Enhancing the sustainability of investment for vaccine manufacturing in Africa

Session 2
Perspectives from the African vaccine industry

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Advance the establishment of sustainable human vaccine manufacturing capacity in Africa
Conclusion

• Space for **multiple major players** in the vaccine production field in Africa

• A number of **hubs** could be established.

• Requires the right level of **political** and **technical** support

  ... to develop the necessary **ecosystem** to establish a viable, competitive and sustainable vaccine manufacturing capability.

• **Long-term vision** - tied to national (health) security and regional health security.
# African Vaccine Manufacturing Industry Forum

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<td>Biovac</td>
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AVMI - key point of contact for multilateral engagement with vaccine manufacturers in Africa.
## Agenda-setting and demand coordination
- Continental strategy delivery and oversight

## Market design and demand intelligence
- African Vaccines Procurement Pooling Mechanism

## Access to Finance
- Vaccine manufacturing deal preparation and financing facility

## Technology transfer and IP
- Vaccine Technology Transfer & IP Enablement Unit

## Regulatory strengthening
- Embedding Vaccines regulatory excellence in NRAs and RCOREs through AMA and AMRH

## R&D and talent development
- Vaccine R&D Centres and R&D coordinating unit

## Infrastructure development
- Capability and Capacity Network
- Advocacy for enabling trade policies for vaccines

### Contributions
- PAVM
- AVATT
- Afrexim/AfDB
- AVMi
- AMA & AMRH
- TBD
- PAVM
- AfCFTA
Manufacturers stress that economic viability still needs to be demonstrated.

- Advance purchase agreements from African governments
- A revision of current the procurement mechanisms in Africa
- Financial mechanisms to counterbalance the initial lack of price-competitiveness for a defined period
Perspectives

- Partnerships
- Beyond Africa
- End to End Manufacture
- Regulatory
- Product Development
- Routine Vaccines

Market
Vaccine market demand certainty – Advanced Market Commitments

• **Single most important issue** to ensure sustainability and attract investments in vaccine development and manufacturing capabilities in Africa.

• **Priority** is to achieve practical and realistic modalities for the procurement of vaccines, both from the international agencies and also from African governments (GAVI and non-GAVI volumes).

• Requires a **transitionary procurement support fund** or similar vehicle.

• **Pricing mechanism needs to support journey to sustainability** and provide a business case for investment.
  
  • A **premium per dose** that manufacturers will be guaranteed.

• **Timeframe**: Recognise that this cannot continue into perpetuity - but it needs to be significant enough (10 years, 15 years)
Partnerships and Collaboration are the backbone

*Technology Transfer Partnerships accelerate capacity building*

- Product Development
- Policy
- Funding
- Regulatory
- Technical Support
- Academic
Perspectives

Full (end-to-end) vaccine manufacturing

• Model should support both DP and DS manufacture and ensure that incentives and design drive full vaccine manufacturing capacity building in Africa.

• In addition models should also support collaborative regional, continental, and international manufacturing value chains.

• Important if Africa is to be in a position to manufacture vaccines in future outbreak and emergency situations (global and regional).
Vaccine product development breaks cycle of dependency.

- Drug Product manufacture: 2 dependencies on a partner
  - Technology know-how (training and transfer)
  - Drug substance supply

- Drug Substance and DP manufacture: 1 dependency on a partner
  - End to end manufacture still leaves a dependency on a TT partner for Technology know-how

- Builds scientific base and know-how.
Worldwide Programme Partners

- 15 programme partners
- 56 people who received the technology transfer intro training (43% are women)
- 122 people who received trainings from other institutions
Building globally recognized product development capability

International Product Development Partnerships

- The Haemophilus Influenza type b vaccine project introduced conjugate vaccine capability at Biovac.

**Hib Conjugate Vaccine**
- Out-licensed to 3 vaccine companies: 2 in Asia and 1 in USA
- WHO PQ
- Bionet Asia

**Pneumococcal Conjugate Vaccine**
- The Pneumococcal conjugate vaccine project allowed Biovac to entrench its conjugate vaccine technology platform.

**Recombinant Vaccines**
- Biovac participated in 2 recombinant vaccine technology projects with international partners.

- Development of a novel Group B Streptococcus conjugate vaccine.

**GBS Conjugate Vaccine**

**Outcomes**
- PATH Partnership
- Chengdu Institute for Biological Products
- Transferred Tech Packages
- Training

**HIV/AIDS Vaccine Candidate – Italian partner**
- BMGF
- PATH
- Inventprise

Tech Transfer on Cholera vaccine with IVI
Bringing International Vaccine Development Expertise to Nigeria through Partnerships and Tech Transfer

**Novel HIV VLP Based Vaccine**
Induced broadly Neutralizing antibodies in Mice model

**Novel Ebola VLP Based Vaccine**
Highly immunogenic in mice model. Plans are underway to developed a bivalent VLP Ebola

**Novel Yellow Fever Vaccine**
Licensed a novel cell based YF vaccine - combines characteristics of DNA and inactivated vaccines. The iDNA YF vaccine induced high neutralizing antibodies in mice. Can be formulated for storage at RT.

**Novel Reassortant Lassa Vaccine**
Licensed a Lassa Candidate Vaccine based on reassortant technology. GMP material is now available for tox study and clinical trials.

**Novel HPV Vaccine**
Developing a trivalent 16,18 and 35 HPV vaccine based on African HPV serotypes. Could protect over 90% of HPV serotypes circulating in Africa based on cross-protections

**Partners:**
Merck KGaA, MilliporeSigma, Technovax LLC, Medigen LLC., Lion’s Head UK, Afreximbank Cairo, ITC Geneva, Bharat Biotech India, Walvax etc
The business case for pandemic vaccines depends on production of routine vaccines

- **Investment case** cannot be built on production of pandemic vaccines. Has to be established on **manufacture of routine vaccines**.
- This is the **pathway to establishing preparedness and readiness** for manufacture of pandemic vaccines.
Perspectives

Time and path to market depends on regulatory capacities

• Need to advance the establishment of harmonized regulatory systems through AMA and NRAs in Africa.

• To ensure optimal use of scarce resources by pooling expertise, capacities and strengthening existing networks.

• Not only important for the capacity to exist but it is vital that it is efficient at expediting approvals to support a viable manufacturing industry in Africa.

• Time: critical impact on economic viability!
Building a diversified and viable vaccine development and manufacturing capability in Africa

- To ensure **vaccine supply security** in Africa
- The value proposition extends to the establishment of a globally diversified vaccine manufacturing value chain so that **African manufacturers contribute to global supply chain and markets** as well.
- **Not only about “in Africa, by Africa, for Africa”**.
The best time to plant a tree was 20 years ago.
The NEXT best time is NOW!

Advancing Vaccine Manufacturing Capacity in Africa

www.avmi-africa.org

Thank You

Breaking the Cycle of Dependency