Workshop Sessions: Potential Opportunities
PACKAGING TECHNOLOGIES

Next-Generation Vaccine Delivery Technology Meeting
Geneva, Switzerland

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Packaging Technologies Workshop – The group

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- Amir Genosar (Akti-vax)
- Osman Mansoor (UNICEF PD)
- Ian Lewis (UNICEF SD)
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- Vivek Malhotra (BD)
- Debbie Kristensen (PATH)
- Simona Zipursky (WHO/EPI)
<table>
<thead>
<tr>
<th>Public Health Need</th>
<th>Ongoing Work</th>
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<tr>
<td>Reduce cold chain volumes.</td>
<td>Work already underway in this area should be continued, manufacturers are already working in this area. This work should be encouraged.</td>
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<td>Improve safety and reduce vaccine wastage, especially for preservative free vaccines</td>
<td>Work by industry, PATH and others to pursue new options such as identifying cost-effective single dose options or multi-dose options that allow sterile withdrawal of doses.</td>
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<td>Improve labeling and product inserts to improve correct product usage.</td>
<td>Work by VPPAG and EMP to update labelling recommendations is ongoing, with endorsement by WHO’s Expert Committee on Biological Standardization. This work should be fast tracked and tied to barcoding/databases.</td>
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<td>Improve access to inventory data (e.g., via barcoding)</td>
<td>Endorse work that is underway by VPPAG subgroup and PATH project is looking at barcoding to optimize product flow, reduce stock-outs, and reduce vaccine wastage.</td>
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<td>Minimize packaging waste.</td>
<td>Potential area for VPPAG work. Should also look at ice packs, as well as containers. Is there a way to create reusable, useful containers for countries?</td>
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<td>Improve safety and product flow by bundling vaccine components.</td>
<td>Work underway by VPPAG. Trade offs need to be assessed.</td>
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GUIDANCE

Short Term

*Define standardized metric by which new packaging/devices and technologies will be assessed, including how trade offs are measured.
  - Metrics to include things such as: safety, value-added to country programs, impact on total systems cost etc.
  - Standardized metric to be developed by Public Sector, with input from manufacturers; conducting assessment responsibility of manufacturers

Public sector to define it’s objectives, problems and targets-- conflicting messages are challenging for manufacturers.
  - This could be part of gPPP

Develop a forum for device manufacturers to seek feedback from VPPAG (through calls, or online)

Better share and publicize the gPPP and PSPQ

Instructions for countries on how to use (or dispose of) materials that vaccines are shipped in—containers, PCMs etc.
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• REGULATORY PROCESSES/REQUIREMENTS

  Short term
  • *Lack of clarity and uniformity on regulatory pathways for devices and technologies
    • Guidance document for technology developers on steps to obtain regulatory approval from NRAs as well as from EMP/PQS etc. What do to when existing specifications don’t exist etc.?
    • Clarify how regulatory approvals for products are obtained– with vaccine? Independently?
  • Explore creation of regulatory advisory group to serve technology developers
  • Clarify in PSPQ document that new packaging technologies are encouraged even if not covered in existing guidance
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• INCENTIVES

  Short term
  • Develop an incentive structure for companies to develop new ‘game changer’ products— in procurement, through other methods
    • Eg: Low cost single dose and/or safe multi-dose that don’t require preservatives and have small cold chain footprints
  • Develop way for countries to select within products for those that best meet their needs (i.e. two 10-dose vials with VVM7 vs. VVM14)
  • Tools to determine relative cost to administer a dose, not only cost to purchase a dose
    • Change procurement and PQ information to include information on

  Long term
  • Develop way to link PSPQ preferred characteristics to procurement process including defining incentives to move in this direction