African Vaccine Initiative (AVI) – A new approach towards Vaccine Self sufficiency in Africa

A background to AVI
Presented by

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&
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at the AVI inaugural meeting
Capetown

13th December, 2010
Introduction and Background

- The recent H1N1 flu pandemic brought into sharp focus Africa’s lack of capacity to manufacture flu pandemic and other strategic vaccines as required in emergency situations.

- Africa stands out like a sore thumb in this regard and it has attracted the attention of WHO, USG - Biomedical Advanced Research and Development Authority (BARDA) and HHS in the US and other global stakeholders.

- In response, a group of interested and concerned Africans (from Nigeria, South Africa, Senegal, Egypt and DRC) used the opportunity at the International Vaccine Technology Workshop (IVTW) in Hyderabad, India on September 17 and 18 2010 to launch an initiative called the African Vaccine Initiative (AVI).
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Of the estimated 30,000 children under 5 years of age that die every day, mainly due to dehydration, undernourishment, and vaccine-preventable diseases worldwide, 60% are in Africa, and yet vaccine accessibility and affordability remains a major issue for the continent.

It has been estimated that nearly 30 million children born every year are not fully immunized and DTP vaccination rate in Africa has lowered around 50% over the past 15 years,

Before GAVI, it often took 10-20 years before the introduction of “new vaccines” in developing countries

Lack of interest and investment by developed manufacturers in vaccines against diseases prevalent in developing countries (so called “neglected diseases”)

With a current GDP of near $1 trillion US dollars, Africa should start the initiative of vaccine self sufficiency
• This situation is attributed to among others to programmatic and system problems such as:
  – Poor health infrastructure (health care system and logistics),
  – Lack of precise policy plans & long-term forecasting
  – Financial weaknesses (pricing & reimbursement, distribution costs),
  – Poor capacity building strategies and regulatory issues (requirements, review timelines).

• To provide effective response to these challenges and access to vaccines in Africa the AVI is established to:
  – enhance sustainable vaccine development/production
  – technology acquisition and technology transfer,
  – develop vaccine manufacturing infrastructure and raise fund to empower the continent to attain vaccine self-sufficiency
Issues discussed

1. Identification of key players on the continent

2. Identification of the need to coordinate and network African vaccine initiatives

3. Collaboration with existing organizations such as ANDI and IVI and potential funding organizations and Research and manufacturing Institutions

4. Creation of an advocacy group to mobilize the continents Leadership for Vaccine and Biologicals R&D and local manufacturing

5. Creation of a network on the basis of existing systems, such as the Infectious Disease Surveillance and ANDI networks, DCVMN, etc

6. Enhance cooperation among players in the continent

7. Source for funding through collaboration with Institutions in developed countries
Points identified for immediate action

1. Identify most appropriate Name of the group

2. Define the Vision, Mission, Goals and Objectives of the group

3. Develop Terms of Reference for AVI

4. Strategies for enhancing local efforts for Vaccines and biologicals development/production

5. Develop, encourage and promote proposals for funding

6. Submit a statement by the group before departure
Names of the Group proposed and endorsed

- Vaccine Initiative for Africa (VIA)
- African Vaccine and Biologicals Initiative (AVBI)
- *African Vaccine Initiative (AVI)* - The name of our group tentatively endorsed by members
- African Vaccine Manufacturing Initiative (AVMI)
- Vaccine Manufacturing Initiative for Africa (VMIA)
Mission and Goal of the Group:

- The purpose of AVMI is to facilitate the establishment of a sustainable African human vaccine manufacturing capacity.

- **Vision:** An Africa that attains manufacturing capacity to meet vaccine needs

- **Mission:** To make Africa self sufficient in Vaccines and Biologicals through establishment of manufacturing facilities and building capacity in the continent...

- **Goal:** To Develop and Establish capacity in Africa for manufacture of Vaccine and Biological of assured quality and at affordable cost
**Aim of the Group:**

- The AVI intends to empower Africa in vaccine and biological production through the transfer of technology in the following areas:

- The purpose of AVMI is to facilitate the establishment of a sustainable African human vaccine manufacturing capacity.

1. R&D capacity
2. Clinical trials
3. Laboratory testing
4. Quality assessment (QC/QA)
5. Vaccine Supply chain management and logistical issues
6. Capacity building
7. Information technology systems
8. Project/human resource management
9. Local production
Identified Challenges for Regional Vaccine Self Sufficiency

- Large and growing Population of Africa
- Increasing demand for Vaccines
- Decreasing Investment in this area in Africa
Identified Strengths:
Distribution of R&D capacity in Africa. Mapping of the top African cities by research output shows hotspots of R&D activity.
Strategic Approach and Confidence Building Mechanism

• The AVI’s strategy is to develop a coordinated and organized approach in Africa which will provide potential partners with a basis of trust and confidence in supporting efforts in Africa to establish sustainable capacity for vaccine and biologicals manufacturing and

• Source for Financial, technical and advocacy support from global partners to realize this goal in Africa.
Concept and Technology Transfer Strategy

• The AVI shall work within the concept of Developing Countries Vaccine Manufacturers (DCVMN) to address areas such as enhancement of R&D and production capacity.

• Organizations such as International Vaccine Institute (IVI), Korea, The Netherlands Vaccine Institute (NVI), Netherlands and similar institutions shall be engaged to serve as the Scientific and technological consultants for this purpose.

• Experts/Consultants within and outside the continent shall be identified for successful implementation of AVI objectives.
AVMI Strategic Objectives is to:

1. Establish advocacy for vaccines in the African continent.
   - Conduct vaccine situational analysis to establish the landscape for the continent.
   - Identify priority areas for Africa in Vaccine development and production.
   - Work with regulatory bodies to empower Africa in areas of vaccine regulation.

2. Assist countries in establishing effective vaccine distribution network.

3. Establish vaccine network systems. (within & externally)

4. Attract and secure funding for establishing vaccine manufacturing capacity. (write proposals, secure political support)

5. Establish vaccine marketing and distributing systems for the African continent.

6. Foster R&D capabilities in vaccines and technology transfer.

7. Foster the development of members to attain WHO pre-qualification standard.
AVI Objectives contd....

8. Empower decision-makers with the knowledge to determine what technologies are best suited to meet the needs of their nation.

9. Identify essential needs and current gaps in vaccine development and manufacturing capacity that must be addressed in order to meet the needs of developing countries.

10. Identify drivers and obstacles to the initiation of sustainable vaccine production capacity, as well as recommendations to overcome these challenges.

11. Identify roles of stakeholders including government agencies and ministries, international organizations, the private sector, and non-governmental organizations in the region.

12. Foster capacity building through manpower development and training.
Objective Categories:

1. Advocacy
2. Brokering Partnerships
3. Sourcing Funds
4. Skills development

Definition of Advocacy:
For strategic objectives advocacy shall mean: Support, encourage, sponsor and promotion
AVI activities

- Identify concrete African region vaccine and biological needs
- Identify key players on the continent in the areas of vaccine and biologicals manufacturing
- Create network of key players and stakeholders
- Increase advocacy for vaccine to enhance access and capacity
- Stimulate local industry and entrepreneurship
- Encourage exchange of knowledge in this area and Share Intellectual Property
- Identify key technical experts and Consultants to enhance speed of project implementation
- Assist existing manufacturers to broader range of products development and manufacturing technologies
- Encourage establishment of new public. Private of public/private manufacturing companies in continent
- Source for funding for innovations, Platform technologies, Manufacturing efficiency, and development of new formulations relevant to the continent
- Sustainable Influenza Vaccine Production Capacity
- Encourage R&D in Adjuvants and Antigen-sparing and stability issues
- Encourage Technology transfer and QC and QA
- Establish Partnership models
- Develop business plan for vaccine manufacture in the continent
**Issues AVI should consider**

- Challenges of building sustainable vaccine manufacturing
- Factors determining what technologies are best-suited for individual nations’ short, mid and long term strategies
- Manufacturing platforms for efficient vaccine production
- Technologies for increasing vaccine effectiveness and Deliverability and long-term goals
- Matching public health needs and market opportunities: factors influencing vaccine capacity building
- Increasing vaccine production capacity in the Continent
- **Building manufacturing capacity for influenza vaccines**
- Building manufacturing capacity for emerging and other relevant infectious diseases of the continent
- Case studies on vaccine technology transfer to developing countries
- Chart the way forward
Important and Immediate Activities for the AVI

• The AVI will, above all, source for information and ideas about production technologies and foster
  – technology acquisition,
  – technology transfer and
  – organize partnerships to enhance local production of Vaccines and Biologicals in the continent.

• The AVI will identify priority areas for vaccine and biological manufacture.

• The AVI will immediately embark on activities that will enhance the production activities of centres already manufacturing vaccine in the region and create markets for them.
During Break: Recognition and Meeting with potential Donors

• The group met with Nils Daulaire – Director, Office of Global health Affairs, in the office of the Secretary, US Dept of Health, Director, US department of International Health 18th of September at 10:30am. All members contributed at the meeting on the following Points:
  • 1. Capacity issues
  • 2. Coordination
  • 3. Empowerment of this group
  • 4. Vulnerability of the African region and the H1N1 Pandemic outbreak experience
  • 5. Prioritization of target diseases

• Individual members spoke with other stakeholders present at the meeting such as Bill and Melinda Gates Foundation, PATH, DCVMN, some Indian manufacturers
Collaboration and Cooperation

• Collaboration with and the support of organizations such as PATH, USA, Bill Gates foundation, USAID, USA, DCMN, Albert B. Sabin Vaccine Institute, USA, WHO, UNIC, etc shall be sought to enable our manufacturers (existing and yet to be established) attain the GLPs, GCPs, GMPs, and high quality manpower.
Regional and International Networking

• The AVI will work with the various manufacturers and research centers on the continent on Vaccine manufacturing and Intellectual Property issues and access to new technologies and new product development

• AVI will encourage partnership among African Vaccine Manufacturers and partnerships with DCVMN member states, ANDI, IAVI, AAVP.

• AVI shall work on identifying training and manpower development needs, particularly specialized training and qualification (manufacturing, innovation & validation)
USG Support

• Dr Nils Daulaire, the Director, Office of Global Health Affairs, in the Office of the Secretary, U.S. Department of Health and Human Services made a public declaration of support and assistance to the AVI by the US Government in his closing remarks at the IVTW, in which he stated clearly that:…….

• “I was heartened to learn that one of the things growing out of the discussions in this Workshop is a nascent African Vaccine Initiative. The United States will be honored to be a partner in such efforts, and we commit ourselves to helping you to build the capacity you need. We recognize this will be neither quick nor easy, but we will walk the road with you.”
Outcome of Hyderabad meeting:

- The AVI task team agreed at their meeting during the IVTW, to convene its inaugural meeting in Cape Town, South Africa.

- The purpose of the meeting would be to deliberate on the necessary structures and framework that we need to put in place for proper running and governance of AVI and how to start working on definite plans and projects.

- The meeting was planned for December 2010.

- A budget for the meeting was to be prepared and funding will have to be secured.
Conclusion

• The meeting concluded that:

• The AVI will seek that African countries speak a common language and have common agenda for finding the most appropriate solutions for low vaccine production capacity in the region, as compared to others and facilitate establishment of manufacturing facilities and access to technologies.

• Come up with proposals and strategies on how key regional Stakeholders such as AU, ECOWAS, SADC, etc and global stakeholders like the US government, WHO, Melinda and Bill Gates Foundation, PATH, GTZ and similar organizations could play a role in assisting the continent with establishing sustainable vaccine development and manufacturing capacity in Africa,

• and thereby improve our capacity in a pandemic preparedness and self sufficiency in vaccines and biologicals.
At the end of the meeting, the AVI members agreed to the following:

i. Endorse the name – African vaccine Initiative
ii. Conduct a follow-up meeting in South Africa, Cape Town (to be coordinated by Dr Tippoo)
iii. Members should endeavour to participate in the ANDI meeting in Nairobi, Kenya
iii. Prof A. Nasidi appointed as the Coordinator with Dr P Tippoo and Sam Adeniyi-Jones to assist. (Hamdallah Zedan volunteered to provide assistance).
v. AVI should commence identification of potential new members, vaccine and biological manufacturers, regulatory bodies and other stakeholders in the continent and come up with a compendium or list.

Establish AVI as a legal entity
• Create network for vaccine and biologicals manufacturers in the Continent (Figure 1)

• Recommend best partnerships and liaisons (Figure 2)

• Ensure product development and production as main outcome of AVI activities (figure 3)
Second Part
Nasidi presentation
Figure 1 – Network/Association

ANDI, IAVI, AAVP-

IAVI-
International AIDS Vaccine Initiative

AVAREF-
African Vaccine Regulatory Forum (AVAREF)

DCVMN

AVI
ANDI as a Health Innovation for Development

• The African Network for Drugs and Diagnostics Innovation (ANDI) is an organization that is being transitioned to Africa, and is owned, managed and governed by Africans, implementing product R&D and ensuring sustainable access to new health products.
ANDI recognised

- **Development is done in isolation in Africa. That’s where innovation needs the most support and where it is least likely to get it from the only agents available – venture capitalists or ‘business angels’. The establishment of ANDI will help us deal with the crisis in R&D for neglected diseases and develop human capital for sustainable development.**

- Ms Naledi Pandor, Minister of Science and Technology in South Africa
ANDI Silent on Vaccines and biologicals

- **ANDI is a key initiative aimed at supporting and promoting African-led health product innovation for the discovery, development and delivery of drugs and diagnostics.**
The African AIDS Vaccine Programme (AAVP)

• AAVP is hosted and supported by the WHO-UNAIDS HIV Vaccine Initiative (HVI). It was conceived in 2000 as a network of African experts, working together to promote and facilitate HIV vaccine research and evaluation in Africa through capacity-building and regional and international collaboration.

• The mission of the African AIDS Vaccine Programme (AAVP) is to advocate and support a coordinated effort to contribute to the global HIV vaccine development goals, ensuring that appropriate and affordable vaccines are developed for Africa in the shortest possible time.
Initiative for Vaccine Research (IVR)

- **Mission**
  - The mission of the WHO Initiative for Vaccine Research (IVR) is to guide, provide vision, enable, support, and facilitate the development, clinical evaluation and world-wide access to safe, effective and affordable vaccines against infectious diseases of public health importance, especially in developing countries.

- **Vision**
  - Being a vaccine research oriented unit of WHO, IVR adopts the long-term vision of the WHO Department of Vaccines and Biologicals: a world in which all people at risk are protected against vaccine-preventable diseases.

- **In addition, specific vision of IVR is:**
  - To develop and promote a global and sustainable R&D pipeline delivering the optimal cost-effective vaccines for IVR priority diseases.
  - IVR will focus on critical steps, leveraging on existing research, developments and management opportunities, proactively identify and promote set of targets for each stage of development to shape the global portfolio at every stage.
African Vaccine Regulatory Forum (AVAREF)

• Established to provide a resource of expert advise to regulators to support their regulatory system for evaluation of vaccines. This forum may be considered as an "ad-hoc" scientific advisory body that will help regulators make an informed regulatory decision with regards to authorizations of clinical trials, evaluation of registration dossiers, or any other challenging issues regarding evaluation of vaccines.

• First meeting of the AVAREF, 19-22 September 2006, Accra, Ghana.
FIRST AFRO VACCINE REGULATORY FORUM (AVAREF)

19-22 September 2006
Coconut Grove Regency Hotel
Accra, Ghana
Figure 2 – Partnerships/Advocacy

WHO GAP

WHO Afro

AVI

Govts

Priv Sect
WHO influenza vaccine production capacity building grant

- To establish a manufacturing capacity for human seasonal and pandemic influenza vaccines within the framework of the WHO Global Pandemic Influenza Action Plan in order to strengthen flu preparedness and response
3rd Meeting with International Partners on Prospects for Influenza Vaccine Technology
Transfer to Developing Country Vaccine Manufacturers
In Institute of Vaccines and Medical Biologicals, Nha Trang, Viet Nam, 5-6 May (morning) 2010

• Review progress in the WHO influenza vaccine production capacity building grants in developing countries
• Update on complementary WHO initiatives: influenza vaccine technology transfer "hub" and LAIV activities, regulatory aspects etc.
• Discussing lessons learnt and future possibilities for partners' input into influenza vaccine development in developing countries
In recognition of the inadequate resources available to Member States to combat epidemics and other public health emergencies in the African Region, the Fifty-ninth session of the WHO Regional Committee for Africa adopted Resolution AFR/RC59/R5 entitled “Strengthening outbreak preparedness and response in the African Region in the context of the current influenza pandemic”. The resolution requested the Regional Director to facilitate the creation of an “African Public Health Emergency Fund” that will support the investigation of and response to epidemics and other public health emergencies.
Figure 3 - Expected Outputs

- Identified needs
- Identified Centres
- Capacity building
- Product Development and Production
Expected Outcome of Inaugural meeting

- TERMS OF REFERENCE FOR THE AVI should include topics as:
  - Agree on Final Name
  - Re-define Vision, Mission, Strategies and Objectives
  - Inclusion criteria for Membership/Representation
  - Accept Language of the Initiative
  - Confirm Operating HQ and country of Registration
  - Frequency of Meetings and Conference(s) or Symposium
  - Define Confidentiality and Conflict of Interest
  - Identify regional and international Resource Persons
  - Identify Funding sources
Recommendations

• Increase Advocacy for vaccine and biologicals self sufficiency for the African region by engaging governments and regional organizations such as AU, ECOWAS, SADC, etc

• Engage International Stakeholders

• Registration of AVI and establishment of Managerial Structure

• Identify key Experts/Consultants for the Region

• Assist countries and individual manufacturers on how to access funds for vaccine and biologicals manufacturing

• Embark on immediate sourcing for funds
Important pronouncements to note

• The World Health Organization (WHO), the U.S. Department of Health, and Human Services (HHS) and other like-minded organizations and governments are committed to assisting in the creation of regionally-based, independent and sustainable vaccine production capacity in developing and emerging economy countries through capacity building and technology transfer.

• As a means of initiating a coordinated discussion among the international community regarding this shared goal, WHO and HHS convened the Sustainable Influenza Vaccine Production Capacity Stakeholders’ Workshop in Washington D.C. in January 2010. Workshop participants identified partnership models, production technologies, and opportunities for technology transfer as some of the elements critical to successful building of sustainable vaccine production capacity worldwide.

• WHO Afro Special Emergency fund
Thank you