Case Study: The UniJect™ Injection System

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Photo: PATH/Siri Wood
**Uniject™** injection system

Uniject is a compact prefilled autodisable device.**

- Label
- Drug reservoir/blister
- One-way valve serves as autodisable feature
- Needle hub
- Needle shield

## Benefits of vaccines in Uniject

<table>
<thead>
<tr>
<th>FEATURES</th>
<th>BENEFITS</th>
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<tbody>
<tr>
<td>Non-reusable (autodisable)</td>
<td>Reduces risk of contamination</td>
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<tr>
<td>Prefilled and single dose</td>
<td>Accurate dose, less buffer stock required, improves logistics (no need for separate auto-disable syringe), minimizes vaccine wastage, decreases missed opportunities, facilitates outreach</td>
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<tr>
<td>Transparent container</td>
<td>Easy to examine vaccine contents</td>
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<td>Less solid waste and no toxic by-products upon incineration</td>
<td>Environmentally friendly</td>
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<tr>
<td>Compact</td>
<td>Less overall volume for transport, storage, and disposal</td>
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<tr>
<td>Few steps required to use</td>
<td>Simplifies training, saves health worker time, can be used by lesser-trained health workers, improves immunization experience for all</td>
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</table>
9 million doses of tetanus toxoid vaccine delivered. Potential procurement of 35 million more.
75 million doses of hepatitis B vaccine delivered.
Up to 12 million doses of Sayana Press* will be delivered in the next three years

- 104 mg Depo-Provera (depot medroxyprogesterone acetate).
- Delivered every three months.
- Prefilled in Uniject.
- Subcutaneous injection.
- 3/8” needle.

*Sayana Press and Depo-Provera are registered trademarks of Pfizer, Inc.
Crucell is launching pentavalent vaccine in Uniject

- WHO prequalification submission expected in Q2 2014.
Uniject delivery system features for pentavalent vaccine

- **Peel-off label**: with integrated vaccine vial monitor
- **Vaccine reservoir**: part of the system that encloses vaccine (max V = 0.63 ml, filled V = 0.60 ml)
- **Disc valve**: discourages attempts to refill the reservoir
- **Isolation barrier**: in the port maintains sterility of the vaccine
- **Needle shield and port**: maintain sterility of the needle through tortuous path closure principle
- **Tamper-evident seal**: makes it easy to recognize if system has been previously activated and/or needle shield was removed
- **23 gauge × 1” needle**: optimal size for intramuscular injection

*New Feature added by Crucell*
New packaging developed by Crucell to protect single Uniject devices and minimize cold chain volume

Resealable packaging has been developed to attain cold chain volume comparable to single-dose vials

- The current design is the result of extensive discussions with key stakeholders on programmatic needs and challenges.
- Several research projects are completed or ongoing to assess the new design and acceptability at all levels.
- Design is also tested on its “integrity”; 20-dose tray has been included in:
  - Stability studies (opened and closed)
  - Packaging validation studies
  - Shipping validation studies
Barriers to Adoption for Vaccines
Technical hurdles are high for new vaccine containers.
Regulatory approvals should not be underestimated.

<table>
<thead>
<tr>
<th>Example</th>
<th>National Regulatory Authority (Korea)</th>
<th>WHO</th>
<th>Importing Countries</th>
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</thead>
<tbody>
<tr>
<td>Uniject</td>
<td>Device registration required (6 months)</td>
<td>Only the finished product (with vaccine) requires registration</td>
<td>Depends on country’s local requirements (3 to 12 months)</td>
</tr>
<tr>
<td>Pentavelent vaccine in Uniject</td>
<td>New registration (9 to 12 months)</td>
<td>New presentation (3 to 6 months)</td>
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The best-case scenario approval time period: 21 months
The worst-case scenario approval time period: 36 months
A more costly technology is more easily adopted as part of a higher-priced vaccine. However, price is a moving target.
The developing-country vaccine market lacks sufficient pull mechanisms for vaccine technologies.

Ease of use, health care worker time savings, impact on coverage, and safety have not been considered in purchase decisions in the past.
Thank you