Methodology to support the development of an African vaccine manufacturing network

DCVMN Annual General Meeting 2022
21 October 2022

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African vaccine manufacturing network mapping project: Strategic Intent

- Provide technical, fact-based information and tools to:
  - Africa CDC's Partnerships for African Vaccine Manufacturing (PAVM) Initiative and other stakeholders
  - Support development of a vaccine manufacturing network that can achieve Africa's continental self-sufficiency, based on African Union (AU) Heads of States and Government's 2040 manufacturing goals.

- Disseminate a unified view of the technical requirements to achieve continental self-sufficiency to the whole ecosystem of global health community
  - Includes funders, NGOs, governments, trans-national bodies, etc.
There is a significant gap between African Union’s 2040 goals & current planned production capacity [as of Mar 2022]

**Legacy**

- Tuberculosis
- Measles (containing)
- Yellow Fever
- Cholera
- Typhoid
- Meningococcal (bundle with Pneumo)
- Hep B, Diphtheria, Tetanus, Whooping Cough

**Expanding**

- Papillomavirus
- Pneumococcal
- Rotavirus
- COVID-19
- Malaria
- HIV†

**Outbreak**

- Ebola
- Influenza (pandemic response)
- Chikungunya†
- Rift Valley fever†
- Lassa fever†

*Data shown are planned production from Feb 2022 estimates
*Source: PAVM FFA
†Vaccine does not exist yet
The current African vaccine manufacturing landscape is mostly focused on fill/finish of COVID-19 vaccines.

The planned fill/finish capacity committed in 2022 exceeds 500 million doses per year and is clustered in North Africa and South Africa.

- Manufacturers in South Africa, Algeria, Morocco, and Egypt have already started, or will soon start, fill/finish activities. The conclusion for 2022 might be an over estimation based on annual production rates.
- The capacity dedicated to vaccines could be increased by some manufacturers, should the opportunity arise; however, some facilities are not equipped to manufacture viral vaccines.
- Potentially, when the COVID-19 emergency ends, the fill/finish capacity could be transitioned to manufacture different vaccines.

Non-confidential current state map presentation available on PATH website: https://www.path.org/resources/mapping-current-state-vaccine-production-infrastructure-africa/
“Pull” model developed to simulate network required to meet AU’s 2040 targets

- We conducted a technical assessment of the minimum manufacturing requirements for 15+ priority vaccines
- For each antigen, we determined the key parameters for a “typical” manufacturing process, such as:
  - Batch size, yield/process losses, process & idle time, QA/QC time & failure
  - Interchangeability of capacity between vaccine production processes
- After understanding the production processes of each antigen, a “pull” model was developed that can simulate the network required to achieve the dose target*

* For full modeling details, refer to:
Initial modeling estimates to meet AU 2040 dose targets:
12 sites, leveraging strategic combination of production sites

<table>
<thead>
<tr>
<th>Estimated # of sites</th>
<th>Vaccine(s) Produced at Site</th>
<th>Estimated Total employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Tetanus, Diphtheria, Pertusis, Hep B (DS only)</td>
<td>966</td>
</tr>
<tr>
<td>1</td>
<td>TT Carrier, PRP (no conjugation) (DS only)</td>
<td>1183</td>
</tr>
<tr>
<td>1</td>
<td>IPV (DS only)</td>
<td>1436</td>
</tr>
<tr>
<td>1</td>
<td>PRP-T conjugation (DS), Hexa (DP)</td>
<td>1275</td>
</tr>
<tr>
<td>1</td>
<td>Measles-Rubella</td>
<td>1675</td>
</tr>
<tr>
<td>1</td>
<td>Rota virus (DS &amp; DP), Cholera (DP)</td>
<td>578</td>
</tr>
<tr>
<td>1</td>
<td>Pneumococcal (DS &amp; DP), Meningococcal (DP), Thryphoid (DP)</td>
<td>750</td>
</tr>
<tr>
<td>1</td>
<td>Covid-19 subunit protein, HPV</td>
<td>939</td>
</tr>
<tr>
<td>1</td>
<td>Covid-19 mRNA, HIV</td>
<td>670</td>
</tr>
<tr>
<td>1</td>
<td>Covid-19 Viral Vaccine</td>
<td>546</td>
</tr>
<tr>
<td>1</td>
<td>BCG</td>
<td>640</td>
</tr>
<tr>
<td>1</td>
<td>Malaria</td>
<td>1229</td>
</tr>
<tr>
<td><strong>12</strong></td>
<td><strong>Total</strong></td>
<td><strong>Approx 12,000</strong></td>
</tr>
</tbody>
</table>

Notes:
1. Important: Site sizing is based on baseline capacity estimations, not model-adjusted capacities
2. Pandemic Flu, Ebola, Chikungunya, Rift Valley and Lassa Vaccines will be merged with existing facility with similar technology
3. Yellow Fever was excluded from the modelling as scale up of Yellow Fever production is already ongoing (IPD Senegal)
Project outputs can be used by multiple PAVM Workstreams

**Factory sizing & requirements estimates**
- Can be used to understand infrastructure requirements

**FTE estimates**
- Can refine the number of people in need of training
- Clarify roles

**Identification of manufacturing gaps between current state & future needs**
- Provide funders with an overview of where investments need to be made
- Provide a deeper understanding of where & when tech transfers may be needed

**Batch level data estimates**
- Can inform the number of lab tests required
- Used to refine the size of NCL network as necessary

**Estimates of production requirements & output**
- Inform cost of goods estimate
- Contribute to evaluating which products have a viable value proposition
- Can be used to better understand the likelihood of supplier and buyer-side alignment

1. Infrastructure
2. Talent Development
3. Access to Finance & Tech Transfer and IP
4. Regulatory Strengthening
5. Market Demand

PAVM Workstreams
The 4 key components of a viable manufacturing network

To develop a viable vaccine manufacturing network, four key workstreams must be addressed*:

• Plan (market demand, business case)
• Source (consumables, raw materials)
• Make (vaccine manufacturing)
• Deliver (shipping, storage, logistics)

Our project focuses on the “Make” component by executing technical network assessments and analysis.

CHAI is collaborating on the project and will be providing support particularly on the “Plan” component

DCVMN is in the process to join the project

* APICS Supply Chain Operations Reference (SCOR) model.
Next steps

- Conduct visits to African manufacturers to assess current and future vaccine capacity, as well as identify technical or commercial challenges to manufacturers operations
- Receive updated market projections from PAVM & CHAI
- Using the KUL model, perform new simulations with refined data to update network estimations
- Make data available to PAVM Workstreams, local African manufacturers and other stakeholders
Thank you