Considerations for Primary Container Decisions: DCVMN Perspective

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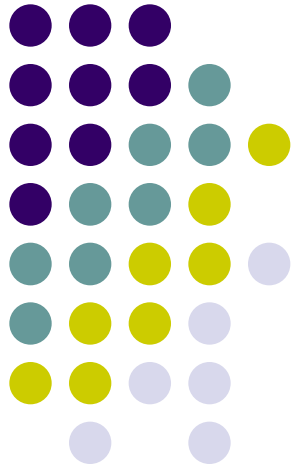
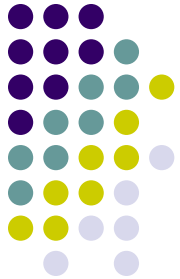


DCVMN- At a Glance



- Some members are WHO pre-qualified and supply vaccines to UN agencies at affordable prices.
- Most of the members businesses are based on low cost-high volume models.
- EPI Vaccines and supplies to UN agencies constitutes major share in total business.
- Few members have capacities to develop newer vaccines such as Meningococcal, Rotavirus, Pneumococcal, etc.
- Production capacities presently caters to more than 80 % supplies to UN agencies for basic EPI Vaccines.

Manufacturer's Preferences

- Have capability to cater all kinds of dose presentations. E.g. single dose, multi-dose, prefilled syringes, Uniject, etc.
- **Dose container consideration**: Choice is driven by expectations from the purchasers/countries, public and private business. For instance:

  -UN/Govt supplies are generally multi-dose. Cheaper vaccines are generally procured in multi-dose vials.

  -Target product profile: UNICEF Tenders (Pneumo vaccine requirement is for low dose multidose vials (2 or 5 dose).

  - Domestic market supplies are generally single dose however is governed by:

    - marketing inputs
    - physician preference
    - end-user preferences

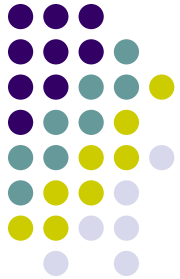
Manufacturer Preferences

- Economics or profits: Single dose is preferred.

- Philanthropic Perspective: Multidose is preferred. For example our recent decisions on pentavalent and Meningococal A Conjugate Vaccine.

Manufacturers try to balance the economics by mix of using both the strategies and finally ensuring affordable price to the end user.

Affordability considerations: Case examples



- Case example 1: MenAfri Vac at less than 50 cents a dose for sub-Saharan Africa.

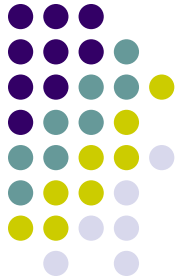
  - MVP Project. A partnership project of WHO and PATH

  - Multidose vial is an essential characteristic of this project

  -Only because of multidose vial (10 dose), SII was able to offer this vaccine at less than 50 cents a dose.

- Case example 2: SII offered Liquid Penta Vaccine (10 dose) to GAVI (DPT-HepB-Hib) at innovative pricing of 1.75 USD/dose.

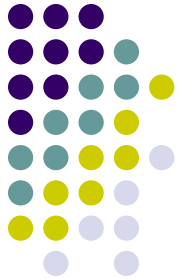
Single dose presentations for relatively newer vaccines



A shift to single dose presentations will have major cost implications with increased raw materials, new production and storage facilities.

- More lots will need to be manufactured with increased production costs.
- Increased testing load for manufacturers and NCLs
- More waste will be generated carrying huge impact on environment.
- Need to establish new filling facilities. Increased space requirements for storage and transport
- Programmatic challenges for vaccination programs because of increased requirement of cold storage.
- Most importantly, cost per dose will increase manifolds for which governments will have to make necessary provisions.

Multidose to single dose: Preservative Issue

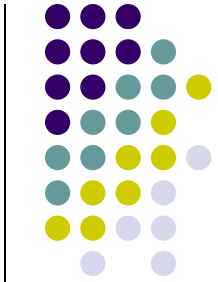


- Option 1: Replace thiomersal: Is there a consensus on effective substitute

Or

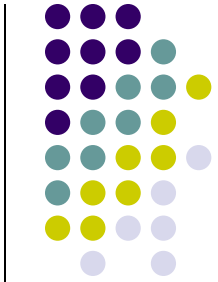
Option 2: Shift to preservative free single dose presentations

Option 2: Single dose presentations



- If forced, there will be shortage of vaccines as current vaccine manufacturing facilities will not be able to cope with increased requirements of containerization thereby disturbing the existing immunization program globally.

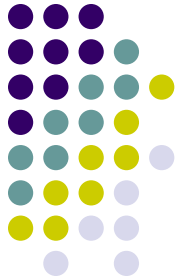
Time frame for such transition



- Obtaining regulatory approval for the new formulated thiomersal-reduced or-removed vaccines involves complex activities that are costly and time consuming and will involve preparing formulations, stability testing and preclinical toxicity testing and clinical trials which can take several years.

- This will be further challenging for DCVMN as we supply affordable vaccines with marginal profits which is made possible because of multi-dose containers.

Preservative Issue: Thiomersal in vaccines



DCVMN Made a presentation to SAGE on this issue.

- SAGE agreed to DCVMN Viewpoint that such transition needs a realistic standpoint on:

  - Does thiomersal really pose a risk
  - Impact on production capacities
  - Does global community have sufficient financial resources to meet such transition
  - Time frame for such transition

DCVM Perspective

- We should take into account the realistic situation in DCs where health budget are miniscule (NMT 2 % of total GDP) and international agencies have limited finances to procure product in single dose containers.
- A political will to implement single dose presentations in immunization programs and make arrangements for increased cold chain, storage and logisitic needs.

Thank You