Local Vaccine Production in Nigeria: The Role of The Private Sector

AGOA
April 19, 2022
“Vaccines are the tugboats of preventive health” - William Foege

- Introduction of BVNL
- Vaccine Manufacturing Scenario: Africa
- BVNL Overarching Strategy
- mRNA Vaccine Manufacturing
- BVNL Capacity & Nigeria Ecosystem
- Needs/Requests
A Synergistic Partnership Between Private and Public Sector

- One of the oldest & top pharmaceutical companies in Nigeria.
- Huge population >206 million with 3rd largest youth population in the world.
- One of Africa’s big economies
- Phased GAVI graduation begins in 2021.

Mandate for long term procurement of vaccines and stage-wise indigenous manufacturing of vaccines.
• Established: 2005
• JVC: FGN & MBN
• SPV to revive LVM in Nigeria
• Activities truncated 2007-2017
• Board Re-inaugurated: 2018
• Head Office: Yaba, Lagos State
• Factory: Ota, Ogun State
1. Infrastructure for Capacity building for Local manufacturing of Essential vaccines

2. Infrastructure for the Development of Novel vaccines critical for the region

3. Institution to support in enhancing awareness and Coverage of EPI vaccines in Nigeria

4. Support in setting up an NCL and strengthening the NRA to make it fully functional

5. Forum to nurture and develop local technical talent to support the capacity building initiative

Support in Achieving GVAP Goals in Nigeria & the Region

‘Nigeria Immunization Coverage Enhancement’ – Initiative

BioVaccines Nigeria Ltd (BVNL)

www.biovaccinesnig.com

CONFIDENTIAL
BVNL has MOU in place with leading vaccine manufacturers & is in an advanced stage of signing definitive agreements for finished products and ready to fill bulk

1. World’s largest vaccine manufacturers supplying vaccines to UNICEF

2. Supplying vaccines in more than 170 countries including Nigeria

3. Highest number of WHO PQ vaccines from DCVMN
- Market Access
- COUNTRIES
  - GAVI
  - COVAX
  - UNICEF
  - AVAT

- WHO
  - Afrigen
  - BIOVAC
  - SAMRC
  - AfricaCDC
  - MPP

- Egypt
- Kenya
- Nigeria
- Senegal
- Tunisia
- South Africa
A tunnel concept based, fully integrated Vial filling line which does, Washing, drying sterilization, cooling, filling, stoppering and capping.

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Capacity Calculations</th>
<th>Absolute vials</th>
<th>Million vials</th>
<th>Single Dose / vial 0.5 ml + appropriate overfill</th>
<th>5 Dose / vial (0.5 ml/dose) 2.5 ml + appropriate overfill</th>
<th>10 dose / vial (0.5 ml/dose) 5.0 ml + appropriate overfill</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Machine Capacity vials/minute</td>
<td>300</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>2</td>
<td>Machine Capacity vials/hour</td>
<td>18,000</td>
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<tr>
<td>3</td>
<td>Machine Capacity vials/day/shift (5 hours fill time)</td>
<td>90,000</td>
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<tr>
<td>a</td>
<td>Annual Capacity @260 days on single shift/day</td>
<td>2,34,00,000</td>
<td>23</td>
<td>23</td>
<td>117</td>
<td>230</td>
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<tr>
<td>b</td>
<td>Annual Capacity @260 days on double shifts/day</td>
<td>4,68,00,000</td>
<td>47</td>
<td>47</td>
<td>234</td>
<td>470</td>
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<tr>
<td>c</td>
<td>Annual Capacity @260 days on three shifts/day</td>
<td>7,02,00,000</td>
<td>70</td>
<td>70</td>
<td>351</td>
<td>700</td>
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</tbody>
</table>
Supply of Locally Manufactured & Formulated Vaccines from 0% to 60% by 2040
FULL SITE = 15.304 hectares

PROPOSED PLOT
4.5 hectares

Integrated Biotech Park Concept
### Biovaccines Estimated Project Cost

#### BUDGET FOR THE PROJECT*

<table>
<thead>
<tr>
<th>SR. NO.</th>
<th>DESCRIPTION</th>
<th>COST IN MILLION USD</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Capital expenditure (Capex)</td>
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</tr>
<tr>
<td>a</td>
<td>Modular Lab **</td>
<td>22.00</td>
</tr>
<tr>
<td>b</td>
<td>Civil construction</td>
<td>6.00</td>
</tr>
<tr>
<td>c</td>
<td>Internal Engineering, equipment and commissioning</td>
<td>18.00</td>
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<tr>
<td></td>
<td><strong>Sub-Total</strong></td>
<td>46.00</td>
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<tr>
<td>2</td>
<td>Operational expenditure (Opex)</td>
<td>4.00</td>
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<tr>
<td>3</td>
<td><strong>Grand Total (Capex+Opex)</strong></td>
<td>50.00</td>
</tr>
</tbody>
</table>

*Funding Support from Nigerian Government – N-10 Billion ($24M)*

Subject to variation, based on make of equipment, level of automation, modular or static systems etc.
History of Vaccine Manufacturing:
- Animal (Bacterial & Viral) for over 75+ years
- Human (Small Pox, Rabies, YF)

**Regulatory Strengthening (NAFDAC)**
- WHO Global Benchmarking: Level 3 (March 22, 2022)
- ISO 9004
- Ongoing of a new NAFDAC vaccine lab
- > 45 Lot release certificates issued for Covid-19 vaccines

**Scientists: Virologist & Vaccinologists**
- Usman Danfodio University (UDUS), Sokoto
- National Institute of Medical Research (NIMR)
- Nigeria Institute of Pharmaceutical Research & Development (NIPRD)
- Irrua Specialist Teaching Hospital (ISTH), Edo
- African Centre of Excellence for Genomics of Infectious Diseases (ACEGID), Osun
1. **Access to Finance:** Investment/Funding – already in discussion with national and international finance agencies

1. **Regulatory Strengthening:**
   - Regulatory Agency NAFDAC to attain Full Functionality, for vaccines
   - Currently at Maturity Level 3 (ML3) for Drug

   *Egypt and Nigeria medicines regulators achieve a high maturity level in WHO classification and WHO launches a list of regulatory authorities that meet international standards. Egypt and Nigeria medicines regulators achieve high maturity level in WHO classification and WHO launches list of regulatory authorities that meet international standards.*
   

3. **Infrastructure:**
   - Flexible vaccine platform - mRNA (Covid and Non-Covid immunization needs)
   - Modular Lab - to initiate fill and finish/development of other vaccines

4. **Talent/Know-How:** Tech Transfer/Training in manufacturing of vaccines
BEYOND COVID VACCINE

Participating in the programme

✓ Accelerates achievement of original Biovaccines mandate for local manufacture of required routine immunization vaccines

✓ Provides training opportunities and capacity building

✓ Offers opportunities for application of new technologies for improved vaccines and development of new vaccines for regional disease priorities
We have begun the journey towards achieving a happy and healthy population.