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Policy Analysis of Regulatory Challenges for Medical Devices and In Vitro Diagnostics in Achieving Universal Health Coverage in Zimbabwe

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Abstract

Zimbabwe's regulation of medical devices and in vitro diagnostics (IVDs) lags behind that of medicines and vaccines despite the country's goal of achieving Universal Health Coverage (UHC) by 2030. This study, conducted from June to December 2022, rigorously evaluated Zimbabwe's regulatory framework for medical devices and IVDs using a comprehensive policy analysis framework. The study's methodology, which included document review and comparative analysis, was designed to align the regulatory framework with the UHC goal. The READ (Ready, Extract, Analyze, and Distill) approach systematically assessed the relationship between medical device regulations and national health strategic goals. Fourteen documents were analysed, revealing that current regulations under the Medicines and Allied Substances Control Act are insufficient for ensuring quality-assured medical devices and IVDs due to a lack of explicit definitions and standards, leading to inconsistent regulatory practices. The study found fragmented regulatory approaches, overlapping institutional responsibilities, and a lack of effective incorporation of medical device and IVD regulations in national health strategy and related policies, hindering UHC achievement. The study recommends comprehensive policy changes to harmonise regulations, clarify institutional roles, and integrate medical device and IVD regulations into the national health strategy. This ensures access to safe, effective, quality medical devices and IVDs, promoting Zimbabwe's UHC goals by 2030.

Keywords: *In Vitro Diagnostics, Medical Devices, Performance, Safety, Quality, Universal Health Coverage.*

Introduction

Medical Device and In Vitro Diagnostic (IVD) Regulations are in place to ensure the safety and efficacy of medical devices and IVDs through the design, manufacturing, clinical trials, distribution, and post-market surveillance stages [1, 2] Medical devices and IVDs are regulated via a risk-based classification system from Class A (lowest risk) to Class D (highest risk). Regulatory evaluations of design, safety, performance, and quality correspond to the risk class. Lower-risk devices undergo less stringent assessments, while higher-risk devices face rigorous evaluations. The International Medical Devices Regulators Forum (IMDRF) mandates manufacturers to ensure product safety and performance, applying risk control measures suited to the device's risk category. These regulations aim to balance safety and economic viability, adhering to Essential Principles

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established by the Global Harmonization Task Force and IMDRF [3, 4].

A 2016 World Health Organization (WHO) desk review revealed that 40% of African countries lacked medical device regulations, 32% had some regulations, and 28% had no data. Globally, 58% of WHO member states regulate medical devices. In Zimbabwe, regulatory data was unclear, but it indicated some regulation of market placement for medical devices without specifying IVDs [5].

Zimbabwe's medical device and IVD regulations lack consistency, with the Medicines Control Authority of Zimbabwe (MCAZ) overseeing medicines and specific items and the Medical Laboratory and Clinical Scientists Council (MLCScCZ) regulating laboratory personnel and IVDs for priority diseases. According to Hubner et al., Zimbabwe's formal medical device regulatory system is absent, with only condoms and gloves being regulated as medical devices. The inconsistent regulation may lead to substandard devices and restricted access to quality-assured products [6]. These regulations aim to provide patients and users access to safe, high-quality devices. Zimbabwe has a legal framework for medical device regulation, but it is not formalised [6]. A study by Dacombe et al. found that the reference laboratory oversees quality monitoring for HIV-Self Testing IVDs in Zimbabwe. Still, regulatory responsibilities in Zimbabwe are divided between the MCAZ and the MLCScCZ, with unclear coordination roles and limited understanding of the regulatory process among stakeholders [7].

Universal Health (UHC) means everyone should have equal access to essential healthcare services, regardless of their financial situation. These services encompass a comprehensive range of healthcare needs, including health promotion, disease prevention, treatment, rehabilitation, and palliative care[8]. Providing adequate resources at both national and subnational levels is crucial to achieve UHC. Figure 1 depicts the processes of achieving UHC, including the healthcare system's essential components. To protect public health, ensuring access to medicines and health technologies requires a strong regulatory system that guarantees safe and high-quality products, such as medical devices and IVDs. The UHC program is closely associated with Sustainable Development Goal (SDG) 3's Objective 3.8, which aims to achieve universal access to safe, effective, quality, and affordable essential medicines and vaccines for all [9].

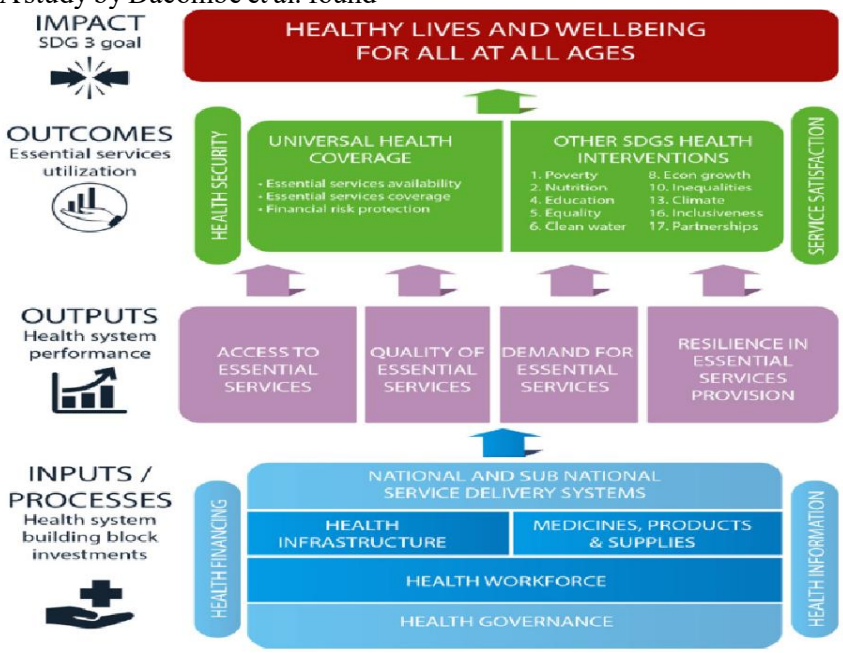

Figure 1. Universal Health Coverage: WHO Regional Office for Africa, 2017 [8].

The figure illustrates the key components and strategies for achieving UHC as outlined by the WHO Regional Office for Africa in 2017. Key elements include healthcare access, quality, and financial protection. Visual representation includes regional disparities and highlights initiatives to improve health systems and services.

In 2007, the WHO's World Health Assembly adopted a resolution emphasising health technologies, particularly medical devices, due to their importance in achieving UHC. In 2014, the WHO committed to enhancing regulatory systems for medical products through Resolution 67.20. Since then, global interest in medical devices has grown, yet many United Nations member states still lack effective regulatory systems [10]. Zimbabwe aims to achieve UHC by 2030. However, it is unclear if this goal has considered regulating medical devices and IVDs as a critical component of the health system.

The study aims to evaluate and enhance Zimbabwe's regulatory framework for medical devices and IVDs, focusing on aligning it with the UHC goal. This involves identifying key challenges, proposing actionable policy recommendations, and assessing their potential impact on health outcomes.

Materials and Methods

This study used qualitative research through document analysis. Walt and Gilson's policy analysis triangle [11], which identifies four interrelated components (policy content, actors, process and context) that influence policy development, adoption and implementation, informed the study approach. The document analysis approach was used to identify issues related to policy analysis because document analysis is closely linked to health policy analysis [12]. Walt and Gilson's policy analysis triangle, which considers four interconnected components–context, content, process, and actors–is central to the document analysis conducted in this study [13]. Figure 2 illustrates the connections between the key components. These components influence the policy formulation, implementation, monitoring, and evaluation. '*Context'* refers to political, economic, and social factors at a national and international level, while '*Process'* refers to how policies are initiated, formulated, implemented, and evaluated. '*Policy conten*t' refers to the substance of a particular policy. '*Actors'* are individuals and organisations that influence these stages in policy making and policy content [14].

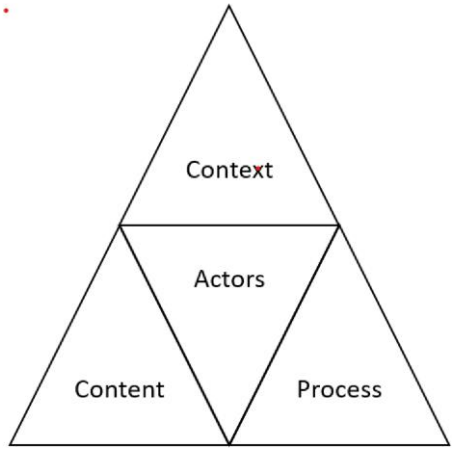

Figure 2: Policy Analysis Triangle from Walt and Gilson [15]

Context: Political, economic, and social factors at both national and international levels that influence policy formulation, implementation, monitoring, and evaluation.

Process: The stages of policy initiation, formulation, implementation, and evaluation.

Policy Content: The substance and details of a particular policy.

Actors: Individuals and organisations that influence the stages of policymaking and the policy content.

Setting

MCAZ regulates medicines, condoms, and gloves as medical devices. The MLCScCZ supervises medical laboratory professionals and operations, evaluating IVDs for national tenders concerning HIV, TB, Malaria, and STIs. The National Microbiology Reference Laboratory (NMRL) conducts evaluations for market approval from the MLCScCZ. The Ministry of Health and Child Care (MoHCC) supports public health initiatives, with its Directorate of Laboratory Services overseeing and enhancing laboratory services' quality, efficiency, and effectiveness. It establishes high standards, ensures accurate diagnostic services, and supports public health through surveillance, research, and disease outbreak responses. Policy documents from these institutions were reviewed for this analysis.

Data Collection

A document review was conducted by analysing publicly available documents from the MoHCC, MCAZ, and MLCScCZ.

Policy analysis utilised the READ method (Review, Extract, Analyze, and Distil) to critically evaluate the relationship between medical device regulations and national health goals. This systematic approach offered evidence-based insights for policy development, decision-making, and implementation—the analysis aimed to address effectiveness, efficiency, equity, and feasibility [16, 17].

Steps Used to Collect and Analyse the Data

Read the Materials

Established eligibility criteria centred on the research question, targeting health policies, strategic plans, parliamentary acts, and regulations on medical devices and IVDs. Assessed publicly accessible documents and unpublished drafts from MCAZ and MLCLScCZ, including those supplied by key informants. Maintained the original content and significance without excluding any time frames (covering several decades since the inception of health product regulation in Zimbabwe) and offered indicative locations for document retrieval within the parameters.

Extract Data

Data were entered into Microsoft Excel and analysed for terms like "medical devices," "In Vitro Diagnostics," "IVDs," "legislation," "law," "regulations," "guidelines," "regulatory system," "market authorisation," "licensing establishment," "technical documentation," "dossier review," "labelling," "labelling review," "product performance evaluation," "manufacturing site inspection," "Quality Management System Audits," "vigilance," "post-market surveillance," "Essential Principles of Safety and Quality," and "conformity assessment." The framing of these terms in medical device regulations was identified. Relevant documents were identified based on the research question, and data were entered into Excel using standardised forms. Validation checks compared entries with original documents, and duplicates were removed. Data were cross-referenced with multiple sources for consistency and accuracy. Incomplete entries were removed, and terminology was standardised.

Analyse the Data

A comprehensive initial assessment of all pertinent documents was conducted, which led to structuring the analysis according to theoretical approaches while simultaneously employing multiple sources to construct a coherent narrative of the policy cycle. Subsequently, this led to responding to thematic inquiries, taking note of variations within and between the documents. The researcher identified key themes and patterns within the data by implementing thematic coding. To ascertain similarities and differences, a comparison of data from different documents was conducted through the application of narrative construction. This resulted in

insightful conclusions surrounding the identified themes, integrating information from various documents. Triangulation involving multiple data sources, was employed to validate the findings and enhance the reliability of the analysis. The data analysis process comprised of several steps, including:

1. Undertaking a comprehensive initial reading of all documents.
2. Employing thematic coding to categorise data into pertinent themes.
3. Developing narratives around identified themes, integrating insights from various documents.
4. Utilising multiple data sources to validate findings and enhance reliability.
5. Recording the responses and developing comprehensive notes to support the results.

Distil Findings

Completed the document review when all of the criteria for inclusion had been satisfied, and the point of data saturation had been reached. Organised the results into theoretical themes and policy narratives and linked them to the data from the questionnaire and interviews. Verified the findings concerning the research questions and drew conclusions that applied to policy.

Results

The results are presented along the four interrelated components of the Health Policy Triangle [15]. Fourteen documents were analysed: 11 documents from the MCAZ related to medical device and IVD regulations, three national documents from the MoHCC, and one developed by the MLCScCZ. Table 1 below shows the documents that were reviewed.

Table 1. Characterisation Table with Key Terms and Source

Document ID	Title	Document Type	Main Objectives	Regulatory Domain	Source
Doc1	Medicines and Allied Substances Control Act (MASCA)	Act of parliament	Provide a legal framework for regulating medicines and allied substances.	Products need to be better defined. Section 38 of MASCA states the following products, "Prohibitions, controls and restrictions in respect of medicines, veterinary medicines and certain substances, devices and articles". The words Allied Substances and Devices are not defined.	https://www.mcaz.co.zw/wp-content/uploads/2021/11/Medicines-and-Allied-Substances-Control-Act-Chapter-1503-2.pdf
Doc2	Statutory Instrument 183 of 2005. Medicines and Allied Substances Control (Condom) Regulations	Regulation	Regulate the quality and safety of condoms.	Approval of condoms submitted for regulatory approval assessment. Importer, manufacturer or wholesaler for submitting applications and meeting the requirements of the applications.	https://www.mcaz.co.zw/wp-content/uploads/2022/01/Condom-Regulations_2005.pdf
Doc3	Statutory Instrument of 2006. Medicines and Allied Substances Control (Gloves) Regulations	Regulation	Regulate the quality and safety of gloves.	Approval of condoms submitted for regulatory approval assessment. Importer, manufacturer or wholesaler for submitting applications and meeting the requirements of the applications.	https://www.mcaz.co.zw/wp-content/uploads/2022/01/Gloves-Regulations-2006.pdf

Doc4	Statutory Instrument 130 of 2014 Medicines and Allied Substances Control (Condom)(Amendment) Regulations	Regulation	Amend regulations related to condoms.	Market authorisation for condoms	https://www.mcaz.co.zw/wp-content/uploads/2022/04/si-130-of-2014.pdf
Doc5	Statutory Instrument 131 of 2014 Medicines and Allied Substances Control (Gloves)(Amendment) Regulations	Regulation	Amend regulations related to gloves.	Market authorisation for gloves.	https://www.mcaz.co.zw/wp-content/uploads/2022/04/si-131-of-2014.pdf
Doc6	Standard Operating Procedure for Drafting and Reviewing Legislation (LC09)	Standard Operating Procedures	Provide procedures for drafting and reviewing legislation.	Legislation formulation.	https://www.mcaz.co.zw/sdm_downloads/sop-for-drafting-and-reviewing-of-legislation/
Doc7	The MCAZ Reliance Policy	Policy Category	Establish reliance mechanisms to expedite regulatory processes.	Regulatory decisions are based on other regulatory authorities.	https://www.mcaz.co.zw/wp-content/uploads/2021/09/MCAZ-RELIANCE-POLICY.pdf
Doc8	The Medicines Control Authority of Zimbabwe 5 Strategic Plan (2022-2026)	Strategic Plan	Outline strategic goals for MCAZ over five years.	Guiding the vision of the regulatory authority	https://www.mcaz.co.zw/sdm_downloads/5-year-strategic-plan-2022-2026/
Doc9	National Health Strategy 2021-2025	Strategic Plan	Outline strategies to achieve UHC by 2025.	Ensure access to health products.	https://www.scribd.com/document/590031144/National-Health-Strategy-for-Zimbabwe-2021-2025#
Doc10	Medicines and Allied Substances Control (Import and Export of	Regulations	Regulate the import and export of medical devices.	Market authorisation of medical devices	Not Published

	Medical Devices) Regulations				
Doc11	Draft Medicines and Allied Substances Control (In Vitro Diagnostic (IVD) Medical Devices) Regulations	Regulation	Regulate IVDs to ensure safety and performance.	Ensure access to safe, effective and quality-assured medical devices.	Not Published
Doc12	National Health Laboratory Strategic Plan 2022-2026	Strategic Plan	Improve and strengthen the quality and management of health laboratory services.	Post-market surveillance of IVDs	Not Published.
Doc13	Health Professions Act Chapter 27:19	Act of Parliament	Regulate the health professions in Zimbabwe.	Not applicable.	Health Professions Act Chapter 27:19.pdf
Doc14	Health Professions (Evaluation and Registration of In-vitro Diagnostics IVD) Regulations, 2015	Regulations	Regulation of IVDs, laboratories and personnel that use IVDs.	Pre-market approval of IVDs, including safety, performance and quality.	Not published

Context

Zimbabwe's current legislative and regulatory frameworks exhibit substantial gaps in the governance of medical devices and IVDs. The legislative framework is outdated, as it was created specifically for medicines.

Overview of Legislative Frameworks Governing Medical Devices and IVDs in Zimbabwe

The Medicines and Allied Substances Control Act (15:3) is the principal legislation governing the registration and control of medicines in Zimbabwe, establishing the MCAZ. However, it lacks explicit provisions for regulating medical devices and IVDs, which creates a significant gap in the comprehensive regulation of these health products.

Specific Regulations and Strategic Plans Analysis

The analysis of various statutory instruments and strategic plans revealed inconsistencies and gaps in the regulatory framework for medical devices and IVDs in the context of UHC:

1. *Statutory Instrument 183 of 2005 and Statutory Instrument of 2006* address condoms and gloves, respectively, but provide limited guidance on conformity assessments and manufacturing site inspections, particularly regarding compliance with International Organisation for Standardisation (ISO) 13485 standards.

2. *The Draft Medicines and Allied Substances Control (Import and Export of Medical Devices) Regulations, 2017, and Medicines and Allied Substances Control (In Vitro Diagnostic (IVD) Medical Devices) Regulations, 2020,* are pending approval and do not adequately refer to the main Act. They also miss critical regulatory details such as the classification of importers and specific importation procedures.

3. *The Health Professions (Evaluation and Registration of In-Vitro Diagnostics IVD) Regulations, 2015, d*rafted by the Medical Laboratory and Clinical Scientists Council of Zimbabwe (MLCScCZ), highlight the disjointed regulatory approach by overlapping with MCAZ duties, without a clear mandate from the Health Professions Act.

The Medicines Control Authority of Zimbabwe's Strategic Plan (2022-2026) aims to achieve WHO Global Benchmarking Tool (GBT) level 3 and full automation by 2026. However, it broadly addresses health products without specific strategies for medical devices and IVDs.

The National Health Strategy 2021-2025 and the National Health Laboratory Services Strategic Plan 2022-2026 also indicate a fragmented approach in selecting health products and a lack of detailed regulatory frameworks for medical devices and IVDs.

Regulatory and Legislative Gaps Identified

1. No detailed regulatory guidance exists for the registration, importation, and post-market surveillance of medical devices and IVDs.
2. Lack of clarity on applying reliance and recognition principles, considering assessments from other jurisdictions.
3. There is insufficient legal backing for the regulatory responsibilities assigned to MLCScCZ, highlighting the need for legislative updates to incorporate comprehensive medical device regulations into the health system.

Actors

The actors identified during the policy analysis were the Minister of Health, MCAZ, Directory of Laboratory Services, MLCScCZ, and NMRL. Their roles and responsibilities are stated in Table 2.

Table 2. Actors, Role and Influence in Regulating Medical Devices and IVDs.

Actors	Roles and influences
MoHCC	It is dedicated to enhancing health services to ensure the well-being of Zimbabweans. Develops and implements policies and programs to improve public health, prevent diseases, and provide accessible, quality care. Manages healthcare facilities, oversees public health campaigns, and ensures the availability of essential medicines and technologies. Focuses on maternal, neonatal, and child health to reduce mortality and improve outcomes. Strives to build a resilient, sustainable healthcare system.
Minister of Health	The MCAZ's chairman and vice-chairman are designated by influence and empowered to implement regulations and address matters necessary for executing the relevant Act, ensuring thorough oversight and guidance in the health sector.
MCAZ	Serves as the national regulatory authority with the mandate to regulate medicines and allied substances. Ensures the safety, quality, effectiveness, and performance of these products.
Directorate of Laboratory Services	The organisation regulates and optimises laboratory services across the health sector, upholding high standards of practice, ensuring precise and prompt diagnostics, and supporting public health through surveillance, research, and outbreak response. It develops and enforces laboratory operations policies and guidelines, fosters innovation, embraces new technologies, and facilitates personnel training and capacity building.
MLCScCZ	The health profession authority for medical laboratory and clinical scientists in Zimbabwe promotes public health, regulates professional training and practice, and upholds training standards. It advises the Minister of Health on professional practice matters, manages professional registration and certification, enforces ethics, and assesses examination and qualification standards.
NMRL	Essential to the healthcare system, emphasising public health microbiology. Engages in disease surveillance, outbreak monitoring, specialised diagnostics, and rigorous quality assurance. Participates in research to tackle infectious diseases and antimicrobial resistance. Trains healthcare and laboratory staff, enhancing Zimbabwe's ability to manage infectious diseases and shape public health policies and programs. Provides crucial diagnostic services for efficient outbreak response and management.

Process

The findings showed that MCAZ has regulated condoms and gloves, although the Medicines And Allied Substances Control Act is not explicit for medical devices. The MCAZ and MLCScCZ drafted regulations or amendments to the Medicines And Allied Substances Control Act before submitting them for review and comments by external stakeholders. The comments were considered and reviewed by experts and legal committees. The documents are sent to the Attorney General for review after the public commenting process concludes. The Minister approves the law when the Attorney General’s office provides an accent.

Discussion

The Medicines and Allied Substances Control Act of 1969 was amended in 2005 to include the regulation of condoms and gloves, but it does not define allied substances or the term 'devices.' As a result, the MCAZ faces difficulty in claiming a mandate to regulate medical devices and IVDs. However, the Zambian Regulatory Authority has defined allied substances to include medical devices and condoms. Therefore, there is a need for the Act to be amended to define medical devices and IVDs within its scope clearly and to establish whose mandate it is to regulate these products [6].

Regulations must clearly define mandates, functions, roles, and responsibilities to prevent overlap when multiple institutions or entities operate at different state levels, covering communication, coordination, and regulatory management. The Medicines And Allied Substances Control Act lacks sufficient post-market surveillance for registered medical devices and exceptions for emergency use authorisation. While the draft Import and Export Regulations and Regulations of In Vitro Diagnostics Medical Devices are in progress, it is crucial to review the Medicines and Allied Substances Control Act to address these gaps and implement regulations with legal support [10]. Strengthening Zimbabwe's regulatory framework for medical devices and IVDs is essential to ensure their safety, effectiveness, and quality. To achieve UHC by 2030, Zimbabwe must update laws, enhance regulatory capacities, and foster inter-agency collaboration, enabling the health system to meet population needs and respond to health challenges.

Vigilance and Post-Market Surveillance ensure the safety and efficacy of medical devices and IVDs. Manufacturers, distributors, and marketing authorisation holders must participate in recalling unsafe or defective products and implementing Field Safety Notices and Corrective Actions. The NRA should have the authority to suspend marketing authorisation, recall specific batches, issue Field Safety Notices, Field Corrective Actions, or a Notice of Concern, and withdraw products from the market [18]. Defective medical devices and IVDs that persist in use due to inadequate post-market surveillance risk patient harm, and adverse health outcomes, and impede progress toward UHC. The absence of mechanisms like Field Safety Notices or Field Corrective Actions hinders the management of medical device and IVD emergencies, prolonging public health crises and increasing morbidity and mortality. A lack of a robust recall system for faulty products delays responses to device failures, exacerbating health issues, prolonging treatments, increasing healthcare costs, and straining resources. The inability to withdraw substandard or falsified products undermines healthcare quality and safety, exposing patients to ineffective interventions that lead to poor outcomes and decreased life expectancy. Insufficient post-market surveillance can result in significant legal and financial repercussions, diverting resources from essential services and investments needed for UHC. Lastly, the continuous use of substandard or falsified devices erodes public trust, reducing healthcare service utilisation and hindering UHC progress.

The Medicines and Allied Substances Control Act grants the Minister of Health authority to establish regulations per Section 74, addressing matters mandated or permitted by the Act or deemed necessary. Despite this, certain draft regulations, such as the In Vitro Diagnostic (IVD) Medical Devices Regulations (2020) and Import and Export of Medical Devices Regulations (2017), have been pending for over two years. Others, including the Evaluation and Registration of In-vitro Diagnostics (IVDs) Regulations (2015) and Establishment of Clinical Laboratory Improvement, Evaluation and Registration of In Vitro Diagnostics (IVD) Centers Regulations (2020), have been drafted by MLCScCZ. The

reasons for delays in approval and implementation are unclear, potentially owing to the regulatory authorities' lack of autonomy.

The draft IVD regulations from MLCScCZ lacked provisions to ensure the safety, quality, and performance of registered IVDs. While regulating tests in licensed laboratories is commendable, it differs from enforcing the Essential Principles for Safety and Performance in the design and manufacturing of medical devices, including IVDs [4]. Manufacturers must ensure the safety and proper functioning of medical and IVD devices throughout their lifecycles by validating and verifying their products. This includes achieving intended performance under expected use conditions. Manufacturers must also establish and maintain a risk management system that adheres to ISO 1497:2019. Risk control measures must align with safety standards and reflect current best practices, and any remaining significant risks must be communicated to end-users [18]. The Essential Safety and Performance Principles require that medical devices and IVDs maintain quality and performance throughout their lifecycle, ensuring patient safety and user safety. Products must be designed, manufactured, and packaged to withstand transport and storage conditions. Clinical Performance Evaluation studies are essential to confirm real-world functionality. Guidelines address sterilisation, microbial contamination, environmental and use conditions, risk protection, and software validation. These extensive requirements highlight the importance of thorough testing, validation, and risk management in manufacturing medical devices and IVDs to ensure safety and efficacy throughout their use [4,19]. Currently, medical devices and IVDs in Zimbabwe may lack quality assurance due to insufficient policies for rigorous testing, validation, and risk management during manufacturing and approval. Implementing these measures could enhance the health system's resilience and inspire confidence in medical products.

The MLCScCZ plans to issue licenses for registered products with MCAZ, but safety, quality, and performance standards for conformity assessments are not clearly defined. The format for technical documentation required for medical device conformity assessment and market approval is also unspecified. Some products require CE marking regardless of risk classification. Under previous EU Directives (98/79/EC and MDD 93/42/EEC), manufacturers could self-declare compliance for some products without undergoing conformity assessment, leading to CE marking. The MLCScCZ may have been unaware of these CE marking requirements [2]. This finding is similar to the general finding of De Maria et al., which is that African countries have an affinity for European regulation. However, they lack the competencies required for implementation [19].

The latest MCAZ Reliance Policy (Document 01/2021) aims to broaden the organisation's reliance due to increasing work volume and complexity and rising demands for faster turnaround times from patients, the healthcare system, the state, and applicants. However, the current legal framework excludes IVDs from regulation, as they are not covered by the Medicines And Allied Substances Control Act, which governs MCAZ's products. Additionally, the Act lacks provisions for reliance and recognition mechanisms, raising doubts about the policy's effective implementation until legal amendments explicitly include these mechanisms [20].

Hubner et al. found that Zimbabwe lacked formal regulatory processes for medical devices, earning a Level 3 rating in medical device regulation, indicating no formal regulatory process compared to its peers in Central, Eastern, and Southern Africa [6]. The Medicines and Allied Substances Control Act is under review and will be introduced as a bill to broaden its scope to regulate all health products, including medical devices. However, the researcher did not access the draft regulations

to verify if the necessary elements for medical device regulation were included.

The data indicates that donor offerings primarily influence the selection of family health products, implying that the MoHCC has not effectively protected public health and has shifted this responsibility to the donor community. This underscores the MoHCC's failure to regulate these products in their strategic plan for achieving UHC by 2030. Furthermore, the National Health Strategy states that the selection of laboratory reagents is the responsibility of the MLCScCZ, but the legal basis for this authority remains unclear.

The National Health Strategy focuses only on reagents for priority diseases such as HIV, Malaria and TB. Considering the complexities of IVDs used in medical laboratories, reagents constitute a small fraction of these devices. IVDs can be equipment or apparatus the manufacturer intends to use as an IVD medical device or reagents, calibrators, control materials, specimen receptacles, software, and related instruments, apparatus, or other articles [21]. Therefore, it is unclear whether the MLCScCZ has the necessary skills and competencies to select a wide range of IVD medical devices considering the intended use claims and suitability for various disease programs. Similarly, IVDs used in the private sector are not selected using the MLCScCZ, which makes it clear that no one knows the quality, safety, and performance of the IVDs used in this sector.

A national medical device and IVD policy is essential for coordinating health strategies, setting goals, and guiding actions. It outlines medium-to-long-term objectives and strategies and establishes coordination mechanisms between the public and private sectors. This policy formalises government commitments, defines sector goals, prioritises efforts, and facilitates national discussions. Without such a policy, there are doubts about the government's dedication to medical device regulations. Current efforts lack specificity, measurability, attainability, realism, and time-bound characteristics, leaving uncertainties about legal mandates, monitoring, evaluation, and timelines for regulatory bodies' establishment.

Additionally, methods for achieving objectives and measurable targets or obligations are unspecified, complicating progress evaluation and success determination. Health product regulations, including testing laboratories, should specify performance characteristics. The strategic plan also emphasises developing and implementing a post-market surveillance framework for laboratory commodities and equipment involving manufacturers, importers, distributors, regulatory authorities, reference laboratories, the Ministry of Health, and users [18]. While the need for post-market surveillance and planning is commendable, more is required to develop, implement, and monitor an effective system based on a valid legal framework. The National Health Strategy must set clear medical device regulation objectives to achieve UHC by 2030. The disconnect between the UHC goals in the National Health, MCAZ, and National Health Laboratory Services Strategic Plans is concerning. The health strategy's omission of medical devices and IVDs may stem from a lack of political will and leadership commitment. Regulation is essential for ensuring health products and technologies' safety, quality, and availability. Without a clear action plan, achieving UHC in Zimbabwe may be challenging. MCAZ's outcome 3 aims to advocate for the approval of the updated Medicines and Allied Substances Control Act Bill, requiring a clear implementation plan with objectives, strategies, inputs, outputs, activities, indicators, data sources, assigned responsibilities, and monitoring and evaluation frequency to meet strategic goals [22]. Lack of regulation for these products may pose public health risks and impede effective medical device and IVD regulations. The MCAZ's 2022-2026 strategic plan does not address this

issue, limiting potential progress. Integrating medical devices and IVDs into the national health strategy is vital for achieving UHC goals, such as equity, quality, and affordability. Ensuring equitable access to essential medical devices and IVDs for all, regardless of socioeconomic status or location, is crucial. A strong regulatory framework can ensure the availability of safe, effective products, improving patient care quality. Policies promoting rational use of medical technologies, optimising procurement, and leveraging economies of scale can reduce costs, making essential devices and diagnostics more affordable for the health system and patients [23].

Integrating IVDs into national health strategies can improve diagnostic capabilities and health outcomes and reduce disease burden. Ensuring the availability and proper use of essential medical devices and IVDs strengthens healthcare delivery and expands services. Investing in training, capacity building, and infrastructure development maximises the benefits of medical technologies. Regular monitoring, evaluation, and strong regulatory oversight maintain safety, quality, and performance. Collaboration with stakeholders, including civil society, patient groups, and community representatives, ensures participation in policy development and implementation. Encouraging context-specific and locally adapted medical devices and IVDs facilitates innovation and technology transfer. Periodically evaluating and adapting national health strategies and policies aligns with evolving UHC priorities, health system requirements, and technological advancements.

Conclusion

The study highlights significant gaps and inconsistencies in Zimbabwe's regulatory framework for medical devices and IVDs, which impede the achievement of UHC. Current regulations lack explicit definitions and standards, leading to inconsistent practices and inadequate safeguards for quality assurance. The fragmented regulatory approach and overlapping responsibilities between institutions further complicate the regulatory landscape. To address these challenges, the study proposes comprehensive policy recommendations to harmonise regulations, clarify institutional roles, and integrate medical device and IVD regulations into the national health strategy. These recommendations ensure access to safe, effective, quality-assured medical devices and IVDs, advancing Zimbabwe's UHC goals by 2030.

This research evaluates Zimbabwe's regulatory framework for medical devices and IVDs, identifying significant gaps and inconsistencies. Utilising a systematic approach, it offers evidence-based insights and comprehensive policy recommendations. Addressing a notable gap in the literature concerning medical device regulation in low- and middle-income countries, the study enhances understanding of optimising regulatory frameworks for healthcare product quality and safety. If adopted, the recommendations could improve the regulatory environment for medical devices and IVDs in Zimbabwe by defining standards, ensuring consistent enforcement, and clarifying institutional roles. These enhancements could increase access to safe and effective medical devices and IVDs, supporting Zimbabwe's UHC goals by 2030. The study also underscores the need for integrated, harmonised regulations aligned with national health strategies and emphasises the importance of policymakers addressing these issues.

Conflict of Interest

The authors declare that there are no conflicts of interest regarding the publication of this article. All authors have no financial, personal, or other relationships with organisations that could inappropriately influence or bias the work presented in this study. The research was conducted

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