Kenya BioVax Institute

Presented at the Global event on enhancing the sustainability of investments for Vaccine Manufacturing in Africa
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Kenya Biovax

• A State Corporation in the Ministry of Health, Government of Kenya (Companies Act, 2015)

• Mandate to manufacture and commercialize vaccines, biotherapeutics and other HPTs.

• We are Kenyan spoke for the WHO mRNA Technology Transfer Programme

Our motto

‘...protecting health, promoting life...’
Situational analysis: Kenya today...

• Kenya requirement / market: >20m doses of ‘routine’ vaccines per year,
  • Valued at USD 30M (KES 4.2B).
  • (EAC regional requirement / market: >200m doses per year / USD 300M).

• Dependence on co-finance mechanism:
  • GoK 12% and UNICEF / GAVI 88%.
  • Accelerated withdrawal of GAVI support; stop in FY 2026/2027.
  • Sustainable self-sufficiency in vaccine needs; health commodity security

• ? Pandemic prevention, preparedness, response, resilience:
  • mRNA platform, continued R&D

• Local manufacturing (economic pillar):
  • Kenya as biotech hub in the region
  • Skilled jobs creation
Strategy & roadmap:

• Fully-fledged, world-class, state-of-the-art **human vaccines manufacturing facility**, to incorporate upstream R&D activity (working with KEMRI), mid-stream formulation activity with vaccine antigens for drug substance, and to downstream ‘fill-and-finish’ for final drug product.

• Partners:
  • Establishment of ‘end-to-end’ vaccines and biopharmaceuticals manufacturing capability; USD 300M+.
  • Technology transfer

• Key vaccines, based on market and financial analyses, include:
  • Childhood immunisation vaccines for pneumonia, influenza, diphtheria, pertussis, tetanus, hepatitis;
  • Adolescent girls’ vaccine to prevent cervical cancers;
  • COVID-19, Malaria, HIV and Tuberculosis vaccines.

• Other products:
  • Insulin for diabetes, Monoclonal antibodies for cancer and other chronic inflammatory diseases, Antivenoms for snake bites and Diagnostic kits

• Target market: East African and ‘Great Lakes’ region;
Ongoing works:

2021

Early 2022
Where we want to be...

- **World-class**, state-of-the-art vaccines production facility.
- **Regional** centre-of-excellence for **biotech**.
- 100 million doses per year of range of human routine & outbreak vaccines and biopharmaceuticals.
- **Local manufacturing**, with >100s highly-skilled employees.
- Biotherapeutics (insulin, mAB), diagnostics.
- **Gross margins >30%;** FOREX earner.
## Risks:

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<thead>
<tr>
<th>Risk:</th>
<th>Risk management plan:</th>
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<tr>
<td>Time-delays in construction - prolonged</td>
<td>Pro-active planning with timely reporting. Applying project management principles from the start.</td>
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<td>Market for product(s)</td>
<td>Market purchase guarantees for finished products, e.g. with GoK. Pooled procurement - UNICEF / GAVI; Africa CDC AVATT; Participate in market-shaping engagements for Africa. Justification for product selection based on critical analyses</td>
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<td>Quality of product</td>
<td>Manufacturing machinery, equipment, processes are GMP-certified. Certification, Qualification, Validation (CQV), incl. WHO Pre-qualification process</td>
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<td>Goodwill / stability - uncertainties.</td>
<td>Sustained communication and stakeholder engagements.</td>
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What Kenya has to offer:

• Market.
  • Huge demand - local, regional.
  • Financials - incl support from exchequer
  • Portfolio of vaccines, biologicals, insulins, sera, anticancer agents, sterile products

• Location.
  • Facility - state of the art; GMP, WHO, ISO accreditations / pre-qualifications.
  • Hub for distribution / connectivity

• Skills
  • Efficient, lean and commercially-astute, focussed organisation
  • Biotechnology, biomedical science, R&D
  • Robust QMS and Biosafety protocols, supported by accreditations

• Well established R&D and National Regulatory Authority.

An investment opportunity with positive socioeconomic returns that could avert over 4 million deaths per year and over 206 million Disability Adjusted Life Years (DALYs) in the region
Thank you: