologies.**
- ▶ **Presentation.**
 - ▶ Doses per container—Monitoring ongoing work.
 - ▶ Multidose liquid vaccines without preservative—Monitoring ongoing work.
- ▶ **Outreach and advocacy.**

Roles for TechNet members...

- ▶ Make VPPAG members aware of presentation and packaging issues.
- ▶ Volunteer to be part of a network of immunization program managers and logisticians willing to provide feedback on new products and concepts.

For More Information

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Debbie Kristensen, PATH (VPPAG Chair) at dkristensen@path.org



Link to VPPAG information on WHO's web site:

<http://tinyurl.com/vppag>