



Presentation to The mRNA Technology Programme

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BioVax - Legal status:



- Established Sept. 2021 as a State Corporation under the MoH, by *Companies Act 2015**.
- Supported by Section 86 of PFM Act: Protocol to be adopted for '*Commercial State Corporations*'.*
- Shareholders & promoters: MoH & NT.
- Governance: Board of Directors and Management Team.

Mandate / Function...



1. **Manufacture and commercialization of vaccines, therapeutics and diagnostics;**
2. **Support technology transfer and commercialization of outputs on healthcare products & technologies (HPTs) from research institutions, universities, etc.**



Goal:

Protect health (outbreak vaccines); promote life (routine vaccines).

Situational analysis - Kenya today...



- Kenya: 16m doses per year valued at KES 3.4B (USD 21m)
- EAC: 150m doses per year valued at KES 27B (USD 170m)
- Import human vaccines; rely on donations.
- Co-financing mechanism ending soon:
 - GoK contributes 12% and UNICEF / GAVI contributes 88%.
 - Accelerated withdrawal of GAVI support; stop in FY 2026/2027.
- Birth rate: + 2.3%.
- ? Preparedness - outbreaks, epidemics, pandemics.
- *UNICEF Report, 2021.

Strategic plan:



10-year plan, 2023 - 2032.

Phased implementation with '*backward integration*':

- Fill-Finish -> Formulation -> R&D.
- 1 to 2 drug products / drug substance per phase
- 1st vial (? polio) by FY 2025/2026

WHO Pre-qualification with GMP certifications.

Align with 'Maturity Level' of Regulatory Authority (the PPB).

Bio-manufacturing 'ecosystem':

- Centre of Excellence/ regional 'powerhouse'.



Progress to-date:

- Premises:
 - Facility refurbishment
 - Offices / furniture / kit-out
- Machinery / equipment:
 - Tenders / contracts - turn-key, GMP consultancy, enabling works
 - Concept designs, fabrication plans, assembly visualisations
- Materials / inputs:
 - Drug substance, drug product - for formulation, for Fill-and-finish
 - Partnerships
- Operations / maintenance:
 - HR instruments to guide workforce recruitment
 - Training and capability development



Gaps / Opportunities



1. Skilled workforce- Training (Management, technical and support)
2. Legislative: Need for waivers to support local manufacturing of biopharmaceuticals - Advocacy
3. Enabling environment for sustainability e.g. incentives, purchase guarantees - Advocacy
4. Maturity level of PPB- Regional collaboration in vaccine lot release

Facility:



Where we want to be...



- **World-class**, state-of-the-art facility.
- **Regional** centre-of-excellence for **biotech**.
- 100 million doses per year of range of routine & outbreak vaccines (public health / UHC); can **scale-up fast**.
- Future - biotherapeutics (insulin, mAB), diagnostics.
- >100 highly-skilled **employees**.
- FOREX earner.

Thank you.

