African Vaccine Manufacturers Initiative

Establishing sustainable vaccine development and manufacturing in Africa
The best time to plant a tree was 20 years ago.

Do not call the forest that shelters you a jungle.
The Current Reality

Africa produces **less than 1%** of its own vaccine needs!
Lack of vaccine manufacturing capacity could potentially lead to:

- **Poor sustainability** due to supply insurance
- **Vulnerability** to epidemics and pandemics
- **Poor emergency preparedness**, e.g. Ebola
- **Weakened National Security**
- **Poor socio-economic development**
A quarter of the world’s population will live in Africa by 2050

Share of global population by region

<table>
<thead>
<tr>
<th>Region</th>
<th>2015</th>
<th>2050</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asia</td>
<td>60%</td>
<td>54%</td>
</tr>
<tr>
<td>Africa</td>
<td>16</td>
<td>25</td>
</tr>
<tr>
<td>Europe</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Americas</td>
<td>13</td>
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</tbody>
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Data: United Nations World Population Prospects 2015 Revision
Vaccine Market at a Glance in 2013

- Global vaccine market estimated at US$ 24B 2013
- Africa Vaccine market estimated at U$1.2B in 2013
- Africa/Global vaccine market: 5.5%
- Low immunization coverage in Africa compared to its share of global population
- Highest global rate of under-five mortality

17% of global pop.
Recent trends in vaccine demand in Africa

• Growing demand
  • Demographic factors
  • Unmet needs
  • Revitalisation of NIP
  • Polio and measles campaigns
  • Introduction of NUV

• Strong donor support to LIC

• Dominant role of UNICEF SD

• Widening gap between supply and demand: the only continent with almost no local production

• Increasing dependancy: supply and financing
No Sub-Saharan African capacity - flu
African Vaccine Manufacturers

- Senegal (IPD): producer WHO pre-qualified vaccine (yellow fever)
- Egypt (Vacsera): DTP and some fill-finish
- South Africa (Biovac): Fill finish
- Tunisia (IPT): limited BCG and rabies
- Ethiopia (EPHI): Starting up…
Public Health Emergencies

• **2009 H1N1 Influenza pandemic** highlighted the African continent’s lack of capacity to develop and manufacture flu pandemic and other strategic vaccines for PHEs.

• **2014 Ebola outbreak** in Western Africa has resulted in strong recommendations from the African Union and others regarding support for acceleration of local vaccine manufacturing.
• Multi-stakeholder effort by the AUC and UNIDO

• Led to the the PMPA, Business Plan 2012
  (Pharmaceutical Manufacturing Plan for Africa)

• Viable pharmaceutical industry in Africa would
  +ve impact
  • African health systems and capacity to respond to the
    health needs of the people
  • Contribute to the overall socioeconomic development
    of the continent.
Vaccine Production in Africa: Rationale

**In Favour**
- Security of vaccine supply
- Address Africa specific disease burden
- Dealing efficiently with pandemic diseases
- Respond to unmet needs
- Growing population and market
- Socioeconomic, industry and life science development

**USE Negatives**
- Good lessons learned from past failures and recent experiences in manufacturing
- New efforts to address the complex/high cost of dev/manuf
- Booming continental market
- Growing availability of human and technical capacity
- Current political will to invest in public health goods and technologies.
African Vaccine Manufacturers Initiative

- AVMI is a partnership platform to promote the establishment of vaccine manufacturing in Africa
- Stakeholders - manufacturers, academics, scientists from 12 countries came together in 2010
An African Initiative

Members from 13 African countries

Democratic Republic of Congo
Egypt
Nigeria
Congo
Senegal
South Africa
Uganda
Ghana
Kenya
Kenya
Ethiopia
Morocco
Tunisia
Guinea
Mobilise the African continent through high level advocacy to manufacture preventive and therapeutic vaccines and/or other biological products against diseases of public health importance.

To promote partnerships between African manufacturers of vaccines and biologicals and other interested stakeholders who have a vision of Africa producing its own vaccines.
Strategic Objectives

Resource Mobilization

To attract and secure skills and financial resources for establishing vaccine manufacturing capacity in Africa

Skills / Capacity Development

To promote adequate scientific and technical capacity building of Africa’s vaccine manufacturers in all aspects of production and distribution of vaccines and/or other biological products
Achievements:

Technical Feasibility Study and Strategic Framework for African Vaccine Manufacturing

With the support of UNIDO and the WHO...

An Africa-wide study: Vaccine Manufacturing and Procurement in Africa (VMPA) study completed.

Provides:

1. an analytical assessment of current vaccine manufacturing capacity and procurement mechanisms in Africa.

2. pragmatic evidence and guidance for consideration by established/new/interested vaccine manufacturers in Africa.
VMPA Study: Scope

Vaccine Manufacturing and Procurement in Africa Study

Focus Area 1
Vaccine Market Dynamics in Africa

Focus Area 2
Vaccine Procurement and Financing Mechanisms

Focus Area 3
Feasibility of Establishing Sustainable Manufacturing Capacity

Focus Area 4
Financing and funding mechanisms to establish sustainable vaccine manufacturing
Key findings VMPA study

Vaccine Market
- African demand is booming i.t.o number of doses, vaccine types, increased populations, immunization coverage and vaccine expenditure
- High entry barriers, increasing cost and high risk of failure – still limits the amount of manufacturers interested

Vaccine Procurement
- UNICEF SD Procurement services is the dominant procurement mechanism is Africa
- 45 our of 54 countries use UNICEF SD
- If status quo remains, African manufacturers should aim to become WHO-prequalified supplier to UNICEF
Key findings of the VMPA study

Vaccine Manufacturing

• Limited to non existing in Africa
• 8 companies with existing or potential manufacturing capacity identified
• Heterogeneous levels of capacities and capabilities, very few with any API capability
• NRA functionality is limited with core emphasis pharmaceuticals
• 171 clinical trials were conducted in Africa between 2002 and 2015

Vaccine Funding

• Building manufacturing facility cost between USD 60 – 130 million, with CAPEX at 60%
• Financing sources: government, grants, fee income, loans or private.
• Various innovative financing schemes possible
A summary of key cost drivers and factors to consider for establishment of a vaccine production facility

Provides:

1. An introduction to the manufacturing of human vaccines,
2. Information about the vaccine market and summarizes the necessary investment costs,
3. Project timeline forecast and other key factors to take into consideration for Human Vaccine Manufacturing
Advocacy Plan

AVMI Advocacy outline:

1. Promote AVMI regionally and globally to highlight local vaccines and biologicals manufacturing in Africa.

2. Promote the development and adoption of a Pan-African vaccines and biologicals policy.

3. Leveraging existing and new PP partnerships

4. Creating a network of advocates across the region for vaccines and biologicals manufacturing in Africa.

5. Promote linkages with infectious diseases initiatives
Value Proposition

AVMI is well positioned to advocate for increased local development and production of vaccines and biologicals in Africa

Vaccine manufacturing is complex! AVMI has a database of consultants and evidence-based guidance documents that can help!

Links to: Tertiary institutes, industry, policy makers, African vaccine manufacturers

AVMI is the only African organisation to which all the presently known vaccine and biologicals manufacturers belong. Best positioned to articulate the views and needs of the industry.
SUMMARY

- Enhance Africa socio-economic status by creating employment and skills
- Strengthen local health systems greatly
- Improve National security improve
- Improve security of vaccine supplies
- Improve epidemic and pandemic preparedness
- Position Africa positively wrt global vaccine supply and sustainability
- Break the cycle of dependency on foreign supply of vaccines
Background

African Vaccine Manufacturing Initiative (AVMI)
In September 2010 during the International Vaccine Technology Workshop (IVTW) in India, a group of interested Africans launched the Africa Vaccine Manufacturers Initiative (AVMI).

Looking beyond the provision of vaccines in emergency situations the AVMI intends to coordinate efforts of African vaccine manufacturers and other interested parties, who have a vision to see Africa produce its own vaccines Read more...