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%.
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.