

Vaccine Presentation and Packaging Advisory Group (VPPAG) DCVMN India 2010

VPPAG-Purpose

To provide a forum for dialogue between the public sector and industry regarding product profile decisions

To facilitate improvements in presentation & packaging (“image”) of vaccines for developing country markets

Establish optimal vaccine presentation & packaging guidelines in conjunction with different vaccination strategies agencies.

VPPAG-Background

Traditional vaccines have been mostly packed in low storage volume, multi-dose vials.

New vaccines are emerging in high-volume presentations that stress cold chain and logistics systems.

New vaccines are also emerging in presentations that are complicated to prepare for use, requiring increased training and supervision.

VPPAG –Current status

Governance transitioned to WHO

Supported by WHO-PATH Optimize project

Advises industry

Provides input to WHO policy development in TPP

VPPAG-Current scope of work

The Vaccine and Presentation Advisory Group (VPPAG) is Reviewing:

1. improved information for vaccinators & the community
2. two labeling issues
 - Expiry date
 - Text size
3. Standardizing of Terminology

VPPAG-Current scope of work

The Vaccine and Presentation Advisory Group (VPPAG) is Reviewing:

4. Visual Cues

5. WHO Programme Suitability for WHO
Pre Qualification-PSPQ

PI INFO

IMPROVED INFORMATION FOR VACCINATORS COMMUNITY

PI INFO

BACKGROUND

1. INFORMATION - PACKAGE INSERT (PI)

- For UN vaccine programs, delivery is normally at an immunisation clinic or by an outreach worker.
- In practice, the PI may not be delivered with vaccine (eg, when the secondary packaging is broken for distribution of doses) and so the vaccinator may not even get to see a PI.
- PI seldom read

PI INFO

BACKGROUND

1. INFORMATION - PACKAGE INSERT (PI)

- PI not necessarily in the local language
- PIs not 'user-friendly' and don't highlight the information the vaccinator needs to know.
- The PI is less useful to the average parent

PI INFO

BACKGROUND

1. INFORMATION - PACKAGE INSERT (PI)

- The data sheet leaflet or PI is a regulatory requirement for all pharmaceuticals, including vaccines.
- WHO GMP guidelines state that the “leaflet in the package,
 - should provide instructions for the use of the product, and
 - mention any contraindications and potential adverse reactions.”

EXPIRY DATE

LABEL

EXPIRY DATE FORMAT

EXPIRY DATE

BACKGROUND

2. LABEL - EXPIRY DATE FORMAT

• There is **no standard format** for expiration date for the primary container label within the existing WHO prequalification requirements for vaccines. Some incorporate letters from the English alphabet.

For example, June 10, 2010 might be expressed as: 06-10-2010; 6-10-10; 10-06-2010; 10-6-10; JUN 10, 2010; 10 JUNE 2010; etc...

(Unfamiliar to some health workers)

EXPIRY DATE

BACKGROUND

2. LABEL - EXPIRY DATE FORMAT

The Guidelines on the International Packaging and Shipping of Vaccines (WHO/IVB/05.23) indicates that for tertiary packaging "the manufacture and expiry date on all labels should be written in full, not in coded form (i.e. June 2005, not 06.05)".

FONT SIZE

LABEL

TEXT FONT SIZE

FONT SIZE

BACKGROUND

2. LABEL - TEXT FONT SIZE

- The text size or font size on some vaccine labels is **too small** to be legible.
- There is **no minimum text size** requirement for primary vaccine container labels within existing WHO prequalification requirements.

Creating a minimum text size/height could increase appropriate size of vaccine products.

DEFINITIONS

STANDARDISING of TERMINOLOGY

DEFINITIONS

Primary-, Secondary- and Tertiary packaging Terminology

<i>Primary container</i>	The immediate vial, ampoule, prefilled syringe, dropper, dispenser, or other receptacle in direct contact with the vaccine as distributed for sale (also known as the “first level” or “final” container). ⁱ
<i>Secondary packaging</i>	The intermediate or second level of packaging that holds the primary container(s) (e.g., cartons containing one or more vials or prefilled syringes of vaccine). ⁱ This is generally the relevant volume for calculation of storage requirements.
<i>Tertiary packaging</i>	The third level of packaging; the outer box or the shipping box containing multiple secondary packages. ⁱ

VISUAL CUE

VISUAL CUES

VISUAL CUE

The use of visual cues on labeling to inform users are widely acknowledged amongst the members.

VISUAL CUE

General Comment:

Concerns:

- To find space on the label – smaller cues preferable
- Unambiguous – Africa, South America and Asia
- Should be applicable to multi dose containers only
- Acceptance of visual cues by all NRA's and agreement amongst all and WHO so to avoid different recommendations.
- If only WHO vaccines – how will users interpret others, especially when used with VVM.

VISUAL CUE

General Comment:

Concerns:

- No universal language (days – d; dias; jour; h – hour; hora,) – icon pairs b, c, d can not be used unless h – hour and d – day is used internationally. Icon pair E is then the choice however it is not good to deviate from the VVM's primary function – confusion.
- Different symbols suggested – need agreement on universal symbol.
- Which icon to use for other recommendations e.g. 4h and 5d?

Icon pairs B



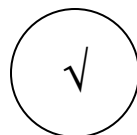
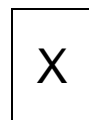
Icon pairs C



Icon pairs D



Icon pairs E

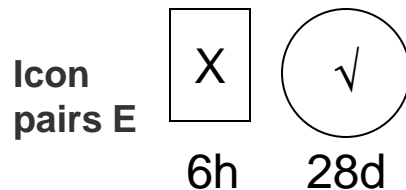


VISUAL CUE

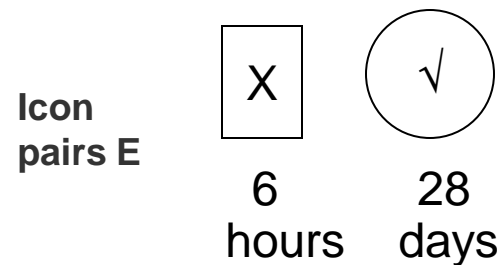
General Comment:

Suggestion:

- Use of Icon pair E including time or country specific language



OR



- The cross refers to one immunization session and max time to be kept and the tick to further vaccination sessions/days. Vaccine always kept stored under recommended conditions

VISUAL CUE

General Comment:

Suggestions:

- Keep icon simple – easy to understand, black & white
- Low impact on label legibility
- Printable
- Health workers must be properly trained and procedure must be included in PI / secondary packaging

- Examples proposed by DCVMN

PSPQ PROCESS

DCVMN COMMENT ON PSPQ PAPER

(Programmatic Suitability of Vaccine Candidates for WHO
Prequalification)

PSPQ PROCESS

For WHO to find out if the new vaccine/s has a different programmatic requirement for shipping, storage, preparation, administration or disposal than the existing commonly used vaccines.

Conclusion

VPPAG is the only formal forum where vaccine industry and immunization program stakeholders interact to discuss details regarding vaccine product characteristics and their impact on immunization programs

END