Vaccine Manufacturing in Africa

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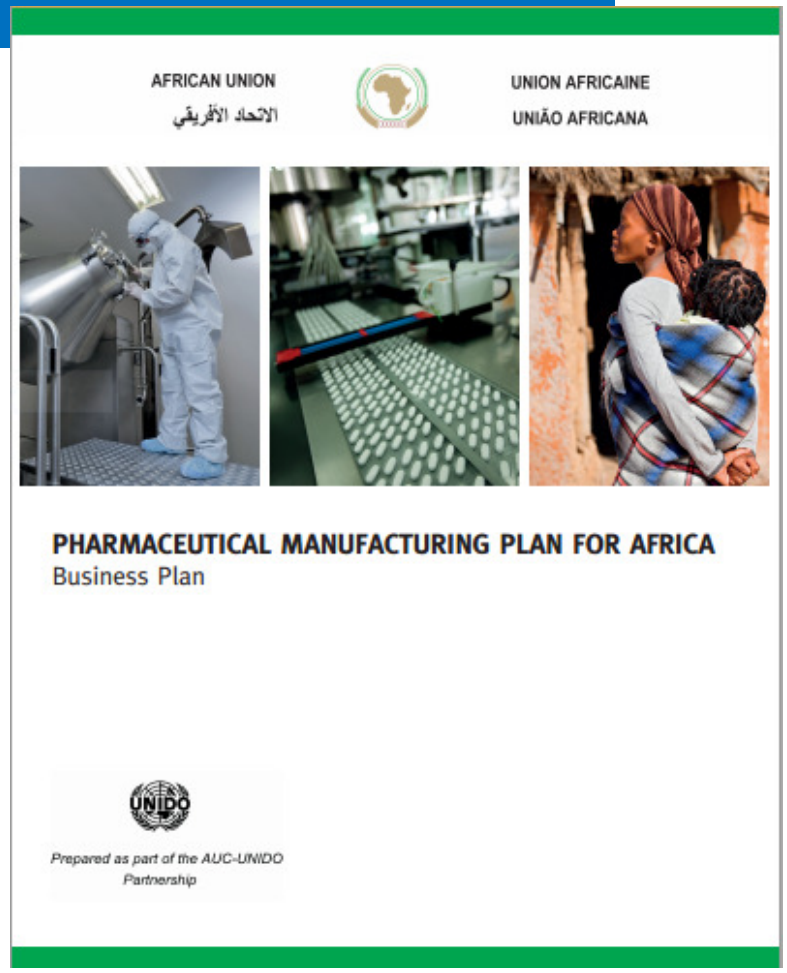
Highlights

- Africa represents 14% of the worlds population!
- But has < 0.1% of the world's vaccine production!
- Should Africa consider self-sufficiency in production?
- What are the challenges to achieving this?
- What are the risks in ignoring this?
- Now is the TIME!
- The question is HOW?

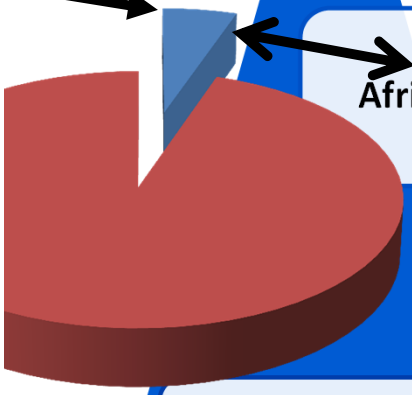
Vaccines vs Pharmaceuticals

- **Pharmaceutical Manufacturing Plan for Africa has been adopted by the AU.**
- **Induced demand**: by health professionals, Governments, donors and WHO
- **Limited number of purchasers**: Governments, health insurance institutions, 2 big procurement agent
  - UNICEF SD, PAHO RF
- **Public demand and funding** is dominant particularly for EPI vaccines
- **Highly subsidized market** (GAVI) for most of Africa



VACCINE MARKET

Vaccine Market: 2013/2014 snapshot



Global market US $ 24 Billion in 2013

Africa market US $1.2 B in 2013

Africa/Global vaccine market: 5 %

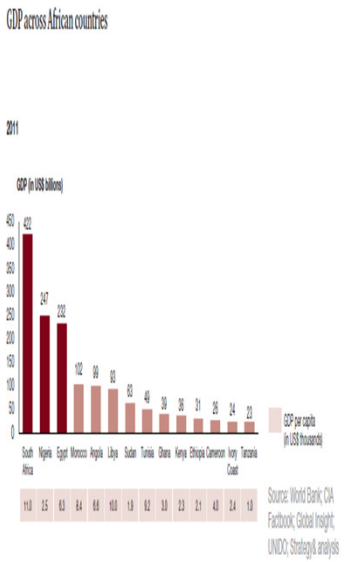
UNICEF vaccine sales to Africa

$810m in 2013: $899 m 2014

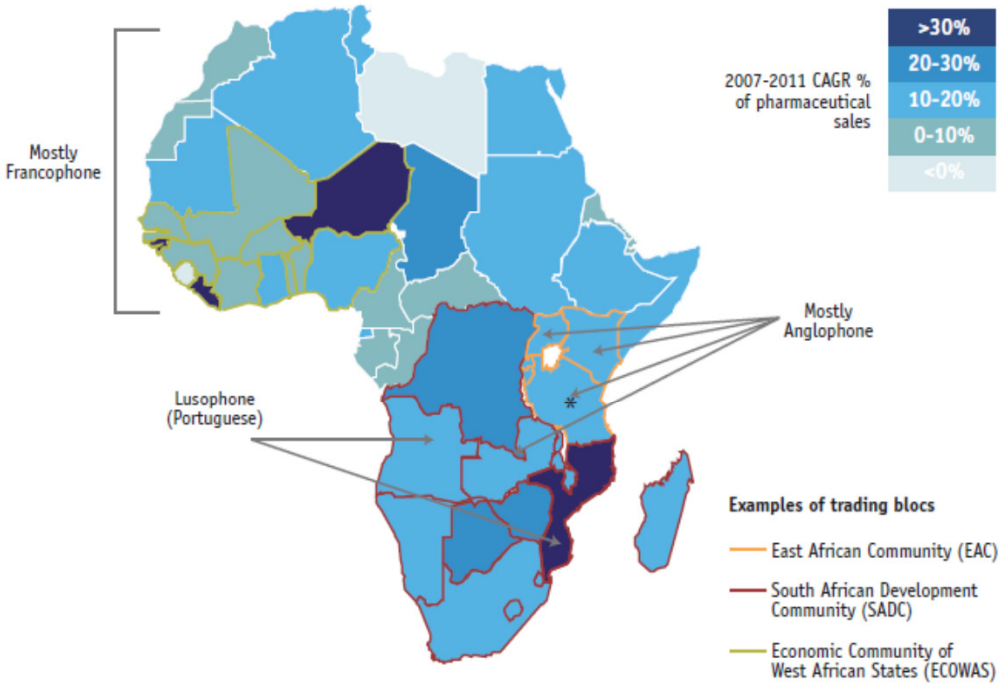
UNICEF; Africa 60% of total sales

45 out of 54 countries use UNICEF SD

AFRICA IS HETEREGENOUS IN TERMS OF VACCINE AND PHARMA GROWTH, LANGUAGES, TRADE BLOCS, INCOME PER CAPITA, SCIENCE AND TECHNOLOGY CAPACITIES

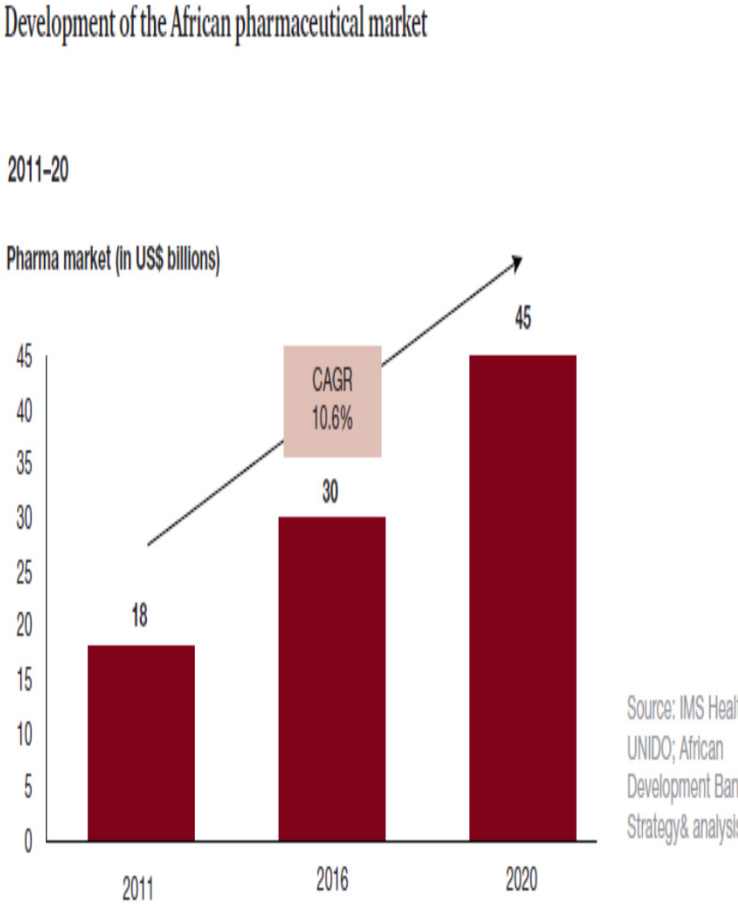


1 to 12,000 GP per capita



* Tanzania is in both the EAC and the SADC.

Source: IMS Health Market Prognosis, Sept 2012, excluding Gabon, Cameroon and The Republic of Congo which use the 2007-2011 CAGR of pharmaceutical import data – UN Comtrade – code 30.



Source: IMS Heal
UNIDO; African
Development Ban
Strategy& analysi

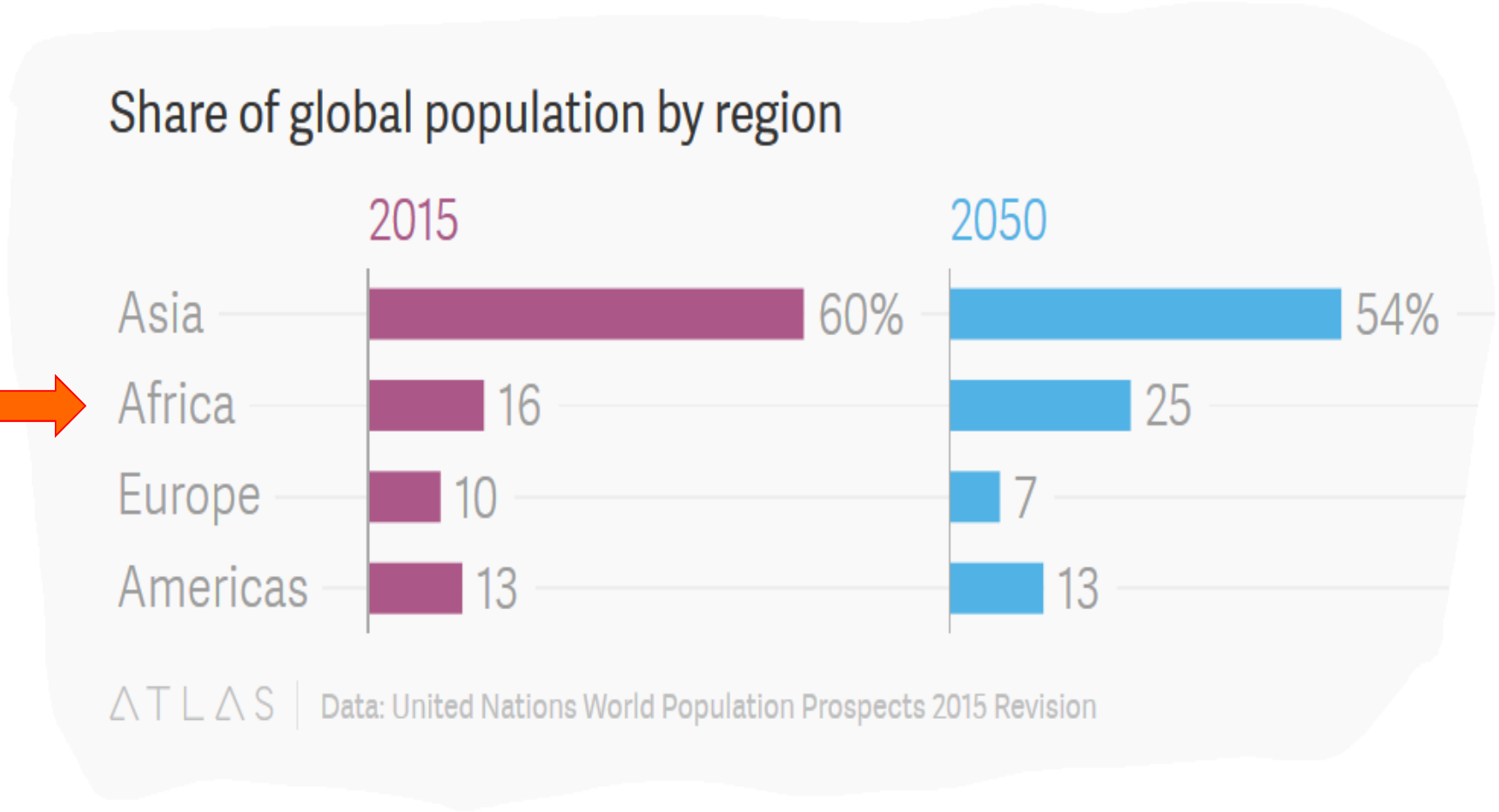
Diverse, Segmented income per capita

- LOW INCOME COUNTRIES
- LOWER MIDDLE INCOME COUNTRIES ($1,046-$4,125: 14 countries)
- UPPER MIDDLE INCOME COUNTRIES ($4,126 to $12,745: 9 countries)
- GAVI ELIGIBLE COUNTRIES
- LANDLOCKED COUNTRIES (LLDC)
- ISLAND COUNTRIES (SIDS)

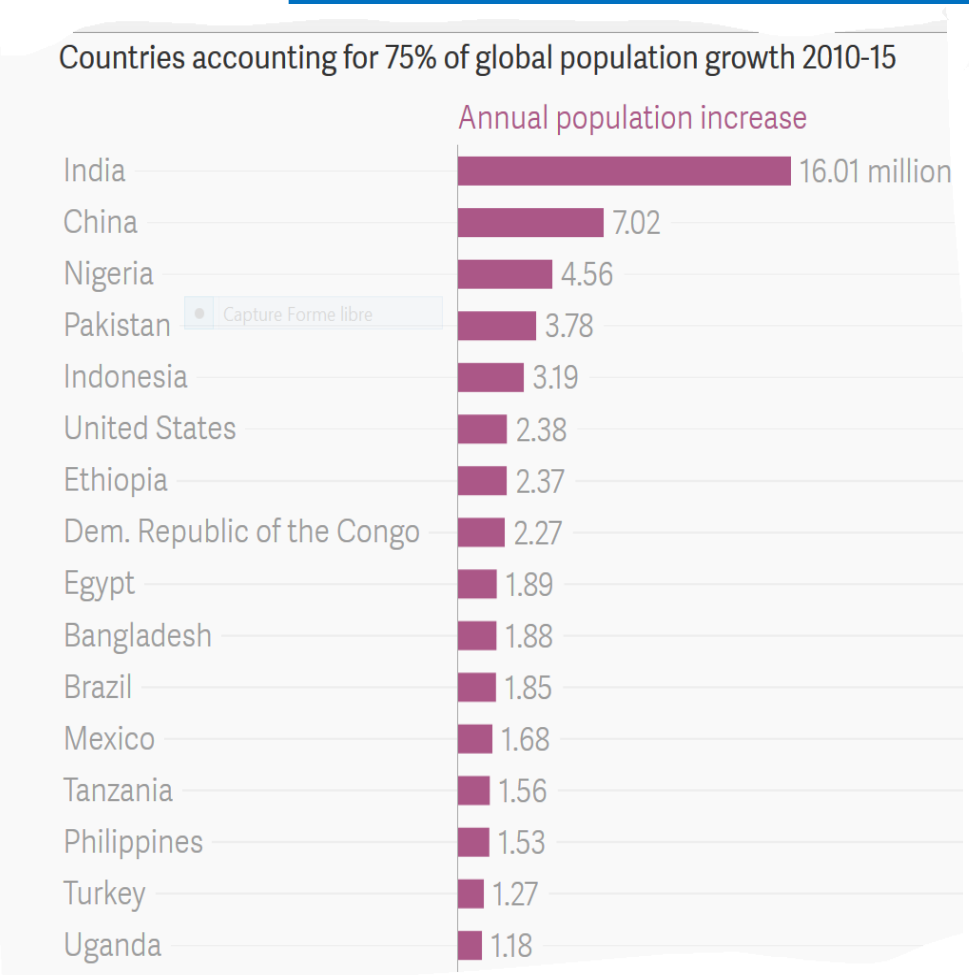
→ DIFFERENT STRATEGIES AND PRACTICES

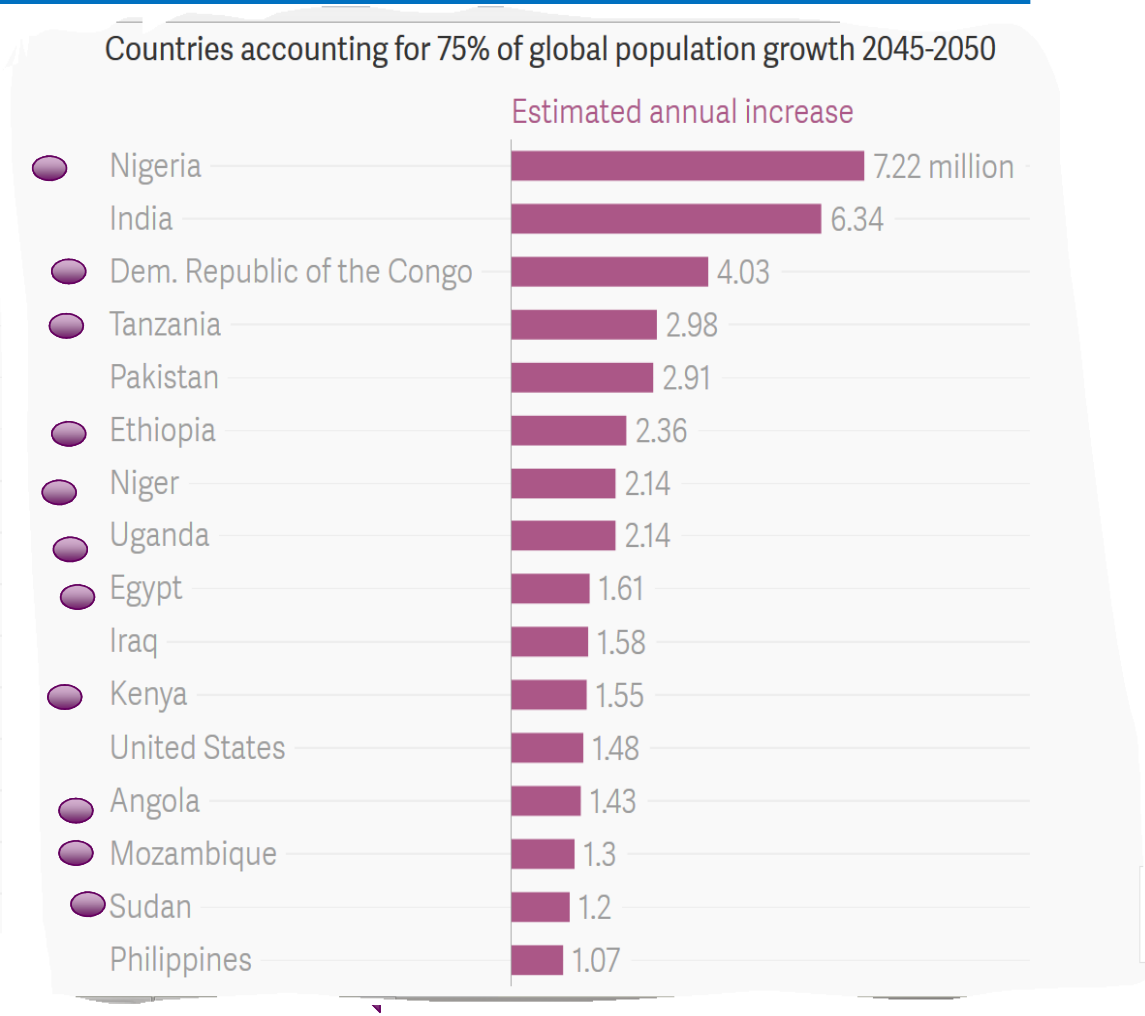
DEMAND

25% of Global population will live in Africa by 2050



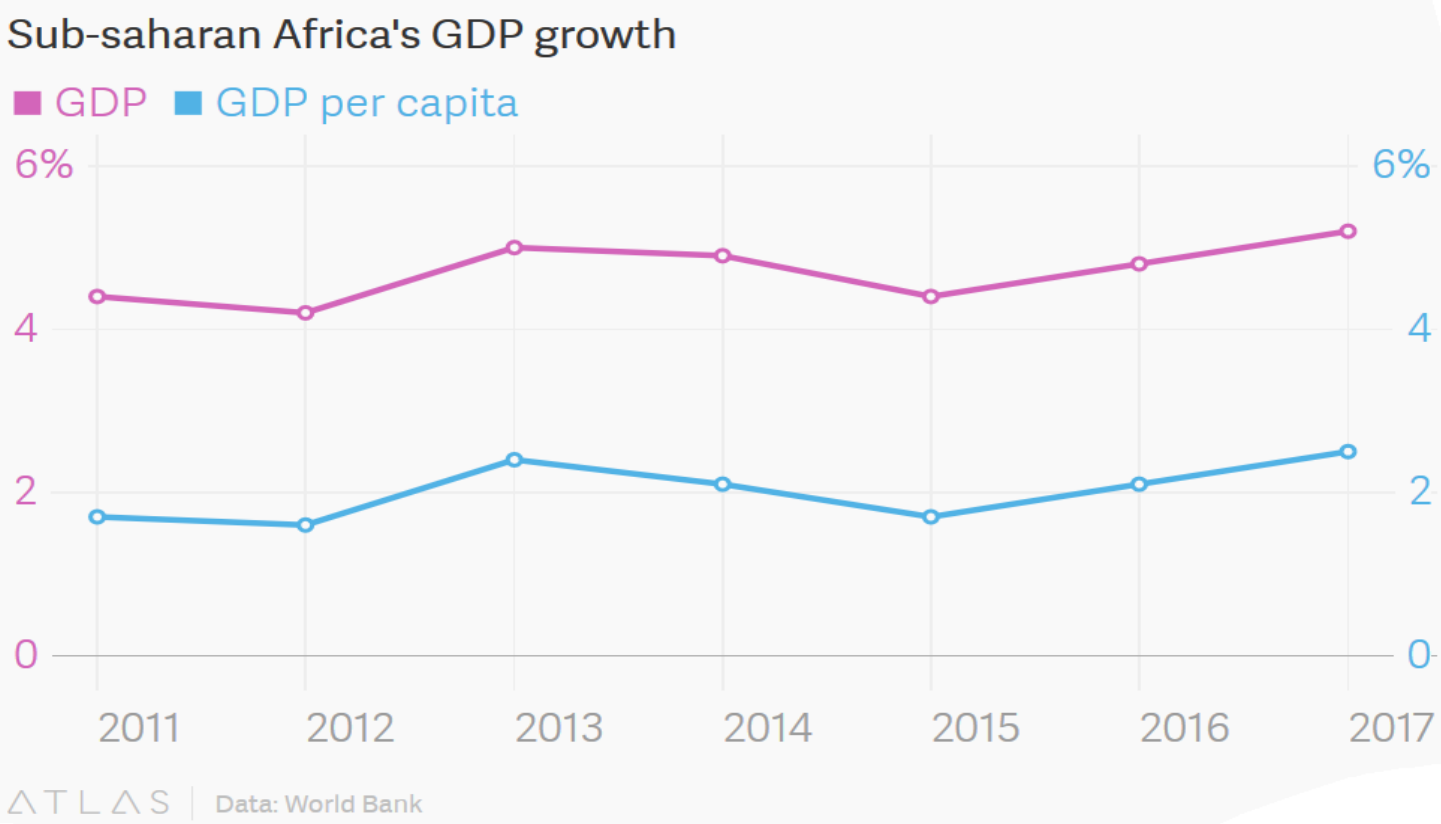
Demographic boom in Africa: 11 out of 16 top high pop. countries by 2050



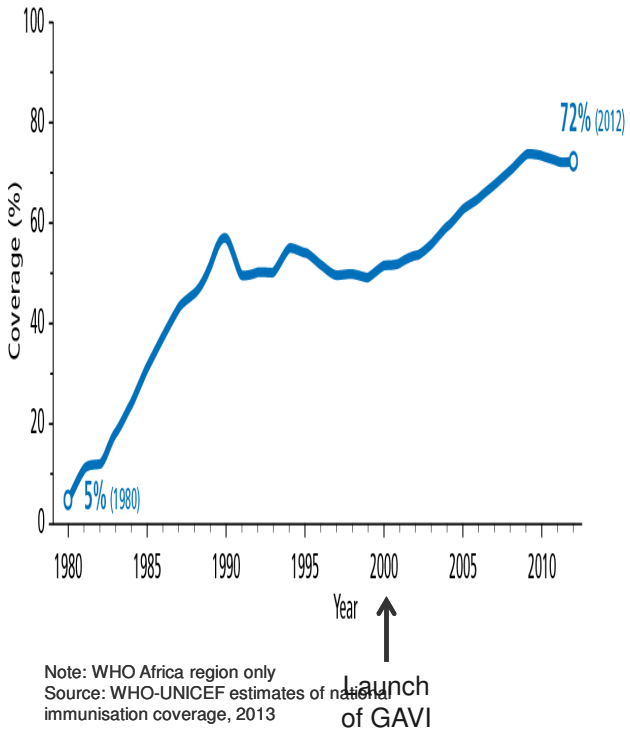


Sources: UN World Population Prospects, 2015

RAPID ECONOMIC GROWTH

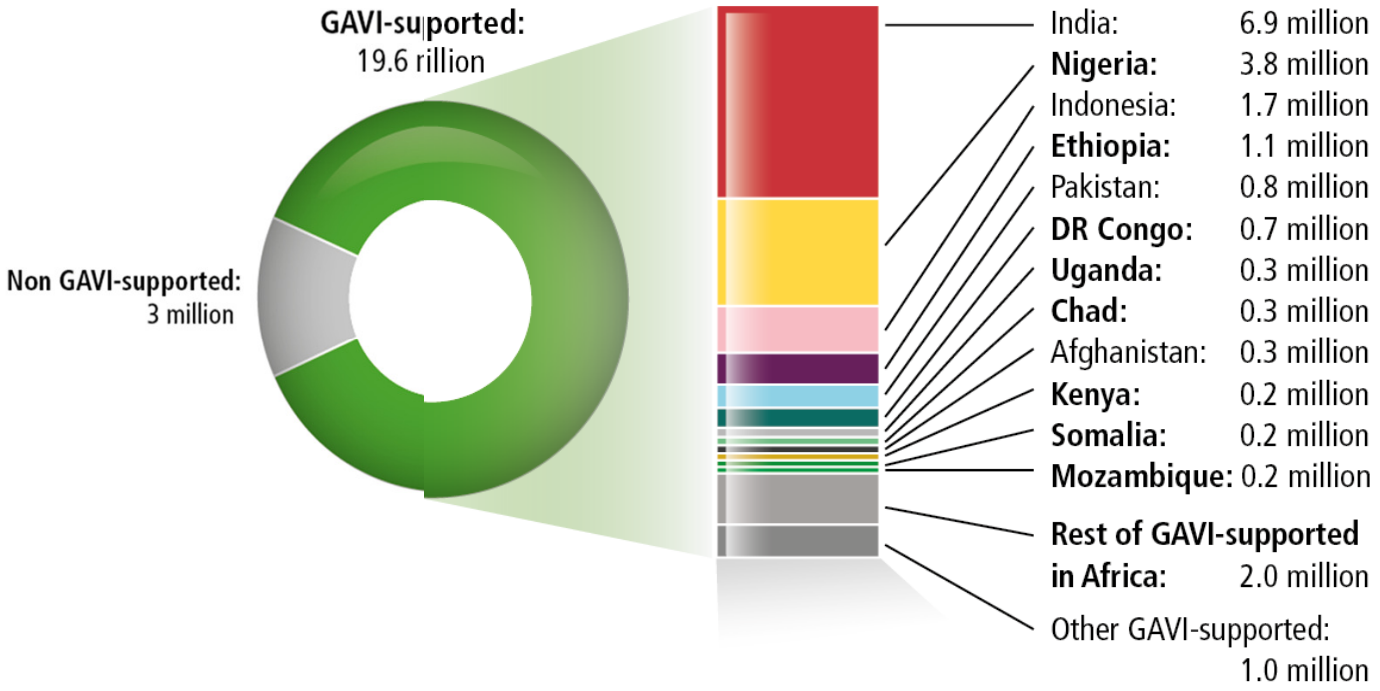


DTP3 coverage in the WHO Africa region increased from 5% to 72%, 1980–2012



Note: WHO Africa region only
Source: WHO-UNICEF estimates of national immunisation coverage, 2013

22.6 million children unimmunised with DTP3 **9 million in GAVI-supported countries in Africa**



Source: Gavi alliance

Recent Trends

- **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 :
- **Increasing interdependancy**:

  supply and financing

Supply

More than 99 % external sources

Less than1% local production

Dominant Vertical relationship

Current vaccine schedule/portfolio: from 6 to… 13

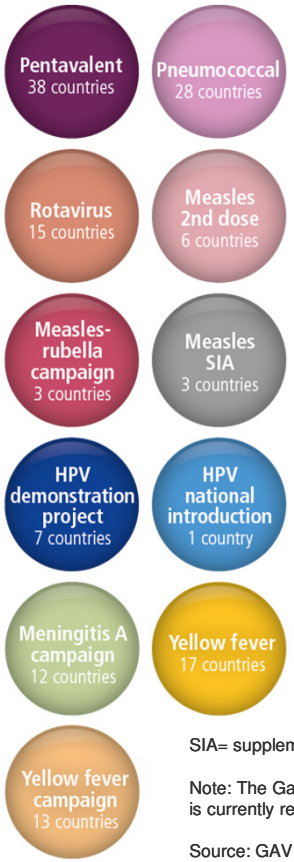
- Traditional routine vaccines
  - BCG, DTP, Hep. B
  - DT/Td, TT
- Measles,
- Polio tOPV, mOPVA, bOPVs,
- Pentavalent vaccine (DTP,HepB, Hib)

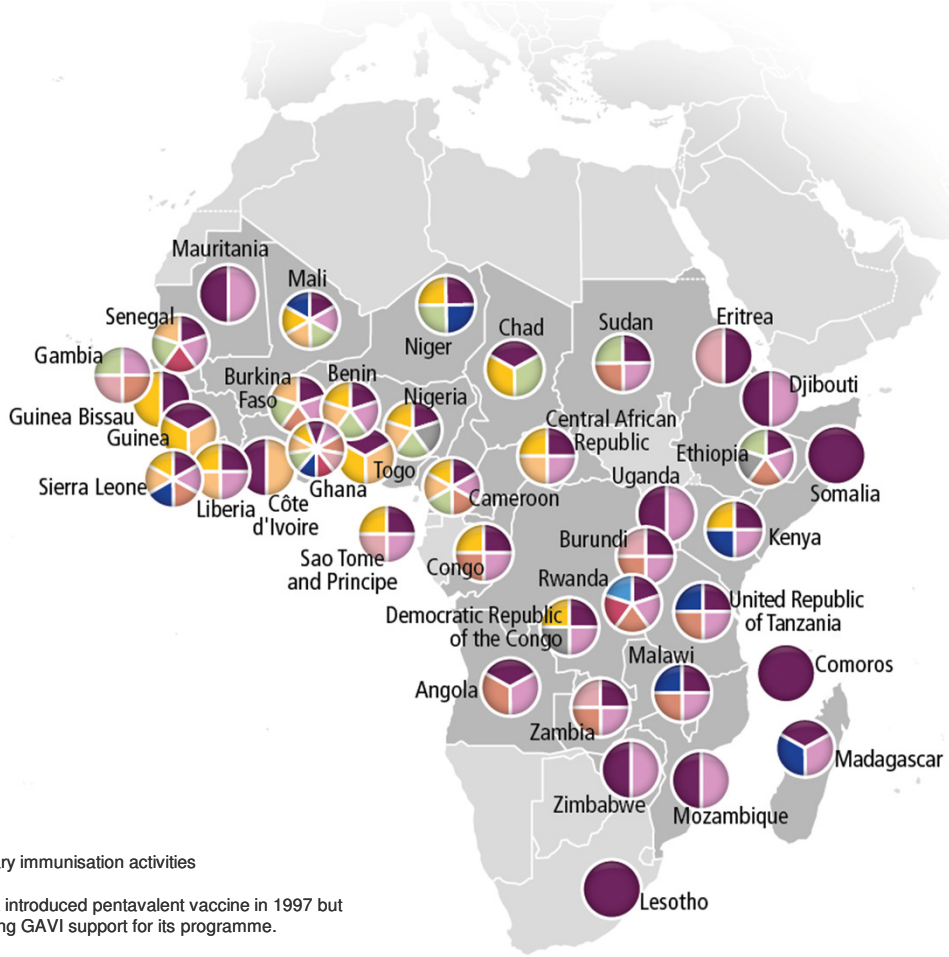
6 antigens in 1980/1990

- MR and MMR
- HPV,
- PCV
- Rotavirus,
- Mening
- YF
- IPV

…Dengue, Cholera, malaria,..

Very dynamic public sector, active donor support
More than 140 GAVI-supported introductions and campaigns in Africa since 2001





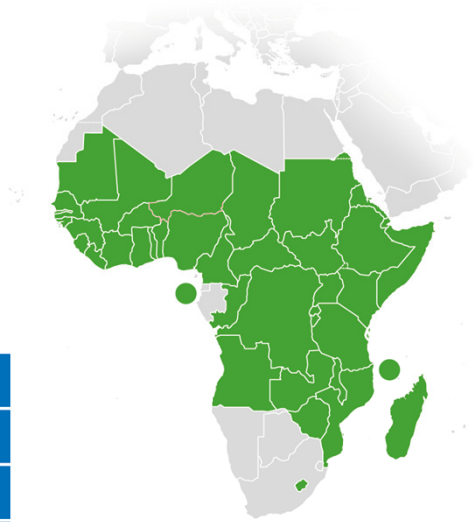
SIA= supplementary immunisation activities

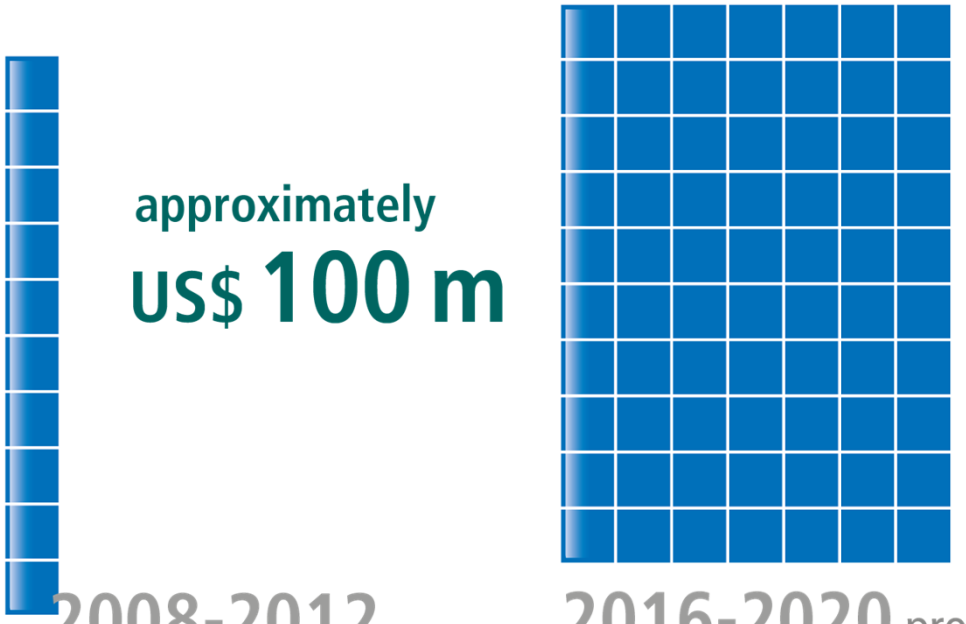
Note: The Gambia introduced pentavalent vaccine in 1997 but is currently receiving GAVI support for its programme.

Source: GAVI Alliance data as of 30 April 2014

GAVI ALLIANCE

African Gavi eligible countries increase their co-financing of new vaccines..





approximately
US$ 100 m

2008-2012

more than
US$ 700 m

2016-2020 projection

Source: GAVI Alliance data as of April 2014

GAVI ALLIANCE

The GAVI-graduation cliff….

- **What will happen when countries graduate from GAVI support ?**

- **Eg: Ethiopia**
  - **$150 M annual vaccine procurement**
    - **Currently $50M from country. $100M from donors**
    - **Will Ethiopia be ready to spend $100M in additional foreign reserves ?**
      - **Local production (save foreign reserves) ?**
      - **Reduced vaccine portfolio ?**

Production of Vaccines in Africa

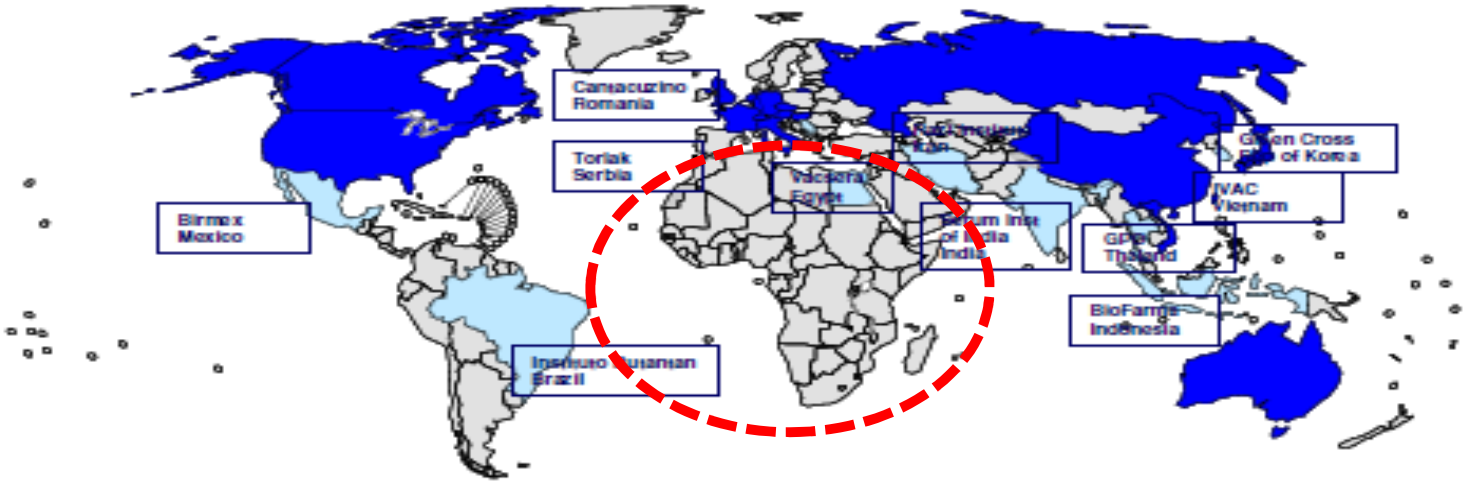
Vaccine Manufacture is a **complex** multi-step process

Antigen/API manufacture	Growing the organism	Inactivation	Purifying the antigen
Formulation & Filling	Blending the vaccine	Filling	Freeze-drying
Packaging & Distribution	Packaging	Storing	Distributing

Each step has specific equipment, facility, skills requirements related to the specific vaccine

No Sub-Saharan African capacity

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



Countries with influenza vaccine production capacity in 2006

Countries with new or planned influenza vaccine production capacity after 2006

WHO

World Health Organization

Current African Manufacturers of Human Vaccines

- Senegal: producer of prequalified vaccine (yellow fever).
- Egypt: DTP and some fill-finish
- South Africa: Fill finish
- Tunisia: very limited BCG and rabies
- Ethiopia: starting….

Can this be expanded ?

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 Manufacturing in the PMPA context

- **Vaccine manufacturing is considered a future area**
  - **Establish in the medium and long term**
  - **the production capacity to rapidly respond to Africa's needs**
  - **provide a sustainable source of high quality products to address vaccine preventable diseases.**

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.

Political Advocacy

- **Importance of developing vaccine manufacturing capacity in Africa** underlined by the **Global Vaccine Action Plan** resolution at the **2015 World Health Assembly**.

- Call for Member States to **seek opportunities for national and regional vaccine production** and to investigate procurement options for improved access and supply.

Socio-Economic Factors

In addition to improving response to emergency situations, African vaccine manufacturing could

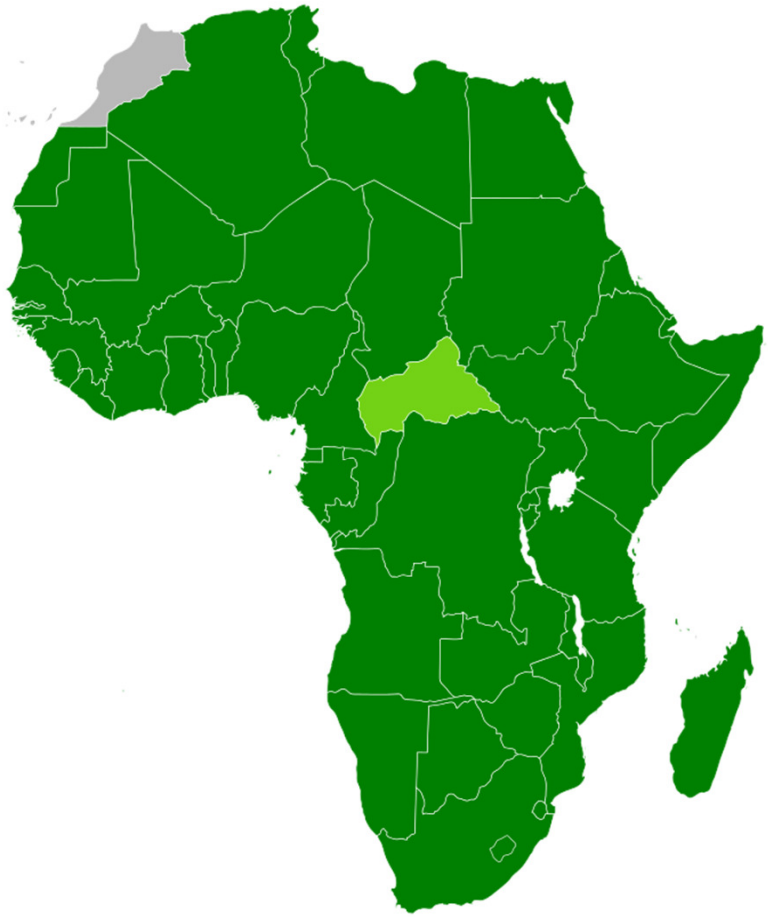
- **improve security** and **sustainability of vaccine supply**
- **respond to unmet health needs** of a growing population
- **aid socioeconomic development** in Africa.

To assess the feasibility of vaccine production in Africa to meet needs of the continent

A group of stakeholders from 12 countries comprising manufacturers, academics, scientists came together in 2010 and established a network

African Vaccine Manufacturers Initiative

AVMI is a partnership platform for the development of vaccine manufacturing capacity in Africa



AVMI 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

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

Vaccine Manufacturing and Procurement in Africa Study

VMPA 2015

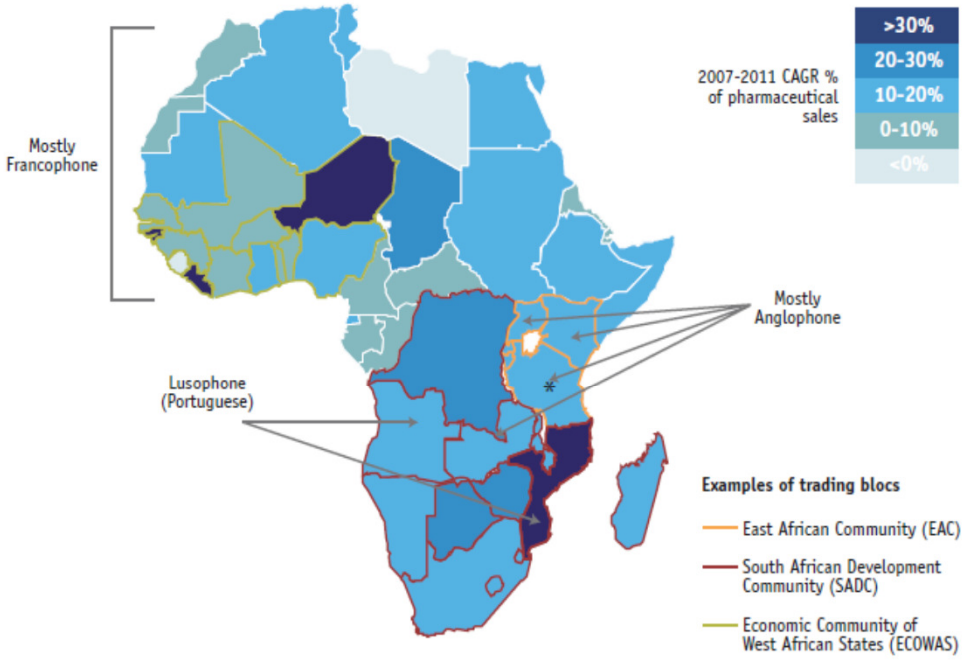
Provides an analytical assessment in Africa of

- vaccine manufacturing capacities

- procurement mechanisms

- suggest options for further consideration

Serve as a feasibility study and strategic framework tool for Africa Vaccine Manufacturing.



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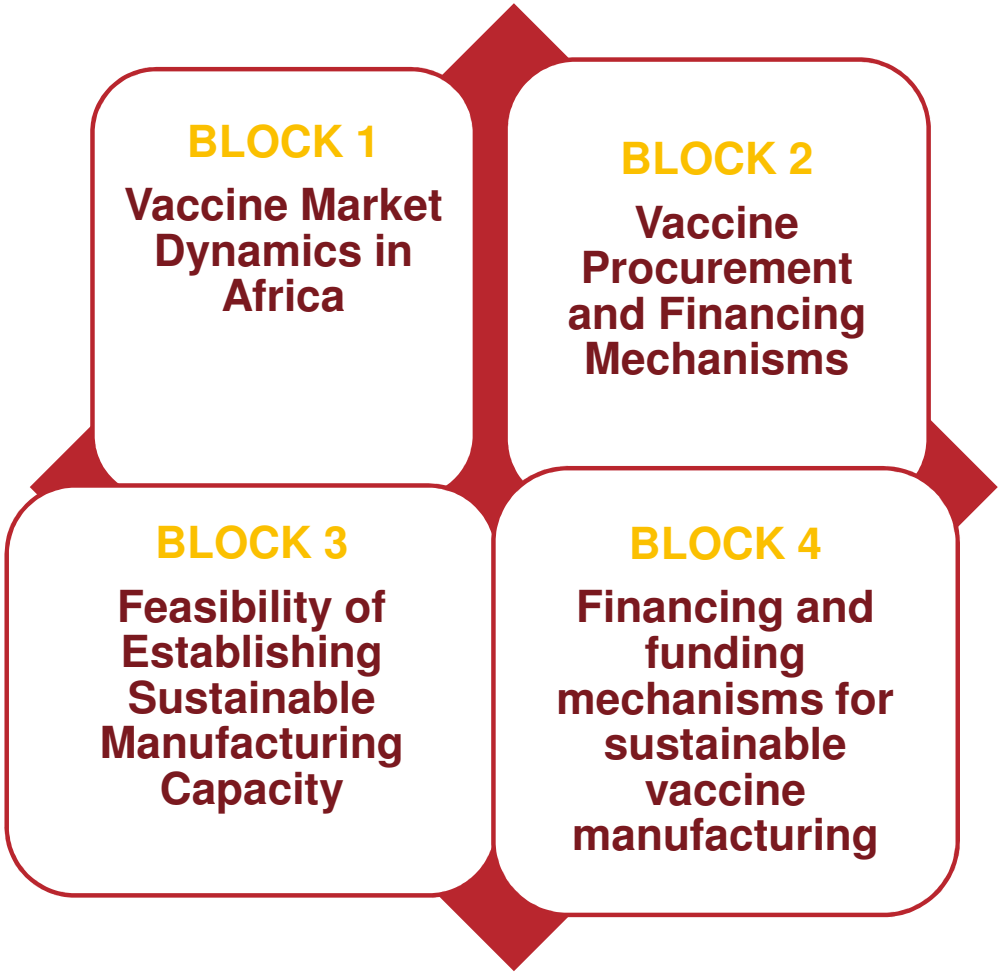
VMPA Study



Key Milestones

- VMPA Study Initiated
  July 2015
- Stakeholder Consultation Meeting – Addis Ababa
  Dec 2015
- Final Report
  April 2016

Next Steps?

Vaccine Production in Africa?

In Favour

- Security of vaccine supply
- Addressing of the Africa specific disease burden
- Dealing efficiently with pandemic diseases,
- Responding the unmet needs
- Growing population and market
- Socioeconomic, industry and life science development

Against

- Failure of the past and recent experiences in manufacturing
- Complexity and high cost of development and manufacturing
- Fragmented and dependent vaccine market in Africa
- Lack of human and technical capacity
- Absence of long term vision and political will to invest in public health goods and technologies.

An Issue of Need…

- Is local / regional production really required ?
  - National security
    - In event of global outbreak…
    - In event of collapse of global supply…
  - Foreign reserves
  - Economic Growth

- Is this enough to justify the investment required ??

A Question of Cost….

- Economy in Scale
  - Cost of production in small-medium factories cannot compete with large manufacturers
  - Most African countries internal market only supports small factories
  - ⇒ National market insufficient : needs regional approach
    - Will African nations procure from their neighbours ???
- African vaccines may cost more to produce than Indian vaccines
  - What will the price differential be ?
  - Will governments accept to pay this ?

A Matter of Time…

- Local production cannot compete with subsidized market
  - While GAVI subsidies in place, local production non-viable (unless pre-qualified)
- Takes 7-10 years to build a vaccine production facility
  - Waiting till local production is needed will be 10 years too late
- Highly skilled human resources are required for bio-manufacturing
  - It takes a generation to build this essential work-force

The best time to plant a tree was 20 years ago. The second best time is now.

Ministerial Conference on Immunization in Africa:

DECLARATION "UNIVERSAL ACCESS TO IMMUNIZATION AS A CORNERSTONE FOR HEALTH AND DEVELOPMENT IN AFRICA"

English | French | Portuguese | Arabic **Feb 2016 Addis Ababa**

Ministers of Health /Finance /Education /Social Affairs / Local Gov. attending ……..convened by the WHO / AU Commission, …. committed to continued investment in immunization programs and a healthy future for all people of the African continent.

….hereby collectively & individually committed to:

- ……..
- **Promoting and investing in regional capacity for the development and production of vaccines in line with the AU Pharmaceutical Manufacturing Plan including the strengthening of national regulatory authorities.**

Addis Ababa Declaration on Immunization to be presented to African Heads of State

- Feb 2016 Conference convened 100s political leaders, technical experts and advocates from Africa and worldwide.
- Celebrated progress toward expanding immunization coverage
- Discussed strategies to tackle challenges facing vaccine efforts
- Fostered country ownership for sustainable financing for immunization
- Advocacy for greater engagement with all stakeholders to ensure sustainable demand for immunization.

- **In June 2016, the Prime Minister of Ethiopia will present the "Addis Ababa Declaration on Immunization" to the African Heads of States at the 26th AU summit.**
- **Support from heads of state will further empower countries to increase efforts to mobilize resources for national immunization programs…….**

…….and vaccine production in Africa

Summary: stepwise approach in motion

- Step 1: Pharmaceutical Manufacturing Plan for Africa
- Step 2: Vaccine Manufacturing and Procurement in Africa Study
- Step 2: African Vaccine Manufacturing and Procurement Framework

To GUIDE…

- Which vaccines?
- Produced in which countries / for which regions?
- At what sustainable scale ?
- What procurement mechanisms need to be put in place ?

acknowledgements - African Vaccine Manufacturing Initiative

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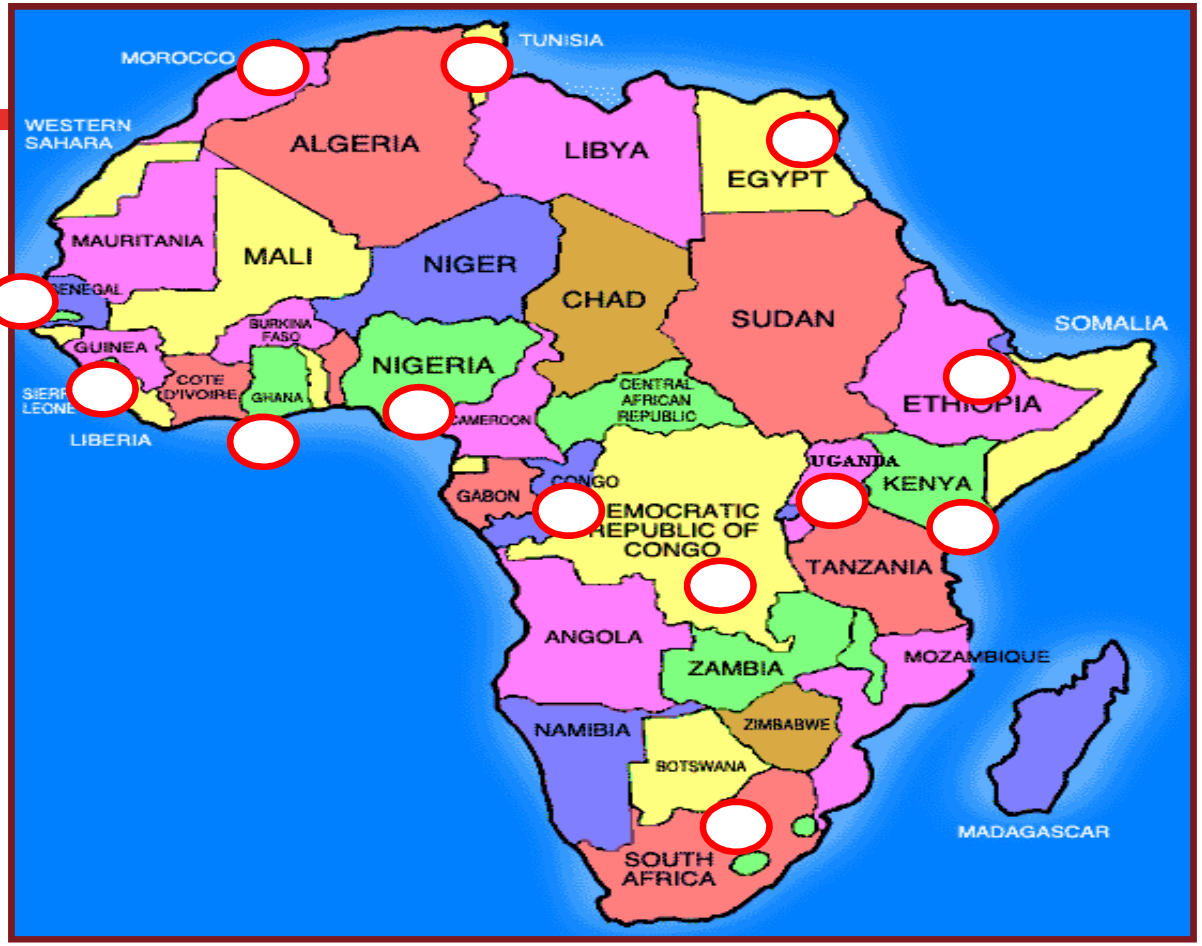

Task team members from several African countries

Democratic Republic of Congo, Egypt, Ethiopia, Ghana, Guinea, Kenya, Morocco, Nigeria, Uganda Senegal, South Africa, Tunisia.

Supported by
WHO,
UNIDO,
US DHHS
GIZ

Stakeholders:
AU, NEPAD, ANDI

African vaccine production: Scylla and ……..??

Smooth seas do not make skillful sailors! ~African Proverb

we must act as if it is not possible to fail!

~ Ashanti

Do not let what you cannot do, tear from your hands, what you can!

~ Ashanti