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ANALYZING THE FEASIBILITY OF ADOPTING THE HUMAN MEDICINES REGULATORY PATHWAYS OF THE EUROPEAN MEDICINES AGENCY FOR THE AFRICAN MEDICINES AGENCY

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ABSTRACT

The implementation of the Centralized Procedure (CP) among European countries was facilitated by the establishment of the European Medicines Agency (EMA) in 1995, which is a culmination of the efforts and milestones made during the harmonization of medicines regulation across Europe. Inspired by the success story of human medicines regulatory harmonization among European countries, the African Union (AU) established the African Medicines Agency (AMA). The objective of this article is to assess the feasibility of adapting regulatory procedures analogous to the EMA framework for the African context and to propose a flexible model tailored to the continent's specific needs. Data were collected using four methods, narrative review, scoping review, comparative analysis, and survey, based on the nature of the required data to assess the feasibility of developing harmonized mechanisms for human medicines approvals among African countries. The European regulatory pathways provide valuable preliminary models for regulatory harmonization in Africa. By using the European framework as foundational blueprint rather than initiating models from the ground up, African countries can accelerate the creation of unique and localized regulatory pathways. Harmonized legal bases are prerequisites for harmonized regulatory frameworks. Therefore, revising the AU Model Law on Medical Products Regulation is recommended, as harmonizing the regulatory frameworks on human medicines is overdue for all African countries. Furthermore, it should be referred to as a directive, as it is not directly binding. Comparative studies of each African country's legal and regulatory frameworks with the Model Law on Medical Products Regulation are advised. Moreover, it is recommended that the African Medicines Regulatory Harmonization (AMRH) initiative be restructured to operate through the Regional Coordination Centers (RCCs) rather than the Regional Economic Communities (RECs). Furthermore, independent monitoring and evaluation are necessary to ensure the success of regulatory harmonization of human medicines among African countries.

KEYWORDS: Drug Regulatory Affairs; Regulatory Harmonization; African Medicines Agency; African Medicines Regulatory Harmonization; AU Model Law on Medical Products Regulation.

1 INTRODUCTION

A single human medicine application initiates one evaluation; if its outcome is positive, centralized market authorization will be granted for this medicine to be accessed in all African countries. An African daydream may become a reality, considering the harmonization efforts among African countries in all aspects, recalling the ambitious plans of Africa's Agenda 2063. Africa holds immense potential because of its vast natural resources and growing demographic base. Africa is the world's second-largest and second-most populous continent after Asia, with an estimated population of over 1.58 billion people in 2026, representing nearly 19 per

cent of the global population.[1] Fifty-five recognized sovereign states shape the continent.[2]

Despite its considerable natural resources and expanding demographic base, Africa faces numerous challenges within the human medicines regulatory sector. These issues include a scarcity of essential medical products and substantial delays in market authorization timelines.[3] Moreover, the absence of legally binding harmonized regulatory frameworks across the African continent poses a significant challenge.[4,5] Furthermore, most African national medicines regulatory authorities (NMRAs) lack the capacity to perform essential core regulatory functions.[6] Notably, there is a significant prevalence of substandard and falsified medicines (SSFFCs), further complicating the public health landscape of the continent.[6,7]

These challenges in the African human medicines regulatory systems were noticed during the coronavirus disease 2019 (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). As reported by the World Health Organization (WHO) in December 2021 only less than 3% of the global vaccine doses were shipped to Africa. Furthermore, approximately 8% of Africans were fully vaccinated; in contrast, more than 60% of the population in many high-income countries (HICs) were fully vaccinated at that time.[8]

There is no doubt that the harmonization of regulatory frameworks is the key driver in promoting efficient evaluation of medicines, reducing workload, and supporting earlier drug access. An example is the establishment of the European Medicines Agency (EMA) in 1995 and the introduction of the Centralized Procedure (CP), which facilitated the evaluation and access to new innovative human medicines across the European Economic Area (EEA).

Moreover, the EMA supports all vital regulatory functions required to maintain the quality of human medicines across the European continent, focusing on the CP.[9] The power of human medicines regulatory harmonization was proven during the COVID-19 pandemic, as the EMA could assess strategic innovative vaccines in a record time.[10]

The EMA's CP is identified as a successful culmination of the efforts and milestones made during the human medicines regulatory harmonization initiatives in the European Union (EU), such as the Multistate Procedure, also known as the Committee for Proprietary Medicinal Products Procedure (CPMP Procedure), and the Concertation Procedure.[11]

In the light of the success of human medicines regulatory harmonization across Europe, the adoption of a centralized procedure similar to the EMA's CP or other European regulatory pathway by the African Medicines Agency (AMA) may enhance regulatory efficiency, reduce duplication of efforts, and facilitate quicker access to safe and effective medicines for the African population.

2 METHODS

Data were collected using four methods, narrative review, scoping review, comparative analysis, and survey, based on the nature of the required data to assess the feasibility of developing harmonized mechanisms for human medicines approvals among African countries. Given the diversity of data required, this hybrid approach allowed appropriate method selection for collecting each dataset separately.

2.1 Narrative Review

A narrative review was conducted to gather data on the historical development of the EU's legal and regulatory harmonization of human medicines. The aim is to extract applicable ideas from the harmonization processes among European countries that could be relevant to African countries. Given that the EMA is operating successfully and that the development steps during the harmonization of human medicines regulatory affairs are historical facts, the narrative review approach is suitable for achieving a broad overview and building a knowledge base while ensuring the flexibility of selected sources.[12,13]

2.2 Scoping Review

A scoping review approach was applied to provide a comprehensive summary and overview of the status of harmonization among African countries because the AMA is still in the early stages of its maturity. Furthermore, this type of review is suitable because there is no need to produce summary answers to the research questions solely from this review. However, the main objective is to identify the gaps hindering the harmonization of human medicines across Africa.[14,15] The data produced from the scoping review were combined with datasets produced by other methods to provide more reliable recommendations.

The preferred reporting items for systematic reviews and meta-analyses extension for scoping reviews (PRISMA-ScR) flow diagram was used to report the scoping review's results.[16–18]

Relevant articles were identified by searching popular databases: Scopus, PubMed, and Google Scholar using the following Boolean operators: "African Medicines Agency" AND (regulatory harmonization OR Pan-African).

The search was then refined by identifying articles that discussed the role of regional regulatory agencies, regional health governance, the need for regulatory harmonization, the AU's Treaty for the Establishment of the AMA, known as the AMA Treaty, and pharmaceutical regulations.

Only articles written in English were considered, and all articles published between January 2017 and May 2024 in the context of the harmonization and evolution of the AMA were included. Moreover, some information was extracted from authentic websites.

2.3 Comparative Analysis

With comparative analysis, various aspects of both agencies, the AMA and the EMA, were compared to highlight the significant differences and similarities between the EMA and the AMA regarding legal frameworks and operations.

2.4 Survey

A web-based survey was administered to gather additional data from industrial and regulatory bodies' perspectives. Therefore, a form was constructed using Google Forms with eight questions; the first four questions were intended to evaluate the feasibility of establishing similar procedures to the EMA's CP or historical models, for example, the Concertation Procedure and the CPMP Procedure, for the AMA. The remaining four questions aimed to develop recommendations for promoting human medicines regulatory harmonization within Africa based on European regulatory procedures.

Online surveys have significant advantages such as global reach, speed, flexibility, and low administration costs. However, some weaknesses may contribute negatively to the results, such as unclear answers, misunderstanding of the questions, receiving the survey via junk mail, privacy concerns, difficulties ensuring that the survey is being answered by the population in scope, and lack of personal contact.[19,20]

Therefore, the survey questions needed to be validated to ensure the clarity and relevance of the eight questions, avoiding bias in the results due to misunderstandings, unclear answering instructions, and random responses. The survey questions were validated using a six-step procedure as recommended by Evans JR & Mathur A (2005).[21] A panel of ten experts was established to validate the survey, ensuring that the questions were clear and relevant. Six of the ten contacted experts supported the validation of the survey, reaching a response rate of 60%. These six experts, with different drug regulatory affairs experiences, validated the survey in face-to-face or online meetings.

The six experts validated each question for clarity and relevance using a 4-point Likert scale and the conclusion of the validation was determined by calculating the Content Validity Index (CVI) indicators according to the recommendations from the research done by Polit & Beck (2006).[22]

3 RESULTS AND DISCUSSION

3.1 Overcoming Drug Regulatory Challenges: The EU Experience

The formation of the EU is a result of finding the conscience between its member states, as it is a union based on protecting the member state's sovereignty while uniting the actions and efforts to deal with the challenges in all sectors, which means that the member states delegate some of their decision-making authority to the collective institutions they have established, enabling democratic decisions on specific matters of shared interest to be made at the EU level.[23] Figure 1 illustrates simplified legal sources of EU Law and the binding nature of their legal instruments.[24,25] This unique formation has a positive impact on the drug regulatory sector, as the drug regulatory sector is a challenging sector that needs united efforts and expertise to ensure the quality and safety of the medicines administered within the EU.[26]

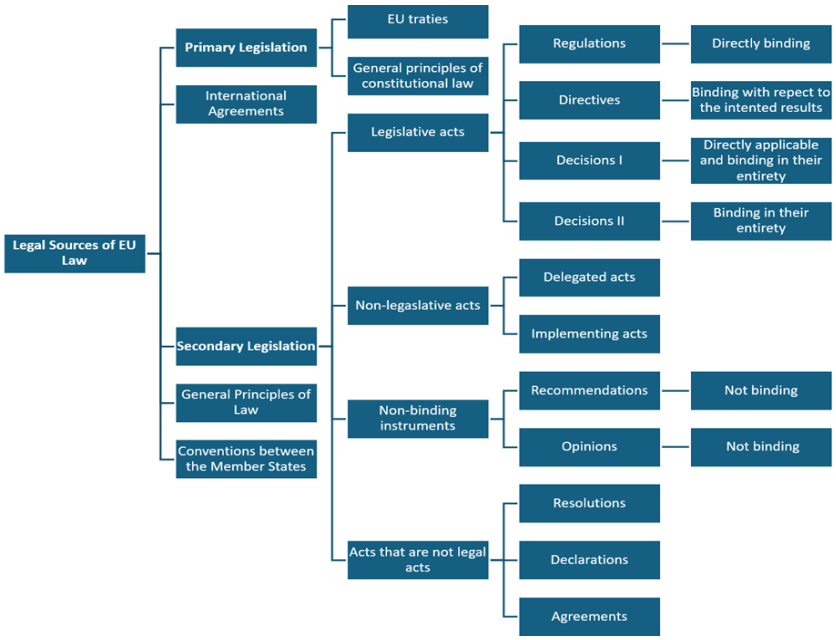

Fig. 1: Simplified legal sources of EU law and binding nature of their legal instruments.

In the EU, legislative power initially established with the representatives of member states' governments meeting in the European council, reflecting the EU's foundation as a union of sovereign states rather than a single European nation. Member states pooled, rather than transferred, their sovereignty, maintaining a joint authority over EU decisions. However, with deeper EU integration, this power dynamic evolved to include a more balanced role for the European Parliament. Furthermore, the parliament's role was consultative, but it gradually gained influence, culminating in the co-decision procedure, where it shares legislative power with the council.[24] The motive for harmonizing the regulation of human medicines among European nations was the thalidomide tragedy in the sixties of the last century.[27] The introduction of harmonized human medicines regulatory frameworks took more than thirty years. It reached its highest point in the nineties of the last century with the formation of the EMA and the introduction of the legally binding CP.[28] Despite those thirty years, human medicines regulatory harmonization has started from draft zero. The journey of harmonizing human medicines regulatory and legal frameworks among European countries marks several milestones that have contributed positively to the introduction of the CP.

These milestones include the introduction of harmonized regulations and directives.[29] Moreover, the introduction of new procedures, for instance the CPMP Procedure and Concertation Procedure.[11,30,31] The CPMP procedure was a landmark in European medicines harmonization. It encouraged manufacturers to seek simultaneous marketing authorization for a drug in several European countries in five or more member states lately; two member states were enough. Despite this, the procedure was not centralized or legally binding. However, it has paved the way for more advanced procedures such as Decentralized Procedure (DCP), Mutual Recognition Procedure (MRP), Repeat Use Procedure (RUP). Moreover, it has signaled the need for harmonized procedures among the European NMRAs.[11,30,32]

The Concertation Procedure was the first to enable a harmonized approach through the evolution of biotechnology and highly innovative drug products. Although this procedure was not legally binding and was not successful at that time, as many European NMRAs have sought arbitration, it has established the need for legally binding CP among European countries, which was possible after the establishment of the EMA as an autonomous centralized body, which is a prerequisite for the coordination of such procedures.[11,31,32] Figure 2 illustrates simplified information about the current regulatory procedures for the marketing authorization (MA) for human medicines registrations in the EEA.[33]

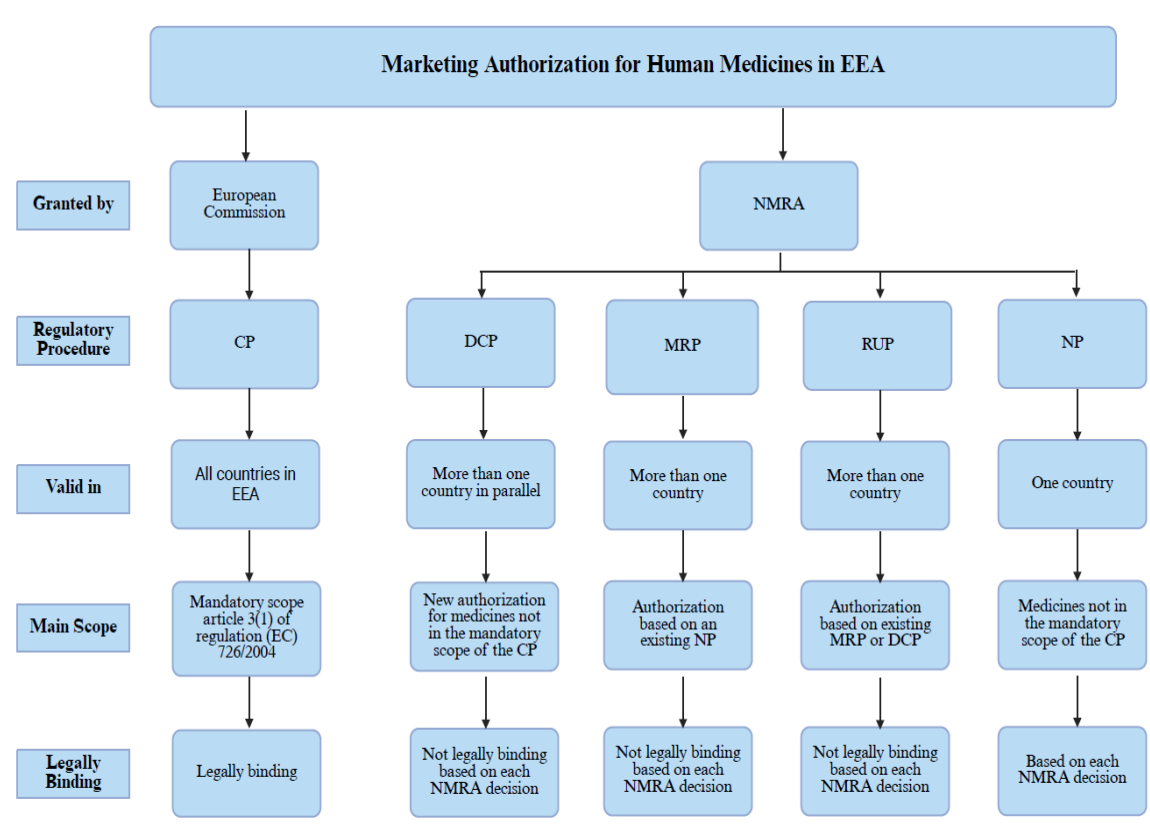

Fig. 2: Overview of marketing authorization (MA) pathways for human medicines in EEA.

Abbreviations for Fig. 2: European Economic Area (EEA), Centralized Procedure (CP), Decentralized Procedure (DCP), Mutual Recognition Procedure (MRP), Repeat Use Procedure (RUP), National procedure (NP), National Medicines Regulatory Authority (NMRA).

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The success of harmonizing the European frameworks was noticed in facing challenges such as Pandemics and the closure of the unmet medical needs' gaps.[34-37] Moreover, the harmonized human medicines regulatory and legal frameworks are seen as an attractive environment for the pharmaceutical industry, which can access the EEA market with one centralized market authorization, reducing the complexity of navigation across different regulatory systems, which played a vital role in flourishing the pharmaceutical industries across the European continent and promoted international cooperation in this field.[38]

3.2 Unlocking Africa's Drug Regulatory Potential

The major findings about the historical development and current state of the African human medicines regulatory harmonization are reported and discussed in the following sections based on the studies identified by scoping review, which were reported with PRISMA-SCR flow diagram as illustrated in figure 3 and assessed using PRISMA-SCR Scheme.[16–18]

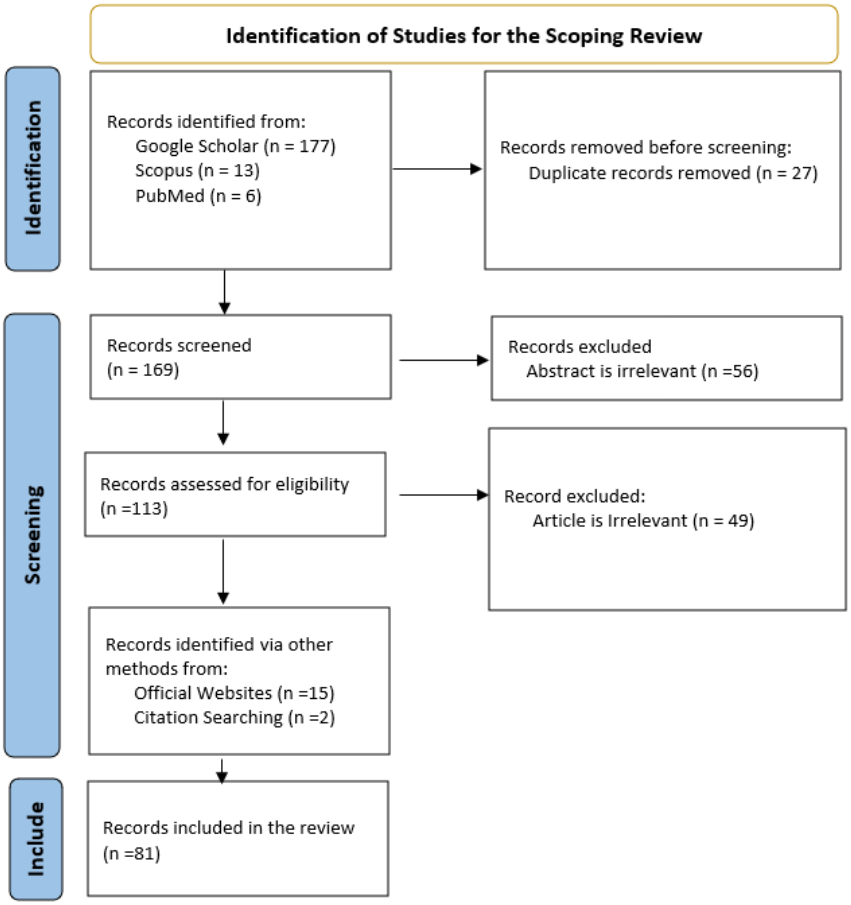

Fig. 3: Modified PRISMA-SCR flow diagram to identify the studies used in the scoping review.

3.2.1 The Challenges in Africa

Before the 21st century, African countries independently operated their drug regulatory policies, leading to significant variations in drug quality and availability across the continent. All African countries, excluding the Sahrawi Republic, have at least some sort of administrative body responsible for drug regulatory functions.[6] However, most of the African NMRAs have minimal or no capacity to support all NMRAs' vital core functions such as market authorization, licensing of manufacturers, inspection of manufacturing premises and distribution channels, market surveillance, quality control, and oversight of clinical trials.[6,39,40] The authorization of human medicines in Africa is regulated locally, as local legislative systems and regulatory procedures are very diverse across African countries. These differences are noticed as well among the countries within the same Regional Economic Community (REC).[6,39,41] Moreover, no regulations obligate African NMRAs to adopt the regulatory decisions made in other countries. Therefore, manufacturers have to submit the same dossier to several African NMRAs. Each submission has significant time implications, highlighting the urgent need for a more harmonized regulatory process.[42,43] The availability of essential medical products among African nations is frequently dispersed because of discrepancies in the legal provisions governing their critical regulatory functions.

This situation underscores the urgent need for these countries to align their regulations within a common framework to ensure a more synchronized and effective regulatory environment.[44]

The lack of a harmonized regulatory framework is a reason for delay, as the regulatory contrast among African countries forces pharmaceutical companies to navigate different compliance demands and regulatory environments, which is not an attractive environment for pharmaceutical industries to flourish.[45]

Furthermore, the approval processes of new innovative drugs in African countries are unpredictable and take significantly longer than those in most countries worldwide. In numerous low- and middle-income countries (LMICs), such as most African countries, procedures to secure market authorization and clinical trial authorization (CTA) for essential global health products, such as vaccines and medicines, have experienced protracted delays spanning four to seven years in comparison to their counterparts in HICs.[3] Moreover, the lack of a qualified regulatory workforce presents a significant challenge for African NMRAs.[42] The global prevalence of substandard and falsified medicines in low- and middle-income countries stands at 13.6%. Within these regions, Africa reports the highest rates of these poor-quality medicines, experiencing an 18.7% prevalence of SSFFCs.[7] The limited data on the funding of African NMRAs indicate that they have different funding models. Research concerning NMRAs in the East African Community (EAC) reveals that African NMRAs such as Tanzania, Kenya, and Uganda collect charges for regulatory activities and receive little to no government support. By contrast, the Zanzibar, Rwanda, and Burundi governments provide full financial support for their NMRAs. In the Southern African Development Community (SADC) area, the governments of Lesotho and Namibia completely subsidize their NMRAs. In contrast, Malawi, Tanzania, Zambia, and Zimbabwe primarily rely on industry fees.[6,40] African NMRAs present a diverse picture regarding their maturity, organizational structures, and activities. Some are more mature and operate as semi-autonomous bodies, whereas others are still developing and functioning within the ministry of health (MoH). This variation in maturity and structure reflects the unique challenges and opportunities faced by each NMRA regarding their regulatory roles. An assessment conducted by the WHO in 2010 for 26 countries in sub-Saharan Africa reported that most NMRAs were departments of MoHs.[40]

Drug authorization procedures and systems are robust in some African countries, such as those with a Global Benchmarking Tool (GBT) maturity level of three, while in other African countries, they function less effectively than expected due to poor regulatory infrastructure.[42,46] Mostly, the information required for submissions is not always clearly stated on official websites, there is a lack of clarity about drug submission processes, and there is poor IT infrastructure to support dossier submissions.[6,47–50]

Since 1997, the WHO has been assessing national regulatory systems using specific indicators.[51] Following the WHO Resolution 67.20 in 2014, the GBT was developed to enhance the evaluation of African NMRAs by assessing their maturity levels.[51,52] This tool, which uses 268 sub-indicators, replaced previous methods and introduced a maturity scale from one to four.[53] The target of the World Health Assembly (WHA) Resolution 67.20 is to reach level three of maturity to achieve a stable, well-functioning, and integrated regulatory system.[52,54] Only NMRAs of nine African countries, Egypt, Ethiopia, Ghana, Nigeria, Rwanda, Senegal, South Africa, Tanzania, and Zimbabwe, have achieved a maturity level of three, with none reaching level four.[46]

Furthermore, the continent is grappling with three significant health challenges: infectious diseases, non-communicable diseases (NCDs), and nutritional disorders. Africa's substantial disease burden and elevated mortality from diseases that are both preventable and treatable can be attributed to insufficient health systems, limited financial and human resources, and the lack of accessible and affordable medicines that meet quality, safety, and efficacy standards.[55]

The challenges in the drug regulatory sector in Africa are immense and coupled with significant drawbacks compared with the European continent. The African continent is roughly seven times larger than the European one, with more than triple the population and a higher level of diversities in all aspects. Moreover, most African NMRAs cannot overtake all essential regulatory functions, including the lack of expertise and qualified workforce, because of the shortage of training institutions, the absence of structured career paths and incentives, and the phenomenon of 'brain drain'.[42]

3.2.2 African Medicines Regulatory Harmonization (AMRH) Initiative

In response to these challenges, the African Medicines Regulatory Harmonization (AMRH) program was initiated in 2009 by the African Union Development Agency–The New Partnership for Africa’s Development (AUDA-NEPAD) as part of the Pharmaceutical Manufacturing Plan for Africa (PMPA) to facilitate access to high-quality, safe, and efficacious medical products, moreover, to establish a suitable environment for the AMA.[56] With its technical committees and partnerships AMRH serves as a ground base for harmonizing the regulatory framework among the African countries. The AMRH consists of several technical committees (TCs) and a partnership platform to support these technical committees. Furthermore, AUDA-NEPAD and WHO formed a joint secretariat for AMRH Initiative.[56]

3.2.3 Regional Centres of Regulatory Excellence (RCOREs)

AMRH has introduced the RCORE centers to build expertise and a highly qualified workforce to support drug regulatory harmonization plans. AMRH has initiated eleven RCOREs to strengthen eight regulatory functions as illustrated in table 1.[57] However, an evaluation of the RCOREs' performance is needed to ensure they function as initially planned and enhance and strengthen their functions. The lack of independent evaluation may challenge the functionality of the whole RCORE idea and may be a possible weakness of the structure.[41,58]

Table 1: Regional Centres of Regulatory Excellence (RCOREs).

Regulatory Functions	RCORE Institutions
Pharmacovigilance	Centre for Advocacy and Training in Pharmacovigilance; University of Ghana Medical School
	Pharmacy & Poisons Board (PPB), Kenya
Training in Core Regulatory Functions	Kilimanjaro School of Pharmacy; St. Luke's Foundation, Tanzania
	Centre for Drug Discovery, Development & Production University of Ibadan, Nigeria
Quality Assurance and Quality Control of medicines	North-West University (NWU) - Potchefstroom Campus, South Africa
	National Agency for Food and Drug Administration and Control (NAFDAC) Laboratory, Nigeria
Licensing of the Manufacture, Import, Export, Distribution and; Inspection and Surveillance of Manufacturers, Importers, Wholesalers and Dispensers of Medicines	National Drug Authority (NDA), Uganda
Clinical Trials Oversight	Direction General de la Pharmacie du Medicament et des Laboratoires, University of Ouagadougou, Burkina Faso
Medicine Evaluation and Registration and Clinical Trials Oversight	Food & Drugs Authority (FDA) Ghana
Medicine Evaluation and Registration	Tanzania Medicines and Medical Devices Authority (TMDA) / School of Pharmacy Muhimbili University of Health and Allied Sciences (MUHAS)
Medicine Registration and Evaluation, Quality Assurance/Quality Control and clinical trials oversight	Medicines Control Authority of Zimbabwe (MCAZ)

3.2.4 Regional Economic Community (REC) and Regional Coordination Centers (RCC)

The AMRH initiative used the existing RECs as building blocks for regional Medicines Regulatory Harmonization (MRH) initiatives to strengthen drug regulatory harmonization among African countries. The RECs were established based on the Treaty Establishing the African Economic Community (AEC), commonly known as the "Abuja Treaty," which entered into force in May 1994.[59]

The AMRH initiative's goal was for NMRAs within each of Africa's RECs to address this problem by coordinating their activities, relying on the work of one another and other trusted regulatory authorities, and applying other principles of smart regulation.[60]

The AU recognizes only eight RECs: the East African Community (EAC), Southern African Development Community (SADC), Economic Community of West African States (ECOWAS), Intergovernmental Authority on Development (IGAD), Economic Community of Central African States (ECCAS), Arab Maghreb Union (AMU), Community of Sahel-Saharan States (CEN-SAD), and Common Market for Eastern and Southern Africa (COMESA).[61]

Currently, the AMRH initiative has been successfully implemented in five RECs: EAC, SADC, ECOWAS, IGAD, and ECCAS.[62] This implementation serves as a promising foundation for further expansion and adoption. It's important to note that there are other RECs, which vary in importance to their members, they are not recognized by the AU. Therefore, the AMRH neglected these RECs during the harmonization efforts.[63]

Notably, African countries have overlapping REC memberships, and most of them are members of more than one REC, which may be counterproductive, increase duplicate work, and increase complexity.[63]

Moreover, multiple memberships may cause a complication known as the spaghetti bowl effect, which can be noticed when different rules are applied or when

different trade agreements are implemented.[64]

Furthermore, the RECs were established in the nineties of the last century prior to the establishment of the AMRH with mainly economic goals. This model includes countries with diverse medical needs in the same REC, which is counterproductive in implementing harmonized regulatory and legal frameworks. Moreover, defining a mandatory scope as a part of a CP in the same REC might be challenging due to including countries with diverse medical needs in the same REC.

The classification of the African countries via the Africa Centres for Disease Control and Prevention (Africa CDC) is more convenient than the RECs, considering the regional similarities and the fact that there is no multiplicity in memberships. The Africa CDC is comprised of five Regional Coordination Centers (RCC) and was launched in January 2017.[65,66] Moreover, the Africa CDC membership considers the medical needs of the member states and is guided by the principles of delegated authority, timely dissemination of information, and transparency, among others, in carrying out its activities. Furthermore, the institution serves as a platform for member states to share and exchange knowledge and lessons from public health interventions.[66]

Furthermore, the number of RCCs is limited to five, which may be considered simple compared to the number of RECs across the African continent. Therefore, AMRH and AMA shall be restructured and built up based on the RCCs of Africa CDC instead of the RECs. The REC model may be beneficial from an economic point of view. However, this model may unnecessarily complicate the human medicines regulatory harmonization landscape among the African countries. Therefore, stronger cooperation between the AMA and the Africa CDC is highly recommended to set priorities that comply with each African region's medical needs. Considering the last two major regional pandemics in Africa, Ebolavirus disease (EVD) and Middle East respiratory syndrome–related coronavirus (MERS-related coronavirus), the classification of Africa CDC is more feasible and convenient to build on human medicines regulatory harmonization frameworks. EVD in 2014 was mainly broken out among the member states of the Western Africa RCC. Historically, most outbreaks have been noticed in Central Africa RCC, Eastern Africa RCC, and Western Africa RCC.[67] Therefore, these three RCCs should consider the medicines for EVD in a mandatory scope and can develop centralized procedure for assessing and developing medicines to prevent and cure this disease. On the other hand, the Northern African RCC shall not consider the medicines for EVD in a mandatory scope, as there were no outbreaks among its countries.

However, the Northern Africa RCC shall consider the medicines for MERS-related coronavirus in a mandatory scope, as the outbreaks were only among its countries in Africa.[68] Therefore, this recommended approach during harmonization is believed to satisfy the needs of each African nation without forcing unaffected nations to prioritize unnecessary medications. This will prevent the abuse of resources and ensure that all nations benefit from the harmonized approach.

3.2.5 Medicines Regulatory Harmonization (MRH) Initiatives Based on REC

Only five RECs have established MRHs, and only three have joint assessment procedures, which are EAC-MRH, SADC-MRH, and ECWAS-MRH.[62] These procedures have similarities and differences, as demonstrated by the study done by Sithole et al. in 2024.[4]

The differences may be required to satisfy the regulatory needs of regional human medicines. However, if the differences among the procedures are immense, they can negatively impact the broader harmonization across the continent. Therefore, the outline shall be similar, and the differences shall only satisfy regional medical needs and not unnecessary complex local legislation.

Notably, all three procedures, EAC-MRH, SADC-MRH, and ECWAS-MRH, are not legally binding and need to be revisited, as these procedures have contributed positively to the regulatory environments across the countries in the same RECs.[4]

Despite the success of these joint procedures, some challenges have drawn them back. The ECOWAS-MRH lacks an information technology infrastructure, which has obstructed the implementation of effective dossier tracking and prevented centralized submission. Furthermore, the initiative faces challenges such as insufficient human resources, manufacturers' failure to adhere to deadlines, and inadequate cooperation of the WA-MRH initiative with the national agencies. Additionally, there is observed inconsistency in regulatory performance across various NMRAs. Moreover, applicants need to receive more detailed information regarding the procedural steps, key milestones, and expected timelines.[47,48]

Despite its achievements, the SADC-MRH and its ZaZiBoNa (an acronym formed from the first two letters of the four founding countries: Zambia, Zimbabwe, Botswana, and Namibia) initiative faces several challenges. Key issues include uneven workload distribution among member countries, insufficient jurisdictional authority, a decreasing volume of applications, and a lack of detailed procedural information for applicants. Additionally, inadequate human resources and delays by applicants in responding to inquiries are significant concerns. Further complications arise from manufacturers' non-compliance with the requirement to submit identical dossiers across all countries, inadequate record-keeping and tracking, and the authorities' neglect to recognize ZaZiBoNa

assessments as part of their formal duties. The initiative is perceived as more stringent than certain national procedures, which complicates the application process. Moreover, ambiguities in submission and follow-up protocols across different countries and variations in how quickly member countries implement ZaZiBoNa recommendations also pose challenges.[69,70] For instance, the recommended timeline for the ZaZiBoNa process is 9 months. However, the timeline fluctuated considerably between 5 to 18 months from 2014 to 2021.[71] This was confirmed in a study done by Sithole et al. in 2020, the median time to receive a ZaZiBoNa recommendation, including the time taken to respond to applicant queries but excluding the individual NMRA time before or after the joint ZaZiBoNa assessment, fluctuated considerably between 5 to 18 months from 2014 to 2019. Furthermore, the adoption of ZaZiBoNa's recommendations by NMRAs varies across countries, indicating limited predictability.[69]

Despite the countries forming EAC having a long history of cooperation in several areas, including the establishment of a suitable legal framework[72,73] and the EAC-MRA website impressively stands out as the most advanced among the African MRHs in terms of the accessibility of its guidelines (74,75), the EAC-MRH faces persisting challenges including the need for more detailed information about national regulatory processes on both national regulatory authority and EAC websites. The absence of a centralized submission and tracking system reduces efficiency. Additionally, the non-mandatory nature of central registration and discrepancies between EAC positive recommendations and individual country approvals necessitate additional information, causing delays. Inadequate human resources and the failure of manufacturers to submit identical dossiers to all countries further complicated the process. Lastly, the lack of an integrated information management system and difficulties in monitoring and tracking assessment reports present significant challenges.[56,4]

3.2.6 International collaborations

The international collaborations and partnerships such as EU-Medicines for all (EU-M4ALL), Marketing Authorisation for Global Health Products (MAGHP), African Vaccine Regulatory Forum (AVAREF), WHO medicines prequalification Procedure (WHO PQ), and Collaborative Procedures for Accelerated Registration (CPR), have benefited the African NMRAs in various regulatory fields. However, according to a report commissioned by PATH and Deutsche Stiftung Weltbevölkerung (DSW) titled "GOING FURTHER TOGETHER—The Case for European Union Partnership with Africa on Regulatory Harmonization", African NMRAs often delay product approval even after receiving a positive opinion under Article 58 procedure, known as EU-M4all procedure. The lack of trust in the quality of the Article 58 opinion among some African countries further complicates this issue.[76] From the procedure's inception in 2004 until July 2020, the EMA issued 11 positive opinions under the EU-M4all procedure, resulting in 138 authorizations in 90 countries worldwide.[77] Out of 138, 75 approvals were granted in Africa.[78] The number of opinions and approvals is considered significantly low compared to the number of opinions EMA typically provides. Moreover, the EMA charges the same fees as the CP, which may not be attractive for African NMRAs or pharmaceutical industries in Africa, given their limited financial resources. However, applicants can request a full or partial fee waiver from the EMA's Executive Director.[79]

3.3 Legal Basis of Drug Regulation Harmonization in Africa

To close the legislative gaps between African countries regarding medicines' regulations, a model law on Medical Products Regulation was drafted in 2014 by the AUDA-NEPAD, supported by key stakeholders such as the Access and Delivery Partnership (ADP), United Nations Development Program (UNPD), and Planning and Coordinating Agency (NPCA). The final version of the AU Model Law on Medical for Medical Products Regulation was officially endorsed by African Heads of State and Government at the AU Summit in January 2016 in Addis Ababa, Ethiopia.[5,80-82] The main objective for the AU Model Law on Medical Products Regulation is to address the challenges and harmonize the drug regulatory requirements among the African countries based on a unified legislative framework.[80,83]

The AU Model Law on Medical Products Regulation is designed to significantly enhance the ambitious plan of the AU PMPA framework. It adheres to the WHO best practices concerning medical products regulation and aligns with specific WHO recommendations. This model law aims to strengthen national legislation on medical product regulation and fosters the autonomy of the African NMRAs. To ensure broad accessibility and appreciation across diverse linguistic regions in Africa, the AU Model Law on Medical Products Regulation is available in four different languages.[84]

With its 35 Articles divided into ten parts, the AU Model Law on Medical Products Regulation is not a rigid regulation but a flexible one. Despite Article 2 defining clearly the model law's superiority in the event of a conflict with any other law on medical products. Furthermore, any existing law in conflict with the AU Model Law on Medical Products Regulation, shall be repealed or amended. However, this model law is not non-prescriptive legislation. Furthermore, Article 35 ensures that this model law shall comply with each state's legislation.[5,81,82]

Despite Article 28 encouraging the harmonization of standards and guidelines, strengthening the regulatory network, legal framework, and mutual recognition, the AU Model Law on Medical Products Regulation neither refers to the AMA nor advanced drug regulatory procedures for harmonization, such as centralized

procedures. It is more about harmonizing African countries' drug regulatory standards and practices.[81,82]

A guideline for domestication of the AU Model Law on Medical Products Regulation was developed by the staff of the AUDA-NEPAD and the Access and Delivery Partnership (ADP) to assist African member states in implementing this model in their local legislative.[81]

Implementing the AU Model Law on Medical Products Regulation among African countries is a domestication process, defined as the legislative action taken to incorporate the AU Model Law on Medical Products Regulation into the national legislation in each African country. The AMRH initiative formed the Technical Working Group on Medicines Policy and Regulatory Reforms (TWG-MPRR) to expedite and guide the domestication process to achieve these targets. The AUDA-NEPAD has also been coordinating legal capacity building and providing technical support to enable African countries to review their existing legislation on medical products regulation and make the required amendments for them to align with the AU Model Law Medical Products Regulation.[81,85] However, the ambitious targets for domestication of the AU Model Law Medical Products Regulation in at least twenty-five African countries by 2020 still need to be met.[5] As of February 2024, only 13 African countries have successfully domesticated the AU Model Law Medical Products Regulation.[86]

According to a study published by Ncube et al. in 2023, the degree of domestication of the AU Model Law on Medical Products Regulation among the twenty-one African NMRAs participated in this study was different; forty-eight per cent of the African NMRAs participated in the study have reported full domestication of the AU Model Law on Medical Products Regulation, however, thirty-eight per cent of the African NMRAs participated in the study have partially domesticated the AU Model Law on Medical Products Regulation.[5]

The introduction of the Model Law on Medical Products Regulation marks a milestone in harmonizing the human medicines regulatory and legal frameworks among African countries. Despite developing a guideline for the domestication of this model law to assist the AU member states in implementing this model low in their local legislation, only a few African countries have legislation compliant with the AU Model Law on Medical Products Regulation.[81] Moreover, the binding degree of the legal instruments among the African countries are not clear, as the AU Constitutive Act does not specify which AU decisions are binding and subject to Article 23 sanctions.[87] In practice, the AU decisions are either in the form of decisions or declarations. Except for those explicitly considered as declarations. It is difficult to ascertain the binding nature of decisions made by the Assembly and the Executive Council. To address this gap, the AU referred to the Abuja Treaty and the EU when developing the rules of procedure for the Assembly and the Executive Council. According to these rules, decisions by the Assembly and the Executive Council can take three forms, similar to those of the EU in terms of binding nature.[88]

Moreover, several elements hinder the implementation of the AU Model Law on Medical Products Regulation. These elements include a shortage of human and financial resources, competing national priorities, overlapping responsibilities among government institutions, and the slow and lengthy process of amending or repealing existing laws.[5]

Furthermore, the Model Law on Medical Products Regulation does not refer to any regulatory procedure, not even to the AMA. Although it is referred to as a regulation, it is not directly binding, as there is no one that fits all AU member states.[81] Moreover, the articles included in the Model Law on Medical Products Regulation should be more precisely formulated to avoid misunderstandings and the development of different legislative. systems among African countries. Therefore, a revision shall be considered, and it should be renamed to be considered a directive instead of regulation.

3.4 African Medicine Agency (AMA)

To face the drug regulatory challenges within the African continent, the AMRH program was initiated in 2009 by AUDA-NEPAD to establish a suitable regulatory environment for the AMA.[89–92] Therefore, the AMA Task Team was established in November 2014.[93]

The AMA's mission is not just promising but also holds the potential to transform the African pharmaceutical industry significantly. It shall support and contribute to the Africa Continental Free Trade Area (AfCFTA) and the promising PMPA, paving the way for a more robust and self-sufficient pharmaceutical sector in Africa.[89]

The AU endorsed the legal basis of the AMA in January 2015 during the twenty-sixth ordinary session of the Executive Council by Decision EX.CL/872(XXVI).[93] The Treaty of the AMA was established in February 2019 based on Decision 735 (XXXII).[94] The Republic of Rwanda was chosen to host the headquarters of the AMA based on the Decision EX.CL/Dec.1179(XLI) and EX.CL/1369(XLI).[95,96]

The AU Executive Council, in its forty-fourth ordinary session, reported in EX.CL/1486(XLIV)A the progress on the establishment and operationalization of AMA and the signing and ratification status of the AMA Treaty.[97] As of November 2023, only twenty-six member states have signed and ratified the treaty establishing the AMA, which means they have deposited the required legal instrument of ratification at the commission.[60] Despite reaching the minimum number of countries needed for the ratification, which was indicated in Article 38 of the AMA Treaty to be at least fifteen member states, a wide

range of challenges among African countries hinder the operationalization of the AMA.[98] The three main challenges reported in EX.CL/1486(XLIV)A are the delayed reactions from the member states regarding the implementation of the AMA Treaty, reliance on external partners to support AMA's activities, and lack of capacity.[97]

The AMA's main objective, as in the AMA Treaty Article 4, is to elevate the capacity of the RECs and the member states to secure access to high-quality, safe, and efficacious medicines among Africans.[98] The AMA is guided by the seven principles in Article 5 of the AMA Treaty: leadership, credibility, ownership, transparency and accountability, value-addition, confidentiality, and commitment to sound quality management. These principles ensure the AMA's capability of functioning and endorsing the main functions, which are Oversight of Clinical Trials, Marketing Authorization (MA), Safety Monitoring, Good Manufacturing Practice (GMP) inspections, Market Surveillance, and Quality Control.[98,99]

Article 7 of the AMA Treaty states that the AMA has to function as a legal entity capable of entering agreements and defending legal procedures.[98] The AMA shall have four core organs: the Conference of State Parties, the Governing Board, the Secretariat, and TCs. The Conference of State Parties should be the highest policy-making organ in the AMA. It shall be able to execute functions such as adopting regulations out of power, approving the structure and administrative guidelines, providing policy directions, and approving RCOREs, among other functions assigned to it in Article 14 of the AMA Treaty.[98]

The establishment of the AMA in February 2019 is a cornerstone in harmonizing human medicines regulations among African countries. Despite reaching the prerequisite number of countries required for ratification, which is fifteen, not all African countries have ratified the treaty of the establishment of the AMA. As of December 2025, only twenty-nine countries have ratified and deposited the treaty, which is considered a low number.[60] It is unclear why ratifying this treaty requires more than five years in most African countries. However, these delays can be justified by the diversity and complexity of the legal systems among African countries.

3.5 Comparative Analysis of EMA and AMA Legislative Frameworks and Operations

As illustrated in table 2, a comparative analysis was conducted to highlight the major differences and similarities between the EMA and the AMA, with a focus on their legal frameworks. The legal basis empowers the agencies to carry out their functions, ensuring a high level of autonomy in fulfilling their mandates. Establishing a well-coordinated structure for regulatory activities, securing sufficient financial resources, and maintaining an adequate number of competent human resources are essential prerequisites for their optimal performance.

Table 2: Comparative analysis of EMA and AMA legislative frameworks and operations.

Aspect	EMA	AMA
Establishment Legislative Framework	EU Regulation 2309/93	AU Desicion EX.CL/872(XXVI)
Major Operating Legislative Framework	Regulation (EC) No 726/2004, Directive 2001/83/EC and several directives and regulations are in place.	AMA Treaty based on AU Decision 735 (XXXII) and AU Model Law. However, not all AU members have ratified the AMA Treaty and not all AU Members have laws compliant with the AU Model Law. Notably, the current version of the AU Model Law does not refer clearly to the AMA.
The availability of Different Degrees of Legislative Framework	EMA is relying on different legal instruments such as regulations, directives, decisions, opinions, and recommendations to operate. These legal instruments are clearly defined in article 288 of the Treaty on the Functioning of the European Union (TFEU).	Based on Abuja Treaty the regulations and decisions respectively article 10 and article 13 are clearly binding. However, it is difficult to ascertain the binding nature of decisions made by the Assembly and the Executive Council, as in practice is not always the case. Based on research report titled "Mapping AU Decision Making Actors and Processes" decisions can take

		three forms, similar to those of the EU in terms of binding nature: Regulations: legally binding Directives: legally binding concerning the intended results Declarations, Resolutions, and Recommendations: not binding
Autonomy	EMA has an advanced level of autonomy.	AMA Shall be autonomy but still not clear, as AMA is still in the establishment's phase.
Member states legal basis status	Harmonised with each other. Moreover, EEA states have legal basis to implement the decisions from EU Commission.	Not harmonised with each other despite the recommendation to harmonise with AU model. The RECs have also guidelines recommending harmonising the law among their member states.
Drug Regulatory Support and Dynamics	EMA has established several mechanisms to support human medicines regulatory harmonisation such as centralised procedure, variation regulation and different procedures to close the gaps formed by unmet medical needs (78–80,82,89,174). Moreover, there are advanced dynamics regarding the update of the legal basis, regulations and directives in place.	No data is available, as the AMA is still in the beginning stage.
Structure	The current structure is considered solid to operate.	The proposed structure could be solid to operate, however no data on the operational nature of the proposed structure is available.
Regulatory Workforce and expertise	Different advanced Technical Committees, high qualified workforce and pool of more than 4000 experts.	Different Technical Committees are in place and some high qualified workforce. However, it was stated in different studies that the lack of expertise is a major issue. Therefore, RCORES have been established.
Finance	For 2026, the total budget of the EMA is €615.5 million. Approximately 91.5% of the Agency's budget comes from fees and charges, 8.2% from the EU's contribution for public health issues, and 0.2% from other sources. It is estimated that in 2026, €240.4 million will be allocated from the Agency's budget to the member NMRAs.	No data is available, and the finance model is not clearly defined.

Moreover, the weak structure of the legal systems and the existence of political motives may hinder the regulatory harmonization of human medicines to preserve sovereignty and financial benefits. However, the financial benefits may be more attractive if the African countries support the AMA. For instance, the total budget of the EMA in 2026 is €615.5 million, from it €240.4 million will be allocated from the Agency's budget to the member NMRAs.[100] A similar model may be feasible across Africa. The loss of sovereignty is not a challenge, as member states shall pool, rather than transfer, their sovereignty, maintaining joint authority over the AU's or AMA's decisions. Furthermore, the regulatory frameworks shall be harmonized with the local legislation. The proposed AMA structure was introduced in the AMA Business Plan.[101] The actual

structure of the AMA still needs to be illustrated. Notably, the proposed structure shares similarities with the EMA and the WHO PQTm.[42] The similarities between the AMA and the EMA may facilitate the cooperation between the two agencies.

3.6 Survey

The survey was administered from 21 June to 15 July 2024, after validating the eight questions for clarity and relevance to gather supplementary data from regulatory affairs professionals, specifically targeting those actively engaged with human medicines regulations in Africa. Of the 82 regulatory professionals contacted, 43 participated in the survey, achieving a response rate of 52.4%. The highest response rates were observed when participants were contacted before the survey was sent out. All participants from the pharmaceutical industry were contacted via telephone or video calls prior to sending the survey. However, there were challenges in reaching health authorities in some African countries, which negatively impacted the number of responses.

Based on the results of the administrated survey, 97.7% of the respondents considered the EMA's CP successful. However, 79.1% of the participants do not consider this approach applicable without modification among the African countries, which is consistent with the existing challenges regarding developing harmonized legal and regulatory frameworks among African countries. Therefore, a modified CP to suit the African continent may be an adequate option, which 53.3% of the respondents have predicted to be feasible, at least among the countries in the same REC or RCC. Furthermore, developing a continent-wide CP for strategic medicines such as COVID-19 vaccines may be a viable option.

Moreover, historical EU procedures such as the Concertation Procedure and the CPMP Procedure may be a feasible option despite their non-binding nature. However, these procedures may be a suitable transition state to assess the feasibility of introducing centralized procedures among African countries. 72.1% of the respondents predicted this.

Most respondents expressed support for the introduction of DCP, MRP, and RUP. They believe that these procedures, if implemented, will not add complexity to the existing regulatory framework in African countries. Similar to the existing EAC-MRH, SADC-MRH, and ECWAS-MRH, these approaches involve approval decisions by local NMRAs and are not legally binding for all countries. Moreover, it facilitates market access, which may be attractive for the pharmaceutical industry. Moreover, they shall be designed to promote harmonization among African countries, encouraging cooperation and reliance.

Strengthening regulatory Reliance-Based Pathways, Work-sharing approaches, and Joint Assessments will be a step forward in harmonizing human medicines among African countries. However, these approaches need to be harmonized. Looking ahead, 69.8% of the respondents see the potential for broader harmonization among regional blocks. They believe that significant progress can be made if countries within the same region harmonize their legal and regulatory pathways and introduce regional procedures.

4 CONCLUSION

By leveraging the knowledge gained from the results and discussion sections, the adoption of the CP among the African countries may pose a significate challenge at present. This procedure is legally binding and operates based on harmonized legal framework. For instance, The EMA's CP operates based on legal frameworks introduced by the European Commission and adopted by all EEA. Despite, the presence of the AU Model Law Medical Products Regulation, it is not domesticated among all the African countries.[5] Moreover, the binding degree of the AU legal instrument is not always clearly defined. However, it should be similar as the ones from the EU based on Abja Treaty, nevertheless, in practice, it is not always the case, which is challenging and hinders the introduction of the CP.[88]

There is no need to start from draft zero as the EMA and the European regulatory systems are proven to be advanced and overcome challenges based on the outcome from the COVID-19 pandemic.[37] Therefore, using the EMA regulatory frameworks as a draft model should be considered during the development of harmonized human regulatory frameworks among the African countries by modifying it to meet the needs of the African continent. Considering the COVID-19 Pandemic, a centralized pathway for strategic human medicines in case of pandemic is highly recommended among the African countries. Moreover, a non-binding centralized human regulatory evaluation similar to the Concertation Procedure among the African NMRAs coordinated by AMA may be feasible and highly recommended to facilitate the AMA's operations and build up capacities, expertise and financial resources.

The introduction of the regional medicines regulatory harmonization initiatives based on the RECs and administrated by AMRH is a milestone in the human medicines' regulatory harmonization among the African countries. However, RECs are built on economic interests and do not prioritize the human medicines regulatory harmonization needs, which is noticed among some RECs including member states with diverse medical needs. Moreover, the multiplicity of the REC memberships may hinder the regulatory harmonization and increase the duplicate work among member states, which has already limited capacity and may cause the spaghetti bowl effect.[64] Therefore, restructuring AMRH to be based on RCCs instead of RECs is recommended. However, necessary comparative studies and evaluations are prerequisites for the restructuring.

The joint assessment procedures in EAC, ECOWAS, and ZaZiBoNa have positively impacted the regulatory harmonization of human medicines. However, the countries within the same REC have no legally binding framework. Therefore, a centralized procedure may be feasible for countries with the same medical needs by introducing a mandatory scope for medicines that have high priority among the countries in the same REC and can be built on the existing regulatory pathways. However, independent performance evaluating studies for the whole REC model are needed.

In the light of the results and discussion, a simplified human medicines regulatory harmonization model based on the European regulatory system has been constructed, as shown in figure 4. However, harmonizing the legal and regulatory frameworks is a prerequisite for these approaches.

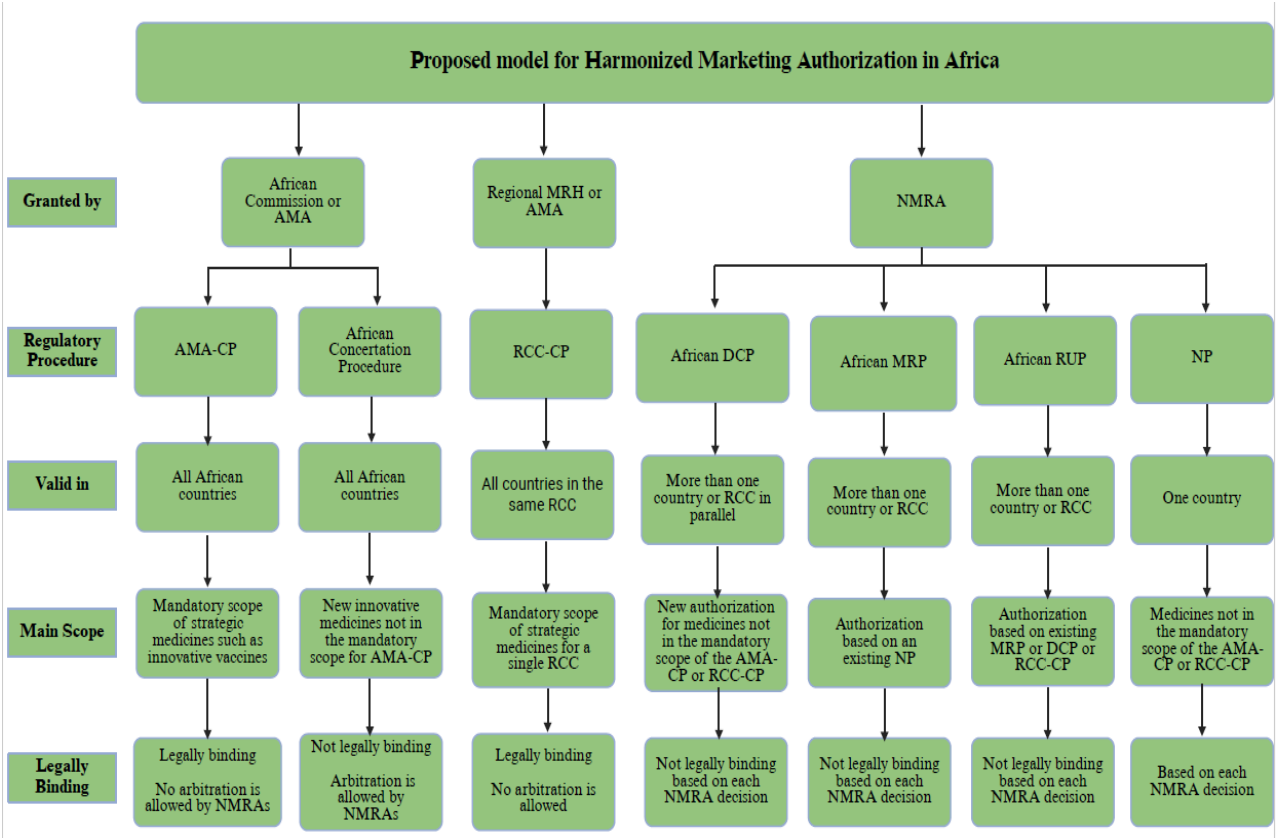

Fig. 4: Proposed model of harmonized marketing authorization in Africa based on the European regulatory pathways. However, modified to meet the African regulatory needs. RCCs are used instead of RECs in this model, as RCCs might be more feasible in promoting human medicines regulatory harmonization.
Abbreviations for Fig. 4: African Medicines Agency (AMA), Regional Coordination Center (RCC), Medicines Regulatory Harmonization Initiative (MRH), Centralized Procedure (CP), Decentralized Procedure (DCP), Mutual Recognition Procedure (MRP), Repeat Use Procedure (RUP), National procedure (NP), National Medicines Regulatory Authority (NMRA).
Created in BioRender. Hatem, K. (2026) https://BioRender.com/7sp1ho0

Furthermore, studies are needed to assess the functionality of RECs regarding human medicines regulatory harmonization, and comparative studies are recommended to compare the feasibility of using the RCCs instead of RECs as building blocks for human medicines regulatory harmonization across the African continent. Moreover, studies are essential to assess the functionality of the RECORs and understand how these centers contribute to building capacities and expertise. Figure 5 provides a proposed roadmap demonstrating the steps needed to reach human medicines regulatory and legal harmonization among the African countries. This roadmap consists of seven steps and aims to facilitate the construction of regulatory pathways based on the European regulatory pathways as illustrated in Figure 4.

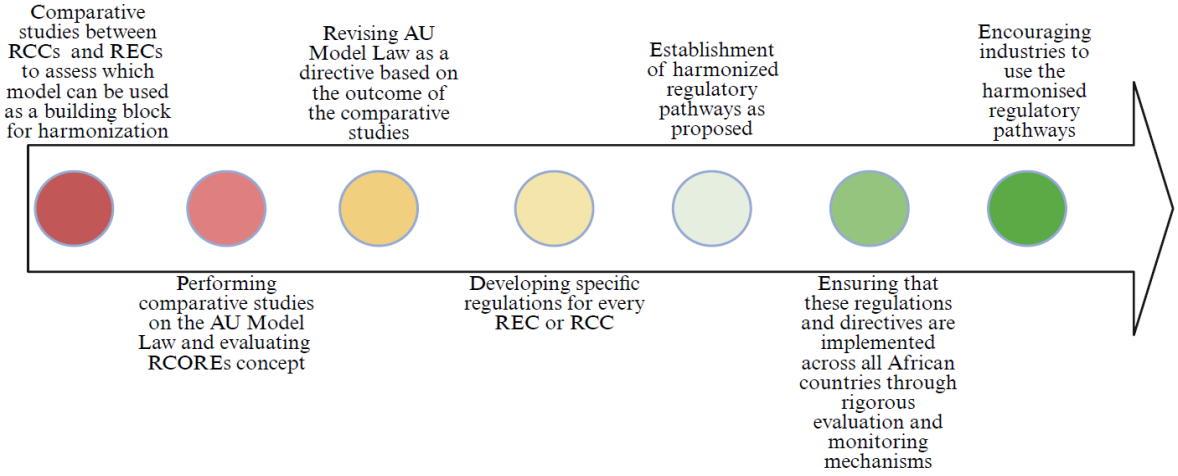

Fig. 5: Proposed Roadmap for actions needed to reach human medicines regulatory harmonization among across the African continent.
Created in BioRender. Hatem, K. (2026) https://BioRender.com/qiwlsw3

5 CONFLICT OF INTEREST

The author declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest. The author is an employee of Dr. Falk Pharma GmbH and declares that no financial support or incentives were received from Dr. Falk Pharma GmbH or any other organization related to this article.

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