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Feasibility of an internationally recognized Conformitè Europëenne equivalent mark for medical devices in Africa: A review of current literature

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Abstract

Background

Medical devices are crucial to health systems and are critical to addressing the disease burden of African countries. In light of the importance of diagnosis and surgical intervention in healthcare, medical devices such as radiation emitting devices and devices incorporating a substance, are held to a high standard of quality and safety. Hence, the regulation of medical devices is required to optimize their use in healthcare within Africa. To successfully transition from the existing unregulated medical device sector to a thorough regulatory framework, many nations lack both the financial and technological resources. Consequently, organizations attempting to manufacture and market medical devices confront numerous obstacles, such as navigating the regulatory frameworks of various other nations and creating sustainable business models for imported medical devices. Many nations, including countries in Africa such as South Africa, Nigeria, and Ghana, require Conformitè Europëenne (CE) marked products which can only be obtained in Europe, making it extremely costly for local African manufacturers of medical devices to bring their products onto the market in these African countries.

Aim and objectives

This study examined the feasibility of establishing an African-based equivalent of Conformitè Europëenne mark (CE mark) with a similar standard to that in Europe for indigenous African medical device manufacturers. The study also explored how such African-based CE mark will encourage innovation and expand access to medical devices in Africa. Specific objectives of the study included:

- Investigation of past and current status of medical devices (MD) regulation in Africa.
- Review of regulatory harmonisation of medical devices in Africa.
- Comparison of EU CE marking to current MD regulation in Africa
- Review of the outcomes and challenges of medical device regulation in Africa.
- Identification of the approval gaps within the African medical device's regulations.

Methods

An electronic literature search of articles and publications was done using the following terms: Medical device regulations, regulatory harmonisation and reliance, regulatory cooperation and convergence, Africa, regulatory authority and local manufacturer. Articles referring to regulatory harmonisation of medical devices and Conformitè Europëenne ,ark in Africa were reviewed in order to determine if it is feasible for Africa to have its CE mark which will be recognized internationally. Journal papers, national and international regulatory guidelines, and other materials were studied in the literature. Sources for the articles included databases including Connect papers, Pubmed, and Google Scholar. There was no limit to publication date for the search. Data from developed and emerging medical devices markets were included in the review.

Results

There was paucity of studies that directly reviewed the probability of Africa having its own CE mark, however medical device regulatory harmonisation strategies and regulatory collaboration were widely reviewed. Many of the research reviewed indicated CE mark procedures were designed to meet the requirements of high-income countries, and this is proving to be a very lengthy and costly process for many local manufacturers. Additionally, infrastructure constraints that many African countries face may be overlooked during the evaluation process. More than half of the African regulatory authorities reviewed have a risk

classification based on the GHTF risk classification; having this classification makes it easier for authorities to unify guidelines and policies. Medical device regulatory harmonisation strategies might be the first step to ensuring the feasibility of Africa medical devices bearing its own CE mark.

Conclusion

African countries face challenges in establishing their own CE mark equivalent due to poor regulatory structures, lack of political will, and sharing of confidential information. Successful regulatory harmonisation and work sharing are crucial for establishing one standard. Research on Africa's CE mark equivalent has not been completely and thoroughly investigated. Overall, this study revealed that harmonisation of medical device regulation will be the driving force behind the feasibility of Africa having its own CE mark equivalent, hence Africa should pay more emphasis on medical devices regulatory convergence.

Declaration

I certify that the literature evaluation on the viability of Africa having its own CE mark equivalent is my original work, has never been submitted for credit or examination at another university, and includes full citations for all sources used..

Khanyisile Z Nkuku

2024

Signed: . . . .

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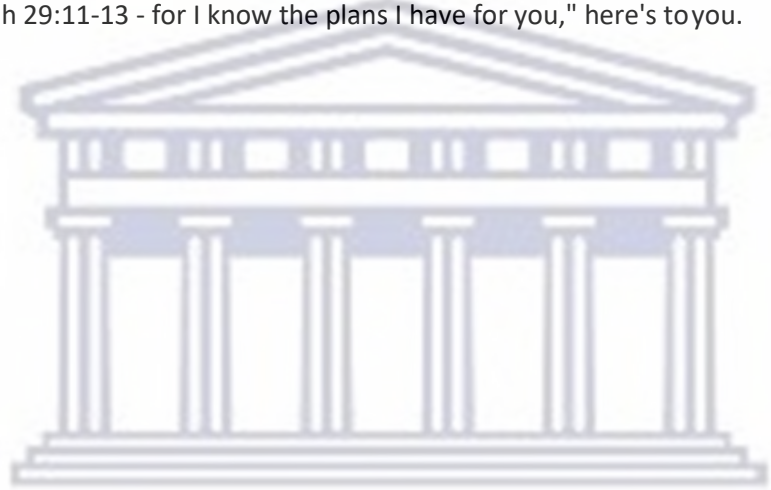

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List of Abbreviations

AMDRF – African Medical Device Regulatory Forum

AMRH – African Medicines Regulatory Harmonisation

CE mark - Conformitè Europëenne Mark

CTD – Common Technical Dossier

EAC – East African Community

EU - European Union

GHTF - Global Harmonization Task Force

IMDRF - International Medical Device Regulators Forum

ISO - International organization of standardization

IVD – In vitro diagnostics

NEPAD - New Partnership for Africa's Development

NMRA – National Medicines Regulatory Agencies

NRAs – National Regulatory Agencies

OSMDs - Open-Source Medical Devices

PAHWP - Pan African Harmonization Working Party

SADC – Southern African Development Community

SAHPRA – South African Health Products Regulatory Authority

UK MHRA - United Kingdom Medicine health Regulatory Authority

US FDA – United States Food and drug Authority

WHO – World Health Organisation

Chapter 1: Introduction

This chapter provides the introduction for medical device framework within Africa. In Africa, foreign medical equipment predominates., this further provides the current hurdle of local manufacturers of medical device face which is having to take their products to Western countries such as Europe, for the devices to be certified with Conformitè Europenne (CE) mark, In order for them to meet the regulatory requirements set by regulatory authorities .

It is imperative to develop medical devices that are designed to address problems faced by African countries to expand access to healthcare (Perry and Hodgins, 2021). Therefore, local manufacturers' participation becomes a critical factor.

In this chapter, the Problem statement and rationale will be provided and discussed in detail. The chapter will also provide the research question, research aims and key objectives to be achieved in the study.

1.1 Introduction and Background

More than 50 countries make up Africa, many of which have a history of exploitation shown in economic inequality, poverty, and class conflict Because of the disparate nature of their health systems, African nations have prioritized other objectives—such as reducing poverty, which may be seen as more important to the continent's residents' well-being—instead of assuring the availability of safe health products. Medical devices, such as self-testing in vitro diagnostics equipment that aid in increasing the diagnosis of diseases like HIV and STDs while also saving time and money, are crucial for reducing the burden of disease. Many obstacles must be overcome in order for medical devices to be developed and imported into African nations. These obstacles include navigating the various legal frameworks of various nations and creating business plans that will sustain product availability while keeping costs in mind (Ndomondo-Sigonda et al., 2017).

The majority of African countries want Conformitè Europenne (CE) marked medical devices, which are only available in Europe. As a result, local African medical devices producers pay exorbitant prices to conformity assessment bodies to certify their products prior to marketing (Saidi & Douglas, 2018).This obstacle faced by local manufacturers not only prevents them from entering the local market but also the international markets.

Regulatory authorities coordinating the technical specifications for the creation and sale of medical items is known as regulatory harmonization (Ncube et al. 2021) . . The cost and availability of in vitro diagnostics (IVDs) and other medical equipment are still high in poor countries, and many diagnostic procedures need specialized people and laboratory facilities that are uncommon in Africa (Rugera et al., 2014).These expenses are passed on to consumers healthcare practitioners and patients who cannot afford them. This further justifies the need for African regulatory authorities to share data. The regulation of medical devices is still in its infancy in many developing countries where regulatory requirements are not yet well- established to forbid the importation or use of substandard medical devices (Saidi and Douglas, 2016).

IVDs may be sold in deregulated countries despite having little or no proof of their effectiveness. Where controls are in place, they may serve as a deterrent to imports. As an illustration, consider the delayed commercialization of a point-of-care CD4 cell counter that enables HIV patients to obtain treatment (Rugera *et al.*, 2014b) . In several African countries, the demand for clinical trials has resulted in enormous effort duplication with little to no scientific value, increased costs, and years of introduction delay. Without access

to medications and medical supplies, Africans are at risk for the three most lethal diseases on the continent, including malaria, TB, and HIV/AIDS (Rugera et al., 2014).

1.2 Problem Statement and Rationale

The means and requirements of high-income countries were taken into consideration when designing a variety of medical devices, and these medical devices have not been modified for the difficulties that frequently occur in many African nations (Perry and Hodgins, 2021). The creation of medical devices designed expressly to address these problems is essential to enhancing African patients' access to healthcare. As a result, the involvement of local manufacturers becomes a crucial consideration (Perry and Hodgins, 2021).

According to the World Health Organization, Africa is home to half the population of all children under five who die globally from diseases like malaria, HIV, tuberculosis, and other illnesses. Therefore, it is crucial for Africa to conduct diagnostic tests for early detection of these infectious diseases (African et al. 2014)) .As a result, there will be a rise in the number of cases treated early for these diseases.

Having a CE mark equivalent standard for local African medical manufacturers will enable innovation, subsequently increasing the profits to local manufacture can enhance their standard of living and pave the way for Africa development. Medical device manufacturing and subsequent market entry are subject to stricter regulations than for any other product because of the nature of their use in the healthcare industry (McAllister and Jeswiet, 2003).This paper looks at the feasibility of Africa having its own CE equivalent mark for medical devices by reviewing published papers on the regulatory harmonization of medical devices.

1.3 Research question

The research question for this literature review is determining how feasible it is for Africa to have its own CE equivalent mark for medical devices which will be recognized internationally. Further reviewing if Africa should follow the European regulatory structure of having notified bodies or other regulatory authorities such as TGA and USFDA whereby performance is determined by the regulatory authorities.

1.4 Research Aims

The main purpose of this study is to understand the feasibility of Africa having its own CE equivalent mark by reviewing current literature as a result concentrating on medical device regulatory harmonisation.

1.5 Specific research objectives

- The Investigation of past and current status of medical devices regulation in Africa
- To review of regulatory harmonisation of medical devices in Africa.
- Comparison of EU CE marking to current MD regulation review of the effects and challenges of medical device regulation in Africa by discussing the approvals gaps within the regulations by looking into western nations regulatory authorities.

Chapter 2: Literature Review

Title: Current state of medical device regulatory framework in Africa

Access to these essential tools is frequently and has been for years restricted in Africa due to onerous and expensive regulatory licensing requirements in some countries. Essential elements of healthcare systems include medical equipment and in vitro diagnostics (IVD). Customers pay more for the product as a result of local manufacturers having to pass on costs to them, which eventually limits access to potentially life-saving diagnoses. Regulatory harmonisation, according to all the research done, ensures that patients can immediately obtain and use safe, high-quality medical devices. The Pan African Harmonization Working Party (PAHWP) has already researched and made suggestions for ways to harmonize laws governing medical devices and diagnostics in Africa (Rugera *et al.*, 2014b).

This chapter examines the study conducted on the African medical device regulatory framework. Numerous regulatory agencies have benefited from the efforts of organizations like the World Health Organization (WHO), the International Medical Device Regulatory Forum (IMDRF), and the African Medicines Regulatory Harmonization (AMRH) in building and streamlining their regulatory framework. The likes of Hubner et al., (2021) and Rugera et al., (2014) have both examined the key issues covered by several African regulatory bodies, including (i) functionality of the National Regulatory Authorities, (ii) regulatory framework, (iii) marketing restrictions, (iv) country review ability, (v) clinical trial requirements, and (vi) priorities and training for harmonization between national authorities (Rugera *et al.*, 2014b).

A study was conducted to evaluate the regulation of medical in the devices in East African Community's (EAC) partner states consisting of 5 countries (Rugera *et al.*, 2014a). Four of the countries recorded legislation in place such as Acts covering health products, including medical devices including IVD's (Rugera *et al.*, 2014a). Two countries noted a lack of consistency in the regulations governing the use of medical devices especially in vitro diagnostics. Uganda, was the only country which has no provisions for the regulation of medical products (Rugera et al., 2014). The review's findings show that the EAC Partner States have not paid enough attention to the regulation of medical devices including IVDS's (Rugera *et al.*, 2014a) .Additionally, it was discovered that despite the fact that most nations are required by law to regulate medical devices, there is a lack of regulation in the region and limited capacity to do so. Through collaboration and mutual recognition of various actions, the Tanzanian mainland and Zanzibar Food and Drug Authorities were able to harmonize several regulatory processes while the researcher's investigation. Tanzania further asserted that medical devices with prior regulatory approval from a stringent National Regulatory Authority (EU, and US FDA) or prequalification by WHO might be reviewed using a simplified dossier (Rugera *et al.*, 2014a) .

In another review,De Maria et al., (2018) compared 5 African countries' medical device legislation with the European regulations. The 5 countries reviewed were Egypt , South Africa, Nigeria, Ethiopia, Uganda, Tanzania and Kenya . In her review she found that African legislation for medical devices is similar to those of the European directive furthermore a number of states have also enacted, harmonised, or indicated interest in developing medical device regulation guidelines in their laws.

Table 1: African countries medical device regulatory framework review

Country	National Regulatory Authority	Directives/Laws	Presence of Risk classification	Technical Safety assessment	Equivalent CE mark - document issued
Egypt	Egyptian Drug Authority (EDA)	93/42/EEC 2007/47/EC	I, IIa, IIb, III	only for Class IIb, III done by third party	Registration certificate and CE Mark
South Africa	Medicines Control Council (MCC) replaced South African health products regulatory authority (SAHPRA)	No. 101/1965	Class A-D	only for COVID 19 test kits, and locally manufactured ventilators	establishment licence and section 21 authorisation
Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC)	Cap N1 L.F.N 2004	Class A-D (Locally produced) Conformity with the nation where the device was made's classification	only Class C & D medical devices	Registration certificate
Ethiopia	Food Medicine and Healthcare Administration And Control Authority of Ethiopia (FMHACA)	No. 661/2009	I, II, III, IV	Self-declaration	approval letter and CE Mark
Uganda	National Drug Authority	140/323/01	A, B, C, D	only Class C & D medical devices	approval letter and CE Mark
Tanzania	Tanzania Food and Drugs Authority (TFDA)	No. 1_2003	A, B, C, D	only Class C & D medical devices	Registration certificate
Kenya	Pharmacy and Poisons Board	Chapter 244_2002	A, B, C, D	only Class C & D medical devices	Registration certificate
Malawi	Pharmacy, Medicines & Poisons Board	No info	No info	No info	No info
Namibia	Medicines Regulatory Council	13 of 2003	A, B, C, D	self-declaration	importation approval letter
Botswana	Botswana Medicines Regulatory Authority	BOMRA/ER/MED/P02 /G01	A, B, C, D	Class C & D medical device	establishment licence
Zimbabwe	Medical Devices Unit, Medicines Control Authority	[15:03] of 1969	in development	in development	in development
Zambia	Zambia Medicines Regulatory Authority	No. 3 of 2013	A, B, C, D	only Class C & D medical devices	in development

This table looks at the current state of the medical device regulatory framework of different African countries. As noted many of the African countries use the Global Harmonization Task Force (**GHFT**) risk classification of Class A-D. Technical assessments are not fully done for all medical devices; the majority of the regulatory authorities prioritize high risk medical devices such as Class C & D medical devices; however, some have aligned with European directives for CE mark purposes.

It costs money for manufacturers, researchers, and developers to implement regulations and comply with them. In developing nations, a lack of regulatory oversight leads to the usage of subpar gadgets, which frequently presents a barrier to individuals who want to create, market, or even donate these devices (De Maria et al., 2018).

In the literature review, it was highlighted that the majority of African countries currently have regulatory bodies in place to control medical devices. Along with adopting or harmonizing their medical device standards with those of stricter nations like the USA and Europe

This literature review found that medical device regulatory harmonisation is the first step African agencies should take before having a CE mark equivalent for locally -manufactured Medical devices. AMDRF main objective to achieve harmonisation is already in place. It is crucial that these products are made readily available to patients in underdeveloped nations and priced affordably. Medical device regulation is lax in underdeveloped nations, which is a problem with diagnostic testing. *In vitro diagnostics* may be sold in nations without regulations with little or no proof of their efficacy.

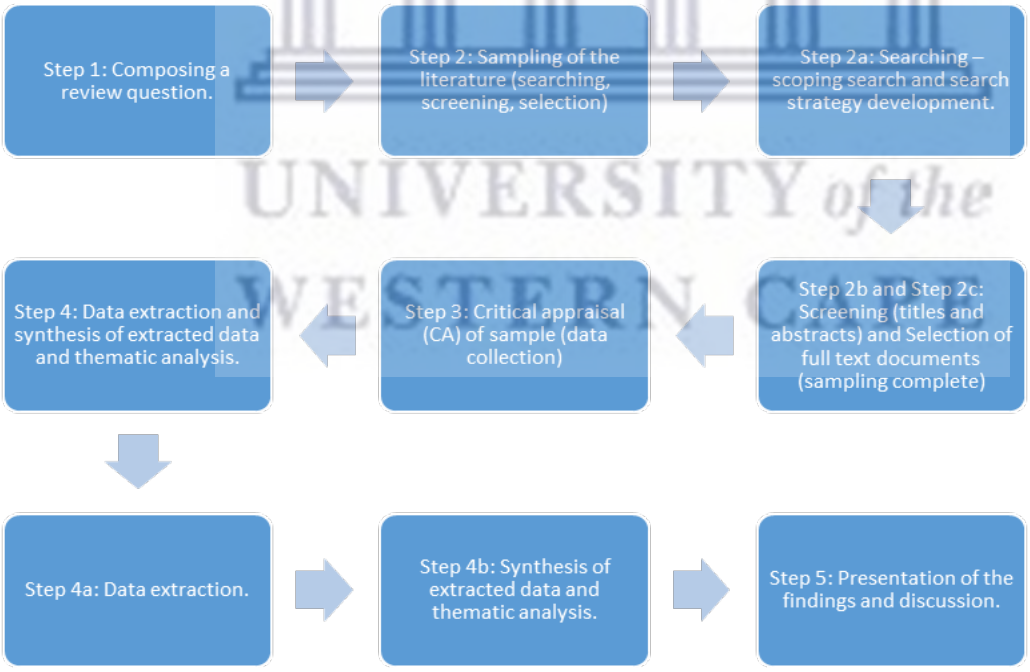
Chapter 3 : Methodology

The process for gathering data is examined in this chapter. An integrated review was chosen rather than a traditional systematic review because it permits the inclusion of primary research findings as well as other resources (such as opinions, discussion papers, and policy documents), which are prohibited in a formal systematic review (Lubbe et al., 2020) . The inclusion and exclusion criteria were also determined in the data collection and analysis. The study design and data collection are well discussed.

3.1 Study Design

Methodological issues arise when qualitative and quantitative research are separated. A methodology should be selected based on how well it will assist in resolving the research issues (Bryan, 2003). An exhaustive literature review is defined as "an iterative, thematic approach to research where qualitative analysis is employed to categorise material found in books and generate conclusions based on qualitative description (Lin, 2009; Jill Jesson, 2011) . This study was conducted utilizing an integrative review since the objective was to evaluate, critique, and summarize the literature on a research issue in a way that allows for the emergence of new theoretical frameworks and viewpoints (Torraco, 2005) . An integrated review enables the inclusion of primary research studies as well as other materials (such as statements of opinion, discussion papers, and policy documents), which are not permitted in a traditional systematic review (Lubbe et al., 2020)

Figure 1: General steps of an integrative review



The processes of an integrative review are shown in Figure 1, commencing with the review question, followed by the literature search, the data evaluation, the data analysis, the result interpretation, and the result presentation. This form of review entails precise and concentrated work, the outcomes of which can be a significant contribution to a specific body of knowledge and, subsequently, to practice and research.

A literature review can be used to accomplish one of the following five goals: review, an update, and criticism of the literature; a meta-analysis of the literature; a review, critique, and synthesis of the literature; a reconceptualization of the issue reviewed in the literature; and lastly a response to specific research questions regarding the topic reviewed in the literature (Lubbe et al., 2020)..

In identifying sources for this literature review, multiple databases were used. An electronic literature search was done. Articles referring to regulatory harmonisation of medical devices and Conformitè Europëenne mark (CE Mark) in Africa were reviewed. Initially "regulatory collaboration and regulatory convergence" were search terms used synonymously with 'Regulatory Harmonisation". Other key words included 'Conformitè Europëenne Mark ', Africa and medical devices. The literature included journal articles, national regulatory guidelines such as South African Health Products Regulatory Authority (SAHPRA) , United States Food and drug Authority, Tanzania Food and Drug Authority (TFDA) , international guidelines such as International Medical Device Regulators Forum (IMDRF) , Global Harmonization Task Force (GHTF)etc.

Databases including Connect papers, Pubmed, and Google Scholar were used to find the articles. Both developed and emerging markets provided information. To get a taste of the different kinds of articles that were available, Connect Papers was initially used. Graphs that draw out publications on related subjects were made available by the search.

Articles discussing regulatory harmonisation for medical devices were included in the study, but they were also included to help with critical lessons because they addressed regulatory harmonisation of medications in Africa. They did so because they also talked about general harmonisation, which included regulatory harmonisation of other health items. Furthermore, only African nations with strict IMDRF-recognized health agencies are included in the study. No limitations applied to the article's place of origin or time of publication. In order to contain information from both developed and emerging markets, a reasonably broad representation of literature—including works from Africa, America, Europe, Asia, and so on—was sought.

The biggest problem was that many promising papers could only be viewed with a subscription, and oftentimes the abstracts were weak and deficient in important details. As a result, I only used the abstracts that contained the needed data. Finding pertinent publications on the regulation of medical devices from the African region presented another issue because the goal was to ascertain whether such systems were present, particularly in African nations.

3.2 Data collection and analysis

From the articles collected, medical device regulatory harmonisation within African countries and research on Africa having its CE mark equivalent was duly noted. The following information was also noted.

- The type of reliance with other jurisdictions
- The source of data, i.e., the author and date of the article
- Region or country
- Gaps in Regulatory approval of medical devices in Africa and see how Western nations' regulatory bodies overcome these gap

Inclusion criteria includes articles discussing regulatory harmonisation in IMDRF countries compared to African countries such as South Africa ,Tanzania and Ghana including their effects. Another inclusion was regulation of medical devices within the mentioned countries. I also included articles that indicate how regulatory harmonisation of medicines has been successful within Africa.

Exclusion criteria includes articles that focus on performance metrics of regulatory authorities instead of the review process as this would not have provided the review with assistance to the research question. A second exclusion was articles that were focused on Western countries regulating medical devices. These are well developed countries, and the main focus is African countries. Most importantly, articles which did not have enough information.

The choice of nations was deliberate, with an emphasis on those in Africa that regulate medical devices and those that are in the same geographic region as the IMDRF (particularly, Europe, the United States, and Japan). Data was gathered from the review processes and procedures used in these mature markets, as well as from how the regulatory authority cooperates with other authorities. There were also publications from organizations established such as Pan African Harmonization Working Party (PAHWP) meetings that offered advice and suggestions on how African countries might harmonise medical equipment. These issues were covered in the review.

Chapter 4: Results

This chapter examines the findings of the papers examined and fifty-two complete articles in total and twelve abstracts were found that matched the search parameters. The results are divided into two subchapters which are regulatory harmonization of medical devices in Africa and Research on Africa CE mark equivalent. Findings on different regulatory systems are highlighted in the chapter per country furthermore a list of African regulatory authorities medical device policy with their implementation date are carefully categorised and the outcome pointed out that most African countries have poor regulatory structures in place, research on Africa having its own CE mark equivalent has not been completely and thoroughly investigated (De Maria *et al.*, 2018a). Rugera *et al* (2014), noted that some nations' National Regulatory Authorities lack the authority to control medical devices.

Access to connect papers allowed for the acquisition of articles. Fifty-two complete articles in total and twelve abstracts were found that matched the search parameters. In order to compile the data gathered from the articles and to obtain a sense of the general consensus about regulatory harmonisation, additional publications, including meeting minutes from the WHO and AMDRF, reports, and other papers from different jurisdictions, were consulted. Eight regions were identified from the search as having the necessary systems: South Africa, Ghana, Tanzania, Australia, Canada, the United States, and the European Union. The focus of this evaluation, regulatory harmonization of medical devices in Africa, and research on the comparable CE mark in Africa, have been separated into the outcomes.

The feasibility of Africa having its own CE mark equivalent is very much dependent on the competency and enforcement of regulatory Authorities within Africa. It is noted that only less than 10% of NRA's have moderately developed capacity and less than 100 % have minimal to no capacity (Ncube et al. 2021) .) .

Market positioning for medical devices is a dynamic area. The only way to ensure that medical products are both inexpensive and of excellent quality is to establish regulating authorities that are well equipped with proper frameworks in place. The key indicators in this review for feasibility will be looking at the current status of regulatory harmonisation by African regulatory authorities, the advantages and disadvantages of harmonising regulatory approval of medical devices in Africa and most importantly scrutinize past research on Africa having its CE mark equivalent.

4.1 Regulatory harmonization of medical devices in Africa

It was proven from the papers examined that a marketing permission from the Regulatory authority is necessary in order to market any medical device. The application process is laborious and challenging. It is geared toward preventing the introduction of substandard imports that pose a health risk. This multistep procedure requires review by competent authorities. partly as a result of both weak regulatory frameworks and a lack of implementation (Hubner *et al.*, 2021), Most African nations today do not properly control medical device (Hubner *et al.*, 2021) . Competent authorities adopt regulations from the International Medical Device Regulators Forum (IMDRF). The IMDRF is made up of stringent regions such as the EU (UK MHRA) and North America (US FDA & Health Canada)(IMDRF, 2017).

Table 2: Review of regulatory processes published

Author, year	Study design	Study duration	Countries included	Main findings
(Maak and Wylie, 2016a)	Systemic review	2 years	United States of America and European Union	In contrast to the European Union approval procedure, which requires that the device carry out its stated purpose, the FDA approval process requires that a device be proven effective when compared to a control or be substantially equivalent to a predicate device (Maak and Wylie, 2016a). The differences between the US and EU regulatory systems start with their inception. Europe, served as the impetus for the creation of the Medical Device Directives. Whereas the US FDA process requires that companies deal directly with , the EU system requires device manufacturers deal with notified bodies (Maak and Wylie, 2016a) .The study found that the US FDA process is more costly and lengthy.
(French-Mowat and Burnett, 2012)	Systemic Review	2 years	Europe	The CE marking procedure involves the participation different bodies such as notified bodies, representative etc. EU state has a notified body overseeing compliance (French-Mowat and Burnett, 2012b).
(Maak and Wylie, 2016a)	Systemic Review	1-2 years	United States of America and European Union	FDA approval was 31 months through the 510(k) pathway and 54 months through the PMA pathway, from first contact with the FDA to device approval (Maak and Wylie, 2016b). In the EU system, approval of similar devices took 7 months and 11 months, respectively (Maak and Wylie, 2016b).
(Hubner *et al.*, 2021)	Systemic Review	1-2 years	Botswana , Burundi,Rwanda,South Sudan ,and Zimbabwe	Although to a lesser extent, these nations regulate medical devices through a legal system. This law is only applicable to legislative actions creating national medicines regulatory authorities that mention medical devices and define them. It does not establish any clear-cut obligations or regulations (Hubner *et al.*, 2021).

Author, year	Study design	Study duration	Countries included	Main findings
(Hubner *et al.*, 2021)	Systemic Review	3- 5 years	South Africa, Ethiopia, Kenya, Sudan, and Tanzania	Medical device regulations in South Africa and a number of other nations, such as Ethiopia, Kenya, Sudan, and Tanzania, demand adherence to these guidelines or a modification to their applicable regulatory regulations. All require compliance to essential principles for safety and performance (Hubner et al., 2021).
(Ncube et al. 2021) .	Periodic review	3-5 years	African countries	Majority of African countries have an NMRA or a unit of government that performs part or all of the NMRA's expected duties. On the other hand, just less than 10% have a moderately developed capacity (Ncube et al. 2021) .
(Sethi et al. 2017)	Periodic review	3-5 years	India	Through notifications published in the gazette, CDSCO regulates a few gadgets in India. They are known as notified devices. a couple of items In India, medical gadgets are categorized as medications while they are devices in other nations. This system does not adhere to international norms. When compared to the US and EU regulatory regimes, the current system appears to be quite primitive (Sethi et al. 2017)
(Chen *et al.*, 2018)	Comparative study	2 years	United States, Europe, Canada, and Taiwan	Manufacturing, premarket assessment, and post market surveillance are all covered under a standard framework for medical device regulations that spans the whole product life cycle. But the diversity and inventiveness of medical devices are making the current regulatory systems difficult (Chen et al., 2018).
(Lamph, 2012)	Comparative study	2 years	United Arab Emirates	Before any device can be sold on the market, the maker or a local authorized representative must submit an application to the Drug Control department's Technical Section for registration. The necessary documentation is built on the GHFT STED model (Lamph, 2012).
(Lamph, 2012)	Comparative study	2 years	China	The 'China Export' emblem, which is not a registered trademark, is permitted to be used on products made in China. The CE mark, which is used to identify products that adhere to EU requirements, is strikingly similar to this sign (Lamph, 2012).

Author, year	Study design	Study duration	Countries included	Main findings
(De Maria *et al.*, 2018a)	Comparative study	2 years	Egypt	According to the European MDD 93/42/EEC, Egypt has adopted the definition and categorization of medical devices. For a medical device to be sold in the nation, it must have a free sale certificate, the CE Certificate , or US FDA authorisation (De Maria et al., 2018a).
(Kedwani et al. 2019)	Comparative study	2 years	Africa, North- and South America ,Asia , Europe,Oceania	Pre- and post-market operations, as well as sensible regulatory definition restrictions and registration requirements, with appropriate implementation by manufacturers. Consequently, guidance and harmonisation procedures should be provided by regulatory organizations during the registration process (Kedwani et al. 2019)

In order to meet national or regional demands, efforts to address the challenges faced by regulatory authorities in resource-constrained situations has been a core focus (Petterik, 2018). The WHO has also urged regulatory bodies to take regulatory convergence into account, interact with other regulators, and acknowledge their contributions in order to lessen the cost of regulation and avoid duplication of effort (African et al. 2014)

Table 3: Summary of regulatory issues observed

Author, year	Issues observed
('DI303-eng', no date)	lack of trained specialists to conduct critical regulatory functions ('DI303-eng', no date).
('DI303-eng', no date)	It may be challenging for NRAs to incorporate or enable dependence in their daily practice due to a lack of government assistance ('DI303-eng', no date).
('DI303-eng', no date)	The lack of access to reports between recognized regulatory authorities ('DI303-eng', no date).
'DI303-eng', no date)	lack of common language or translation ('DI303-eng', no date)
'DI303-eng', no date)	differences in country application requirements ('DI303-eng', no date;
('DI303-eng', no date)	Differences in risk classifications ('DI303-eng', no date)
('DI303-eng', no date)	inconsistent practices with amendments and modifications to products in various countries ('DI303-eng', no date)

Author, year	Issues observed
('DI303-eng', no date)	The need for in country clinical evidence and data ('DI303-eng', no date)
('DI303-eng', no date)	Different levels of skills and regulatory operations ('DI303-eng', no date)
(De Maria *et al.*, 2018a)	Cost implications of implementing an effective regulatory system (De Maria et al., 2018).
(Ramakrishna *et al.*, 2015)	Regulatory obstacle, for instance, a medical product that has received USFDA approval might not be allowed to access another market in China without CFDA approval, despite having gone through the most rigorous processes in the world that were required by the USFDA (Ramakrishna et al., 2015).
(Kaushik *et al.*, 2010)	As global market competitiveness increases, there are more unintended consequences of ineffective regulation (Kaushik et al., 2010).
(Kaule *et al.*, 2020)	Longer waiting periods for approval of innovative products (Kaule et al., 2020).

In 2014, the 67TH World Health Assembly adopted Resolution WHA67.20, which emphasized the importance of efficient regulatory systems and alluded to barriers to health products (Keyter, 2020) . The African Medicines Regulatory Harmonization (AMRH) Initiative, which is administered by the African Union's New Partnership for Africa's Development (NEPAD) (Rugera *et al.*, 2014b) . They have emphasized the importance of having robust regulatory frameworks and competent regulatory mechanisms (Keyter, 2020). The main objective of the AMRH Programme is to advance health in Africa by enhancing accessibility to quality, safe and performing medical products through regulatory harmonization, including a reduction in the time for application approval (Rugera *et al.*, 2014a).

The Tanzania Food and Drug Agency (TFDA) and the South African Health Products Regulatory Authority (SAHPRA) are two examples of developing authorities that are aware of the capacity and resource limitations, value harmonization efforts, and have investigated the possibility of implementing reliance mechanisms. The Pan African Harmonization Working Party (PAHWP) researches and suggests approaches for harmonizing medical device and diagnostics legislation throughout Africa.

The African Medical Device Regulatory Forum (AMDRF), which has similarities with the AMRH,even though AMDRF's members are able to share information about related products, such as diagnostic tests, with the aim of boosting the availability of secure and reasonably priced medical devices on the continent, access to in vitro diagnostic tests (IVD) is frequently restricted in Africa (Rugera *et al.*, 2014b). National Regulatory Authorities are in charge of guaranteeing the efficacy, effectiveness, and quality of healthcare products as well as providing easy access to innovative, useful goods. The availability to new products may be facilitated while delays and needless spending are reduced by streamlining and standardizing regulatory processes.

In order to foster dependence and recognition frameworks with other regulatory bodies, the Green-Thompson Report underlined the necessity for international and regional harmonization (Keyter *et al.*, 2018) . The US Food and Drug Administration (US FDA), Swissmedic, the UK Medicines and Healthcare Products

Regulatory Agency (UK MHRA), and the Australian Therapeutic Goods Administration (TGA) are among the regulatory agencies that have been asked to evaluate and compare regulatory (Keyter, 2020)practices in specific areas. They have also been asked to look into information-sharing systems and mechanisms that would create mutual recognition for product approval and registration requirements. These activities also tried to maximize regulatory competence and operations by comprehending how these firms operate in accordance with global best practice standards (Keyter et al., 2018).

Regulatory bodies may enter into agreements or memorandums of understanding with other regulatory bodies in order to share assessment findings on dossiers they have looked at, with the applicant's assent. However, it would be challenging to follow the reviews undertaken by the agencies providing their reports if the dossier formats varied (Mashingia *et al.*, 2020). If all of the territories utilize the same international standards and formats, manufacturers may also submit dossiers with ease across many different jurisdictions, saving them a lot of time and money from having to create custom applications (Mashingia et al., 2020) .

4.2 Research on Africa CE mark equivalent

Technologies used in medical devices span from straightforward bandages to extremely sophisticated gear. Quality of design and manufacture is crucial, especially for electrically powered systems where a malfunction could result in catastrophic harm or death (Rugera *et al.*, 2014a). The sophistication of diagnostic tests also varies, from straightforward colorimetric dip-stick devices to complicated computerized tools like Elisa molecular assays. For some conditions, there is also an abundance of items that can be used at various levels of the healthcare delivery system.

The international organization of standardization (ISO) has the responsibility of forming international standards for all products globally (Aggarwal, 2016). The majority of medical device manufacturers use ISO 13485 as their quality management system to demonstrate their capacity for consistency in the design, development, and safe delivery of their medical devices and related services fulfilling regulatory compliance and client objectives (Aggarwal, 2016).

Most regulatory agencies accept the reliance paradigm, in which medical devices must be registered in another jurisdiction, as evidence of compliance with the high safety criteria.. Multiple Manufactures, therefore, take their products to European countries to be CE marked before marketing them in the country of origin. The CE mark serves as a manufacturer's declaration that the product complies with all applicable laws, including those pertaining to safety and performance (De Maria et al., 2018).

Despite their strictness, African medical device rules have a lot in common with European directives, according to De Maria *et al.* (2018) research. Many of these countries have standardized medical device regulation guidelines or are working in establishing them (Perry and Hodgins, 2021). Arguments might be made that African countries could just accept the CE Mark or US FDA approval, which is essentially what many other governments are already doing. This, however, is not ideal because the US FDA and CE mark procedures were created to meet the requirements of high-income countries, and this is proving to be a very lengthy and costly process for many local manufacturers in addition, Infrastructural constraints that many African countries face may be overlooked during the evaluation process.

Table 4: List of African regulatory authority's medical device policy with their implementation date

Country	National Regulatory Authority	Year	Presence of Risk classification	Technical Safety assessment	Equivalent CE mark - document issued
Egypt	Egyptian Drug Authority (EDA)	1993	I, IIa, IIb, III	only for Class IIb, III done by third party	Registration certificate and CE Mark
South Africa	Medicines Control Council (MCC) replaced South African health products regulatory authority(SAHPRA)	MCC -1965 SAHPRA -2018	Class A-D	only for COVID 19 test kits and Ventilators	establishment licence and section 21 authorisation
Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC)	2004	Class A-D (Locally manufactured) Compliance to Classification of the country where the device is manufactured	only Class C & D medical devices	Registration certificate
Ethiopia	Food Medicine and Healthcare Administration and Control Authority of Ethiopia (FMHACA)	2009	I, II, III, IV	Self-declaration	approval letter and CE Mark
Uganda	National Drug Authority	1993	A, B, C, D	only Class C & D medical devices	approval letter and CE Mark
Tanzania	Tanzania Food and Drugs Authority (TFDA)	2003	A, B, C, D	only Class C & D medical devices	Registration certificate
Kenya	Pharmacy and Poisons Board	1957	A, B, C, D	only Class B, C & D medical devices	Registration certificate
Malawi	Pharmacy, Medicines & Poisons Board	2019	No info	No info	No info
Namibia	Medicines Regulatory Council	2003	A, B, C, D	self-declaration	importation approval letter

Country	National Regulatory Authority	Year	Presence of Risk classification	Technical Safety assessment	Equivalent CE mark - document issued
Botswana	Botswana Medicines Regulatory Authority	2013 (The MRSA of 2013 replaced the repealed Drugs and Related Substances Act No. 18 of 1992 which was previously enforced by the Drugs Regulatory Unit (DRU) under the Ministry of Health and Wellness)	A, B, C, D	Class C & D medical device	Establishment licence Have called up certain High risk medical devices for registration asof September 2023
Zimbabwe	Medical Devices Unit, Medicines Control Authority	1969	in development	in development	in development
Zambia	Zambia Medicines Regulatory Authority	2013	in development	in development	in development

This table shows that many African countries have regulatory authorities which have started regulating medical devices. The table shows that 60% of the countries reviewed have a risk classification according to GHTF risk classification, having this classification makes it easier to harmonise guidelines and policies amongst authorities. Due to poor regulatory structures in place, technical safety assessment is still not fully completed for many medical devices, as seen in the table, the main focus is high risk medical devices and in countries such as South Africa , it is only for covid 19 test kits due to the pandemic.

Because of the poor regulatory structures in place, research on Africa having its own CE mark equivalent has not been completely and thoroughly investigated (De Maria et al., 2018). Rugera et al., (2014) observed that in some nations, National Regulatory Authorities do not have the authority to regulate medical devices. Organizations that operate in laboratories are required to guarantee the caliber of the products used. In research laboratories, certain IVD evaluation procedures are carried out, although post-market surveillance is uncommon (Ncube et al. 2021) . .Training and capacitating already existing staff is a gateway to strengthening regulatory authorities (Ncube et al. 2021) .

Chapter 5: Discussion

This chapter briefly discusses the regulatory gaps for medical devices in Africa, how harmonization has worked with medicines, the impact of Western regulations on Africa, the challenges of regulatory harmonization of medical devices in Africa, the benefits of regulatory harmonization of medical devices in Africa, and the direction that medical device regulation in Africa is headed. The availability of medical equipment may be ensured by convergence and harmonisation, according to this chapter, which delves closely into how well-equipped African regulatory authorities are to regulate medical devices.

5.1 Introduction

National regulatory agencies are in charge of making judgments about regulations that have an impact on access to health products. Frameworks promoting the decision-making may need to be reinforced in order to encourage consistency, openness , and responsibility in decision-making processes. Regulators from all over the world have been compelled to reengineer regulatory procedures in order to increase the efficiency of regulatory operations as the demand for NRAs rises. International comparisons to other NRAs that are already established have inspired several NRA.

Despite the vital function that NRAs play within national healthcare systems, the relevance of medical product regulation is frequently overlooked and underfunded (Keyter *et al.*, 2018) . According to the WHO, less than half of NRAs lack the competency to conduct key regulatory responsibilities, and regulatory bodies lack the essential resources to sustain effective medical product regulation (Keyter et al., 2018).Identifying the challenges and advantages will assist in foreseeing how African regulatory authorities can harmonize medical device approvals. The COVID-19 pandemic amply illustrated the significance of guaranteeing equal access to reliable, safe medical device approval.

5.2 Medical device regulatory approval gaps within Africa

A large and quickly growing industry, medical device regulations are frequently complicated by legal and technical issues, such as patent status, the need for market approvals in other countries due to regulatory requirements, safety and efficacy data, engineering considerations, and so forth (Sethi et al. 2017).

Globally, laws that specify the obligations of the producers by referring to technical specifications regulate the sale of medical equipment in each nation. may consist of specifications, benchmarks, or characteristics for the design and manufacture of medical devices, such as test procedures and approval standards. Globally, a wide variety of medical device rules exist, varying in rigor from adequate to inadequate. (De Maria *et al.*, 2018a).The variation in legislation and technical documents for different medical devices creates a hurdle for regulatory harmonisation.

In Africa, medical device regulations gaps are quite large, ranging from legislation to regulatory skills. One key gap is the difference in risk-based classification of medical devices categorized in Table 5. Despite the gaps, the African countries included in Table 5 have legislation in place and have harmonised with other NRAs, making the harmonisation process and CE mark much easier process.

The table below looks at the regulation of medical devices in the African countries below.

Table 5: Review of medical devices in Seven African countries

Country	Regulatory Authority	Risk-based classification
South Africa	South African Health Products Regulatory Authority	A-D
Tanzania	Tanzania Food and Drug Authority/Private Health Lab Board	A-D
Ghana	Ghana food and Drug Authority	I -IV
Uganda	National Drug Authority/Allied Health Professionals Council of Uganda	A-D
Zanzibar	Zanzibar Food and Drugs Board	A-D
Kenya	Kenya Medical Laboratory Technicians and Technologist Board/Pharmacy and Poisons Board	A-D
Egypt	Egyptian Drug Authority (EDA) Southern	I -IV

The table above shows how different African countries classify medical devices. Five of the countries use the classification according to IMDRF. The Risk is uses Class A (Low Risk to Class D (High risk). Two of the countries fall the European classification which uses Class I (low risk) to Class IV (high risk). The principle is based on the intended use of the device, the amount of risk to patients, users, and other people (the likelihood that harm will occur and the severity of that harm), the degree of invasiveness in the human body, the duration of use, and exposure (Call-up, 2018) . Among the countries that uses a risk based classification , South Africa, and Tanzania rely heavily on one another , Especially since Tanzania is way ahead with registration of medical devices .The risk based classification is a four-tier based system as recommended by Global Harmonization Task Force (GHTF) (GHTF, 2012). The European and GHTF categories, which both utilize four classes, are essentially identical. Devices are assigned to a class based on their inherent risk for patient harm and intended usage (De Maria et al., 2018) . In this investigation, South Africa is the only nation having precise rules governing the use of in vitro diagnostic devices (Hubner *et al.*, 2021) .

5.3 How Harmonisation has worked with medicines.

The South African Development Community (SADC) has previously taken part in regional cooperation projects including the ZaZiBoNa collaborative work-sharing procedure, which tries to coordinate regulatory activities among regional NRAs. SAHPRA has included in their act the requirement to communicate with and engage into agreements with any other regulatory bodies and stakeholders allowing for the enabling of harmonisation efforts actively (Keyter *et al.*, 2018). Instead than reinventing the wheel, it is essential to

examine how regulatory harmonization for medicines worked in order for medical device harmonization to be successful.

With Regulatory Harmonization in the East African Community (EAC's), the time frame for registering is less than 100 days for NRAs such Tanzania and Zanzibar and less than 200 days for the NRAs such as Kenya, Rwanda, (Mashingia *et al.*, 2020)rating (Mashingia *et al.*, 2020) . Partner states frequently have confidence in the results of joint assessments and inspections due to the higher amount of knowledge involved and the belief that they are more transparent and rigorous than national assessments (Mashingia *et al.*, 2020). Evidently, the EAC's harmonization drive cut the time it required to register medications in various nations in half. To achieve this, it implemented several regionally consistent regulatory standards and procedures and strengthened the ability of all of its NMRAs to carry out regulatory tasks.

The main goal of harmonization in the pharmaceutical industry is to move away from relying on donor funding and toward self-sufficiency (Mashingia *et al.*, 2020). It also aims to maximize collaboration between regulatory agencies with various levels of expertise and resources, as well as to create a more (Arik *et al.*, 2020)ndly system (Arik *et al.*, 2020). Regulations of medicine have been successfully harmonised over the course of time.

5.4 Lessons from western regulations for Africa

In 1992, the European Union (EU), the United States of America (USA), Canada, and Japan made the initial proposal for an international partnership between medical device regulators and the regulated industry. The GHTF was created in 1993 to synchronize medical device laws throughout the world (De Maria *et al.*, 2018a) .The GHTF was disbanded in 2011 and The IMDRF was founded to discuss future paths in medical device regulatory harmonisation development (De Maria *et al.*, 2018b). The IMDRF, which is made up of stringent regulatory authorities such as USFDA, EU & Health Canada, with the World Health Organization (WHO) as an official observer, is currently developing harmonised guidelines related to medical devices (IMDRF, 2017; De Maria *et al.*, 2018a).

One of the ways the EU was able to harmonize regulatory frameworks was using notified bodies, but many academics have pointed to this lack of consistency in the audit processes by notified bodies among Competent Authorities as one of the main causes of the greatly variable quality of notified body performance (Contardi, 2019). Undoubtedly, this division has resulted in varying degrees of health and safety protection and has hampered the internal market (Contardi, 2019) .This is an important factor to avoid in Africa as it can create long timeframe for approvals. African countries can curb this factor by sharing of data, sharing inspections of Manufacturers applying in multiple countries. This has proven to be successful collaboration with regulatory harmonisation of medicines.

Lessons can also be gleaned from the Brazilian regulatory authority ANVISA, which experienced up to four-year audit delays, greatly slowing the clearance and release of medical devices to the market (Saidi and Douglas, 2018). In India, medical device laws were cumbersome and the growth of the medical device industry was hindered by limits on medicines (Saidi and Douglas, 2018).

It is crucial to set policies in place that ensure the efficacy of the registration system in order to promote innovation and encourage manufacturers to register their products (Saidi and Douglas, 2018). For instance, Singapore has implemented a flexible regulatory framework for medical devices that has less onerous requirements, lower registration costs, and quicker market access than the previous regulations. In addition,

Singapore established an expedited evaluation channel for the registration of Class C and Class D devices in 2013 (Saidi and Douglas, 2018).

All the above-listed challenges and processes which were faced by other jurisdictions have impacted regulatory authorities within Africa largely. One is the use of notified bodies in the EU, this acts as a stumbling block for local manufacturers when entering the market as theymust go through the notified bodies.

5.5 Challenges of Regulatory harmonization of medical devices in Africa

Through the African Medicines Regulatory Harmonization (AMRH) initiative, several regional harmonization initiatives were launched in response to national regulatory challenges in Africa. These efforts included accelerating the market authorization of medical products and facilitating the alignment of national legislative frameworks with the AU Model Law on Medical Products Regulation (Ncube et al. 2021) .. The model law seeks to foster more cooperation between nations and to speed up the process of regional harmonization as a whole (Ncube et al. 2021) .

Currently, the accessibility of IVDs and other medical equipment in poor nations is constrained by their cost and accessibility. In Africa, it is also difficult to find the laboratory equipment and skilled workers needed for many diagnostic tests. For the purpose of identifying serious diseases, a new generation of diagnostic tools is now being created. These include point-of-care testing that don't need to be referred to specialized facilities (Rugera *et al.*, 2014a). Patients in underdeveloped nations must be given prompt access to these treatments, and their cost needs to be reduced (Rugera *et al.*, 2014b). In developing nations, there is less oversight of medical devices, which is problematic for diagnostic testing in particular. Without much to no evidence of their efficacy, IVDs may be sold in countries with unregulated markets. Controls that are in place could prevent the import of particular commodities where they exist. As an example, take the delayed commercialization of a point-of-care CD4 cell counter that enables HIV patients to receive therapy (Rugera *et al.*, 2014a). Clinical trial requirements in many nations have led to significant effort duplication with little to no scientific benefit. This has also raised prices and years-long delays in their introduction in some African nations (Rugera *et al.*, 2014a).

A recent study by Ndomondo-Sigonda et al., (2020) assessing the financial sustainability of National Medicine Regulatory Agencies (NMRAs) in the East African Community (EAC) concluded that financial capabilities vary country to country , from donor funding to generation of fees from applications .The main factors that support the financial sustainability of NMRAs are government regulation, the legal system, and fee structures"('AMRH Q4 2020 newsletter - English[1]', no date). This crucial relationship between funds and enablers is essential for guaranteeing the quality, safety, and efficacy of new health products that are being registered, which necessitates agencies having both an effective and efficient regulatory process.

Medical device businesses are discouraged from selling in some countries due to the disparities in regulatory requirements between nations, which require manufacturers to create unique processes (Nasir *et al.*, 2023).

5.6 Advantages of Regulatory harmonization of medical devices in Africa

By enhancing regulatory convergence and taking part in collaboration and partnership initiatives, the regulatory load and strain on regulatory authorities will be reduced. Harmonization will enable efforts to decrease regulatory effort duplication and increase the likelihood of making better use of the limited resources available for post-marketing monitoring operations (Keyter *et al.*, 2018).

The IMDRF and WHO are both aimed at accelerating harmonization and convergence to achieve greater uniformity between national regulatory authorities for medical devices. The problem for the authorities is to make the approval process better while making sure they "say what they do, do what they say, prove it and improve it." This calls for the implementation of operational measures. Authorities are particularly concerned with ensuring that the review is completed on time, balancing the effort, resource, and expense, which is related to the process' efficiency (‘AMRH Q4 2020 newsletter - English[1]’, no date). African Authorities should harmonize requirements to international standards, which will strengthen the regulatory approval in Africa and supports the use of reliance within and across jurisdictions. Streamlining and standardizing regulatory procedures may decrease delays and wasteful spending while facilitating access to new products (Rugera *et al.*, 2014a).

The IMDRF established a list of essential principles for medical devices including in vitro diagnostic devices. These principles included (1) The manufacture should conduct a risk assessment to identify known and foreseeable risks and to mitigate these risks in the design, production, and use of the medical device(Hubner *et al.*, 2021). (2) The manufacturer should ensure that design and production processes of a medical device is safe when used according to the intended purpose and does not compromise the clinical condition of the patient or the health of the user (Hubner et al., 2021).

5.7 Way forward for Medical Devices regulation in Africa

In order for Africa to have its own CE equivalent mark, It is imperative that guidelines are aligned. Reviewing table 1 shows that many of the leading regulatory authorities already use reliance models to approve medical devices. The table also highlighted the difference in the classification system which will require alignment.

In addition to having a legislative and regulatory framework for medical diagnostics and devices that is suited for harmonization, building processes and capacity for regulation that would feed into harmonised regulation is a step in the right direction (Rugera *et al.*, 2014a). Well-established regulatory organizations should collaborate with authorities where there is a lack of IVDs and medical device legislation and policy framework in order to hasten the creation of new legislation and policy framework and to pinpoint areas where existing frameworks may be enhanced. weighing the labour, resources, and costs in relation to the process' efficiency.

Agencies should implement quality measures and monitoring e.g., having effective IT infrastructure, this will enable sharing of data amongst regulatory authorities (‘AMRH Q4 2020 newsletter - English[1]’, no date). De Maria et al., (2018) recommended the use of “Open Source Medical Devices” (OSMDs), which is designed following collaborative strategies. It might help bring down the price of making medical devices while upholding formal regulatory procedures and keeping safety standards for equivalent medical devices at least equal. By creating an OSMD, you may create a medical device system where you can collaborate with other expert medical device designers to share design files, documentation, and prototypes (De Maria *et al.*, 2018b). Because everyone can evaluate the design dossier, the open approach has the benefits of accessibility, sustainability, lower costs, and, under ideal circumstances, enhanced performance and safety (De Maria *et al.*, 2018b) . Another implementation which has been seen globally is having a regulatory information management system (RIMS) in place to manage reports, technical dossiers, and recommendations. Rwanda is currently piloting implementation of the system with other countries such as South Africa following.

Furthermore, the WHO Global benchmarking tool for medical devices is a steppingstone towards achieving regulatory convergence and harmonisation, which provides unified indicators designed to evaluate medical

devices that regulatory authorities can use to approve medical devices .The indicators/tools examine convergence for the regulatory framework; indicators include the laws, rules, and regulations needed to establish the regulatory framework.; Arrangement for effective organization and good governance; Regulatory system is supported with leadership and crisis management plans ('WHO Drug Information', 2021). If African regulatory authorities can engage and implement the WHO GBT tool for medical devices, It will be easier to create the CE mark as the approval criteria and regulatory framework of each regulatory authority will be common for many products.

It will be advantageous if various medical device industry stakeholders are actively involved as partners in the execution of the laws.

Chapter 6: Conclusion

This literature review found that medical device regulatory harmonisation is the first step African agencies should take before having a CE mark equivalent for locally Manufactured Medical devices. The AMDRF which is formed to bring together has a main objective to achieve harmonisation within medical device regulation is already in place. It is crucial that patients in impoverished nations have quick access to these treatments and that they be made accessible for a reasonable priced(Rugera *et al.*, 2014a). In developing nations, there is less oversight of medical devices, which is problematic for diagnostic testing in particular. IVDs may be sold in nations where they are unregulated with little or no proof of their effectiveness..

If CE Mark equivalent is made available in Africa, healthcare professionals will benefit from having additional options for treating patients to improve patient management. By having access to new markets and being better prepared to satisfy regulatory criteria connected to product registration, the medical device industry will learn a lot (De Maria *et al.*, 2018b). Most significantly, patients will gain from an increase in the availability of devices, access to high-quality ones that adhere to strict safety, quality, and efficacy standards, and a reduced chance of utilizing dangerous one (De Maria et al., 2018).

The deficiencies identified have shown that well-established regulatory agencies should work together with other agencies to develop IVDs and medical device legislation and policy frameworks where they are lacking and to identify areas for improvement of those that already exist (Rugera *et al.*, 2014a). African agencies do not need to implement policies from scratch however they can adopt from organisations such as AMDRF, IMDRF and WHO and most importantly rely on each other.

The WHO Global benchmarking tool for medical devices is a steppingstone towards achieving regulatory convergence and harmonisation, which provides unified indicators designed to evaluate medical devices that regulatory authorities can use to approve medical devices.

Lastly If countries can have a regulatory information management system (RIMS) which is centralized and they can all share medical device inspection reports and registration recommendations, this will be a big win for African countries. Countries such as Rwanda, Tanzania , Nigeria and soon to be implemented South Africa , already use the system .The system will avoid redundancy and manual effort , Improves efficiency and collaboration with increased speed and quality of the submission ;medical devices approved by one country will be approved faster in another country. The antiquated approach of using several spreadsheets, disjointed systems, SharePoint, and isolated working teams is unable to keep up with the dynamic and ever-changing global regulatory submission requirements. Reliance will be more successful, and a CE certificate will be much easier to issue.

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