African In the Global Vaccines Manufacturing Landscape: Regional Perspectives

24-25 September, 2018, Radisson BLU Hotel, Freetown

Mrs Sybil Ossei – Agyeman - Yeboah
Pharmaceutical and Quality Assurance Analyst
Professional Officer: Essential Medicines and Vaccines
West African Health Organization
Bobo-Dioulasso-Burkina Faso

PRESENTATION OUTLINE

- Introduction
- Political Commitment and Willingness
- A Consolidated approach – ECOWAS Regional Pharmaceutical Plan (ERPP)
- Progress on of Work by WAHO
- Vaccines Manufacturing and Development in Africa
- Stakeholders Engagement
- Challenges
- Conclusion

Economic Community of West African States (ECOWAS)

ECOWAS Commission in Abuja

West African Health Organization (WAHO) in Bobo - Dioulasso

15 West African Member States

Population of about 365 million.

- **A huge disease burden:**
  - **Malaria; kills abt 9.33 per 1000, 28.2 % of mortality of chd under five.1.58 % of chd. 5-14yrs , 52.2% of all deaths and 0.6 per 1000 in Adults. 6% of deaths. 40% of hospital cases.**
  - **HIV/AIDS; 17million infested cases are under treatment**

    (PEFPAR 2013 report)
  - **Tuberculosis and Neglected tropical diseases;**
  - **And other newly emerging infectious diseases like the Ebola virus. Infested about 23,000 and killed 11,200 people in WA . WHO- 15 March, 2015 report**
  - **Zika infection –look out**
- **Poverty and malnutrition also impact on the types of medicines required.**
- **Importation of medicines ranges from 70-98%. PRSAO 2008 report**
- **Currently local production is ranges from 0-30%. PRSAO 2008 report**

A consolidated approach- ECOWAS Regional Pharmaceutical Plan (ERPP)

43rd Ordinary Session of the ECOWAS Authority of Heads of State and Government (Abuja, July 2013): adopted the ECOWAS Charter on PPP on Local Pharmaceutical Production of Essential Medicines.

July 2013

Nov 2013

Joint Multi-stakeholder Consultation for the Implementation of the ECOWAS Charter on PPP Initiative (Bobo-Dioulasso, November 2013)

5th April 2013

14th AHM in (Cape Verde, 5th April 2013, signed and adopted the ECOWAS Charter on Public-Private Partnership on Local Pharmaceutical Production of Essential Medicines

A consolidated approach- ECOWAS Regional Pharmaceutical Plan (ERPP)

Adoption by ECOWAS Health Ministers Assembly; Niamey , 13th March, 2015

11th May 2015

Adoption Council of Ministers and Heads of State and Government

23rd April, 2015

13th March 2015

Adoption by the Assembly of Health Ministers 23rd April, 2015, Accra

April 2014

Technical Validation of he ERPP (Ouagadougou, April 2014)

47th Conference of ECOWAS Heads of State and Government, Abuja, 11th May, 2015

Adoption by Two Ministerial Meetings

ECOWAS Ministers in charge of Industry
Accra, Ghana, 24-25 April, 2015

Validation of the strategy for implementation of the West Africa Common Industrial Policy (WACIP 2015-2020), designed to facilitate the industrialization of the region

ECOWAS Heath Ministers Assembly, Niamey, Niger, 13 March 2015

Validation of the **ECOWAS Regional Pharmaceutical Plan:** To achieve with the collaboration of all the major players in the production and distribution of quality, efficacious, safe and affordable essential medicines throughout the region.

The 74th Ordinary Session of the ECOWAS Council of Ministers (17th May 2015 in Accra, Ghana) adopted both documents

VISION AND GOAL OF THE PLAN

Vision:- A strong regional pharmaceutical sector, incorporating a vibrant manufacturing industry and a robust regulatory system that is enduring, sustainable, competitive and managed in an integrated manner to be able to provide quality, affordable, safe and efficacious essential medicines that meet the needs of the ECOWAS region and for exports of medicines by 2025.

Goal:- To provide a strategic framework intended to make easier investment in the pharmaceutical sector capacity, not only to provide self-sufficiency in the production, access to and rational use of affordable essential medicines and other medical products of proven quality, safety and efficacy, but also generate jobs and integrate health in an agenda of long-term regional development and research

Strategic objectives

The NMRA activities have great influence on all these 8 objectives which impact on local pharmaceutical manufacturing

ECOWAS/WAHO Support to the Pharmaceutical Sector Development

- **Advocate for financial and political support in the implementation of the ECOWAS Regional Pharmaceutical Plan, WAHO/XVI.AHM/2015/Res-04/p;**

- **Enhance government support and patronage of locally produced medicines (ECW/CM/LXXV111) 78th Ordinary Session of ECOWAS Council of Ministers (1-2 June, 2017, Monrovia) and protect local production of medicines;**

- **Adoption of Common External Tariff regulation on pharmaceutical raw materials, packaging and equipment at national level, (ECW/CM/LXXV111) 78th Ordinary Session of ECOWAS Council of Ministers (1-2 June, 2017, Monrovia);**

- **Support the assessment of the pharmaceutical manufactures and the implementation of the Good Manufacturing Practices Roadmap, GMP roadmap launched by the Health Ministers on 16 June, 2017 at AHM in Abuja**

- **Exemption of Value Added Tax (VAT) for locally manufactured pharmaceutical products and the protection of locally produced medicines, Ghana and Nigeria;**

How can these be possible? Effective collaboration between the ECOWAS, WAHO, Health Ministers and partners

Progress on WA-MRH

- **WA-MRH Implementation Efforts**
  - Consensus Meeting between WAHO, UEMOA , Member States and Partners on the WA –MRH 30 June-4 July 2014 in Ouagadougou
  - Launched of the Steering Committee & EWG of WA-MRH in Accra, 2-5 February, 2015. 2nd MRH SC Meeting in 18-20 April, 2016 Abidjan, 3rd MRH SC 23-25July,2018 Ouagadougou
  - Mentoring/Twining of NMRAs Sept-Oct, 2016
  - April, 2016 included vaccines in the regulatory harmonization process
  - Final validation of Common Technical Document (CTD) for MRH Harmonization, 11-15 Sept , 2017, Ouagadougou
  - 7 Expert Working Groups established, March, 2018

Progress on WA-MRH

- **A draft ECOWAS Policy, Legislation and Regulation (**In accordance with the AU Model law)
  - To be completed from 27-29 Sept, 2018 in Monrovia and valeted in November, 2018

- **Quality Management System (QMS) implementation for ISO 9001 and PICs ascension**
  - 15 NMRAs conducted, roadmap develop for each country, validated implementation plan – 2015/2017;
  - Ghana FDA is ISO 9001:15 Certified

- **SWEDD Project / ECOWAS MRH project**
  - Supported by the World Bank to Improving the Medicines Regulatory Harmonization.
    - **Dossier evaluation, GMP and Inspection, Quality Management Systems, Information management Systems, Quality Control, Pharmacovigilance /Clinical Trials, Policy/Legislation;**

- **Two WHO NRA Assisted Self-Benchmarking of ECOWAS MS Workshops with WHO**
  - 26-28 September, 2017 in Cape Verde and
  - 12-14 December, 2017 in Dakar

Progress on MRH

- **Strategic Direction to Strengthen Pharmacovigilance**
  - **Concept Paper Pharmacovigilance Systems Strengthening in ECOWAS Regions 13th July, 2017 (NEPAD/WAHO).** The Region had had:
  - Four (4) day workshop held in 10th – 13th May 2010 in Accra,
  - Three day workshop for six countries held in WHO-CC Accra 6-8 April, 2011.
  - Workshop in Communication and Crises Management in PV . Accra, 22-24 February 2012 .

- **WAHO Implementation Status on Quality Control Laboratories**
  - Five Quality Control Laboratories (Ghana, Nigeria and Cape Verde attained ISO 17025 certification.
  - 15 QCLs in ECOWAS including Chad and Mauritania decided to join the Networks of Official Medicines Control Laboratories (NOMCoL) to ensure standards and international accreditation. Now known as African Quality Medicines Forum (AQMF)
  - Assessment of Laboratory equipment in the region

- **WAHO Efforts to Ensure Quality and Safe Medicines (fighting counterfeit and illicit trade in medicine)**
  - Drafting of the Legal Directive for Counterfeit and Illicit Trade in Medicines 2014.
  - 2018 -2019 –preparing to conduct regional situational analysis of the counterfeit status

- **TRIPS Flexibilities for Pharmaceutical Products**
  - Validation and Adoption of Regional Trips Flexibilities Policy/Legislation and Guidelines.
  - Advocacy document developed in 2013 to strengthen political understanding.

Progress on MRH

- **Supporting the Pharmaceutical Industry**
  - ECOWAS has amended the Common External Tariff (CET) to Include APIs, Finish products, Packaging material at zero tariff for pharmaceutical products produced locally (complete political commitment).
  - Exemption of Value Added Tax (VAT) for locally manufactured pharmaceutical products and the protection of locally produced medicines;
  - 4 WHO Good Manufacturing Practices GMP compliant companies.

- **Good Manufacturing Practices (GMP) Roadmap Initiative**
  - Both WHO and UNIDO made inputs into the ECOWAS Regional Pharmaceutical Plan (ERPP) and the implementation plan;
  - Progressive transformation of the West African Pharmaceutical Manufacturers Association (WAPMA).
  - Regional and National Good Manufacturing Practices (GMP) Road Rap for the ECOWAS region.;
    - Kick-off meeting 28 Feb-1March, 2017 in Accra
    - Political Launch 12-16th June, 2017 in Abuja
    - 2nd Regional Workshop December 4-6, 2017
    - Launched and assessment done in 15 Countries
    - 75 Manufacturers has been assessed, 2017 -2018

- **WAHO Stock Security**
  - Patronage of N-PSP Cote D'Ivoire for medical products - ARVs

ECOWAS CET and Pharmaceutical Industry 2

Items	Extant Tariff Policy	Proposal for CET Tariff	Justification
Pharmaceutical Raw Materials	5%	0%	No local manufacturer in the region
Pharmaceutical Machinery	0% - 5%	0%	No local manufacturer in the region
Pharmaceutical Packaging	10%-20%	0%	Cost on locally produced medicines
Finished Pharmaceutical Products	20%	Supplementary protection measures at country levels	Retention of 20% duty tariff or more at country levels
Vaccines, Biologicals and Diagnostic Products	0%	0%	To promote access to medicines
VAT on Finished Pharmaceuticals	0%	Exemption	Medicines exempted from VAT
VAT Pharmaceutical Inputs	0%	Exemption	Reduce cost of locally produced medicines
Products on Imported Prohibition	Import prohibition list in counties	Supplementary protection measures at country levels	Local industry has adequate capacity

Collaborations

- **Partners Collaboration**
  - A mission to key partners (WAPMA, AUC, WHO, UNAIDS, IFPMA, Global Fund and UNIDO), for a buy-in and to seek for support and technical assistance for the implementation of the ECOWAS Regional Pharmaceutical Plan 2014-2020;
  - To strengthen the capacities of:
    - the pharmaceutical sector as being vital,
    - the industrial development;
    - regulatory oversight were paramount for every nation;
    - Strengthening of the quality control laboratories.

Vaccines Manufacturing and Development in Africa

Speeding Access to Vaccines in Low- and Middle-Income Countries

Donor aid agencies have demonstrably saved millions of lives through increased access to quality-assured vaccines. Yet, these health interventions continues to face a time lag due to factors which remain poorly understood.

- **The Question is WHY ?- Is it because we are not self-sufficient?**
- **How then do we speed up to improve vaccines and medicines security?**
  - An comprehensive and efficient harmonized vaccine registration process in Africa to reduce registration timelines;
  - Strategic approach to establish manufacturing facilities for vaccines for certain communicable diseases;
  - A broad set of stakeholders involvement and shared responsibilities (national regulatory authorities, manufacturers, procurers, and other experts);
  - Adequate and sustainable capital investment;
  - Specialty capacity development in both manufacturers and regulators
  - Comprehensive electronic information management systems-platform for information sharing

Great progress has been made in across Africa to vaccinate, resulting in significant health benefits

Number of reported cases in the African region

	2014	2013	2012	2011	2010	2000	1990	1980	
Diphtheria	1	128	27	13	50	4'038	2'588	8'771	
Hib meningitis	-	-	-	5'921	10'418	5'532	-	-	
Measles	73'914	171'178	108'004	195'620	199'174	520'102	481'204	1'240'993	
Mumps	7	8'147	2'401	10'808	13'836	38'713	-	-	
Pertussis	10'098	9'930	16'839	5'816	4'929	52'008	89'515	367'961	
Polio	13	92	168	397	649	1'863	4'228	5'126	
Rubella	7'402	13'739	10'850	16'190	2'754	865	-	-	
Rubella (CRS)	14	3	69	0	16	0	-	-	
Tetanus (neonatal)	835	1'449	2'049	1'908	1'937	5'175	7'029	2'265	
Tetanus (total)	2'900	5'149	4'737	4'355	4'311	5'835	12'281	17'241	
Yellow fever	31	268	246	2'574	714	593	4'248	24	

Vaccines remain on the “best buys” as a tool of public health

Vaccines are among the most efficient tools for promoting individual and public health

Disease control benefits	• Eradication • Elimination
Control of morbidity, mortality & complications	• Individual • Society • Mitigation of disease severity • Prevention of infection
Protection of the unvaccinated populations	• Protection • Source drying
Prevention of related diseases & cancer	•Protection against related diseases •Cancer prevention
Societal & other benefits	•Health-care & other savings for society •Preventing development of antibiotic resistance •Safe travel and mobility •Extending life expectancy

The Vaccine Procurement in Africa is worth over US$1bn per year

Vaccines account for 2-3% of the global pharmaceutical market.

Sub-Saharan African continent, vaccines account for a far greater proportion of overall pharmaceutical spend, with a total value of US$1.16bn in 2017 or around 12.5% of the total Sub-Saharan market excluding South Africa.

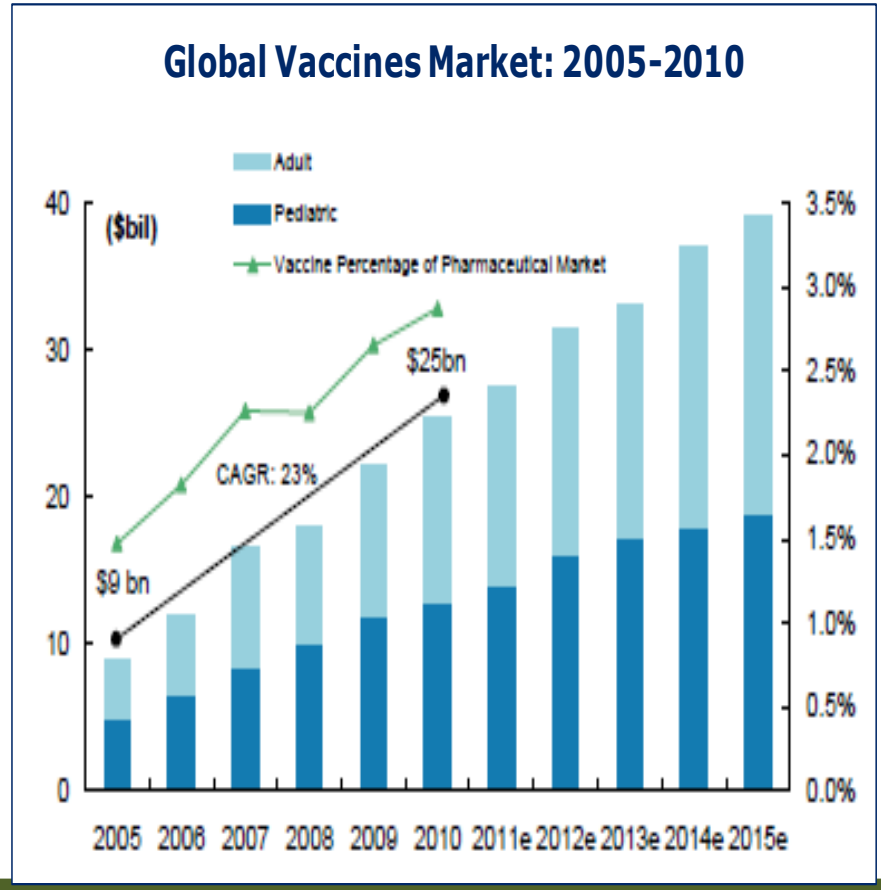
Vaccine market in Africa is even more import dependent than the prescription pharmaceutical market with almost 90-100% of human vaccines being imported.

In value terms, 50% of all vaccines in the region are exported from Belgium with 22% originating from India and a further 16% coming from the USA.

The largest importers of vaccines in 2014 were Tanzania, Nigeria, Ethiopia, Kenya and the Democratic Republic of the Congo.

Global vaccines market financials

- **Large market:** USD$32B
- **High growth:** 9% annual
- **Solid profits:** 25%-40% (OPM)



Current market environment

- Attractive profitability driven by significant growth opportunity

Key trends

- The global vaccines market grew 23%+ CAGR from $9B to $25B from 2005-2010, outpacing pharmaceuticals (6% CAGR)
- Adult vaccines represented a large segment of growth
- The vaccines market is expected to expand to $39B by 2015

http://www.wahooas.org
175, Avenue Ouezzin Coulibaly, 01 BP 153 Bobo-Dioulasso 01, Burkina Faso

African Vaccine Regulatory Forum (AVAREF)

Network approach to Capacity building & Harmonization for regulation in the WHO AFR Region New vaccines in clinical development

- *Through AVAREF many countries have worked together on **joint reviews of clinical trial applications and GCP inspections.** This model has set the foundation for stronger collaboration and harmonization of procedures, e.g. -**"Harmonized Good Clinical Practice (GCP) Guidelines for AVAREF countries"** [2]*

- ***Channels of communication** among African regulators and with regulators from developed countries have created confidence, strength and willingness to harmonize processes*

This has resulted in:

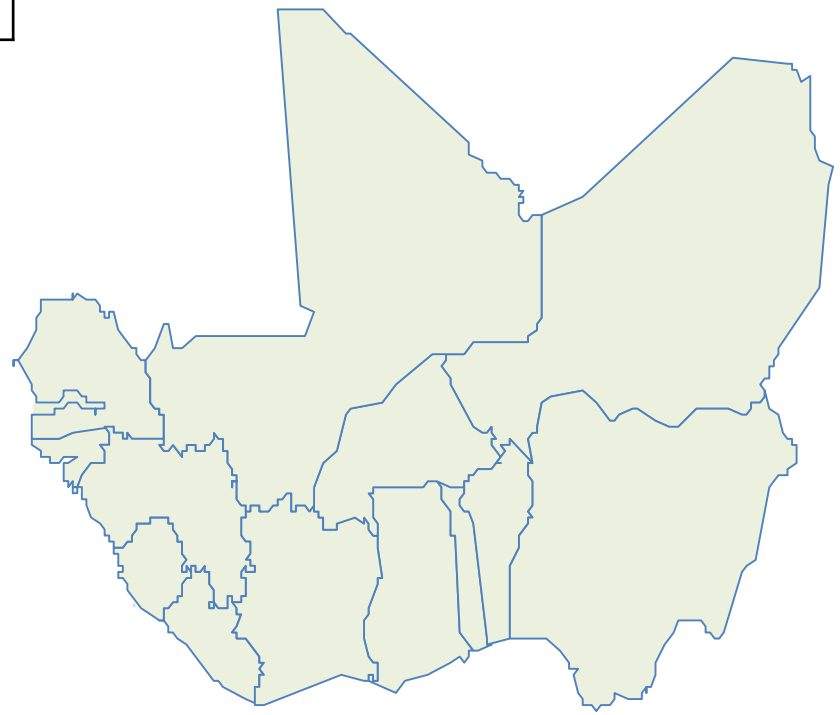
- *High level of expertise and commitment exists in countries*
- *Mutual recognition and acceptance of common challenges provides incentive to create the space to work together*
- *Capacity building activities (development of regulatory procedures for CTs, joint reviews and inspections) provided a foundation for harmonization and learning opportunities*
- *Review of 2009 draft GCP guidelines ref. to RECs efforts 24-25 Sept, 2018*

The ECOWAS region now consumes around US$400mn in vaccines each year

Total ECOWAS Region

Vaccines consumed 2014 : $400Mn

Growth '09-14': 91%



Mali	
2014 spend:	$22M

Senegal	
2014 spend:	$37M

Guinea	
2014 spend:	$4M

Sierra Leone	
2014 Spend:	*$10Mn*

Liberia	
2014 Spend:	*$3Mn*

Cote D'Ivoire	
2014 spend:	$23M

Ghana	
2014 Spend:	*$23M*

Togo	
2014 Spend:	*$24Mn*

Benin	
2014 Spend:	*$32Mn*

Nigeria	
2014 Spend:	*$123Mn*

Burkina Faso	
2014 Spend:	*$40Mn*

Niger	
2014 Spend:	*$60Mn*

.wahooas.org
175, Avenue Ouezzin Coulibaly, 01 BP 153 Bobo-Dioulasso 01, Burkina Faso

Current vaccine regulatory capacity of ECOWAS region

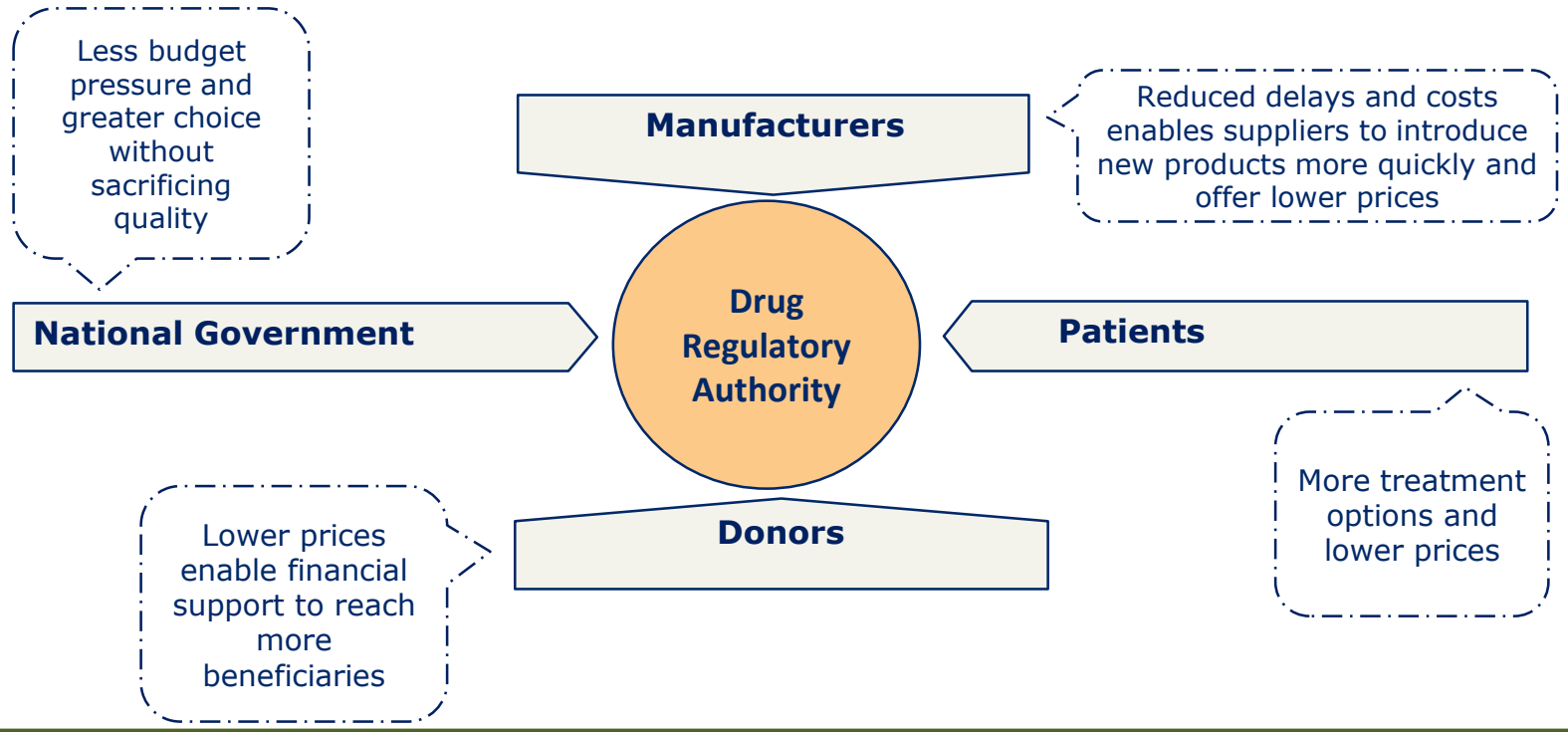
Regulatory Capacity	High	Low
Economies (World Bank Classification)		
Lower middle income	Ghana	Cape Verde Côte d'Ivoire
Lower income	Nigeria Liberia Burkina Faso Togo	Benin, Niger Sierra Leone Guinea Guinea Bissau

- Vaccines/biological are registered in 11 countries;
- ECOWAS/WAHO has developed in the path towards regulatory harmonization, with initiatives such as capacity building, training and staff transfers between regulators;
- **Ghana, Burkina Faso and Nigeria** could play the role of Champion countries for mentoring and supporting the development of countries with weak regulatory capacities;

Harmonization of Vaccine regulations offers many potential gains

Benefits of vaccine regulatory harmonization

- *Increased and Faster access to Vaccines,*
- *Common regulatory standards for evaluation and inspection*
- *Communication and information sharing*
- *Boost investments in the pharmaceutical sector*
- *Effective utilization of public funds by ensuring quality and safe medicines*



What is the role of the Pharmaceutical Industry in West Africa in Vaccines Production?

- Among the over 200 pharmaceutical industries in West Africa, there is currently only one (Institut Pasteur-Dakar) that is WHO Pre-qualified for Yellow-Fever vaccines;

- May and Baker in collaboration with Bio-vaccines and Nigerian Government to Produce Meningitis vaccines;

- In Ghana- Merck KGaA and Ridge Management Solutions (RMS Innovativ), have signed a Memorandum of Understanding, opening the opportunity for Ghana to have a dedicated human vaccine manufacturing factory

Stakeholders Engagement

- Managing and integrating efforts of vaccines manufacturers;
  - Foster collaboration by identifying specific roles and responsibilities of the private and public sector stakeholders;
- Engaging Politicians;
  - Ensuring political buy-in by national governments and regional organizations;
- Vaccine Working Group: Formation of a Vaccine Working Group (VWG) at REC level that work in close collaboration

Challenges

- Unhealthy competition among manufacturers;
- Government reliability on donor agencies;
- Technology gap;
- Inadequate specialties (human resource);
- Effective information sharing;
- Capital (investment);
- Obtaining international certifications.

Perspectives

- AVMI involvement in enhancing regulatory system to **centralised procedure** that would allow the marketing of medicines on the basis of a single West Africa wide assessment and marketing authorisation which is valid throughout the ECOWAS region.

- Through the:
  - Application of common technical documents and guidelines;
  - Utilization of common policy, legislation and regulation;
  - Common safety monitoring of medicines circulating on the regional market;
  - Common database of information on clinical trials, pharmacovigilance, and tracking of counterfeit and substandard medicines
  - And a unified procurement, distribution and supply chain of medicines

Conclusion

- Attainment of self-sufficiency in essential vaccines to serve the public healthcare and population, while creating much needed employment;

- Envisage a strategic plan that matches short-term to long-term goals with specific technology solutions to help meet the goals of access to quality safe and affordable medicines and vaccines;

- These can only be achieved success through concerted efforts.