



### 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

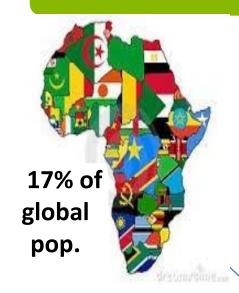
### A quarter of the world's population will live in Africa by 2050





### 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

### Recent trends vaccine demand in Africa



- Growing demand
  - Demographic factors
  - Unmet needs
  - Revitalisation of NIP
  - Polio and measles campaigns
  - Introduction of NIIIV

- Strong donor support to LIC
- Dominant role of UNICEF SD

- Increasing dependancy: supply and financing
- Widening gap between supply and demand : <u>the</u> <u>only continent with almost</u> <u>no local production</u>

### No Sub-Saharan African capacity - flu AVIVI



Countries with influenza vaccine production capacity in 2006 and following implementation of the WHO Technology transfer project



production capacity in 2006

Countries with new or planned influenza vaccine production capacity after 2006

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### **African Vaccine Manufacturers**





Senegal (IPD): producer WHO pre-qualified vaccine (yellow fever)

Ethiopia 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.

### **POLICY - Pharmaceutical Manufacturing Plan for Africa 2012**



- 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 AVIV



### **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

Ethiopia

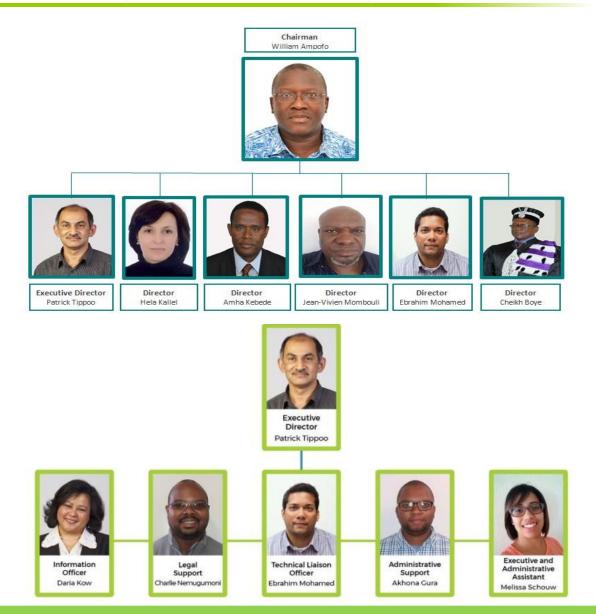
Morocco

Tunisia

Guinea

### **Board, Secretariat, Partners**





PARTNERS
WHO
WHO AFRO
HHS
GIZ
UNIDO
AU

**NEPAD** 

### **Strategic Objectives**



# High level Advocacy

# 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

# Facilitate partnerships

## 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

# Skills / Capacity Development

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

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:**

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

### White Paper: Vaccine Production



### 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



### **AVMI Advocacy outline:**

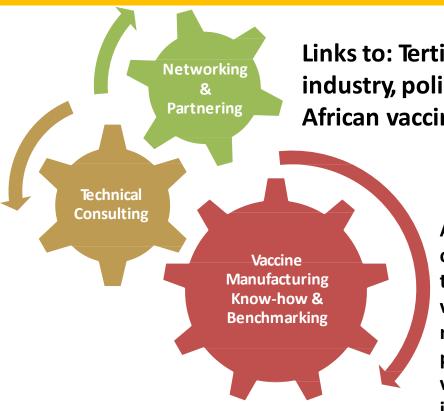
- 1. Promote AVMI regionally and globally to highlight local vaccines and biologicals manufacturing in Africa.
- 2. Promote the development and adoption of a Pan-African vaccines and biologicals policy.
- 3. Leveraging existing and new PP partnerships
- **4. Creating a network of advocates** across the 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!



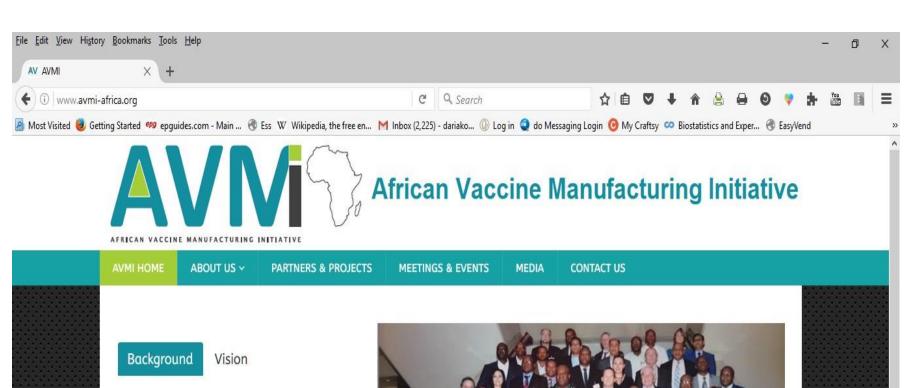
Links to: Tertiary institutes, industry, policy makers,
African vaccine manufacturers

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 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



#### 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...

