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Monitoring and Evaluation of Medical Products Regulatory Systems and Harmonization in West Africa

By

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DECLARATION

I, Navoda Lakshani Hettige (4112408), hereby declare that the work described in this project dissertation was exclusively carried out by myself under the supervisors given above, and I certify that the report on this work has not been submitted in the whole or part to any other university or institution for another degree.

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26/09/2023 ..... navoda .....

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ABSTRACT

The Food & Drug Authority (FDA) defined regulatory harmonization as a process where regulatory agencies align technical guidelines for marketing and the development of pharmaceutical products all over the world. Regulatory harmonization can increase efficiencies in regulatory agencies worldwide and reduce duplication of efforts. The African Medicines Regulatory Harmonization (AMRH) initiative is recognized as the bedrock of medicine regulations in the African region. As the first step, the AMRH initiative established the East African Community Medicines Regulation Harmonization (EAC-MRH) program in 2012 in the East African Community (EAC). The Medicines Regulatory Harmonization project harmonized the different aspects and legal frameworks within that regional economic community and proposed a reliance model for medicine registration. As a result, there was increased access to quality medicines and the emergence of medicine manufacturers in Africa. In 2015, the AMRH initiative established the Economic Community of West African States Medicines Regulatory Harmonization (ECOWAS-MRH) program in Ghana to enhance medicine regulation in West Africa with the collaboration of the World Health Organization (WHO) and the New Partnership for Africa's Development (AUDA-NEPAD).

The AMRH initiative conducts monitoring & evaluation studies to assess the performance of quality management systems (QMS), good manufacturing practices (GMP), information management systems (IMS), and registration systems in national medicines regulatory authorities of countries within a respective regional economic community. This study aimed to analyze the monitoring and evaluating data from the ongoing implementation of the Medicines Regulatory Authorities' (MRAs) regulatory systems and harmonization program in the ECOWAS region by AUDA-NEPAD. The data were collected by administering a previously validated questionnaire to the heads of the departments in each National Medicines Regulatory Authority (NMRA) and Regional Economic Community (REC) Secretariat. The questionnaire was designed based on nine categories following the WHO Global Benchmarking Tool (GBT). All these nine categories were further divided into sixteen indicators for ease of understanding. This project used the data collected by AUDA-NEPAD as a secondary data source. The data collected were qualitative and quantitative; therefore, a mixed-method approach was used to analyze the data.

Out of the 15 countries in West Africa, responses were obtained from Nigeria, Cape Verde, and Ghana. The results showed that the National Agency for Food and Drug Administration and Control (NAFDAC)- Nigeria and FDA-Ghana were able to acquire the Maturity Level 3 and even the ISO 9001:2015 certification. Entidade Reguladora Independente da Saude (ERIS)-Cape Verde and NAFDAC-Nigeria were independent bodies, while the FDA-Ghana was identified as a semi-autonomous institute under the Ministry of Health. Only the NAFDAC-Nigeria used all regional harmonized guidelines for medicine registration while the ERIS-Cape Verde and FDA-Ghana used reliance models for marketing authorization decisions. None of the three NMRAs used regional recommendations for joint inspection of manufacturing sites.

In conclusion, all three NMRAs showed considerable progress in medicine regulatory systems strengthening. This is evident by the positive responses to the regulatory strengthening indicators like medicine policies, legal frameworks, NMRA governance, received funding, QMS, IMS, and human resource capacity. However, there was little progress in the medicine regulatory harmonization process in all three countries as evidenced by the negative response to the indicators related to the medicine regulatory harmonization process. Hence, continuous support from stakeholders and cooperation is still needed to achieve the main aim of the AMRH program. With the limited statistics, it is abstruse to emerge the whole picture of medical products regulation and harmonization at the West African regional level. Hence, the participation of the other twelve countries should be encouraged in future studies. Attainment of the aim of the AMRH program will help patients access safe, quality, efficacious, and affordable medicine in the ECOWAS region.

Keywords: **Regulatory authorities, African Medicines Regulatory Harmonization initiative, Medicines Regulatory Harmonization program, ECOWAS region**

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ABBREVIATIONS

AMRH	**- The African Medicines Regulatory Harmonization**
AfRO	**- African Regional Office**
AMDF	**- African Medical Device Forum**
AMH	**- African Medicines Harmonization**
AU	**- The African Union**
AUDA-NEPAD	**- The African Union Development Agency NEPAD**
AVAREF	**- African Vaccine Regulatory Forum**
CHAI	**- The Clinton Health Access Initiative**
CT	**- Clinical trial oversight**
CTD	**- The Common Technical Document**
DFID	**- The UK Department for International Development**
EAC	**- The East African Community**
ECCAS	**- The Economic Community of Central African States**
ECOWAS	**- The Economic Community of West African States**
EMA	**- European Medicines Agency**
GBT	**- The Global Benchmarking Tool**
GDP	**- Gross Domestic Products**
GMP	**- Good Manufacturing Practices**
IDP	**- The Institutional Development Plan**
IGAD	**- The Intergovernmental Authority for Development**
IGAE	**- General Intervention of the State Administration**
IMS	**- The Information Management System**

INFARMED - National Authority for Medicines and Health Products

LT - Laboratory Testing

MA - Marketing Authorization

MAGHP - Marketing Authorization for Global Health Products

MC - Market Surveillance and Control

MRH - Medicines Regulation Harmonization

NEPAD - The New Partnership for Africa's Development Agency

NMP - The National Medicines Policy

NMRA - National Medicines Regulatory Authority

NRA - National Regulatory Authority

PAP - The Pan African Parliament

PMPA - Pharmaceutical Manufacturing Plan for Africa

QMS - The Quality Management System

REC - Regional Economic Community

SADC - The Southern African Development Community

SOP - Standard Operating Procedure

SQHIA - Strategy for Quality Health Infrastructure in Africa

TWG - The Technical Working Group

UNAIDS - The Joint United Nations Program on HIV/AIDS

VL - Vigilance

WAHO - The West African Health Organization

WHO - World Health Organization

CHAPTER 01

INTRODUCTION

According to the Worldometer website, there are 195 countries in the world [1]. However, only a few countries have a higher mark on the Human Development Index (HDI) [2]. The HDI is a measurement introduced by the United Nations (UN) for evaluating a selected country's health, education, and life expectancy [2]. The index ranges from zero to one, and the countries with an index higher than 0.8 are considered developed countries. Hence, health and life expectancy are crucial when rating a country's development status. Quality healthcare service is essential for good health and life expectancy [2].

According to the World Health Organization (WHO) fact sheets, quality healthcare is a service that provides safe, effective, and people-centered health benefits to achieve Universal Health Coverage (UHC) [3]. Moreover, quality health care requires that all health services be equitable to everyone regardless of geographic location, timely accessible without delay, integrated throughout the course of treatment, and efficient. Access to quality medicine is pivotal to the quality of health service delivery. To get access to quality medicines, there is a need to have well-established medicine regulations and policies in place. As a result, the National Medicines Regulatory Authorities (NMRA) were set up in most countries to ensure the availability of safe, quality medical products [3].

NMRAs are responsible for registering medicines and related products, marketing authorization, pharmacovigilance, licensing establishments, market surveillance & control, clinical trials oversight, site inspections, laboratory testing, and NMRA lot release [4]. These institutions play a significant role in the health system within a country. However, the efficiency and performance of these NMRAs vary based on several factors, including the level of funds received, support by the government, available professionals in the field, and existing standards, policies, frameworks & regulations. The WHO introduced maturity level (ML) as an indicator to show the efficiency and the level of performance of NMRAs. A recent report by WHO stated that, out of the 28 countries assessed in 2022, Singapore's NMRA was the world's first NMRA to achieve a Maturity Level of four (ML 4) in the WHO classification. The ML was assigned to these authorities based on an assessment against specified indicators included in WHO Global Benchmarking Tool (WHO

GBT) [5]. From this report, most of the NMRAs still need support and guidance from relevant authorities/ organizations to achieve a higher maturity level [5].

A lower maturity level revealed that the performance of regulatory authorities needed to be stabilized and needed further improvements to perform basic regulatory functions. With the immense development of the medicine development industry, regulatory authorities and medicine manufacturers faced many difficulties, including mismatches in technical requirements, lengthy processes, & high-cost test procedures. During the Covid-19 pandemic, these difficulties bedeviled the entering of new medicines into most regional markets. Hence the importance of regional regulatory harmonization of medical products has increased over the period of Covid-19 [5, 6]. However, in April 1990, the International Council for Harmonization (ICH) was established among three regions, Europe, the United States & Japan, to harmonize the available medicine regulatory processes within these regions [6].

Regulatory harmonization is when regulatory agencies across regions or countries set up similar technical guidelines, scientific principles, standards, similar or common procedures, and practices for developing and marketing medicines, vaccines, and medical devices to achieve Universal Health Coverage [7]. This regulatory harmonization concept ensures favorable marketing conditions to support early access to pharmaceutical products, encouraging competition and efficiency, reducing unwanted duplication of clinical testing and post-marketing surveillance, and preventing unnecessary animal testing. Furthermore, regulatory harmonization guarantees that high-quality, safe, effective, and affordable medicines are developed and registered while meeting approved standards in developed and low- and middle-income countries [7, 8].

Currently, most developed countries have robust medicine regulations and policies, leading to fewer substandard and falsified medicines in the market. Moreover, due to the well-established medicine regulatory systems, the number of medicine manufacturers, medicine development studies, and market access to medicines has increased over time. In contrast, the status of the medicine regulatory system in most developing countries is far from that of developed countries. The regulatory authorities in the emerging world could only perform some of the responsibilities unassisted, and most of the regulatory systems are at different levels of performance. The main drawbacks in these regions are lack of financial strength, lack of necessary infrastructure, high

staff turnover, and lack of professionals. Therefore, harmonized regulation of medical products in the emerging world allows optimizing the use of limited resources, minimizing the cost of duplication efforts, and promoting sharing of regulatory decisions among regulatory authorities within the same region [9].

Most African countries are classified as developing countries suggesting they have limited financial resources, limited infrastructure, fewer professionals, a high disease burden, and widespread circulation of sub-standard medicines. With the Medicines Regulation Harmonization concept's commencement, African countries tried to harmonize their drug regulatory frameworks with the help of different organizations. With the support of the New Partnership for Africa's Development (AUDA-NEPAD) Agency and other partners, the African Medicines Regulatory Harmonization (AMRH) Initiative was established. The AMRH initiative is guided by the African Union (AU) Model Law, endorsed in January 2016 in Ethiopia [10]. Since the inception of the AMRH initiative, the AUDA-NEPAD agency has started different programs in medicines regulation harmonization in each Regional Economic Community (REC). The East African Community (EAC) is the REC, where the first Medicines Regulatory Harmonization (MRH) Program was launched. Since then, AUDA-NEPAD initiated MRH programs in the Southern African Development Community (SADC), the Intergovernmental Authority for Development (IGAD), the Economic Community of Central African States (ECCAS), and Economic Community of West African States (ECOWAS) regions [11].

Annually, the AUDA-NEPAD agency operates evaluation programs in RECs, including EAC, ECOWAS, SADC, IGAD, and ECCAS. This study was designed to evaluate and monitor the status of medical products' regulatory harmonization in NMRAs in the ECOWAS region in 2021. There are 15 countries in the ECOWAS region, and all are still in the developing stage of medicines regulatory harmonization. Besides that, the regulatory harmonization process is still novel to the African region, and the availability of literature sources is limited. So, this study set out to achieve the following objectives.

Overall objectives

1. To assess the status of the medicinal product regulatory systems and harmonization process in the ECOWAS countries (Nigeria, Cape Verde, and Ghana).

2. To identify the progress, achievements, and gaps in the regulatory systems and harmonization process in the ECOWAS countries (Nigeria. Cape Verde, and Ghana).

3. To determine areas that need further development in the three ECOWAS countries (Nigeria, Cape Verde, and Ghana).

The following chapters will elaborate on the literature review, study design, results, discussion, conclusion, references, and annexures (questionnaire).

CHAPTER 02

LITERATURE REVIEW

This chapter discusses medical products regulation in general, the current scenario in Africa (in health and medical products regulation perspectives), the AMRH Initiative, medical products regulation in West Africa, and at the end, the motivation for the study.

2.1. Medical products regulation

According to WHO, access to effective, safe medical products is a fundamental human right [12]. Moreover, health interventions should not be denied to anyone in any part of the world based on social or economic causes. However, some parts of the world still need help to fulfill their basic health needs due to the weaknesses in health systems. The United Nations (UN) defined "Access to medicine as the availability of at least 20 drugs from the essential medicines list in a selected country and availability of these drugs in a health facility within a one-hour walk from anyone's home" [12]. It clearly stated that the effectiveness of health interventions mainly relies on the availability, affordability, acceptability, and accessibility of medicines. However, medicines should be regulated according to a standardized system. Therefore, most countries established National Medicines Regulatory Agencies (NMRAs) to regulate medical products in their territories [12].

Countries with less-resourced regulatory systems or without NMRAs may have weak health systems that ultimately impact patient health outcomes. Furthermore, such a weakened health system prevents access to quality, safe, and effective medicines. Moreover, it holds back new medicinal products from entering the market due to laborious pathways for approving those products for use in the region. Most emerging-economy countries, including low- and middle-income countries, have limited access to medicinal products and a lesser capacity for NMRAs to perform vital regulatory functions within their territories. Inadequate facilities, staff turnover, and disjointed policies and regulatory frameworks are the key challenges in medical product regulation in these developing countries [13]. Consequently, there is a limited capacity to guarantee medicinal products' safety, quality, and efficacy.

Additionally, disjointed policies and dissimilarities in regulatory frameworks among NMRAs slow the process of researchers and manufacturers approving new medical entities because of the need

to navigate through different regulatory systems to get marketing authorization for the same product in countries within a region. To ensure the essential medicines' availability, access to quality, safe, effective medication, and innovation of new medical products, most countries in the same region adopt common strategies to their regulatory systems. Most of these strategies focus on medical product pre-qualifications and post-marketing surveillance. Prequalification, assess all the medical products, including drugs, diagnostics, medical devices, and vaccines against approved standards before releasing the product into the market. Post-marketing surveillance; evaluate and monitor pharmaceutical products after release of the product into the market. Both processes ensure the standards of the health products at different stages of the medicine manufacturing cycle. However, in some regions of the world, these strategies differ from country to country, and there is a need to have a reliance model to increase efficiency within the systems [14].

2.2. The current scenario in Africa

Africa consists of 55 countries, with an estimated population of nearly 1.2 billion, meaning that around 15% of the world's population lives in this region [15]. Of those living in Africa, most suffer from communicable or non-communicable diseases, and it accounts for 24% of the global disease burden [15,16]. Almost half of the deaths caused by communicable diseases are reported in Africa [16]. According to the reports from WHO and the African Regional Office (AfRO), a larger proportion of the world's population having HIV/AIDS and Malaria are being reported from Africa [15]. Moreover, out of the 20 countries with higher maternal mortality rates, 19 were in Africa. As per the estimations by Strategy for Quality Health Infrastructure in Africa (SQHIA) 2021-2031, there will be a 0.5% increase in Gross Domestic Products (GDP) per annum if common health issues can be overcome throughout the continent [16, 17].

One of the leading health issues in the African region is poor-quality medicines. The prevalence of counterfeit and falsified medicines in Africa was about 18.7%. Moreover, most of the countries in the African region mainly depend on medicines from other countries abroad. Therefore, the supply chain of these medical products should be properly regulated to ensure access to quality essential medicines [18].

Except for the Sahrawi Republic, most of the countries in the African region have Medicine Regulatory Authorities or related institutes that are responsible for medicine regulatory and

administrative purposes. According to the reports by WHO, it is stated that among 46 Sub-Saharan African countries, 7% have National Regulatory Authorities, 63% have minimal capacities, and 30% have no regulations on medicinal products and medical devices [19].

Hence, regulatory frameworks in most of the countries within the region have several mismatches in different processes, including medicinal product registration and regulation. Therefore, most manufacturers and applicants must submit the same dossier to various regulatory authorities to get approval for the same pharmaceutical product in each country where they intend to market it. This process is both time and money consuming. As a result, most manufacturers are not interested in marketing their products in the region which limits access to new medicinal products. Hence, there was an urgent need to have harmonized medicine regulatory policies in hand to overcome these challenges [9]. The African Union Model Law was endorsed in January 2016 by the New Partnership for Africa's Development (NEPAD) Agency, which now stands as the African Union Development Agency NEPAD (AUDA-NEPAD), to furnish legal policies in pharmaceutical regulation throughout the region. Besides that, this Model Law supports the development of harmonized medicinal product regulation policies in each regional community. Furthermore, it ultimately ensures that quality, safe, and effective medicines are innovated, analyzed, and marketed to fulfill the basic needs of the health sector [17].

2.3. The AMRH Initiative

The African Medicines Regulatory Harmonization (AMRH) initiative was recognized as the foundation for establishing the African Medicines Agency (AMA). It was formalized in 2009 due to the African Union Assembly sentence 55 in January 2005. The main aim of the AMRH initiative is to design well-organized, efficient, effective, and explicit regulatory frameworks in African countries with the support of existing policies in other regions to attain speedy approvals for medical products [16, 17].

Furthermore, the AMRH Initiative mainly focuses on (i). Regulatory frameworks and policies harmonization in member states; (ii). Increasing humane and institutional capacity considering regulating medicinal products and technologies; (iii). Coordinating and promoting R&D and awareness of drug regulation at continental, regional, and country levels; (iv). Effective coordination and alignment of medicinal products regulation pursuits with the African Medicines Agency and the AMRH Framework. All these four areas have a hand in key strategic programs in AU, including (i). Pharmaceutical Manufacturing Plan for Africa (PMPA). (ii). Health Research Strategy for Africa (iii). The African Health Strategy (iv). and the Road Map on Shared Responsibility on Global Solidarity on HIV/AIDS, Tuberculosis and Malaria Response in Africa [20].

The AMRH is a confederation consisting of the Pan African Parliament (PAP), the New Partnership for Africa's Development (NEPAD) Agency, the UK Department for International Development (DFID), the Bill & Melinda Gates Foundation, the Clinton Health Access Initiative (CHAI), the Joint United Nations Program on HIV/AIDS (UNAIDS), and the World Health Organization (WHO) [21]. Since AMRH has been implemented, five Regional Economic Communities (RECs) have been set up, the East African Community (EAC), the Southern African Development Community (SADC), the Economic Community of West African States (ECOWAS), the Economic Community of Central African States (ECCAS) and, the Intergovernmental Authority for Development (IGAD) [22].

With continuous guidance and support, the East African Community (EAC) launched the first Medicines Regulatory Harmonization (MRH) program, East African Community Medicines Regulatory Harmonization (EAC MRH), on 30th March 2012. The AUDA-NEPAD and the WHO

worked together to make this a success by giving their immense support in advocacy, political, and technical points of view. The Southern African Development Community Medicines Regulatory Harmonization (SADC MRH) program was launched in 2015, and now, the SADC Collaborative Medicines Registration (ZaZiBoNa) is also within that SADC MRH program [24].

2.4. Pharmaceutical Regulation in West Africa

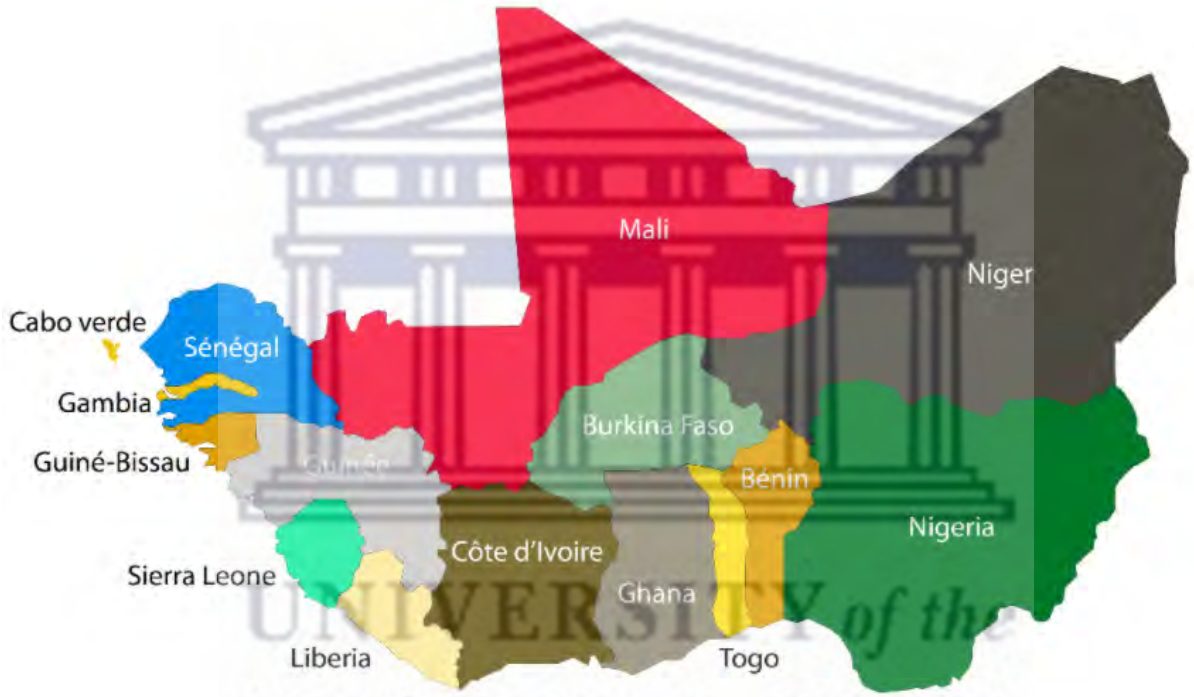

Figure 1: Fifteen member states in West Africa (ECOWAS) [25].

West Africa comprises 15 member states (Benin, Burkina Faso, Cape Verde, Côte d'Ivoire, The Gambia, Ghana, Guinea, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone, and Togo) allied in REC named the ECOWAS and a regional health organization called WAHO (West African Health Organization) [26]. West Africa has a faster population growth rate, making it home to 5% of the world's population (367 million in 2015), and most still live in rural areas [27].

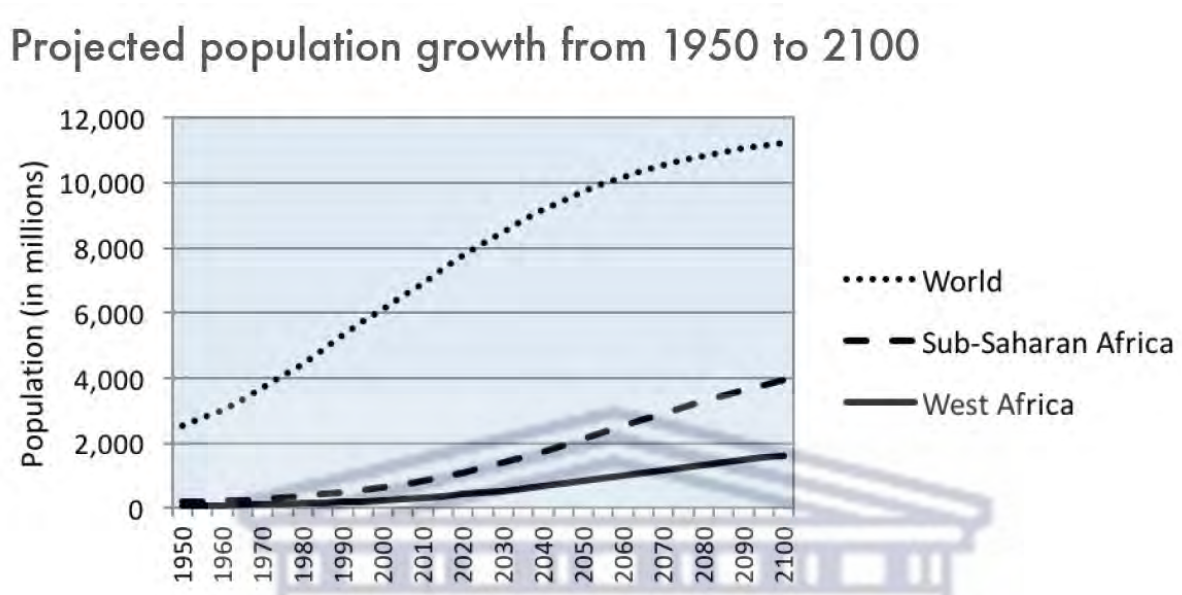

Figure 2: Projected population growth from 1950 to 2100 in West Africa [27].

In the last couple of years, the Ebola virus has had wide outbreaks throughout the West African region, with Guinea, Liberia, and Sierra Leone being mostly affected [16]. Apart from those diseases, Malaria, HIV/AIDS, Tuberculosis, and issues affecting the drug development, manufacturing, and delivery of medicines are also similar in the West African region as in other African countries. Based on the literature, and other sources of information, some of the challenges were identified in this regard. Lack of human resources, challenges in drug manufacturing, lack of concern by the government, patents, high-priced medicines, poor medicines regulatory system, low level of literacy, corrupt practices, and challenges in the supply chain were up on the list [21, 22, 24].

Apart from those challenges, the National Health Policy 2020 stated that, in most West African countries, the number of falsified and counterfeit medicines available in the market is high. For this reason, most diseases have become more prolonged and complicated. Moreover, it caused widespread misuse and abuse of drugs among people, and when it came to antibiotics, the negative consequences that arose should be cautiously negotiated. Because according to the antimicrobial resistance surveillance report (AMR), 2017, drug resistance in antimicrobials has risen to 78.7% in common diseases caused by microbes [24]. Besides that, in a recent drug tragedy in Gambia, sixty-six children died after using cough/cold syrup from an Indian manufacturer with lethal

amounts of ethylene glycol and diethylene glycol [25]. A little over a decade earlier, the same scenario happened in Nigeria. In 2009 around 84 children died from the lethal amounts of the same compounds in a syrup named "My Pikin Baby," a teething mixture that caused severe liver and kidney damage [26]. Moreover, in 1990, after consuming paracetamol syrup, 47 children died in Jos University Teaching Hospital, Nigeria, due to the same toxic compound [27]. In 1996, during the meningitis epidemic, 11 young adults died owing to a clinical trial done by Pfizer for the Trovan and Ceftriaxone drugs in Kano, Nigeria [28]. All these events could have been minimized if well-regulated drug regulatory systems had been used.

However, NMRAs are found in each 15 member states in the ECOWAS region. And they may differ either in functionality or system due to their social, economic, cultural, and political diversity in the region. Francophone countries (Benin, Burkina Faso, Côte d'Ivoire, Guinea, Mali, Niger, Senegal, and Togo) had a regulatory system similar to France's. Anglophone countries (The Gambia, Sierra Leone, Liberia, Ghana, Nigeria) had a different system to that, and Portuguese-speaking countries (Cape Verde, Guinea-Bissau) had another system [35]. Therefore, manufacturers had to submit lengthy applications for different NMRAs; each had its requirements and fees. Furthermore, transparency in the registration process and a clear timeline or accountability were unpredictable [36]. So, the lack of a harmonized regulatory system in ECOWAS discouraged drug manufacturers from entering the market. Therefore, the NEPAD Agency and other partners launched the ECOWAS-MRH program in 2015 in Accra, Ghana. The joint MRH Program Steering Committee and seven Technical Working Groups (TWGs) were also established in collaboration with this MRH project [37].

The MRH project mainly focused on executing a Common Technical Document (CTD) for registering medicines, a common Information Management System (IMS), a Quality Management System (QMS), harmonized registration process, and setting up technical standards in each NMRA in the concerned states [36].

2.5. Motivation for the study

Since ECOWAS-MRH's inception, there has been a need to assess the current standards of medical products regulatory systems and the harmonization process of NMRAs in the ECOWAS region. The WHO introduced a global tool with several indicators to assess the critical points in the system. According to WHO Global Benchmarking Tool (GBT), it helps regulatory authorities to figure out their strengths, areas for development, gaps in the system, the institutional development plan (IDP), progress, and achievements [38].

This study will help NMRAs in the ECOWAS region to expand their regulatory framework/systems to meet international standards and evaluate their current level of progression in harmonized activities. This study will recommend a harmonized regulatory framework in the ECOWAS and will be further supported by having strategic regulatory systems in NMRAs within the REC.

CHAPTER 03

METHODS

3.1. Definition of terms

National Medicines Policy (NMP)

The WHO recommended that all countries establish a comprehensive national medicines policy to guarantee the availability of safe, quality, effective, and affordable medical products in the market [39].

This approach promoted the development of medical products and health systems in low- and middle-income countries, thereby increasing access to essential medicines and treatments for common diseases [40].

There was a need that NMP to comply with universal principles. Still, it allowed for some changes depending on historical and cultural factors, including the political values of the government, the level of expenditure on medicines, economic growth, and the workforce to regulate and enforce quality assurance [41].

Institutional Development Plan (IDP)

It is a work plan developed for two to three years by National Regulatory Authorities with support from WHO. Furthermore, it includes proposed regulatory activities, recommendations for identified gaps, milestones or deadlines, and responsible departments and staff [42].

Governance

In most countries, Medicines Regulatory Agencies are governed by a unit under the Ministry of Health or act as either semi-autonomous or autonomous. Besides, some countries neither have a regulatory system nor a relevant specified institution for regulatory activities [43].

Good Manufacturing Practices (GMP) inspection system and GMP

The GMP Inspection system was introduced to verify compliance with GMP standards. This process ensures the quality of already registered pharmaceutical products, which are still in the registration process, re-registration, and manufacturing sites [44, 45].

Quality Management System (QMS)

QMS assures all the tasks in NMRA are met with defined, uniform standards and archives every step in the regulatory process. Besides that, this includes all critical and sensitive functions such as license issuing, dossier reviewing, site inspections, and handling site master files [45].

Information Management System (IMS)

The Information Management System assures the transparency and accountability of the NMRAs and helps to maintain the relationship with stakeholders and other NMRAs within the region. With an up-to-date IMS system, anyone can access the data, including the number of products registered, recalled products, withdrawn products, guidelines, acts, legislation, etc.

3.2. Study design.

The data collection project in the ECOWAS region was done by the AUDA NEPAD, and the data collected were used as a secondary source in this research project. To collect data from NMRAs and ECOWAS Secretariat, they used a validated questionnaire [Annexure 02] designed following the WHO GBT. The mixed-method design approach was well suited for the study as it extracts both qualitative and quantitative data. All the quantitative data were compared in table format while the qualitative data were presented in illustrative quotes.

The questionnaire was split up into nine categories, (1) Policy, strategy, and legal framework (2) NMRA Governance, (3) NMRA Financing, (4) Medicines Evaluation and Registration, and Good Manufacturing Practices (GMP) Inspection System, (5) Functional Quality Management System, (6) Information Management System, (7) Transparency. Accountability and Communication, (8) NMRA Human Resource Capacity, and (9) Partnerships and Coordination. Furthermore, those nine categories were grouped into 16 indicators, as indicated in Annexure 01. Besides that,

Annexure 01 shows the purpose of the indicator, the unit of measurement, and the data type, whether qualitative or quantitative.

The indicators were developed through a consultative process and with the help of the WHO NMRA GBT and other WHO guidelines. Indicators were further divided into sub-indicators for easy understanding of participants in relevant institutes. The questionnaire was sent to the Head of the institute or one of the senior members (experts) in each NMRA. Furthermore, the questionnaire was designed as an Excel sheet or a Google document form. The Francophone countries could use the Excel form questionnaire as it was available in French.

CHAPTER 04

RESULTS AND DATA ANALYSIS

Only three countries in the ECOWAS region responded to the questionnaire given by AUDA-NEPAD. Therefore, only the data from Ghana, Nigeria, and Cape Verde were analyzed. For ease of understanding, all the data were grouped using nine categories, (1) Policy, strategy, and legal framework, (2) NMRA Governance, (3) NMRA Funding, (4) Medicines evaluation and registration, and Good Manufacturing Practice (GMP) Inspection systems, (5) QMS, (6) IMS, (7) Transparency, Accountability, and Communication, (8) NMRA Human Resource capacity, and (9) Partnership and Coordination.

(1) Policy, Strategy, and Legal Framework

Table 1: Policy, strategy, and legal framework in Ghana, Cape Verde, and Nigeria.

National Medicines Regulatory Authority	Ghana	Cape Verde	Nigeria
Availability of an NMP	Yes	Yes	Yes
NMP provides for regional cooperation and harmonization	Yes	Yes	No
NMP has been reviewed within the past five years	Yes 2017	Yes 2018	No
Availability of an IDP	Yes	Yes	Yes
Is the IDP being implemented?	Yes	No	Yes
Availability of Medicines Regulatory Law	Yes	Yes	Yes
Enactment year of medicines law	1992	2006	2004
Last review/ amendment of the medicines law	2012	N/A	2004

From the data from the NMRAs, the above table showed that Ghana, Cape Verde, and Nigeria had their own National Medicines Policies in active use. The NMPs in Ghana and Cape Verde provided for regional cooperation and harmonization, and both the NMPs were reviewed in 2017 and 2018, respectively.

All three countries, Ghana, Cape Verde, and Nigeria had Institutional Development plans (IDP), and Cape Verde's IDP is yet to be implemented. The IDP in Nigeria's National Agency for Food and Drug Administration Control (NAFDAC) was getting support from other external partners in the following sectors: Capacity building, Analysis, Surveys, Improvements, Evaluation, Implementation, and Financial and Human resources. FDA Ghana IDP was collaborating with other partners in Capacity strengthening for vaccine lot release, Upgrade of infrastructure and equipment for quality control of vaccines (upgrade of the microbiology laboratory to biosafety level), Establishing molecular biology labs, Strengthening of Information Technology systems for documentation and data management for vaccine regulation. Nevertheless, Cape Verde's IDP is not yet implemented, and they stated that they need support in the development and implementation of IMS for all stages of medicines regulation (priority for marketing authorization, inspections, licensing), implementation of a training plan for the NMRA; implementation of a QMS aiming an ISO 9001:2015 certification.

Moreover, the three countries had Medicines Regulatory laws in action. Ghana enacted those laws in 1992, Cape Verde in 2006, and Nigeria in 2004. The law was last reviewed/amended in 2012 and 2004 in Ghana and Nigeria, respectively.

(2) NMRA Governance

Table 2: NMRA governance in Ghana, Cape Verde, and Nigeria.

National Medicines Regulatory Authority	Ghana	Cape Verde	Nigeria
NMRA's Level of Autonomy	Semi-autonomous and it is under the Ministry of Health	Autonomous	Autonomous
Has the power to the NMRA to make decisions including participation in regional harmonization activities	Yes	Yes	Yes

Entidade Reguladora independente da Saúde Cape Verde (ERIS), the Food and Drug Authority Ghana, and Nigeria's NAFDAC were operating as autonomous agencies, which means they were working as independent bodies and not under their respective Ministry of Health. However, FDA-Ghana was semi-autonomous and under the Ministry of Health Administration. All three countries had their power in decision-making and participated in all regional harmonization activities.

(3) NMRA Funding

Source of funding

Table 3: Source of the financing in NMRAs in Ghana. Cape Verde, and Nigeria.

NMRA	Ghana	Cape Verde	Nigeria
Government		✓	✓
Service/ Industry fees	✓	✓	✓
Donors		✓	✓
Regional MRH Project			
Other			✓

The governments allocated annual budgets for NMRAs in all three countries but not for

participating in regional activities. FDA Ghana stated that they regulate food and medicines, and providing a budget for only medicines was challenging. Furthermore, there was no budget allocation for regional activities, but they actively participated in regional activities at the ECOWAS and AU levels.

Besides annual government budgets, NMRAs receive funds from different sectors. Cape Verde and Nigeria received funds as service/industry fees and from donors. While Ghana only received service/industry fees. None of the countries received funds from the Regional MRH project.

(4) Medicines evaluation and registration, and Good Manufacturing Practice (GMP) Inspection systems

Marketing Authorization and Registration

Table 4: Maturity levels of NMRAs in Ghana, Cape Verde, and Nigeria.

NMRA	Ghana	Cape Verde	Nigeria
NMRA has been fully benchmarked using WHO GBT	Yes	No	Yes
Maturity Level	ML 3	N/A	ML 3
Use all regional harmonized guidelines for the registration of medicines	No	No	Yes
NMRA used regional recommendations on the joint assessment	No	No	N/A

Nigeria and Ghana have been fully benchmarked using WHO GBT and the NMRAs were in maturity level three (ML 3). ERIS, Cape Verde, still needed to be benchmarked according to the WHO GBT, and the maturity level still required to be confirmed.

Moreover, Nigeria's NAFDAC, used all regional harmonized guidelines to register medicines, while the other two countries did not. The FDA-Ghana adopted AVAREF (African Vaccine Regulatory Forum) and AMDF (Africa Medical Device Forum) guidelines regarding Vaccines, Medical Devices, and In Vitro diagnostics registration.

The AMDF guidelines were designed based on the WHO global model for Medical Devices Regulatory framework, and these guidelines help to assess quality, safe, effective medical devices and In Vitro Diagnostics and their availability throughout Africa. The AVAREF guidelines help all NMRAs and ethics committees in the African region have a harmonized vaccine development and registration system.

Number of product applications with Registration decisions

Table 5: No. of product applications with registration decisions in Ghana, Cape Verde, and Nigeria.

NMRA	Ghana	Cape Verde	Nigeria
No. of products registered based as per the regional joint review	0	0	0
No. of products MA granted based on reliance or recognition within the region	0	0	0
NMRA uses the reliance models for MA decisions	Yes	Yes	No

None of the products were registered based on the regional joint review in all three countries. Furthermore, the number of products that were granted marketing authorization (MA) based on reliance or recognition within the region was also nil in each country. However, FDA Ghana stated that they approve all the products that are approved by WAHO before they were submitted to WAHO for joint review.

The FDA Ghana and ERIS Cape Verde also used the reliance models for MA decision-making processes. The FDA Ghana used AVAREF, European Medicines Agency (EMA) Article 58, Swiss medic marketing authorization for global health products (MAGHP), and WHO Collaborative Registration procedure as reference standards in MA decisions making. In contrast, ERIS Cape Verde used Mutual Recognition of a product registered in other countries as the reference standard.

NMRA's participation in Joint Assessment

Table 6: NMRAs' participation in Joint Assessment in Ghana, Cape Verde, and Nigeria.

NMRA	Ghana	Cape Verde	Nigeria
NMRA participates in regional joint assessment	Yes	No	Yes
No. of joint assessments NMRA took part in 2021	2	N/A	2

The FDA-Ghana and Nigeria's NAFDAC participated in regional joint assessments and took part in two joint assessments in 2021.

Regulatory GMP inspection

Table 7: Regulatory GMP inspection in Ghana, Cape Verde, and Nigeria.

NMRA	Ghana	Cape Verde	Nigeria
NMRA used regional recommendations for joint inspection of manufacturing sites	No	No	No
No of the manufacturing sites inspected by NMRA in 2021	24	1	102
No GMP inspection decisions were made based on the document review/inspection report in 2021	0	0	31

For the reported year, 2021, the NMRAs in all three countries did not use regional recommendations for joint inspection of manufacturing sites. The FDA Ghana had used WHO GMP Guidelines as reliance models for GMP inspection where applicable.

In 2021, the FDA Ghana, ERIS Cape Verde, and Nigeria's NAFDAC inspected 24, 1, and 102 manufacturing sites, respectively. Based on the document review/ inspection report Nigeria's NAFDAC made 31 GMP inspection decisions. The inspection made in 2021 by ERIS-Cape Verde was a follow-up inspection, and it did not lead to an inspection decision.

(5) Quality Management System

Table 8: The No. of QMS staff and ISO certification in NMRAs in Ghana, Cape Verde, and Nigeria.

NMRA	Ghana	Cape Verde	Nigeria
Is the NMRA ISO 9001: 2015 certified	Yes	No	Yes
No. of QMS staff	40	2	1500

According to WHO-GBT, FDA-Ghana indicated over 85% implementation of the QMS within the NMRA; that percentage in the other two NMRAs was unknown. Both the NMRAs, in Nigeria and Ghana were ISO 9001: 2015 certified, and ERIS-Cape Verde is yet to be certified. QMS was in place and used in all NAFDAC formations in Nigeria, and they successfully maintained the certification for three years.

The number of QMS-trained staff in 2021 was 40 and 2 in FDA-Ghana and ERIS-Cape Verde, respectively. Regarding Nigeria, there was more than 1500 trained staff on QMS in all NAFDAC directorates and the nation's 36 states.

(6) Information Management System

Table 9: IMS in NAFDAC, FDA-Ghana, and ERIS-Cape Verde.

NMRA	Ghana	Cape Verde	Nigeria
Product Module	No	N/A	Yes
GMP Module	No	N/A	No
Premises Module	No	N/A	N/A
Inspection Module	Yes	N/A	No
Import and export Module	Yes	N/A	Yes
Finance management Module	Yes	N/A	Yes

The FDA-Ghana and NAFDAC-Nigeria implemented IMS modules within the NMRA. The Import and Export module and Finance Management module were available in IMSs in both the NMRAs. Besides that, the inspection module was only available in IMS FDA-Ghana. The product module available in NAFDAC-Nigeria was an automated Product Administration and Monitoring System (NAPAMS).

(7) Transparency, Accountability, and Communication

Table 10: The level of transparency, accountability, and communication within the NMRAs within the region.

NMRA	Ghana	Cape Verde	Nigeria
NMRA shares regulatory info with others in ECOWAS	Yes	No	No
NMRA IMS linked to other NMRAs in the region	No	No	No
NMRA IMS linked to ECOWAS Secretariat	No	No	No
NMRA has its own page with timely information/public access to related legal provisions, guidelines SOPs, and decisions	Yes	Yes	Yes

Of all three NMRAs, only FDA-Ghana shared the regulatory information with others in the ECOWAS region. None of the IMSs in NMRAs in three countries were linked to other NMRAs in the region and the ECOWAS secretariat. Even so, each NMRA in the three countries had its own web page with up to-date information that gave the public access to related legal provisions, SOPs, decisions, and guidelines.

The information that is available to the public via a website

Table 11: Available forms of data via a website to the public.

NMRA	Ghana	Cape Verde	Nigeria
Medicines Policy	Yes	Yes	Yes
Medicines Law	Yes	Yes	Yes
Regulations	Yes	Yes	Yes
Guidelines	Yes	Yes	Yes
Procedures for applications and decision-making processes	Yes	Yes	Yes
Summary inspection reports	No	No	Yes
List of registered premises, registered products, renewals, and withdrawals	Yes	No	Yes
Appeals against NMRA decision	N/A	No	Yes
Safety alerts	Yes	Yes	Yes
Banned products	Yes	Yes	No
Withdrawn products	Yes	Yes	No
Recalled products	Yes	Yes	Yes
Prohibited products	Yes	Yes	No
Restricted products	Yes	Yes	No

Through the publicly available websites in all three countries' NMRAs, the public could access medicines policies, laws, regulations, guidelines, application procedures and decision-making processes, safety alerts, and recalled products. In addition to this information, the web pages in

FDA-Ghana and ERIS-Cape Verde included information on prohibited, restricted, withdrawn, and banned products. Only NAFDAC-Nigeria exposed details on inspection reports (summaries) and appeals against NMRA decisions. The lists of registered premises, registered products, renewals, and withdrawals were accessible on both web pages in FDA-Ghana and NAFDAC-Nigeria.

(8) NMRA Human Resource Capacity

Table 12: No. of staff as product assessors and GMP inspectors.

NMRA	Ghana	Cape Verde	Nigeria
No of the Product assessors in the NMRA 2021	25	2	12
No GMP Inspectors in the NMRA 2021	9	2	62

The FDA-Ghana had the highest number of product assessors, 25, and ERIS-Cape Verde had the least, being only two. There were 12 product assessors in NAFDAC-Nigeria, and the number of GMP inspectors in the NMRA was 62. However, the number of GMP inspectors in FDA-Ghana and ERIS-Cape Verde was comparatively lesser than NAFDAC-Nigeria, which is nine and two, respectively.

Moreover, the GMP inspection department of FDA-Ghana relied on the expertise of staff drawn from cross-functional departments such as the Centre for Laboratory Services and Research, Vaccine and Biological Products, Drugs, and Nutraceutical Department, and others when necessary to constitute a GMP team.

(9) Partnerships and Coordination

For all NMRAs in three countries, there were mechanisms for coordinating partners at the country level, and they provided support for various regulatory functions. Through the AMRH Partnership platform, the FDA-Ghana got support in multiple sectors, including vigilance (VL), clinical trial oversight (CT), and financing. While ERIS-Cape Verde got support in regulatory inspection (RI/GMP), market surveillance and control (MC), and laboratory testing (LT). Besides that, FDA-Ghana also received support on vigilance activities from Non-AMRH Partnership platforms.

The support that has been received from the partners was from a technical, financial, or advocacy perspective. The FDA-Ghana received technical and financial support from Paul Ehrlich Institute (technical and financial), France and Europe Union (technical), European and Developing Countries, Clinical Trial Partnership (technical), AUDA-NEPAD (financial), and Task for Global Health (financial). The ERIS-Cape Verde got technical support on inspections from IGAE (General Intervention of the State Administration) and technical support on quality control from INFARMED (National Authority for Medicines and Health Products).

Summary of the results based on the objectives.

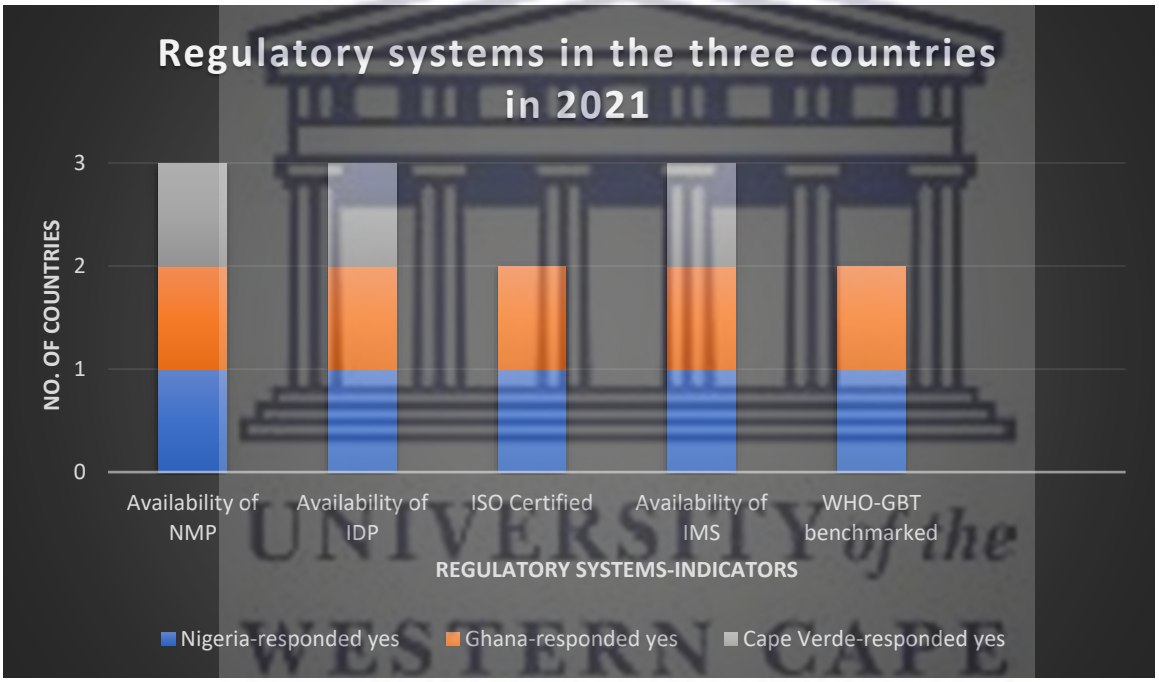

Figure 3 : Regulatory systems in the three countries in 2021.

Figure 4 : Regulatory harmonization in the three countries in 2021.

CHAPTER 05

DISCUSSION

The study mainly assessed the medical products regulatory systems and harmonization within the counties in the REC of West Africa. The study area (adopting reliance models in medical products regulation and harmonization at regional level) is still novel to the region, and limited resources were available as reference materials. As shown in the data analyzing part, the AUDA-NEPAD received data from three countries in the ECOWAS region, including Ghana, Cape Verde, and Nigeria. The data received shows that the regulatory systems in all three countries had the key regulatory standards/functions in action [Figure 3]. Having well-established institutional frameworks, systems, and structures related to the medical products regulatory harmonization process at national, regional, and sub-regional, levels. However, the implementation of the regulatory harmonization process still needs to be well established in all three NMRAs [Figure: 4].

Based on the indicators in the study, Ghana and Nigeria have indicated more growth rate than Cape Verde's authority. Accordingly, the Maturity Levels of the three authorities were varied. Thereby, Ghana and Nigeria acquired ML3, while Cape Verde had yet to receive an ML. In Nigeria, and Ghana, earning Maturity level three proved that the NMRA has an integrated, stable, and well-functioning regulatory system [45, 46, 47, 48] [Figure 5]. With continuous improvements in the regulatory systems together with advanced performance, NMRAs will get the chance to get a maturity level of four in both countries. From this benchmarking process, the regulatory authorities can self-evaluate their gaps, improvements, progress, achievements, strengths, and interventions [47].

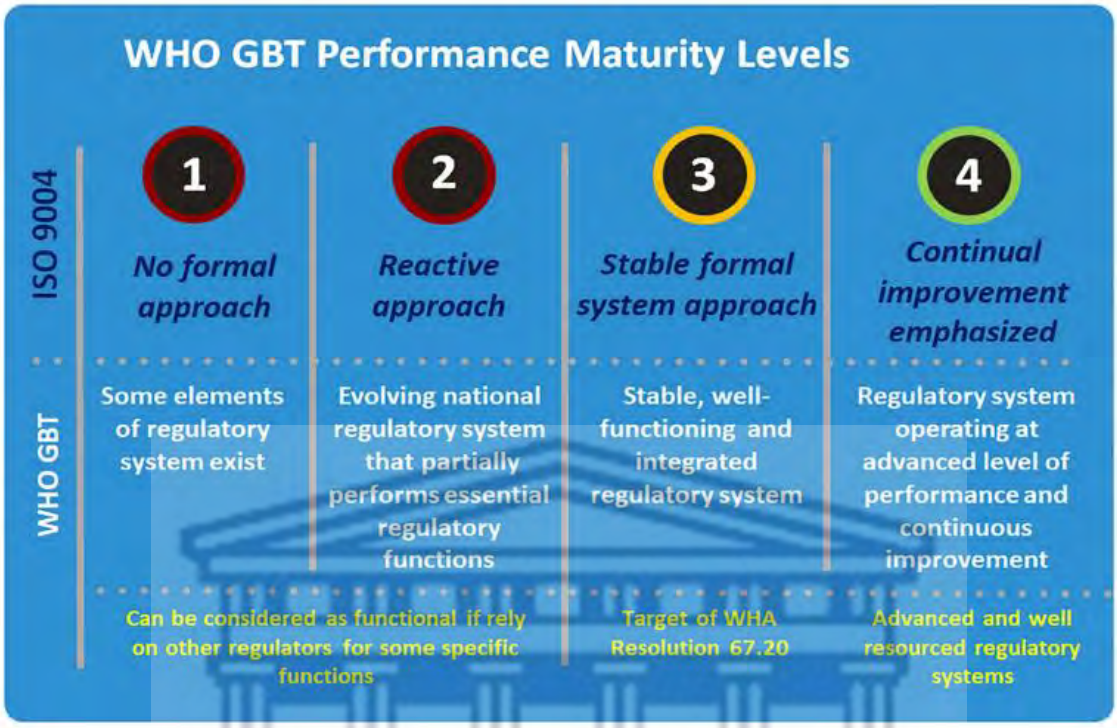

Figure 5: WHO-GBT performance maturity levels [48].

ERIS-Cape Verde's IDP is yet to be implemented; thereby, still, they were in the process of WHO-GBT benchmarking. As they stated, if they can get support in implementing IMS, and QMS, they can apply for ISO 9001:2015 certification and WHO benchmarking. However, ERIS-Cape Verde still got support from IGAE (General Intervention of the State Administration) and INFARMED (National Authority for Medicines and Health Products) in technical terms for activities like inspection, market surveillance, and laboratory testing. Even so, Cape Verde's NMRA did not participate in any joint assessments in the region. Consequently, the governments should allocate more budget for medical products-related activities, so it will help them actively participate in regional activities.

Except for Nigeria, the other two countries used reliance models in Marketing Authorization decisions. However, none of those countries registered or granted marketing authorization for any product based on a regional joint review. This suggests that other states of the region rarely recognize the decisions made by individual states. With this adjoined regional joint review process, NMRAs can minimize the work pressure among the staff, which will provide solutions for the few

professionals in the sector. Moreover, this joint review process allows early market access to medical products and minimizes the duplication of effort [45, 47, 49].

The drug tragedies in Nigeria and Gambia, makes it mandatory to publish the banned, withdrawn, prohibited, and restricted products to the public via their web page [25, 26, 27, 28, 50]. So that anyone can look into the products already removed from the market. Moreover, the Information Management Systems of neither of the three countries link to the region's other IMSs or the ECOWAS secretariat. It will be more effective if those systems connect, which will help overcome many drug-related issues within the region [49, 50].

The three countries needed more resources to fulfill the regulatory and statutory legal functions. Hence, it is essential to identify the responsible factors, and based on that, remedial actions should be taken. Moreover, the NMRAs need continuous support from stakeholders to level up the productivity of the medical products registration harmonization process. Accordingly, communication capacities among the NMRAs and stakeholders should be strengthened. Government budget allocations should be provided to get the full benefits from the medical products harmonization process. So NMRAs have enough funding for operational activities and participation in regional activities. Furthermore, enough funding will help arrange professional training sessions and allow the same knowledge to be shared among ECOWAS. Some countries need to improve human resource capacity, and countries with fewer staff should get support from other member states.

The data received from the three countries showed that they built the foundation for medical product harmonization but still need to get the full benefits as presumed. In many cases, NMRA implemented the systems IMS, QMS, and IDP in medical products regulation but failed to follow up in practice. However, it will not be much of a burden for the NMRAs if they get continuous guidance and the proper support from the governments and other partner organizations/stakeholders [45, 47, 49, 50]. This will help overcome the real issues in drug regulations and ensure the availability of safe, quality, effective, and affordable medicines in the market.

Limitations

This study had some limitations as no responses were received from the remaining twelve countries in the ECOWAS region for the questionnaire emailed by the AUDA-NEPAD. The paucity of data received makes it challenging to assess the level of harmonization in medical product regulations within the ECOWAS region. However, this study gave an overall idea of harmonized medicine regulation systems and the current status of the NMRAs in Nigeria, Ghana, and Cape Verde. Since establishing the AMRH Initiative and WAHO, ECOWAS region countries have accomplished most of the basic concepts in the medical products' regulatory systems and harmonization process (implementing IDP, QMS, IMS, ISO certification, WHO-GBT benchmarking, etc.). Moreover, this study pointed out the achievements and progression and gave recommendations to overcome gaps and drawbacks in the present systems. Future follow-up studies should encourage more NMRAs to actively participate so that a clear picture of the region can emerge.

Table 13: The recommendations based on the categories assessed in the three countries in the ECOWAS in 2021.

Category	***Observed indicator***	***Observed status in the three countries***	***Recommendations for improvement***
Policy, Strategy, and Legal Framework	• Availability of NMP, and IDP in line with WHO recommendations. • Availability of legal framework to regulate medical products, and comprehensiveness based on the AU Model law.	• NMPs were available. • IDPs were implemented and not much established. • Medicines laws were available. However, not been reviewed recently.	• Need to track down the changes in medical products regulatory laws in all ECOWAS countries and do necessary amendments to have a harmonized platform throughout the region. • Need to get continuous collaboration from

			stakeholders, in order to maintain the IDPs as documented.
NMRA Governance	• Autonomy of NMRA. • Accessibility of frameworks to help NMRA decision-making.	• Autonomous and semi-autonomous NMRAs. • Had decision-making powers on their own.	• NMRAs under the other institutes (semi-autonomous) should get the whole power in medical products regulation and should become independent bodies with the guidance from the governments and other partner organizations.
NMRA Funding	• The sources of receiving funds. • Ability of NMRA to sustain its activities using the revenue generated.	• Government subventions, service/industry fees, and donors were the main sources of received funds. • Not enough funding for regional activities.	• Governments should provide enough budget line for medical products regulation including, participating in regional activities. • NMRAs should use service/industry fees to participate in regional activities. • Enough funding will help to arrange staff training sessions.

Medicines evaluation and registration and GMP Inspection systems	• Availability of core components in medicine registration, and GMP. • Maturity level • Percentage of product applications with registration decisions. • NMRA's participation in joint assessments, and its impact on the national decision-making processes. • Use of regionally harmonized guidelines for medicines registration. • Level of reliance of the NMRA on other NMRAs. • Proportion of jointly assessed medical products, and GMP inspections.	• Two NMRAs were WHO-GBT fully benchmarked and gained Maturity level 3. • Most of them did not use regional guidelines and regional recommendations in medicines registration. • No medical products were registered based on a regional joint review. • Use reliance models in MA decision-making. However, no medical products were granted marketing authorization based on the reliance model. • Most of them participated in regional joint assessments. • None of the NMRAs used regional recommendations for joint inspections of manufacturing sites.	• Partner organizations should encourage and guide NMRAs to become fully benchmarked. • Training sessions for staff would be beneficial for having the same knowledge among member countries. It will improve trust within NMRAs. • Effective use of harmonized process should be encouraged in medical products regulation. • Arrange platforms for give technical support for the less resourced NMRAs within the region.
QMS	• Implementation of QMS by the NMRAs based on ISO 9001.	• Two NMRAs were ISO certified. The other one had not enough QMS staff.	• Partner organizations should give support in QMS activities.

IMS	• Availability of integrated IMS.	• Two NMRAs had IMSs in use. However, progression is still needed in some sections.	• Partner organizations should give support in IMS activities.
Transparency, Accountability, and Communication	• Availability of regulatory information to the public domain and sharing of information at the regional level.	• All NMRAs had a public domain on their own. • Most of them did not share information at the regional level.	• Should encouraged NMRAs to effective sharing of information among them. • Sharing information would help in developing trust among member states.
NMRA Human Resource Capacity	• Availability of staff with relevant qualifications, skills, and knowledge to perform core regulatory and managerial functions.	• Some NMRAs had not enough professionals to perform core regulatory functions.	• Train staff members to perform specific regulatory tasks. • Should get support from other member states. • Adherence to harmonization process and make it a success.
Partnership and Coordination	• Available partnerships coordinated by the AMRH program on regulatory systems strengthening.	• All three NMRAs had partnerships with different stakeholders to get support in regulatory systems strengthening.	• Should get continuous support from partners, in order to maintain core regulatory functions and to strengthen the harmonization activities.

CONCLUSION

Harmonized medical products regulatory system is one of the best ways to mitigate overburdened staff, sub-standard medical products in the market, fewer professionals in the field, lengthy registration and marketing authorization processes. Furthermore, this harmonization process helps less-resourced NMRAs collaborate to gain benefits, such as sharing limited resources, getting support in decision-making, building confidence in regulatory decision outcomes, allowing learning from the experiences of others, and minimizing the duplication of effort. The study identified the issues, challenges, and benefits of the ECOWAS-MRH program based on the data from the three NMRAs in Nigeria, Ghana, and Cape Verde. Consequently, remedial actions were identified and proposed.

Considering the harmonization perspective, medicines registration guidelines, legal regulatory aspects, duration in the medicine's registration process, medical products registration charges, medical products' application assessments, and manufacturing sites' inspections should be encouraged in the ECOWAS region. However, to get the assumed benefits of the regulatory harmonization process, NMRAs should adhere to and follow the basic concepts in practice. Ultimately it will help overcome the severity and diversity of health issues by allowing patients access to quality, safe, effective, and affordable medical products in the West African region.

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ANNEXURES

Annexure 1: Purpose, Unit of measurement, and the Data type of the indicators of M&E Tool.

	DEFINITION OF INDICATOR	PURPOSE	UNIT OF MEASUREMENT	DATA TYPE
CATEGORY 01	POLICY, STRATEGY, AND LEGAL FRAMEWORK			
INDICATOR 01	EXISTENCE OF NATIONAL POLICY (NMP)	Assess whether the country has a National Medicines Policy (NMP) and is the policy within the WHO recommendations		QUALITATIVE
Sub-indicator 1.1	Does NMRA have a National Medicines Policy (NMP)		YES/NO	
Sub-indictor 1.2	Does the NMP provide for regional cooperation?		YES/NO	
Sub-indicator 1.4	Has the NMP been reviewed within the past 5 years?		YES/NO & YEAR	
INDICATOR 02	EXISTENCE OF INSTITUTIONAL DEVELOPMENT PLAN (IDP)	Assess whether the country has an Institutional Development Policy (IDP)		QUALITATIVE
Sub-indicator 2.1	NMRA Institutional Development Plan (IDP) is available		YES/NO	
Sub-indicator 2.2	Is the IDP being implemented?		YES/NO	
Sub-indicator 2.3	List activities from the IDP that require support from partners (top 3 priorities)			
INDICATOR 03	AVAILABILITY OF LEGAL FRAMEWORK GOVERNING THE REGULATION OF MEDICAL PRODUCTS	Assess whether the country has a legal framework governing the regulation of medical products and is the framework follows the AU Model Law.		QUALITATIVE
Sub-indicator 3.1	Do you have a Law for regulating medicine in your country?		YES/NO	
Sub-indicator 3.2	Year of enactment of medicine law		YEAR	
Sub-indicator 3.3	Date of last review or amendment of the medicines law.		YEAR	
CATEGORY 02	NMRA GOVERNANCE			

INDICATOR 04	LEVEL OF AUTONOMY OF THE NMRA	Assess the level of autonomy of the NMRA		QUALITATIVE
Sub-indicator 4.1	Is the NMRA autonomous according to AU model law?		YES/NO	
Sub-indicator 4.2	NMRA decision making power including participation in regional harmonization activities		YES/NO	
Sub-indicator 4.3	Department under the Ministry of Health/Not autonomous		YES/NO	
CATEGORY 03	NMRA/ REC FINANCING			
INDICATOR 05	LEVEL OF NMRA FUNDING	Assess the level of funding of the NMRA (the actual money received to the NMRA in the given year)		QUANTITATIVE
Sub-indicator 5.1	The total planned annual budget for NMRA		USD	
Sub-indicator 5.2	Total annual budget in the NMRA budget allocated for participating in regional activities		USD	
INDICATOR 06	RELIABILITY OF NMRA FUNDING	Assess the capability of the NMRA to achieve its goals within the limits of revenue generated from different sectors and the government.		QUANTITATIVE
Sub-indicator 6.1	NMRA source of funding (Government, service/industry fees, donors, Regional MRH Project, other)		YES/NO	
Sub-indicator 6.2	Total regional MRH project funds received		USD	
CATEGORY 04	MEDICINES EVALUATION AND REGISTRATION, AND GOOD MANUFACTURING PRACTICES			
INDICATOR 07	MARKETING AUTHORIZATION AND REGISTRATION	Assess the marketing authorization and registration process and is it in		QUALITATIVE
Sub-indicator 7.1	NMRA has been benchmarking using WHO GBT		YES/NO	

Sub-indicator 7.2	According to WHO GBT, at which maturity level is NMRA operating	compliance with the WHO GBT.		
Sub-indicator 7.3	NMRA is using all regional harmonized guidelines for the registration of medicines {utilization}		YES/NO	
Sub-indicator 7.4	Has the NMRA used regional recommendations on joint assessment for the reporting period		YES/NO	
Sub-indicator 7.5	Has the NMRA adopted any of the following African Medicines Regulatory Harmonization (AMRH) continental technical guidelines (AVAREF Guidelines, AMDH Guidelines, Other)		YES/NO	
INDICATOR 08	NUMBER OF PRODUCTS APPLICATIONS WITH REGISTRATION DECISIONS FOR 2021	Assess the number of product applications with registration decisions in the year 2021 and the is the authorization is based on a reliance model.		QUANTITATIVE
Sub-indicator 8.1	Number of products registered based on Regional Joint Review in the year 2021		NUMBER	
Sub-indicator 8.2	Number of products marketing authorization granted based on reliance or recognition within the region in 2021		NUMBER	
Sub-indicator 8.3	Is the NMRA utilizing the reliance models for marketing authorization (MA) decisions?		YES/NO	

Sub-indicator 8.4	If the response for the above is YES, what are the regulatory pathways used as reference standards? (AVAREF/ EMA Article 58/ Swissmedic MAGHP/ WHO Collaboration Registration Procedure/ Mutual Recognition of a product registered in other countries/ other)			
Sub-indicator 8.5	If the response for the above is OTHER, what is the reliance method?			
INDICATOR 09	NMRA PARTICIPATION IN JOINT ASSESSMENT	Assess the level of harmonization within the region by evaluating the number of joint assessments NMRA took part in 2021.		QUANTITATIVE
Sub-indicator 9.1	NMRA participating in regional joint assessments		YES/NO	
Sub-indicator 9.2	Number of joint assessments NMRA took part in 2021		NUMBER	
INDICATOR 10	REGULATORY GOOD MANUFACTURING PRACTICES (GMP) INSPECTIONS	Assess whether the NMRA uses regional recommendations on joint inspection of manufacturing sites within the period. And the reliance model that follows in GMP inspections.		QUALITATIVE
Sub-indicator 10.1	Has the NMRA used regional recommendations on joint inspection of manufacturing sites for the reporting period		YES/NO	
Sub-indicator 10.2	If the response to the above is YES, how many companies/products have been issued GMP approval based on the outcome of		NUMBER	

	the regional inspection			
Sub-indicator 10.3	Is the NMRA utilizing any reliance models for GMP inspection such as desk document review?		YES/NO	
INDICATOR 11	REGULATORY GOOD MANUFACTURING PRACTICES (GMP) INSPECTION (NUMBERS)	Evaluate the number of manufacturing sites inspected by NMRA and the number of GMP inspection decisions made.		QUANTITATIVE
Sub-indicator 11.1	Number of manufacturing sites inspected by NMRA in the year 2021		NUMBER	
Sub-indicator 11.2	Number of GMP inspections decisions made based on document review/inspection report in the year 2021		NUMBER	
CATEGORY 05	FUNCTIONAL QUALITY MANAGEMENT SYSTEMS (QMS)			
INDICATOR 12	IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEMS (QMS) REQUIREMENTS BY NMRA	Measures implementation of QMS by the NMRA based on ISO 9001.		QUANTITATIVE
Sub-indicator 12.1	According to WHO GBT, the percentage implementation of the Quality Management Systems (QMS) in the NMRA		NUMBER	QUALITATIVE
Sub-indicator 12.2	NMRA ISO 9001: 2015 certified		YES/NO	QUANTITATIVE
Sub-indicator 12.3	The number of trained staff on QMS in the year 2021?		NUMBER	
CATEGORY 06	INFORMATION MANAGEMENT SYSTEM (IMS)			
INDICATOR 13	IMPLEMENTATION OF REQUIREMENTS FOR AN INTEGRATED IMS	Assess whether the NMRA has an IMS that helps maintain accountability and		QUANTITATIVE

Sub-indicator 13.1	Implementation of IMS modules by NMRA	transparency within the institutions and stakeholders in decision-making, sharing information, and timelines of approval of registration decisions.	YES/NO	
CATEGORY 07	TRANSPARENCY, ACCOUNTABILITY, AND COMMUNICATION			
INDICATOR 14	COMMUNICATION AND INFORMATION SHARING	Assessing the availability of regulatory information in the public domain and sharing information at the regional, continental, and international levels are key for public confidence and NMRA credibility.		QUALITATIVE
Sub-indicator 14.1	NMRA sharing regulatory information with others in the REC region		YES/NO	
Sub-indicator 14.2	NMRA IMS linked to other NMRAs in the region		YES/NO	
Sub-indicator 14.3	NMRA IMS linked to REC Secretariat		YES/NO	
Sub-indicator 14.4	The NMRA has its web page with timely information that gives the public access to related legal provisions, guidelines SOPs, and decisions		YES/NO	
Sub-indicator 14.5	The key information is available to the public via a website a. Medicines Policy b. Medicines law c. Regulations d. Guidelines e. Procedure for application and decision-making processes		YES/NO	

	f. Summary inspection reports g. List of registered premises, registered products, renewals, and withdrawals h. Appeals against NMRA decision i. Safety alerts j. Banned products k. Withdrawn products l. Recalled products m. Prohibited products n. Restricted products			
CATEGORY 08	NMRA HUMAN RESOURCE CAPACITY			
INDICATOR 15	MEDICINAL PRODUCTS REGULATORY EXPERTS' DENSITY	Evaluate the number of professionals in the NMRA with relevant qualifications to manage critical regulatory functions.		QUANTITATIVE
Sub-indicator 15.1	Product assessment: total number of assessors in the NMRA in the year 2021		NUMBER	
Sub-indicator 15.2	GMP Inspections: total number of GMP Inspectors in the NMRA in the year 2021		NUMBER	
CATEGORY 09	PARTNERSHIPS AND COORDINATION			
INDICATOR 16	PARTNERSHIP COORDINATION TOWARDS COLLECTIVE IMPACT ON REGULATORY	Assess the number of partnerships that are coordinated by the AMRH initiative toward collective		QUALITATIVE

	SYSTEMS STRENGTHENING AND HARMONIZATION	impact on regulatory systems strengthening.		
Sub-indicator 16.1	Availability of mechanism for coordination of partners at country levels		YES/NO	
Sub-indicator 16.2	Partners providing support at the country level on various regulatory functions/ mechanisms		YES/NO	

Annexure 2: The Questionnaire

NMRA- AMRH M&E Data Collection Tool

Email: ……..

Name of Respondent: ……

Designation of the Respondent: ……

Name of the NMRA/Institution: ……

Name of the Country: …….

The REC in which you belong: ……

INTRODUCTION

The AMRH Secretariat is collecting Data for 2021 using the AMRH indicators. Please endeavor to respond to all questions.

Reporting year –

Category 1: Policy, Strategy, and Legal Framework

Indicator 1: Existence of National Medicines Policy (NMP)

Sub Indicator 1.1: Does NMRA have a National Medicines Policy (NMP)

Yes ☐

No ☐

Yes, but still being Drafted ☐

Please Upload a copy of the National Medicines Policy……

Sub indicator 1.2: Does the NMP provide for regional cooperation and harmonization

Yes ☐

No ☐

Sub indicator 1.3: Has the NMP been reviewed within the past 5 years?

Yes ☐

No ☐

If YES, in Sub-indicator 1.3 above, please select the year when the NMP was last reviewed

a. Before 2015 ☐
b. 2015 ☐
c. 2016 ☐
d. 2017 ☐
e. 2018 ☐
f. 2019 ☐
g. 2020 ☐

Any comment regarding indicator 1. ……..

Indicator 2: Existence of Institutional Development Plan (IDP)

Sub indicator 2.1: Does NMRA have Institutional Development Plan (IDP)?

Yes ☐

Yes, but still being drafted ☐

No ☐

Sub indicator 2.2: Is the IDP being implemented?

Yes ☐

No ☐

List activities from the IDP that require support from Partners (top 3 priorities)

…….

Indicator 3: Availability of Legal Framework Governing the Regulation of Medical Products

Sub indicator 3.1: Do you have a Law for regulating medicines in your country

Yes ☐

Yes, but the draft in Parliament ☐

No ☐

Sub indicator 3.2: Year of enactment of medicines law……..

Sub indicator 3.3: Date of last review or amendment of the medicines law…….

Any comments regarding indicator 3?.....

Category 2: NMRA Governance

Indicator 4: Level of autonomy of the NMRA

Sub indicator 4.1: Is the NMRA autonomous according to AU model law (rating autonomous or semi-autonomous)

a. Autonomous ☐
b. Semi-autonomous linked to Ministry of Health ☐
c. Not autonomous and Part of the Ministry of Health ☐
d. Other ☐

If you selected Other, please provide comments below

……

Sub indicator 4.2: NMRA has decision making power including participation in regional harmonization activities

Yes ☐

No ☐

Any comments regarding indicator 4? ……

Category 3: NMRA Financing

Indicator 5: Level of NMRA funding

Sub indicator 5.1: Total planned annual budget in USD for NMRA in the year 2021. Please indicate the calendar year (or fiscal year) in your country i.e. January 1 to December 31; July 1 to June 30 etc.

……..

Sub indicator 5.2: Total annual budget (in USD) in the NMRA budget allocated for participating in regional activities by NMRA.

……

Any comments regarding indicator 5? ……..

Indicator 6: Reliability of NMRA funding

Sub indicator 6.1: NMRA Source of Funding

a. Government ☐
b. Service/Industry fees ☐
c. Donors ☐
d. Regional MRH Project ☐
e. Other ☐

Sub indicator 6.2: Total regional MRH Project funds received (in USD) by NMRA in the year 2021. Please indicate the calendar year (or fiscal year) in your country i.e January 1 to December 31; July 1 to June 30 etc.

……

Any comments regarding indicator 6? ……

Category 4: Medicines evaluation and registration and good manufacturing practice (GMP) inspection systems

Indicator 7: Marketing authorization and registration

Sub indicator 7.1: NMRA has been fully benchmarked using WHO GBT (not NMRA self-assessment)

Yes ☐

No ☐

Sub indicator 7.2: According to WHO GBT, at which maturity level is NMRA operating?

…….

Sub indicator 7.3: NMRA is using all regional harmonized guidelines for registration of medicines {utilization}

Yes ☐

No ☐

Sub indicator 7.4: Has the NMRA used regional recommendations on joint assessment for the reporting period?

Yes ☐

No ☐

Sub indicator 7.5: Has the NMRA adopted any of the following African Medicines Regulatory Harmonization (AMRH) continental technical guidelines

a. AVAREF Guidelines Yes ☐ No ☐
b. AMDF Guidelines Yes ☐ No ☐
c. Other(s) Yes ☐ No ☐

If your response to the question above was OTHER(S), please mention the technical guideline below.

……..

Any comments regarding indicator 7? ……

Indicator 8: Number of products applications with registration decisions for 2021

Sub indicator 8.1: Number of products registered based on Regional Joint Review in the year 2021?.

……

Sub indicator 8.2: Number of products marketing authorization granted based on reliance or recognition within the region in the year 2021?

……

Sub indicator 8.3: Is the NMRA utilizing the reliance models for marketing authorization (MA) decisions?

Yes ☐

No ☐

Sub indicator 8.4: If your response to the question above was YES, please indicate if the following regulatory pathways are used as reference standard

a. AVAREF ☐
b. EMA Article 58 ☐
c. Swissmedic MAGHP ☐
d. WHO Collaboration Registration Procedure ☐
e. Mutual Recognition of products registered in other countries ☐
f. Other(s) ☐

Sub indicator 8.5: If your response to the question above was OTHER(S), please mention the reliance method below.

……

Any comments regarding indicator 8? …….

Indicator 9: NMRA participation in joint assessments for 2021

Sub indicator 9.1: Is NMRA participating in regional joint assessments

Yes ☐

No ☐

Sub indicator 9.2: Number of joint assessments NMRA took part in the year 2021?

…….

Indicator 10: Regulatory Good Manufacturing Practices (GMP) inspection

Sub indicator 10.1: Has the NMRA used regional recommendations on joint inspection of manufacturing sites for the reporting period?

Yes ☐

No ☐

Sub indicator 10.2: If your response to the question above is YES, how many companies/products have been issued GMP approval based on the outcome of the regional inspection?

……

Sub indicator 10.3: Is the NMRA utilizing any reliance models for GMP inspection such as desk document review?

Yes ☐

No ☐

If your response to the question above is YES, please indicate the reference GMP standard?

…….

Any comment regarding Indicator 10? …….

Indicator 11: Regulatory Good Manufacturing Practices (GMP) inspection (Numbers)

Sub indicator 11.1: Number of manufacturing sites inspected by NMRA in the year 2021?

……..

Sub indicator 11.2: Number of GMP inspection decisions made based on document review/ inspection report in the year 2021?

……

Any comment regarding Indicator 11? …….

Category 5: Functional Quality Management Systems (QMS)

Indicator 12: Implementation of Quality Management Systems (QMS) requirements by NMRA

Sub indicator 12.1: According to WHO GBT, please indicate the percentage implementation of the Quality Management System (QMS) in the NMRA?

a. Less than 10% ☐
b. 11-20% ☐
c. 21-30% ☐
d. 31-40% ☐
e. 41-50% ☐
f. 51-60% ☐
g. 61-70% ☐
h. 71-85% ☐
i. Over 85% ☐
j. Not Known ☐

Sub indicator 12.2: NMRA ISO 9001: 2015 QMS certified

Yes ☐

No ☐

Yes, but ISO 9001: 2008 ☐

Undergone initial ISO audit ☐

Sub indicator 12. 3: Number of trained staff on QMS in the year 2021?

…….

Any comment regarding Indicator 12? ……

Category 6: Information Management System (IMS)

Indicator 13: implementation of requirements for an integrated IMS

Sub indicator 13.1: Implementation of IMS modules by NMRA

Yes ☐

No ☐

Module in the IMS available in the NMRA

a. Product module Yes ☐ No ☐
b. GMP module Yes ☐ No ☐
c. Premises module Yes ☐ No ☐
d. Inspection module Yes ☐ No ☐
e. Import and export module Yes ☐ No ☐
f. Finance management module Yes ☐ No ☐
g. Other 1 Yes ☐ No ☐

In case your response was OTHER, please provide details.

……

Any comment regarding Indicator 13? …….

Category 7: Transparency, Accountability, and Communication

Indicator 14: Communication and Information sharing

Sub indicator 14.1: NMRA sharing regulatory information with others in the REC region?

Yes ☐

No ☐

Sub indicator 14.2: NMRA IMS linked to other NMRAs in the region?

Yes ☐

No ☐

Sub indicator 14.3: NMRA IMS linked to REC Secretariat?

Yes ☐

No ☐

Sub indicator 14.4: The NMRA has its own web page with timely information that gives the public access to related legal provisions, guidelines SOPs, and decisions?

Yes ☐

No ☐

In case your response to the previous question was YES, please provide the website below?

……

Sub indicator 14.5: The following key information is available to the public via a website:

	Yes	No
a. Medicines Policy	☐	☐
b. Medicines Law	☐	☐
c. Regulations	☐	☐
d. Guidelines	☐	☐
e. Procedures for applications and decision-making processes	☐	☐
f. Summary inspection reports	☐	☐
g. List of registered premises, registered products, renewals, and withdrawals	☐	☐
h. Appeals against NMRA decision	☐	☐
i. Safety alerts	☐	☐
j. Banned products	☐	☐
k. Withdrawn products	☐	☐
l. Recalled products	☐	☐
m. Prohibited products	☐	☐
n. Restricted products	☐	☐

Any comments regarding indicator 14? ……

Category 8: NMRA Human Resource Capacity

Indicator 15: Medicinal products regulatory experts' density

Sub indicator 15.1: Product Assessment: Total number of assessors in the NMRA in the year 2021?

……..

Sub indicator 15.2: GMP Inspections: The total number of GMP Inspectors in the NMRA in the year 2021?

……

Any comment regarding Indicator 15? ……..

Category 9: Partnerships and Coordination

Indicator 16: Partnership coordination towards the collective impact on regulatory systems strengthening and harmonization

Sub indicator 16.1: Availability of mechanism for coordination of partners at country levels

Yes ☐

No ☐

Sub indicator 16.2: Partners providing support at the country level on various regulatory functions/ mechanisms

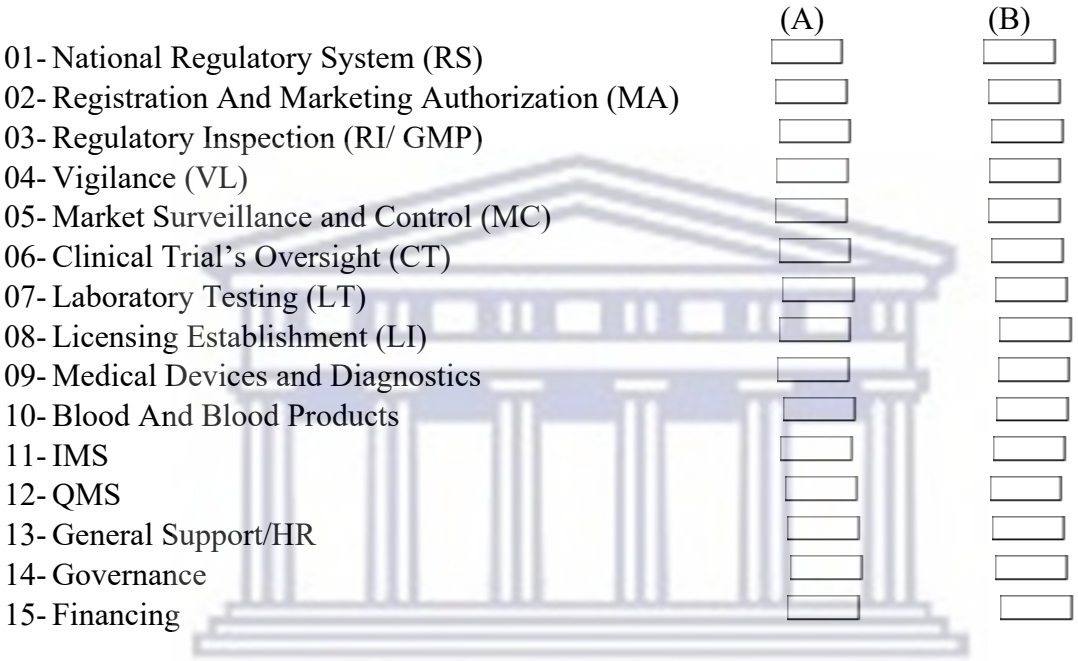
Yes ☐

No ☐

Sub indicator 16.3: Development partners and international agencies providing support to NMRA on various regulatory functions/mechanisms at the country level

(A) Member of AMRH Partnership Platform

(B) Not a member of the AMRH Partnership Platform



For each of the Partners indicated above, please provide the Name of the Partner, and the type of support (Technical, Financial, or advocacy)?

……

Any comment regarding Indicator 16? …….