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Medical Devices Regulation in West Africa – A Situation Analysis

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Introduction

Current trends in medical devices regulation

- International Medical Devices Regulator's Forum
- Global Medical Devices Nomenclature
- Medical Devices Single Audit Program

Objective

To understand the current state of medical devices regulations in West Africa.

Research questions

1. What is the situation of medical devices regulations in West Africa?
2. Is West Africa trending along with the global harmonization of medical devices regulation?

Method

Publicly available data were reviewed

- World Health Organization website
- Website of National Medicines Regulatory Authority

Results

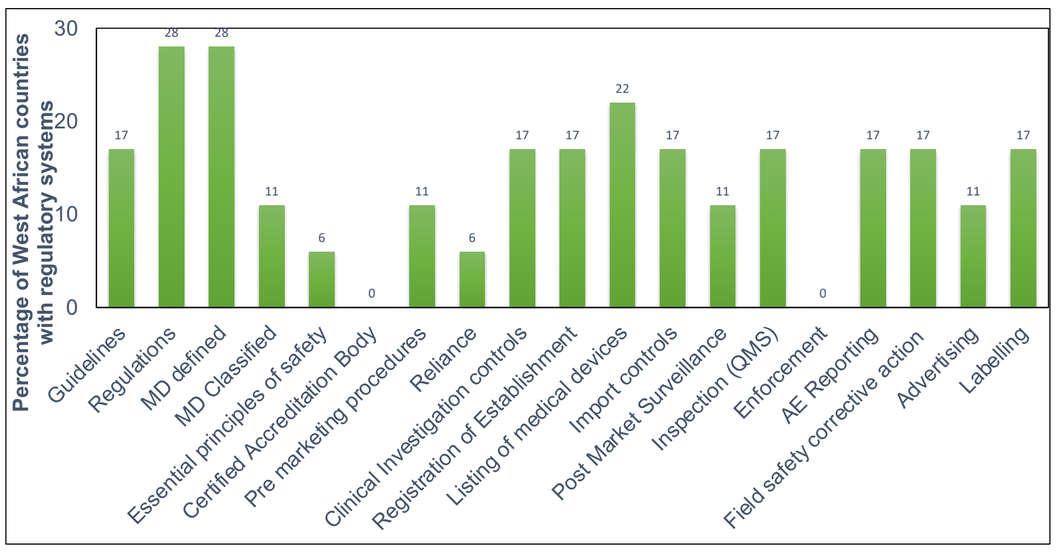

Fig 1. Summary of the state of medical devices regulations in West Africa

Table 1. Heat maps – State of medical devices regulatory systems in West African countries.

Available (green) Not available (grey)

A Only few countries have legal structures – Legislation establishing NMRA and guidelines for Medical devices

Country	Legal Framework	Authorising Legislation	Guidelines	NRA Present	Name	Responsibilities
Benin						
Burkinafaso						
Cabo Verde						
Cameroon						
Chad	No Information- Website page could not be assessed					
Cote d'Ivoire						
Equitorial Guinea						
Gambia						
Ghana						
Guinea						
Guinea-Bissau						
Liberia						
Mali						
Mauritania						
Niger						
Nigeria						
Senegal						
Sierra Leone						

B Only few countries have a definition and classification of medical devices

Country	MD Defined	IVD Defined	Classification	Categories	Classification rules
Benin					
Burkinafaso					
Cabo Verde					
Cameroon					
Chad	No Information- Website page could not be assessed				
Cote d'Ivoire					
Equitorial Guinea					
Gambia					
Ghana					
Guinea					
Guinea-Bissau					
Liberia					
Mali					
Mauritania					
Niger					
Nigeria					
Senegal					
Sierra Leone					

C. Only one country has and applies the essential principles of safety and performance of medical devices

Country	Essential Principles	Certified Accreditation Body	Pre-marketing Procedures
Benin			
Burkinafaso			
Cabo Verde			
Cameroon			
Chad	No Information- Website page could not be assessed		
Cote d'Ivoire			
Equitorial Guinea			
Gambia			
Ghana			
Guinea			
Guinea-Bissau			
Liberia			
Mali			
Mauritania			
Niger			
Nigeria			
Senegal			
Sierra Leone			

D. Only 1 country has reliance procedures; only 3 countries conduct clinical investigations

Country	Reliance	Jurisdictions	Clinical Investigation controls
Benin			
Burkinafaso		EU, USA	
Cabo Verde			
Cameroon			
Chad	No Information on WHO website & Website page could not be assessed		
Cote d'Ivoire			
Equitorial Guinea			
Gambia			
Ghana			
Guinea			
Guinea-Bissau			
Liberia			
Mali			
Mauritania			
Niger			
Nigeria			
Senegal			
Sierra Leone			

E. Few countries have registration and import control requirements.

Country	Registration of Establishment	Listing of medical devices	Import controls
Benin			
Burkinafaso			
Cabo Verde			
Cameroon			
Chad	No Information- Website page could not be assessed		
Cote d'Ivoire			
Equitorial Guinea			
Gambia			
Ghana			
Guinea			
Guinea-Bissau			
Liberia			
Mali			
Mauritania			
Niger			
Nigeria			
Senegal			
Sierra Leone			

F. Few countries have post-market controls

Country	Post Market Surveillance	Inspection (QMS)	Enforcement	AE Reportin	Field safety	Advertising	Labelling
Benin							
Burkinafaso							
Cabo Verde							
Cameroon							
Chad	No Information- Website page could not be assessed						
Cote d'Ivoire							
Equitorial Guinea							
Gambia							
Ghana							
Guinea							
Guinea-Bissau							
Liberia							
Mali							
Mauritania							
Niger							
Nigeria							
Senegal							
Sierra Leone							

Conclusion

- West African countries are lagging behind in the regulation of medical devices. Only 28% and 17% of the countries in West Africa have regulations and guidelines respectively. The heat maps reveal that many do not have established regulatory systems.
- Recommendation - sensitization, education and support of NMRAs in West Africa to build regulatory framework for medical devices using the WHO's model.

References

WHO | Medical devices regulatory systems at country level. (2017) World Health Organization. https://www.who.int/medical_devices/countries/regulations/en//. Accessed September 20, 2019

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