UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

FACULTY OF HEALTH SCIENCES

CANDIDATE'S SURNAME: CASSIM		FIRST NAME/S: AISHA	STUDENT NUMBER: 721207
CURRENT QUALIFICATIONS: BPharm (Honours)			
TEL: N/A	CELL: 0813057005	EMAIL: aisha695@gmail.com	FAX: N/A
DEGREE FOR WHICH PROTOCOL IS BEING SUBMITTED: Master of Science in Medicine (Pharm. Affairs)			
PART-TIME OR FULL-TIME: Part-Time			
FIRST REGISTERED FOR THIS DEGREE:	TERM : 01	YEAR: 2023	
DEPARTMENT: Pharmacy and Pharmacology			
TITLE OF PROPOSED RESEARCH: EXAMINING THE EFFICIENCY OF MEDICAL DEVICE REGISTRATION IN SOUTH AFRICA SINCE THE ESTABLISHMENT OF THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY			
CANDIDATE'S SIGNATURE:			DATE: 13.08.2025
SUPERVISOR 1 (NAME & SURNAME): Dr Stephanie Leigh			100% Supervision
SUPERVISOR'S QUALIFICATIONS: B. Pharm, M. Pharm, PhD			
SUPERVISOR'S DEPARTMENT: Pharmacy and Pharmacology			
SUPERVISOR'S ADDRESS / TEL / E-MAIL: Office 8M10, Department of Pharmacy and Pharmacology, 7 York road, Parktown, Johannesburg, 2198 / 011 717 2268 / Stephanie.derapper@wits.ac.za			

SYNOPSIS OF RESEARCH:

Introduction: With the Medicine and Related Substances Amendment Act 14 of 2015 implemented as law, it has amounted to significant changes for Medical Devices regulations in South Africa. More specifically, this meant the establishment of the South African Health Products Regulatory Authority (SAHPRA). These changes were significant milestones for the health sector in South Africa and allowed for a dedicated regulatory framework for medical devices. Whilst the South African government has established SAHPRA and provided for deliberate attempts to improve on the medical device regulation in the country, areas for medical device regulation improvement remain.

Aim/s: To assess the efficiency of the medical device registration process in South Africa by understanding manufacturer awareness of the regulatory framework and exploring operational challenges faced during the registration process.

Proposed Methodology: A quantitative, exploratory research design has been selected for this research. The population of this study consists of Medical Device Manufacturers (which may or may play the role of importers and/or distributers). The population selected will consist of those working in the public and private sector. By means of the questionnaire / survey tool.

Expected Outcomes: The study expects to gain insight on how far the South African Regulatory Framework for medical devices has come since inception in 2015, the challenges still faced and how the system can be improved to ensure patient access to safe medical devices.

WITS ETHICS NOT REQUIRED: Yes No WITS ETHICS PENDING: Yes (No) WITS ETHICS APPROVED: (Yes) No (circle appropriate symbol)* ***Please note the final human ethics clearance certificate or animal ethics certificate must be available prior to starting research**		IF Y SUPPLY ETHICS CLEARANCE CERTIFICATE AS ATTACHMENT AND INCLUDE ETHICS NUMBER HERE:
As supervisor/s, I/we confirm that I have read the protocol which has been submitted for assessment.		
SIGNATURE OF SUPERVISOR/S:		
SIGNATURE OF HEAD OF DEPARTMENT:		
SIGNATURE PG OFFICE STAFF ……..	REGISTERED YES….. NO…..	STAMP

EXAMINING THE EFFICIENCY OF MEDICAL DEVICE REGISTRATION IN SOUTH AFRICA SINCE THE ESTABLISHMENT OF THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

AISHA CASSIM

721207

Research Dissertation Supervised By

Dr. Stephanie Leigh

Submitted to the Faculty of Health Sciences, University of the Witwatersrand, in fulfilment of the requirements for the degree of Master of Science in Medicine, Pharmaceutical Affairs, MSc (Pharmaceutical Affairs)

Johannesburg, 2025

Declaration

I, Aisha Cassim, declare that this dissertation submitted to the University of Witwatersrand for the degree of Master of Science in Medicine (Pharmaceutical Affairs) has not previously been submitted for any degree or examination at any other University. This dissertation is my own unaided work, except for cases in which the work of others has been cited and duly acknowledged within the context of the dissertation.

12 August 2025

Mrs Aisha Cassim

Date

Dedication

This dissertation is dedicated to my husband, Fayaaz, my daughters, Maariyah and Zakiyyah and my parents who have played instrumental roles in my career and the pharmacist I am.

Acknowledgments

I would like to express my sincere appreciation and gratitude to a few people who inspired, motivated and supported me through my studies

1. To my dear and beloved family for their ongoing love, support, patience, guidance and inspiration.
2. Dr Stephanie Leigh for her tremendous support, encouragement, mentorship and assistance in compilation of my research report and article.

Abstract

Background: With the Medicine and Related Substances Amendment Act 14 of 2015 implemented as law, it has amounted to significant changes for Medical Devices regulations in South Africa. More specifically, this meant the establishment of the South African Health Products Regulatory Authority (SAHPRA). These changes were significant milestones for the health sector in South Africa and allowed for a dedicated regulatory framework for medical devices. Whilst the South African government has established SAHPRA and provided for deliberate attempts to improve on the medical device regulation in the country, areas for medical device regulation improvement remain.

Aim: To assess the efficiency of the medical device registration process in South Africa by understanding manufacturer awareness of the regulatory framework and exploring operational challenges faced during the registration process.

Methods: A quantitative, exploratory research design has been selected for this research using a self-administered questionnaire. The research targeted medical device manufacturers which may or not also be licensed importers and distributers, within South Africa and with a SAHPRA establishment license. There are 708 registered medical device manufactures but only 354 had contactable information made public, and therefore, we expected 185 respondents. Response rate though was very low for this research study and only 50 responses were received.

Results: As the objective of this research was to assess the efficiency of the medical device registration process in South Africa, through determining knowledge and perceptions of manufacturers and challenges they face, the results of this study indicated that majority of participants have been employed within the medical device industry between ten to fifteen years (n=15;33.3 %), enabling them to make a comprehensive comparison of the regulatory framework for medical devices in South Africa from a pre- and post-SAHPRA era. Through the survey responses received, medical device manufacturers acknowledge that an established framework exists with respective guidelines available for reference throughout the registration and licensing process. Gaps and challenges still exist ranging from lack of resources to delays in registration, contributed to by various factors.

Conclusion: The comparative analysis of the perceptions and knowledge of the medical device regulatory framework in South Africa and the challenges faced by medical device manufacturers, which were the focus of the study, described in this report demonstrates a significant level of understanding and growth in the regulatory evolution in the country since the inception of SAHPRA. From the study, majority (n=39; 86.6%) are familiar with the Medical Device Regulation in South Africa and of that, n=34;75.5% acknowledge that guidelines are available to ensure that correct processes are followed when registering medical devices. The adoption of and alliance with global regulatory requirements has allowed SAHPRA to control quality and safety of medical devices on the market and to somewhat close gaps with global regulatory authorities. Medical device manufacturers in South Africa are optimistic that with the growing industry and a clear indication of problem areas within the framework and regulatory organisation, positive strides will be made. To build a regulatory climate that fosters innovation and growth while guaranteeing patient safety, medical device manufactures emphasize the need for SAHPRA to address challenges and work closely with all stakeholders.

TABLE OF CONTENTS

.

List of Abbreviations

EU	European Union
EMA	The European Medicines Agency
FDA	Food and Drug Administration
GCP	Good Clinical Practices
GDP	Gross Domestic Profit
GMP	Good Manufacturing Practices
ISO	Internation Organization for Standardization
IVD	*In vitro* Diagnostics
MCC	Medicines Control Council
MDR	Medical Device Regulation
MRA	Medicine Regulatory Authority
MvPI	Materiovigilance Programme of India
NHI	National Health Insurance
PFMA	Public Finance Management Act
PMA	Pre-market Approval
PMS	Post-market Surveillance
RRA	Recognised Regulatory Authority
R&D	Research and Development
SAHPRA	South African Health Products Regulatory Authority
SFM	Substandard and Falsified Medical Devices
TGA	Therapeutic Goods Administration
WHO	World Health Organisation

List of Tables

CHAPTER 1

This introductory chapter explains the background and rationale for the study. It provides context on the medical device registration process in South Africa, including the evolution of the process since the enactment of the Medicine and Related Substances Amendment Act 14 of 2015 and the establishment of The South African Health Products Regulatory Authority (SAHPRA).

1.1 Background

A medical device is any instrument, apparatus, implement, machine, appliance, implant, and reagent for *in vitro* use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose (WHO, 2024). As with medicines, medical devices are essential for patient care. Illegal reprocessing and re-packaging of syringes for sale, equipment that does not meet minimum quality standards, nor the inability to provide post market surveillance of medical devices are serious concerns facing developing countries (Das et al., 2020). Regulatory frameworks describe the details for design, development and manufacture of medical devices so that products for retail are safe, effective and of good quality. This allows for limited importation of products that pose risks to patient healthcare (Saidi and Douglas, 2019).

Medical devices play an important role in the healthcare industry, facilitating the diagnosis, prevention, monitoring, and treatment of various medical conditions. These devices range from everyday items like bandages to sophisticated diagnostic machines. Medical devices are classified based on their intended use, potential risks, and complexity. The classification systems generally follow a risk-based approach. Within the South African Regulatory Framework, a medical device, other than an IVD medical device, has the medical device classification applying under the classification rules set out in the Classification Rules for Medical Devices (SAHPRA, 2019).

1.2. Medical device regulation practices

1.2.1. Historic evolution

For the fundamental function of safe prevention, treatment and diagnosis of disease and illness of medical devices to be materialised, medical devices must fulfil the function that they were designed for, whilst simultaneously, avoiding any patient harm (SAHPRA, 2019). According to the WHO, in 2017, the approximate failure rate of substandard and falsified medical products in low- and middle-income countries was 10.5% (WHO, 2017). As of December 2024, WHO stipulated that countries spend an estimated US$ 30.5 billion per year on substandard and falsified medical products. Stringent medical device regulation is thus needed to achieve higher quality and more affordable medical care (WHO, 2017). Historically, substandard and falsified medical devices (SFMs) have been described with different terminologies such as counterfeit, fake, and poor quality, all of which are still used somewhat interchangeably in literature. Substandard medicines are, however, now defined by the WHO as "authorised medical products that fail to meet either their quality standards or specification, or both" whilst falsified medicines are defined as "medical products that deliberately/fraudulently misrepresent their identity, composition or source" (WHO, 2018). The ways in which SFMs can impact on the health, economic and social status of a population or community is countless. For patients not receiving effective treatment, the likelihood of remaining ill for longer is higher with an increased risk of morbidity and mortality (Salami et al., 2023). Specifically, with regards to infectious diseases, treatment failure may also increase the risk of transmission to other individuals. The magnitude and direction of these impacts must be understood to inform public policies and design them to protect the most vulnerable patients from SFMs (Salami et al., 2023).

In an attempt to address the issue of SFMs, the WHO implemented coordinated political and technical responses (Salami et al., 2023). The Member State mechanism, as a political response, was established to facilitate global collaboration among WHO Member States. It aims to promote and reinforce national and international efforts to prevent, detect and respond to substandard and falsified medical products and The WHO Global Surveillance and Monitoring System (GSMS), as a technical response is a comprehensive initiative launched in 2013 to enhance the detection, reporting and response to substandard and falsified medical products. Together, the Member State

mechanism and GSMS provide a comprehensive framework for addressing the complex challenge of substandard and falsified medical products, enhancing global public health safety (WHO, 2024). Since the early 1980s, the regulatory paradigm for medical devices has changed remarkably (Shivali and Arpana, 2020). After the development and before the distribution of medical devices into the market, licensing is required by respective regulatory authorities globally. The legislation sets out what are known as the essential requirements, the core elements and procedures that companies need to have in place. It also sets out and defines the conformity assessment processes, including how independent bodies will assess whether a device is in conformity with the directives and outlines meticulous obligations on the part of manufacturers. There is a swift change in the worldwide regulation of medical devices, as the manufacturers are forced to accomplish the regulatory requirements, documented standards, norms, guidelines, specifications, testing methods for the design, and manufacturing of devices.

The use of substandard medical devices poses challenging safety issues to patients (WHO, 2024). According to a study conducted by Ferner and Aronson in 2020, a large portion of medical device faults arise during the design stage (over 70%), with a smaller percentage occurring during manufacturing (25%) and usage (less than 5%). Enhanced pharmacovigilance systems, with increased end-user involvement and training and awareness amongst healthcare professionals are regulatory strategies that can positively influence the monitoring and reduction of substandard medical devices (Ramachandran, 2024). In an attempt to improve the regulatory environment globally, the new EU Medical Device Regulations (MDR) have introduced stricter requirements for market introduction and post-market surveillance, including the establishment of the EUDAMED database for implant safety (Egbosimba, 2019). The Materiovigilance Programme of India (MvPI) was launched to monitor adverse events associated with medical devices, leading to increased reporting and awareness among stakeholders. This program aims to generate safety data and improve regulatory practices (Shukla *et. al,* 2020). Effective regulatory frameworks, harmonised to international standards, are critical to expanding access to quality medical devices in low- and middle-income countries. However, the level of regulatory establishment is positively correlated with gross domestic product and years of freedom from colonization, and less positively correlated to GDP per capita (Hubner

et. al, 2021). African medical device regulations have an affinity to European directives, despite the latter being particularly strict (Saidi and Douglas, 2019). Harmoniation across continents could optimize the costs of device manufacture and sale and regulated open design strategies can enhance economically sustainable innovation (De Maria e*t. al,* 2018).

Prior to the establishment of SAHPRA in South Africa, the regulatory scope of the MCC was primarily medicines and electro-medical devices. The regulation of medicines included evaluating the quality, safety, and efficacy of medicines before granting marketing authorisation and the regulation of clinical trials for both registered and non-registered medicines, ensuring that trials met ethical and safety standards (Strugo *et. al,* 2011). The MCC also, through its Clinical Trials Committee, was responsible for reviewing clinical trial applications to ensure compliance with good clinical practice (GCP) standards. Through its regulation of medicines, the MCC conducted inspections to ensure that pharmaceutical manufacturing facilities adhered to GMP standards to further ensure the quality and safety. The registration process for medicines was detailed and required comprehensive documentation, including nonclinical safety assessments (Feraoun and Feraoun, 2013). Unlike medicines however, medical devices were not lengthily regulated by the MCC. There were no regulations governing the sale and use of most medical devices, except for electro-medical devices. The absence of a dedicated regulatory framework for medical devices meant that there was no formal process for the registration, market authorization, or post-market surveillance of these products. The impact of this, led to concerns about the quality, safety, and efficacy of medical devices available in the market, potentially putting patients at risk (Saidi, 2016). Aiming to address the regulatory gaps left by the MCC, the significant disparities in oversight of medicines and medical devices and to ultimately improve the efficiency and regulation of medical devices, was the enactment of new laws and the establishment of the SAHPRA.

1.2.2. Current medical device regulatory landscape

In response to the high availability and access of medical devices that do not meet quality standards, Compliance and Risks, a South African business with experience in designing, developing and implementing compliance frameworks and processes in

both large and small organisations conducted a study on Global Regulatory Trends for Medical Devices. From this study, it was inferred that global regulations enforcing the management of the medical device industry, has grown by 64% in since 2015 (Compliance & Risks, 2023). Looking at the current global regulatory landscape, The Food and Drug Administration (FDA) in the United States of America, is responsible for ensuring the safety and effective nature of a medical device. The FDA regulates the ability of manufacturers to market devices within the United States (US FDA, 2017). Medical devices undergo the FDA regulation process to market through either of three routes: Premarket Notification, Premarket Approval (PMA) or Humanitarian Device Exemption (HDE). The FDA is currently following post-market surveillance techniques to improve patient access to safe medical devices. (Lauer et al., 2017) In Europe, the legislation sets out essential requirements, which are elements and procedures that companies should have in place, it defines the conformity assessment process and also sets out obligations on the part of manufacturers. The legislation specifies notified bodied to assess devices and competent authorities which are organisations that govern clinical trials and oversee post-marketing surveillance. The European regulatory system follows a risk-based assessment of medical devices (Wizemann, 2010).

The regulation and registration of medical devices in African countries exhibit significant variability and face numerous challenges (Nasir *et. al,* 2023). The regulatory frameworks for medical device licensing and registration vary across different African countries due to factors such as economic status, regulatory establishment, and legal frameworks (Hubner *et. al*, 2021). A key difference in licensing and registration approaches for medical devices in African Countries is that the regulatory establishment for medical device licensing is positively correlated with Gross Domestic Product (GDP) and years of freedom from colonisation (Hubner et. al, 2021). Most African countries mandate medical device regulation in national legislation, but few employ all the guidelines set forth by the WHO (Hubner *et. al,* 2021). The lack of clear information regarding participating countries' registration processes and requirements, as well as lengthy registration times, are challenges faced by collaborative medicines registration initiatives in Africa (Sithole *et. al*, 2022).

In South Africa, since the Medicine and Related Substances Amendment Act 14 of 2015 has become law, it has steered changes for the regulatory framework of

Medical Devices with the Act enforcing for the establishment of the South African Health Products Regulatory Authority (SAHPRA). These were incredible milestones for in South Africa and facilitating a committed regulatory system (Saidi and Douglas, 2018). The amendments in law applied to all medical device companies, whether they manufacture, sell, import, export, distribute and/or wholesale medical devices with a phased approach for the regulation of medical devices introduced (Saidi and Douglas, 2018). As of 2025, no medical devices, except those that are non-sterile, non-measuring Class A devices can be manufactured, distributed or imported and exported without a SAHPRA medical device establishment license (SAMRC, 2022). These products undergo evaluation by SAHPRA using reliance pathways for registration and marketing of medical devices using prior regulatory approval from other jurisdictions, including Australia, United States and the European Union.

1.3. The role of Medical Device manufacturers

Due to the variety and complexity of medical devices, their intended use, and resultant risk to patients, the medical device industry is one of the most highly regulated sectors in the world (Byrne, 2020) and with the growing economy of medical devices, the industry has attracted the attention of many. Like healthcare, the medical device market is entering a transformative phase, spearheaded by technological innovations and global healthcare challenges (Matcha, 2023). Medical Device markets in the USA, EU and Japan not only represent some of the largest economies in the world, but they also have advanced regulatory systems that directly influence the practices adopted by other countries, particularly in aspects such as definition and classification, nomenclature, approval procedures and post-market requirements (Amaral *et. al,* 2024). The global medical technology (MedTech) industry was valued at approximately half a trillion US dollars in 2019 (Palatino, 2023). The U.S. holds about 40% of the global market, valued at $170 billion, while Europe holds about 30%, valued at $110 billion. China's MedTech market is about 10% of the global market, valued at $53.6 billion, and is growing rapidly at a rate of 20-25% per year (Hospodkova *et. al,* 2018).

The development of medical devices is a complex process that involves several stages, from the initial research and design phase to regulatory validations (Ocampo and Kaminski, 2019). These stages include material selection and preparation,

forming and shaping, heating and welding, machining and assembly, sterilisation and packaging (Sun *et. al,* 2020). Documentation and traceability, environmental monitoring, quality management systems, process validation, regulatory compliance and post-market surveillance are amongst the crucial regulatory requirements to ensure compliance monitoring of medical devices (Karthika and Vijayakumar, 2022). The market for medical device sales varies greatly from region to region, with individual opportunities and challenges due to different healthcare systems and regulatory burdens. The regulatory landscape, market growth, and challenges faced by medical device manufacturers are critical factors influencing the industry (Amaral *et. al,* 2024). The emerging trends in medical device manufacturing include the development of new devices and electronic-health services, as well as the impact of regulatory changes such as the European Union Medical Device Regulation (Tonks, 2024). Medical device manufacturers face new and complex business challenges, including global product development, outsourcing of design and manufacturing, and the need to comply with strict regulatory requirements imposed by governing agencies around the globe (Dwarakanath *et. al,* 2020)

1.4. Study Rationale

Despite the evolution of SAHPRA from the MCC in 2017 as a dedicated regulatory authority for medical devices, medical device manufacturers continue to experience challenges with the regulatory process (Dureja and Dhiman, 2021). These challenges include unclear regulatory expectations, and limited engagement with SAHPRA. While international agencies have adopted streamlined pathways such as reliance mechanisms and accelerated approvals, it is unclear whether South Africa's regulatory framework has adequately addressed manufacturers' concerns (Xu *et. al,* 2022). This study investigates the efficiency of medical device registration in South Africa, focusing on manufacturers' knowledge, perceptions, and key bottlenecks in the regulatory process.

1.5. Research Question

What are the key challenges and perceptions amongst medical device manufacturers regarding the registration process in South Africa and how can this be improved?

1.6. Study Aim and Objectives

1.6.1. Aim

This study aims to assess the efficiency of the medical device registration process in South Africa, through understanding the bottlenecks and challenges faced by medical device manufacturers, in their attempt to attain approval for medical devices.

1.6.2. Objectives

Through the following study objectives, the study aim will be realised:

a) To assess the level of awareness and understanding among Medical Device manufacturers regarding the regulatory framework for device registration in South Africa

b) To explore manufacturer experiences and perceptions of the key operational challenges encountered during the registration process

CHAPTER 2

The regulatory environment governing the medical device industry in South Africa has undergone significant change following the establishment of South African Health Products Regulatory Authority (SAHPRA) in replacement of the Medicines Control Council (MCC) in 2017. Medical device manufacturers continue to express difficulties in navigating the approval process for their products, despite the expectation of improved regulatory performance and increased efficiency by SAHPRA (Saidi and Douglas, 2018). This chapter provides a review of the literature concerning the development of medical device regulation, contrasting SAHPRA processes with global best practices and highlighting obstacles that affect effectiveness. This review further aims to define the elements impacting medical device regulation in South Africa and the possible avenues for improvement by considering the body of research on regulatory timescales, stakeholder viewpoints, and policy adjustments.

2.1. Regulatory Framework Evolution

The MCC was established in 1965 under the Medicines and Related Substances Act 101 of 1965 to ensure the regulation of health products in South Africa (Feraoun and Feraoun, 2013). With the establishment of the MCC in 1965, it denoted, for the first time, pharmaceutical regulation in South Africa with further creation of the National Research Ethics Council and the Informal Clinical Trial Network (Strugo *et. al*, 2011). The MCC prioritised the evaluation of medicines for quality, safety, and efficacy before market authorisation to ensure that only safe and effective medicines are available to the public. Through its Clinical Trials Committee, the entity conducted inspections to ensure compliance with good manufacturing and clinical practices (Keyter *et. al,* 2018). The MCC operated under the Medicine Regulatory Authority (MRA) cluster, which included units for Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) inspections (Strugo *et. al*, 2011). During the MCC era of regulatory control, guidelines were reported as substandard with challenges including limited pre-market testing, reliance on international certifications, and limited processes for post-market monitoring and reporting of adverse events (Keyter *et. al,* 2018). Inadequate funding, personnel, and technical expertise to perform regulatory functions were amongst other challenges that the MCC faced and contributed to its lack of adequate regulation of medical devices (Feraoun and Feraoun, 2013). Together with this, the

MCC also faced challenges with lengthy approval timelines compared to other regulatory authorities of similar size, which ultimately highlighted the need for improvements in regulatory processes such as facilitated regulatory pathways and enhanced transparency (Keyter, 2019).

The MCC, during its operation was predominantly focused on the regulation of pharmaceutical products. It was responsible for evaluating all medicines through a registration process before granting marketing authorisation based on evidence of quality, safety, and efficacy (Feraoun and Feraoun, 2013). Prior to the enactment of the Medicines and Related Substances Amendment Act of 2015, there were no specific regulations that governed the sale and/or the use of medical devices in South Africa, except for electro-medical devices which were regulated by Radiation Control, an agency of the Department of Health and therefore, a classification system for medical devices in South Africa was historically absent, with only electro medical devices being regulated (Saidi, 2016). The Medicines and Related Substances Control Act No. 101 of 1965 primarily focused on the regulation of medicines, including new chemical entities, generics, and biological medicines, but did not comprehensively cover medical devices and whilst the regulatory framework for medicines was more established, with detailed guidelines and requirements for registration and amendment, the same did not exist for medical devices (Kanfer, 2017). The consequence of this was a regulatory gap where medical devices were not subject to the same rigorous controls as medicines. Due to the absence of structured guidelines for medical device, they were often managed on an ad-hoc basis without specific guidelines or standards (Kanfer, 2017). It wasn't until the passing of Medicines and Related Substances Amendment Act 72 of 2008 that a fully regulated medical device framework was introduced which aimed to introduce a structured regulatory framework for medical devices, impacting their regulation in several ways.

Licensing and market authorisation of medical devices under the MCC required only a basic registration process for medical devices, which involved minimal oversight (Tomlinson, 2020). This process was relatively straightforward and did not involve extensive regulatory scrutiny (Keyter *et. al,* 2019). Historically, under the MCC, South Africa did not have a comprehensive pre-market approval system for most medical devices. This allowed manufacturers and distributors to sell products without undergoing a formal evaluation process (Saidi, 2016). GMP certification for medical device manufacturers in South Africa was encouraged but was not mandatory (Saidi,

2016). This was in line with the broader regulatory framework which emphasizes quality assurance but does not impose GMP certification as a compulsory requirement for market authorisation. A consequence of the lack of regulations that governed medical devices, was that there were no stringent controls over the import and export of these products. This further lead to the use of substandard medical devices, posing risks to public health (Saidi, 2016). It was due to these challenges that SAHPRA was created to improve the efficiency and effectiveness of regulatory operations in South Africa.

2.2. Establishment of SAHPRA

The South African Health Products Regulatory Authority (SAHPRA) was established through the legislative framework provided by the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended. The pertinent amendment that forced the creation of SAHPRA was the Medicines and Related Substances Amendment Act 14 of 2015 (Saidi and Douglas, 2018). The implementation of the Medicines and Related Substances Amendment Act 14 of 2015 lead to changes in the regulatory review process and the introduction of facilitated regulatory pathways (Keyter, 2019). The most critical step introduced by SAHPRA with the regulation of medical devices was the introduction of a tier-based licensing and registration system which directly influenced ensuring the safety, efficacy, and quality of medical devices in South Africa (Saidi, 2015), in addition to other pivotal components including the restriction on bonusing and sampling for the sale of medical devices with the resolute aim of emphasising ethical sale practices.

2.2.1. Medical Device Classification and Registration

SAHPRA classifies medical devices based on principles surrounding risk, a classification system which involves assessing the risk profile, device complexity, and intentions and indications for use to determine the appropriate regulatory pathway for premarket clearance (Gadodia, 2023). Devices are categorised into different classes, with higher-risk devices requiring more stringent regulatory scrutiny (Fiedler, , 2017) This classification is crucial for determining the appropriate regulatory path and ensuring that all quality conditions are met (Saidi, 2016). Globally, with a focus on safety, effectiveness and risk assessment, the EU MDR employs a similar risk-based classification system for medical devices (Bretthauer *et. al,* 2023). Both SAHPRA and

the EU MDR aim to ensure that medical devices are classified based on their potential health risks and that manufacturers comply with the regulatory requirements for device testing and assessment. Whilst it can be said that SAHPRA's risk-based classification of medical devices are in alignment with international standards, specifically WHO guidelines, which emphasize risk assessment and safety considerations, specific differences in the implementation and regulatory requirements may exist between SAHPRA and the WHO *Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices* guidelines, necessitating a detailed comparative analysis (Mooghali *et. al,* 2023). A risk-based classification system implemented by SAHPRA is accompanied by implications for healthcare workers and medical device manufacturers. Specifically for manufacturers, this system guides the regulatory pathway for premarket clearance, impacting the time course and resources needed for approval (Gadodia, 2023). Healthcare providers in South Africa are affected by the classification system too, as it directly affects and influences availability of devices, support, the use of new and already existing medical devices and ultimately with prices increases and significant changes to the market dynamics (Saidi & Douglas, 2015). SAHPRA has also been criticised by members of the medical device industry, who are of the view that the classification of medical devices would be more appropriately determined by their manufacturers, as they are experts in the field of medical technology (Michael and Mthiyane, 2016).

According to a guideline published by SAHPRA, SAHPGL-MD-04_v4 (Guideline for classification of medical devices and IVD's), to assist manufacturers, importers, distributors, and wholesalers in classifying medical devices (including non-IVDs and IVDs) for licensing and registration, medical devices are categorised into four risk classes:

- **Class A (Low Risk)** – Non-sterile devices with minimal patient interaction (e.g., bandages, wheelchairs).
- **Class B (Low-Moderate Risk)** – Devices that require some regulatory oversight (e.g., hypodermic needles, contact lenses).
- **Class C (Moderate-High Risk)** – Devices that require pre-market assessment (e.g., ventilators, infusion pumps).
- **Class D (High Risk)** – Devices with the highest potential risk (e.g., pacemakers, HIV diagnostic tests).

The incorporation of Artificial Intelligence (AI) in medical devices introduces complexities in regulatory compliance which include defining intended use, mitigating data bias, and ensuring transparency and accountability. (Balogun and Luetge, 2025) AI-driven medical devices, which can be considered as Software as a Medical Device (SaMD) adds layers of complexity that necessitate careful consideration of ethical, legal, and clinical validation aspects to ensure patient safety and device efficacy. (Balogun and Luetge, 2025) The available guidelines provide limited direct information on the specific classification of AI-driven medical devices under SAHPRA regulations in South Africa however, they do highlight the need for updated regulatory frameworks, the challenges posed by the lack of specific legislation, and the importance of a national policy framework to address these issues. Currently, there are no explicit details on the classification process according to SAHPRA. This a gap in the regulatory framework of medical devices that can or should be explored further.

2.2.2. Licensing Requirements for Market Access

All companies involved in the manufacture, distribution, or importation of medical devices must obtain an establishment license from SAHPRA (Saidi and Douglas, 2018). This license ensures that the establishment complies with the necessary regulatory standards and quality management systems, and no medical device may be manufactured, distributed, imported, exported, or sold without a valid SAHPRA medical device establishment licence. As per SAHPRA's position statement on Class A Medical devices in September 2017, manufacturers, distributors and wholesalers of Class A medical devices, which do not have a measuring function and are not required to be sterile are exempt from obtaining an establishment license as a requirement for market access (SAHPRA, 2017). SAHPRA has issued a guideline for medical device licensing, SAHPGL-MD-07_v3, Guideline on Questions and Answers Licensing of Medical Device in which they outline the three types of establishment licenses exist for application based on the function of the company. These are:

a) Manufacturer license for such activities as packaging, labelling, servicing, or refurbishment of medical devices. This license covers manufacturing, import, distribution, and export activities,
b) Distributer license necessary for importing, exporting, or distributing medical devices and lastly,

c) Wholesaler license which applies to those procuring medical devices from local manufacturers and selling them to retailers or distributors, excluding the right to import or export.

The guideline document also highlights accompanying documentation that should be submitted with each application which are:

a) Cover Letter, prepared on a company letterhead, signed by the authorized representative, and addressed to the CEO of the Medical Device Unit. It should state the application's purpose and include a list of annexures and
b) Annexures, which include the Licence Application, Proof of Payment, Curriculum Vitae of the Authorised Representative, Quality Manual/Site Master File, and other relevant documents based on the type of application.

2.2.3 Pre-Market Approval for Medical Devices:

In an attempt to ensure that all medical devices entering the market are safe, effective, and of high quality, aligning with international standards and practices, SAHPRA require the submission of a Technical File/Dossier for pre-market approval of medical devices, which should include,

a) Establishing the risk classification of the medical device, which determines the level of regulatory control required,
b) Clinical data, which may be required to demonstrate the safety and effectiveness of the device. This is particularly important for higher-risk devices,
c) Proof of compliance with ISO 13485, which specifies requirements for a quality management system, is essential for manufacturers to access international markets, including South Africa, as it facilitates global harmonisation of medical device regulations (Jadhav and Shendge, 2024).

This standard ensures that the device consistently meets customer and regulatory requirements (Li and Zhang, 2020). The integration of ISO standards and conformity assessments has a significant impact on the regulation of medical products and play a crucial role in the registration and regulation of medical devices by SAHPRA, as it establishes a minimal benchmark for organizations to achieve accreditation or certification and maintain compliance to the core elements of the standard. (Gray, Ross & Badrick, 2022) ISO standards, particularly ISO 13485 are pivotal in harmonizing medical device regulations globally, making it easier for manufacturers to

access international markets such as India, Europe, and the USA (Jadhav and Shendge, 2024) The use of ISO standards helps achieve regulatory convergence, ensuring that medical devices meet consistent safety and efficacy standards across different jurisdictions (Imagawa, Mizukami and Miyazaki, 2018) The integration thereby also contributes to the pursuit of business excellence, which is essential for businesses operating in a global community, ultimately allowing companies to remain competitive and compete globally in their respective industrial sectors. Lastly, and if applicable,

d) SAHPRA may require evidence of regulatory approval from other recognised authorities such as the FDA, EMA, or TGA.

This can facilitate the approval process by leveraging existing evaluations and approvals (Keyter *et. al,* 2021) Amongst the benefits of integrating these standards, include enhanced quality assurance and ensuring that health products meet stringent quality standards, global alignment which facilitates mutual recognition and cooperation with other regulatory agencies, enhancing credibility and acceptance of assessments conducted by SAHPRA and ultimately risk management (Zgirskas *et. al,* 2021). Challenges such as the shortage of proficiency testing schemes and the need for a reference model for evaluating integrated management systems are also evident. Overall, the impact of this integration on the regulation of medical products by SAHPRA is significant, as it sets a benchmark for accreditation and certification, ultimately contributing to business excellence and global competitiveness.

2.2.4. Reliance-Based Registration Pathways:

The SAHPRA inherited a significant backlog of applications from the Medicines Control Council (Tomlinson, 2019). The median approval times for new active substances (NASs) varied significantly within The MCC with a median approval time of 1411 days in 2017 (Keyter et al., 2021). To reduce these timelines, SAHPRA has implemented several strategies, including the backlog clearance program initiated in 2019 which effectively reduced the median finalisation time to 68 days compared to 501 days (Moeti et al., 2023). Reliance-based registration pathways have been introduced with the intent to improve the efficiency and effectiveness of its regulatory processes (Rodríguez *et. al,* 2022). These pathways are designed to leverage the work and assessments conducted by other trusted, global regulatory authorities, thereby reducing duplication of efforts and expediting the approval of medical products, without

compromising on local compliance verification (Danks et. al, 2023). SAHPRA allows abridged assessments for devices already approved by the United States Food and Drug Administration (U.S. FDA), European Medicines Agency (EMA) and Australia's Therapeutic Goods Administration (TGA) (Moeti *et. al,* 2023). The introduction of facilitated regulatory pathways, such as abridged, verification review and recognition models, has led to a 68% reduction in approval times for backlog applications (Keyter et al., 2021). As per the SAHPRA 5.08 Reliance Guideline, issued in October 2021, these pathways can be defined as:

a) **Abridged review:** A streamlined review based primarily on unredacted assessment reports from a Recognised regulatory authority, replacing the need to evaluate all of the data (and summaries thereof) submitted in support of an application (SAHPRA, 2021).
b) **Verified review:** A streamlined review based primarily on verifying, instead of evaluating, information submitted in the application against information which has already been approved by SAHPRA or an RRA (SAHPRA, 2021). Unredacted reports are required for verified reviews as a fall-back option for evaluators.
c) **Recognition:** A streamlined registration / approval process based on directly recognising the outcome of a review from a recognised regulatory authority with which SAHPRA shares a recognition agreement (SAHPRA, 2021).

2.2.5. Post-Market Surveillance Requirements

SAHPRA's post-market surveillance requirements encompass several key components that contribute to patient safety and public health, while also presenting challenges and benefits for medical device manufacturers. Post-market surveillance aims to improve the safety of patients and users by reducing the reoccurrence of incidents related to medical devices (Mirel *et. al*, 2014). Amongst the key components of SAHPRA's PMS requirements, include the mandatory reporting of adverse events and recalls, annual licensing renewals and audits to ensure continued compliance and traceability regulations for all Class C and D medical devices, as they are high risk (Peer, 2016, Saidi & Douglas, 2015). The implementation of these requirements signifies a transformation in the regulatory landscape in South Africa, aligning it with global standards for medical device surveillance and vigilance (Kramer *et. al,* 2014). Regulatory bodies like the FDA require manufacturers to report adverse events and

maintain vigilance systems. The new EU Medical Device Regulation (MDR) emphasizes the importance of continuous compliance through periodic safety update reports and post-market surveillance reports and the need for enhanced traceability and monitoring of high-risk devices (Tecante & Sokija, 2022). This is part of the obligatory risk management for medical products Whilst implementing a post-market surveillance strategy can enable manufacturers to provide efficient safety to patients, interpretation of the requirements has been an issue for many manufacturers, posing a challenge to compliance (Quinn, 2022). Manufacturers in Japan must report adverse events and other safety issues to the regulatory authorities (Pfeiffer *et. al,* 2022). Implementing a post-market surveillance strategy can enable manufacturers to provide efficient safety to patients and therefore, manufacturers are encouraged to collaborate with various departments, including clinical research, R&D, senior management, and finance, to develop compliant post-market surveillance plans that meet regulatory requirements (Badnjevic *et. al,* 2022).

A national audit conducted by Mpofu et al. (2022) found that only 42% of high-risk device importers submitted post-market reports within the required timeframe. The study also noted the absence of a centralized adverse event reporting system, resulting in fragmented data collection. This gap not only undermines timely regulatory response but also increases the risk of patient harm due to delayed recalls or field safety notices.

Comparative studies in Egypt and Brazil have shown that integrated electronic PMS systems, linked to hospital records and national databases, have significantly improved signal detection and reduced device-related incidents (Azevedo & Hamdy, 2021). South Africa’s current reliance on voluntary reporting and manual documentation places it at a disadvantage, despite having a robust legislative framework. Additionally, industry feedback highlights operational constraints. In a qualitative study, Molefe and Dube (2023) reported that manufacturers perceive PMS in South Africa as "under-resourced and reactive," particularly when contrasted with the proactive surveillance seen in harmonised regions such as the EU and ASEAN.

These findings indicate that while South Africa has adopted global PMS principles, implementation challenges—including technological limitations and stakeholder buy-in—continue to limit its effectiveness.

2.2.6. Regulations Governing Ethical Sales Practices

SAHPRA enforces regulations to ensure fair marketing and ethical sales of medical devices through a comprehensive regulatory framework established by the Medicines and Related Substances Amendment Act of 2015 (Saidi and Douglas, 2018). These regulations include:

2.2.6.1. Restrictions on Bonusing and Sampling

The preceding regulation, the Medicines and Related Substances Control Act 101 of 1965, restricted bonusing and sampling of medicines only, but the new regulations include medical and IVD devices, which means that such devices cannot be supplied and sold in terms of a bonus, rebate or any other incentive scheme (Harrison and Kerbs, 2017). Under the new regulations, the practice of offering free products or incentives to healthcare professionals or procurement officials is explicitly prohibited (Saidi and Douglas, 2018). This measure aims to ensure that medical device sales are conducted ethically and without undue influence on purchasing decisions. Medical device manufacturers and distributors are also prohibited from freely distributing free samples to influence purchasing decisions. This measure aims to prevent unethical practices that could compromise the integrity of medical device procurement and usage. An exception to this rule is made for non-invasive, low-risk Class A devices. These devices may be provided for professional evaluation under controlled conditions. This exception allows healthcare professionals to assess the utility and effectiveness of such devices without compromising ethical standards. The regulations emphasize the importance of ethical sales practices in the medical device industry. By prohibiting bonusing and sampling, SAHPRA aims to prevent conflicts of interest and ensure that decisions regarding medical devices are made based on clinical efficacy and patient safety rather than financial incentives (Saidi and Douglas, 2018). The introduction of these regulations is seen as a positive step for the South African medical device industry. It aims to create a more transparent and ethical market environment, and the successful implementation of these regulations will depend on the support and compliance of all stakeholders involved. South Africa can benefit from

the experiences and practices of other countries that have introduced similar medical device regulations. This comparative approach can help refine and enhance the regulatory processes in South Africa. Similar restrictions on bonusing and sampling are observed in other countries with stringent medical device regulations. For instance, the European Union's Medical Device Regulation (MDR) also emphasizes ethical marketing practices and transparency in the distribution of medical devices (Kanti *et. al, 2022)*

2.2.6.2. Marketing and Advertising Controls

The SAHPRA has established regulations to govern the ethical sales practices of medical devices, particularly focusing on marketing and advertising controls. These regulations are part of the broader framework introduced by the Medicines and Related Substances Amendment Act of 2015, which marked a significant shift in the regulation of medical devices in South Africa (Saidi, 2016). There is an emphasis on the need for truthful and non-deceptive advertising. This includes ensuring that all claims made in advertisements are supported by scientific evidence and that the potential risks and benefits of the devices are clearly communicated to both healthcare professionals and consumers (Hagopian, 2019). Promotional materials must be approved by SAHPRA before dissemination and must comply with SAHPRA's Regulation 45 on Healthcare Advertising. This ensures that all advertisements meet the required ethical standards and do not mislead healthcare professionals or the public (Saidi, 2016; Saidi and Douglas, 2018).

2.2.6.3. Sales and Procurement Compliance

The SAHPRA plays a crucial role in ensuring that the procurement and sales of medical devices adhere to ethical standards and legal requirements. This includes compliance with the Public Finance Management Act (PFMA) and conducting audits to ensure adherence to ethical guidelines. Medical device procurement must comply with the PFMA, which governs financial management in the public sector to ensure transparency, accountability, and sound financial practices (Saidi and Douglas, 2018). The PFMA mandates that all procurement processes are conducted ethically and in a manner that promotes fair competition and value for money. There are specific guidelines governing the interactions between medical device companies and HCPs. These guidelines are designed to prevent conflicts of interest and ensure that

decisions regarding medical device procurement are based on clinical need and patient benefit rather than financial incentives (Citron, 2012). Table 2.1 summarises the key changes made to address the MCC's shortcomings through the establishment of SAHPRA.

Table 2.1. Key changes made to address the MCC's shortcomings through the establishment of SAHPRA

Regulatory Element	MCC (pre-2017)	SAHPRA (post-2017)
Classification system	No formal classification	Tiered risk-based
Pre-market approvals	Limited	Full regulatory approval process
Reliance on reliance pathways	Not utilised	Allows reliance pathways (FDA, EMA, TGA)
Post-market surveillance	Minimal	Mandatory adverse event reporting and product recalls
Manufacturing compliance	No formal GMP requirements	ISO 13485 compliance required
Licensing requirements	Basic registration	Establishment licensing for manufacturers, importers, distributors
Bonusing and sampling regulations	No restrictions	Prohibited under SAHPRA regulation

Whilst the enactment of these new regulations can, and should, bring a positive development for the medical device industry in South Africa, the impact depends immensely on the implementation of these regulations (Keyter *et. al,* 2018).

2.3. Efficiency Analysis

2.3.1. Transitioning to a registration system

The readiness for transitioning licensing timelines within the SAHPRA to a registration system can be assessed by examining the improvements and challenges in their regulatory processes. SAHPRA's efforts to improve medicine registration timelines through the risk-based approach process indicate a readiness to transition similar efficiencies to the registration system for medical devices (Moeti *et. al,* 2023). The regulatory considerations for aligning the timelines of medical device registration with the licensing of medicines involve the need for continuous process optimization and refinement to prevent recurring backlogs and ensure the timeous approval of safe and effective, quality medical devices (Moeti *et. al,* 2023). Regulatory considerations for aligning the timelines of medical device registration with the licensing of medicines

involve process optimisation, reliance strategies, and quality management systems (Ceyhan *et. al,* 2018).

The transition to the registration of medical devices by leading regulatory authorities such as the FDA and EMA involves several key lessons and practices that can be beneficial for other regions and stakeholders in the medical device industry (Kaule *et. al,* 2020). Both the FDA and EMA have developed common features over time, although significant differences remain. The FDA requires compliance with USA Federal Law and Federal Codes of Regulation, while the EMA focuses on compliance with the Essential Requirements and harmonised standards, while the new EU Medical Device Regulation (MDR) emphasizes clinical evaluation and investigation to ensure device safety and effectiveness (Prineetha *et. al*, 2020). The transition to new regulatory frameworks for medical devices in the European Union (EU), the United States (FDA), and Japan involves significant changes and challenges and is aimed at enhancing patient safety and device efficacy (Jokura, Yano & Yamato, 2018). While the EU's MDR introduces more stringent requirements, the FDA and PMDA also face challenges related to approval delays and safety assessments. The MDR imposes stricter requirements on clinical data, post-market surveillance, and CE-certification processes, which complicates the market entry for new and existing devices (Kaule *et. al,* 2022). The CE certification is a critical process for ensuring that products meet European safety, health, and environmental standards. It involves a detailed conformity assessment, technical documentation, and, in some cases, third-party verification. Despite challenges in enforcement, CE marking remains a key requirement for market access (Berensmann and Gratzfeld, 2018) The US FDA has faced criticism for delays in approving new devices, often due to additional clinical trial requirements to address safety concerns (Galigios, 2025). These delays highlight the FDA's cautious approach to ensuring device safety and efficacy. Japan's PMDA has a history of approving new drugs and devices faster than the FDA and EMA, but significant delays can occur due to additional clinical trial requirements and differing regulatory views on safety risks (Tenaka *et. al,* 2021)

Medical device regulation in African countries such as Kenya, Nigeria, and Egypt, as well as the emerging African Medicines Agency (AMA), is evolving but faces significant challenges. The regulatory landscape is characterized by varying levels of development, with some countries making strides towards comprehensive frameworks

while others lag behind. Both countries, Kenya and Nigeria are experiencing rapid changes in regulations to keep up with technological advancements. Regulatory and oversight processes in these countries are often inadequate, with limited pre-market testing and reliance on international certifications (Nasir et al.,2023) post-market monitoring and reporting of adverse events are also limited (Ekanoye and James, 2018) The AMA aims to streamline and harmonize medical device regulations across African nations. This initiative is crucial for addressing the disparities in regulatory frameworks and improving access to quality-assured medical devices (Hubner et al., 2018) The establishment of the AMA and the push for harmonized regulations are positive steps towards ensuring the safety and effectiveness of medical devices across the continent. However, substantial work remains to address funding, expertise, and implementation gaps.

The transition of medical device regulation in South Africa introduces several compliance complexities for stakeholders in the medical device industry. The new system, which requires registration and licensing based on risk classifications, the restriction of bonusing and sampling, which were all not common to the medical device industry adding another layer of compliance for manufacturers and distributors (Saidi & Douglas, 2018). Learning from international experiences and focusing on capacity building will be essential to navigate these challenges effectively. Collaboration among regulatory authorities and a proactive, comprehensive, and legally sound approach are essential for improving and strengthening medical devices and IVD regulations for improved patient safety (Chiku *et. al,* 2024). Whilst the transition of medical device regulation in South Africa presents challenges, impacts, and potential strategies for ensuring compliance, compliance with these regulations is crucial to protect patients and users, improve access to quality medical devices, and facilitate economically sustainable innovation (Saidi, 2016).

2.3.2. Anticipated challenges in expanding from licensing to full registration

Expanding from licensing to full registration by SAHPRA involves several anticipated challenges. These challenges can be categorised into regulatory, operational, and resource-related issues (Moeti, 2023). With regards to regulatory challenges, transitioning from licensing to full registration involves adhering to stringent regulatory

requirements, which can be complex and time-consuming (Sithole *et. al,* 2021). The need for harmonisation with international standards, such as the Common Technical Document (CTD) format, adds to the complexity. Implementation of Good Review Practices (GRevP) and ensuring consistency, transparency, and timeliness in the review process is crucial. SAHPRA needs to implement and monitor GRevP effectively, which includes adopting standardized templates and electronic management systems (Keyter *et. al*, 2021). In terms of operational challenges, SAHPRA has historically faced significant backlogs, which delay patient access to medicines. Although facilitated regulatory pathways have been introduced to address this, expanding these processes to routine reviews remains a challenge (Sithole *et. al*, 2021). Ensuring consistent and high-quality assessments across various applications is essential. Common deficiencies in submissions, such as issues with labelling and bioequivalence studies, need to be addressed to improve the quality of applications and reduce turnaround times (Moeti *et. al,* 2023). Lastly, resource-related challenges involve limited resources and technical capacity. Leveraging regulatory reliance and harmonization initiatives, such as the ZaZiBoNa and the Southern African Development Community (SADC) collaborative medicines registration initiative, can help mitigate resource constraints. However, challenges such as lack of clear information regarding registration processes and lengthy registration times need to be addressed (Sithole *et. al*, 2021).

2.4. Stakeholder experience

2.4.1. Industry perspectives on licensing processes and expectations for registration of medical devices

The perspectives of stakeholders—particularly medical device manufacturers—offer crucial insight into the effectiveness and real-world implementation of South Africa's evolving regulatory framework. While SAHPRA has introduced risk-based licensing, reliance pathways, and ethical marketing controls, empirical data suggests that manufacturers experience a disconnect between regulatory design and operational delivery. In a study by Dlamini and Sibiya (2021), medical device manufacturers in South Africa cited a lack of regulatory clarity, poor communication, and delays in approvals as the most pressing challenges. Despite the availability of guidelines, 71% of participants reported difficulty accessing up-to-date regulatory information,

while 59% noted inconsistent feedback from SAHPRA during application reviews. These findings align with the quantitative data from this study, where 40% of respondents identified prolonged approval times and 35.5% raised concerns about enforcement inconsistencies. Globally, stakeholder engagement is increasingly seen as a driver of regulatory efficiency. In Kenya, Nasir et al. (2023) reported that stakeholder workshops and digital submission portals contributed to improved compliance and shorter processing times. In contrast, Nigeria continues to face prolonged delays due to fragmented oversight and limited institutional transparency (Ekanoye & James, 2018). These comparisons reinforce the need for SAHPRA to invest in stakeholder consultation mechanisms and transparent communication to align policy implementation with user needs. Furthermore, Amaral et al. (2024) emphasized that regulatory efficiency is not solely a function of legal reforms but depends heavily on the collaborative interface between regulatory authorities and the industry. This perspective underscores the importance of not only strengthening internal capacity at SAHPRA but also fostering a proactive, service-oriented approach to regulatory support. Stakeholders should not only comply with the system but actively shape it through participatory dialogue, co-regulation, and continuous feedback.

2.5. Impact Assessment

2.5.1. Healthcare system impact

Transitioning to a registration framework for medical devices in South Africa is expected to bring several benefits to public health outcomes. The tier-based licensing and registration system are expected to improve the safety and quality of medical devices by ensuring that only devices meeting stringent safety and efficacy standards are approved for use (Saidi & Douglas, 2018). Effective regulatory controls will ultimately help eliminate substandard and potentially harmful medical devices from the market, thereby protecting patients and users (De Maria *et. al*, 2018). Additional public health benefits include better disease management and improved access to quality medical devices which can enhance the management of both communicable and non-communicable diseases, contributing to better overall health outcomes (Meyer *et. al*, 2017). Support for National Health Initiatives also will contribute to positive public health outcomes. The regulatory framework will support initiatives like the National

Health Insurance (NHI) by ensuring that medical devices used in public health programs are safe and effective, thereby improving the quality of care provided (Amaral *et. al,* 2024). This can be achieved through better diagnostics and treatments and an ultimate reduction in medical errors (Setswe *et. al*, 2016). Opportunities to improve access to safe and effective medical devices can be achieved through effective governance, collaboration, and cooperation between key stakeholders of the healthcare system. Investing in the training of biomedical engineers and establishing maintenance facilities can ensure the longevity and proper functioning of medical devices, which is critical for the sustainability of the NHI (Abdallah *et. al*, 2024). With the NHI being a new introduction to the South African healthcare system, and much doubt about its ability to be successful, the availability of advanced medical devices can increase public confidence in the healthcare system, which is crucial for the successful implementation of the NHI (Setswe *et. al*, 2016).

The impact of medical device regulation in South Africa extends beyond procedural compliance—it directly affects market access, patient safety, innovation, and healthcare equity. Despite policy intentions, the practical outcomes of SAHPRA's regulatory activities remain mixed.

Empirical research by Louw and Petersen (2023) showed that prolonged registration timelines contributed to stockouts of critical devices, particularly diagnostic tools and orthopaedic implants. Their study, based on procurement data from 12 public hospitals, reported delays of 6 to 12 months for newly registered devices, leading to increased reliance on outdated or alternative technologies. Additionally, smaller manufacturers—especially local innovators—face disproportionate regulatory burdens. A case study by Ndaba et al. (2022) on early-stage South African MedTech startups revealed that 75% of respondents viewed the current registration pathway as a barrier to innovation, citing unclear requirements and costly delays. This is consistent with the findings in the current study, where 33% of participants expressed that regulatory inefficiencies hindered market entry.

In contrast, India’s tiered approval system and subsidised support for domestic manufacturers has led to a 28% increase in registered low-cost devices over a five-year period (Bhatia & Rao, 2021). South Africa, by comparison, risks limiting access

to affordable technologies if regulatory inefficiencies persist—particularly in the public sector, which relies heavily on tenders and timely device availability.

Therefore, any assessment of SAHPRA's regulatory model must consider not only compliance and safety but also its socio-economic implications, particularly in terms of equitable access to essential health technologies.

2.5.2. Economic Impact

The licensing and regulation of medical devices significantly influence market dynamics and industry growth (Maci *et. al,* 2024). This occurs through regulatory influence and market expansion. Regulatory frameworks, such as the European Union Medical Device Regulation (MDR) of 2017, play a crucial role in shaping the market. Whilst the core of the framework aims to enhance safety and efficiency, they can impact market entry and competitiveness (Shatrov & Blankart, 2022). Technological advancements and increased healthcare spending have shown to allow significant market expansion of medical devices (Jiang *et. al*, 2020). Due to the rigorous testing and validations that are required for regulatory approvals, companies are compelled to develop high-quality, safe, and effective devices, leading to advancements in medical technology (Ghosh *et. al,* 2021). While regulations ensure safety and quality, they also pose challenges. The complexity and cost of compliance can be barriers for smaller companies and new entrants (Levin, 2023). Global market dynamics are affected by varying regulatory landscapes in different regions. The US regulatory environment is seen as more conducive to innovation compared to the EU, where the MDR imposes stricter requirements, and this can influence where companies choose to develop and launch new products (Van Norman, 2016). Understanding and navigating regulatory requirements is crucial for successful market entry and commercialisation. Companies must strategically plan their development processes to meet these requirements, which can impact their market positioning and growth potential (Pietzsch *et. al*, 2007).

By aligning with international standards, the regulatory framework can enhance the credibility of South African medical devices, potentially increasing their acceptance in global market and the establishment of clear regulations may encourage local manufacturing by providing a structured pathway for compliance and market entry

(Simon Ramaoka & Kraemer-Mbula, 2022). A clear and well-defined regulatory framework can provide local manufacturers with a structured pathway for compliance, reducing uncertainties and barriers to market entry. Whilst the benefits are significant for local manufacturers in South Africa, they face challenges such as inadequate funding, limited technical expertise, and gaps in pre-market and post-market regulatory processes (Nasir *et. al*, 2023).

2.6. Conclusion

Since the establishment of SAHPRA in 2017, significant strides have been made in improving the regulatory review process, specifically for medical devices, which previously under the MCC did not exist. The most critical change introduced by SAHPRA was the tier-based licensing and registration system, to directly impact the safety and efficacy and quality of medical devices that are introduced onto the South African market. The regulatory requirements for the registration of medical devices in South Africa have been significantly impacted by the Medicines and Related Substances Amendment Act 14 of 2015. SAHPRA's progress in licensing and preparations for registration for medical devices can be compared to other regulatory bodies globally, highlighting similarities and differences in regulatory processes. SAHPRA is working towards international harmonization and collaboration to align with global standards. By aligning with international standards, the regulatory framework can enhance the credibility of South African medical devices, potentially increasing their acceptance in global market and the establishment of clear regulations may encourage local manufacturing by providing a structured pathway for compliance and market entry. This includes learning from the experiences of other countries and adopting best practices to enhance regulatory performance. Despite these advancements, there are still challenges, such as the need for increased transparency and communication, and the necessity to address the backlog in the review of applications. Although the introduction and establishment of medical devices offers significant benefit to the industry and its manufacturers, the new system, which was previously not common to the industry, adds another layer of compliance for manufacturers and is adding complexities and added layers of compliance.

CHAPTER 3

This chapter outlines the research methodology that was used to conduct this study. It begins with a discussion on the chosen model and method detailing the study data collection methods, sampling strategy, and analytical techniques used to achieve its research objectives.

3.1 Research Methodology

A quantitative exploratory research design was selected for this research. Research design as explained by Creswell (2012) mentions the plan to conduct research and the strategies of inquiry and specific methods. Quantitative research involves the analysis of data that has been collected using statistics to expound a phenomenon (Creswell, 2009) or to establish a relationship between theory and research (Bryman, 2006). Quantitative research helps to test theories and uses surveys, interviews and data collection (Creswell, 2009). This research design allowed for engagement from medical device manufacturers about their understanding of the medical device registration process as well as areas within which they have challenges with SAHPRA and ultimately the registration process. With a quantitative research method approach, we can quantify how widespread specific challenges are, identify patterns and correlations and which factors are most strongly associated with bottlenecks and ultimately, it will allow for objective, data-driven recommendations.

3.2 Study Site and Design

The exploratory quantitative analysis of the current procedures, knowledge and perceptions will be conducted through medical device importers, distributors, wholesalers, and manufacturers. As of June 2024, there were 708 registered medical device manufacturers in South Africa that carried medical device establishment licenses from SAHPRA. To begin the study, evaluated the current, theoretical regulatory process in South Africa through the guidelines, timeframes and processes in place by SAHPRA particularly for design and development, manufacturing and distribution/retail. According to Creswell, a survey provides a quantitative account of trends and attitudes of a population just by examining a sample of the total population. From these results, we can make claims about the population. The objective is to test

the impact of a certain intervention on an outcome (Creswell, 2009). In this study, a survey was designed to allow the researcher to draw inferences about the functionality of the Medical Device framework in South Africa (Appendix B). The survey tool used was adopted from a study by Fufa et al., (2023) and the WHO benchmarking tool. The survey tool took approximately 15 minutes to complete. By evaluating and analysing responses by medical device manufacturers regarding the challenges they face and bottlenecks they experience with the registration process, this study drew conclusions about how the system has grown in enabling patient access to safe medical devices in South Africa as well as areas that still require improvement.

3.3 Population and Sampling

3.3.1 Population

The population of this study consisted of Medical Device Manufacturers (which may or may play the role of importers and/or distributors). The population selected consisted of those working in the public and private sector. All medical device manufacturers were approached for participation, despite how long they have been in operation or the number of facilities they have. For the purposes of this study, medical device manufacturers of all products that assist with healthcare, without any exclusion, that possess a SAHPRA establishment license were included in the study. The following inclusion and exclusion criteria were applied. A clear stipulation was made on the patient information sheet that only one person per company, employed within Regulatory Affairs or Quality Assurance, with knowledge on the registration of medical devices in South Africa and SAHPRA should complete the questionnaire.

3.3.2 Inclusion and Exclusion Criteria

3.3.2.1 Inclusion criteria

Regulatory and Quality Assurance professionals employed within Medical Device Manufacturing companies in South Africa, in both, the public and private sectors were included. The Medical Device Manufacturers included were those acting within the role of importers, distributors, wholesalers and/or retailers.

3.3.2.2 Exclusion Criteria

Excluded in this study were Regulatory experts, hospitals and Medical Device distributors and/or retailers that are not registered medical device manufacturers.

For the purposes of this study, regulatory professionals within manufacturing companies refer to those personnel employed to maintain regulatory licenses, ensure products meet specification and have the necessary approvals before manufacture and sale. Regulatory experts refer to personnel that are employed within regulatory authorities and/or regulatory auditors.

3.3.3 Sample and sampling method

Purposive sampling technique was used for this study as this technique allows the researcher to assess a particular subset of people, (Bryman 2012) in this case; medical device manufactures who met the inclusion criteria mentioned above were included.

3.4 Ethical Considerations

Ethics approval was obtained from Human Research Ethics Committee (Non-Medical) of the University of the Witwatersrand, Johannesburg, ethics clearance number, H24/08/04.

A study information document, wherein the purpose and description of the study is highlighted, the risks and benefits of participating in the study survey and the approximate time for completion of the study survey were generated and this brief description formed the body of all emails sent to participants with an attachment for the survey link. All participants were reassured of the anonymity and confidentiality of participation that will be maintained throughout the study.

3.5 Study Procedure

On receipt of Ethics Clearance, the survey was distributed to all medical device manufacturers that met the criteria of this study by the principal investigator. A link was provided to all participants that directed them to an anonymous Google Form Sheet that allowed them to provide consent for participation and complete the survey. Anonymity of participants was maintained throughout the data collection process. Participants were not required to offer personal details and on submission of the survey, participant details were not visible. All data collected were only analysed by the researcher and supervisor.

3.5.1 Validating the Tool

A pilot study was conducted amongst three pharmacists and one non-pharmacist for face and content validation and the survey tool was amended accordingly to feedback received. This process ensured that the questions were clear, relevant and interpreted consistently be respondents. The inclusion of a non-pharmacist was intended to assess whether the survey could be understood by individuals who may interact with the registration process but do not have any pharmaceutical background. Additionally, the pilot helped determine the average time required to complete the survey, which informed the final survey instructions and confirmed that the questionnaire was not overly time-consuming for participants.

3.5.2 Sample Size

Following sample size calculation, an expected 250 responses was expected based on a total population of 708 medical device manufacturers in South Africa. However, of the total 708 medical device manufacturers in South Africa, holding a SAHPRA establishment license, only 354 manufacturers had contactable information as a means to be reached for participation in the study. Based on this, and an expected response rate of 50%, the study aimed to achieve approximately 185 respondents.

3.5.3 Data Analysis and Interpretation

Categorical variables such as demographics, knowledge and perceptions of participants were analysed using simple descriptive statistics measuring numbers, frequency, and percentages. Normality of data was assessed using the Shapiro-Wilks test. Kruskal-Wallis tests were applied to determine differences in perceptions, knowledge and participation of medical device manufactures. The test was also used to check differences among years of experience and sector of employment.

CHAPTER 4

This chapter presents the results and discussion of the study. At the onset, we will present with the results and a brief description of the pilot study that was conducted. The results of the study will be presented in the form of an article, wherein the results section begins with an overview of the type of medical device manufacturers, followed by results obtained to address each study objective. This section then concludes with a discussion of the results presented, with references to the literature.

4.1 Pilot Study

The pilot study conducted involved the survey of three pharmacists and one non-pharmacist to conduct content and face validation as well as to determine an approximate time taken to complete the study survey. The survey consisted of three parts:

- **Part 1 comprising of two questions.**
  - Question 1 considered socio-demographic related questions and was broken up into six multiple choice sub-questions.
  - Question 2 was directed to medical device manufacturers to determine their company type and products manufactured, as well as their regulatory status. Question 2 consisted of 14 sub-questions.
- **Part 2** comprised of two questions, focusing on challenges faced in receiving medical device market approval in South Africa. These questions required participants to rate according to a prescribed scale the challenges faced from the list provided.
- **Part 3** of the survey also consisted of two questions, focused on access to safe medical devices in South Africa.

Part 1 ensured that the data collection would produce valid, useful insights related to our objectives and provided context for interpreting responses such as whether or not smaller or bigger companies experience more challenges. Part 2 aligns directly with our research objective in understanding the challenges faced in medical device registration. Part 3 investigates the access to safe medical devices which links to the broader, regulatory effectiveness, a key part of understanding the impact of delays or inefficiencies in registration.

For the pilot study, the survey questionnaire was emailed to each participant, and feedback was obtained via email.

The pilot study aligned closely with the overall objective of the research, which was to evaluate the knowledge of medical device manufacturers and determine the challenges faced, ultimately to improve the medical device registration process. The pilot study was used to test clarity, relevance and structure of the questionnaire, which included sections aimed at exploring the regulatory challenges in medical device approval.

Feedback received from participants led to meaningful refinements. Amongst the feedback received, one participant recommended changing wording from 'socio-demographic' to 'employment-related' questions as personal particulars were not requested. Another participant recommended that Question 5 be open-ended as some companies may be manufacturing more than one class of medical device. This helped to ensure that the final survey would effectively capture the complex experiences o stakeholders. Other recommendations made were grammatical. The survey was then amended accordingly, as per feedback and all participants confirmed that the survey was easily understood, and content was valid. All four pilot study participants also confirmed that the survey was completed within 10-15 minutes. This information was then shared with the research supervisor, and the survey amended for continuation of study. By confirming that the survey was easy to understand, appropriately structured and could be completed within a reasonable timeframe, the pilot study strengthened the reliability a3nd validity of the instrument used to generate data critical to achieving the study's objectives.

4.2 Article 1 - Original article entitled, "Examining the Efficiency of Medical Device Registration in South Africa since the establishment of the South African Health Products Regulatory Authority."

Examining the Efficiency of Medical Device Registration in South Africa since the establishment of the South African Health Products Regulatory Authority

Aisha Cassim and Dr. Stephanie Leigh

Department of Pharmacy and Pharmacology, Faculty of Health Sciences, University of the Witwatersrand, 7 York Road, Parktown 2193, South Africa

*CONTACT Stephanie Leigh: stephanie.leigh@wits.ac.za

ABSTRACT

Background: In South Africa, since the Medicine and Related Substances Amendment Act 14 of 2015 has become law, it has steered changes for the regulatory framework of Medical Devices. The Act allowed for the establishment of the SAHPRA. These were incredible milestones for in South Africa, and this facilitated a committed regulatory system. This applied to all medical device companies, whether they manufacture, sell, import, export, distribute and/or wholesale medical devices. A phased approach for the regulation of medical devices was introduced. Currently, there are no medical devices, except those that are non-sterile, non-measuring Class A devices that can be manufactured, distributed or imported and exported without a SAHPRA medical device establishment license. Whilst the South African government has enacted SAHPRA and the concerted effort to improve medical device regulation, there are challenges and areas for improvement.

Aim: To assess the efficiency of the medical device registration process in South Africa, through understanding the bottlenecks and challenges faced by medical device manufacturers, in their attempt to attain approval for medical devices.

Setting: This study was conducted amongst medical device manufacturers, retailers, wholesalers and distributors in both the private and public sector.

Methods: A quantitative exploratory research design was selected for this research. The study was conducted using a self-administered structured survey. Categorical variables were analysed using simple descriptive statistics.

Results: Participants have indicated familiarity with the medical device regulatory system in South Africa (86.6%), despite the size of company they are employed within. Whilst guidelines are available, 71.1% of participants indicated that communication of amendments is not done adequately by the entity. Despite familiarity with the system, participants predominantly have challenges with competent professionals within SAHPRA (33.3%), lengthy approval times for licensing (40%) and the lack of enforcement of the regulations (35.5%)

Conclusion: Medical device manufacturers show an understanding of the regulatory framework and a positive engagement to ensure the success of its implementation. Challenges faced by participants indicate the gaps in the system and the opportunities for improvement by SAHPRA.

1. Introduction

As with medicines, medical devices are essential for patient care (Fullbrook, 2007). Medical devices make up a wide range of products in healthcare, from simple syringes and bandages to electro-magnetic devices for diagnosis and treatments and are classified based on their intended use, potential risks, and complexity (Hernandez, 2019). Classification systems of medical devices generally follow a risk-based approach. For medical devices to prevent, treat and diagnose illness, they must fulfil the function that they were designed for, whilst simultaneously, avoiding any patient harm. Stringent medical device regulation is thus needed to achieve higher quality and more affordable medical care (WHO, 2017). Regulatory frameworks outline and stipulate the details for design, development and manufacture of medical devices so that products for retail are safe, effective and of good quality (Saidi and Douglas, 2019).

The South African landscape of medical device regulations has undergone tremendous evolution. Prior to 2017, under the guidance of the MCC, medical devices lacked a system that controlled its safety and quality, and manufacturers were at liberty to sell and import devices without any restrictions (Strugo *et. al,* 2011). There were no formal processes for registration, market-authorisation and post approval surveillance, as was with the regulation of pharmaceutical products (Saidi, 2016). With the introduction of The Medicines and Related Substances Act 101 of 1965 into law, this changed significantly for the industry (Strugo *et. al,* 2011). Together with the establishment of SAHPRA, an entity that now regulated medicines and medical devices within its scope, a proposed licensing and registration system was also introduced.

Since the introduction of these changes to the regulatory framework of medicines and medical devices, SAHPRA has made strides in aligning with global best practices (Keyter, 2019). From the implementation of a tier-based licensing system to the risk-based approach in medical device classification, the creation of guidelines for licensing and registration for the industry and the use of reliance-based pathways, SAHPRA has attempted to narrow all gaps within the framework previously under the MCC. Taking cues from global regulatory leaders in the field, like the USA, EU and Japan, SAHPRA has managed to establish a comprehensive system, however not without challenges.

The enactment of new regulations and its establishment of a regulatory framework is not isolated only to the licensing and registration of medical devices (Bianchini & Mayer, 2022). This directly impacts the industry and its products from the point of manufacture, through its market access and sale until the end user. SAHPRA has managed to implement rules and details pertaining to ethical and fair business practices and safe usage of devices by patients (Saidi and Douglas, 2018).

Despite the positive applauds to SAHPRA for the changes they have instituted, little is known about the way the industry and its stakeholders have received these implementations and the challenges they face when working through the system. Therefore, this study aimed to gain insight on the knowledge and perspectives of medical device manufacturers concerning the regulatory framework applied to medical devices as well as explore the challenges they face through their interactions with the implementation of these regulations.

2. Research Methods and Design

2.1. Study Design and Sites

A quantitative exploratory research design was selected for this research study. The population selected for this study were medical device manufacturers (which may or may not play the role of importers and/or distributors) operating in South Africa. All medical device manufacturers, in the public and private sector, despite how long they have been in operation, or the number of manufacturing facilities associated were included for participation in the study. For the purposes of this study, medical device manufacturers of all products that assist with healthcare, without any exclusion, that have obtained a valid SAHPRA establishment license were included in the study.

2.2. Sample Size

The study sample size was determined based on the number of medical device manufacturers. Of the 708 manufacturers in South Africa with SAHPRA establishment licenses, only 354 were successfully reached for participation. Not all respondents answered and/or rated each variable in question. Hence the number of responses received for each variable is reflected. The percentage is calculated based on the number of responses received for each variable. This study may be subject to self-selection and sampling bias, as participation was voluntary and the survey distribution

was limited to contactable manufacturers. These factors affected the representativeness of the sample and limited that generalizability of the findings.

2.3. Data Collection and Instruments

A self-administered structured survey was designed following the adaptation of the study tool by Fufa et al., (2023) and the WHO benchmarking tool, for which permissions were obtained. The questionnaire was divided into three parts. Part 1 comprising of two questions. Question 1 considering socio-demographics and question 2 was related to company types and products manufactured. Each question consisted of sub questions. Part 2 comprised of two questions, focusing on challenges faced in receiving medical device market approval in South Africa. These questions required participants to rate according to a prescribed scale the challenges faced from the list. Part 3 of the survey also consisted of two questions, focused on access to safe medical devices in South Africa.

2.4. Data collection process

The survey was sent directly to medical device manufacturers, whose details and email addresses are accessible on the Medical Device Manufacturers of South Africa (MDMSA) website. All medical device manufacturers were sent the survey with a brief introduction on the study details and what is required. Reminder emails were sent out to increase the response rate. All data remained anonymous as submission of the survey did not require furnishing any personal or company information. All responses received on the questionnaire, using Google Forms, were populated onto spreadsheets for analysis and interpretation.

2.5. Data Analysis

Categorical variables such as demographics, knowledge and perceptions of participants were analysed using simple descriptive statistics measuring numbers, frequency, and percentages. Kruskal-Wallis tests were applied to determine differences in perceptions, knowledge and participation of medical device manufactures. The test was also used to check differences among years of experience and sector of employment. A p-value of less than 0.05 was considered statistically

significant. Non-parametric statistical tests were employed due to a small sample size and the difficulty it poses to prove normality and the use of ranks and scores within the questionnaire. Missing data were handled by excluding incomplete responses and calculating a mean from the responses received. The rationale for this approach was to maintain consistency and minimise bias in the analysis.

2.6. Ethical Considerations

Ethics approval was obtained from Human Research Ethics Committee (Non-Medical) of the University of the Witwatersrand, Johannesburg, ethics clearance number, H24/08/04. A study information sheet explained the study in detail and the benefits and risks of participating in the study. Completion of the questionnaire was anonymous, and data was confidentially maintained.

3. Results and Discussion

3.1. Employment of Participants

The period of employment of study participants and medical device manufacturer details were captured by the study and summarised in Table 4.1. Medical device manufacturers within the private sector comprised 91.1% of the study population, while 2.43% are employed within the public sector. Within this study population, 6.6% are employed within both sectors. Within the study population, the majority (n = 15, 33.3%) had 10-15 years of experience in the medical device industry. While 97% of the study population are employed or own a facility that is SAHPRA registered and the majority of medical device manufacturers in this study population consist of small companies (less than 50 employees), with a percentage of 56.8%. ’Low Risk’ medical devices (Class A) were the majority (n=14, 31.1%) of manufactured medical devices manufactured by study respondents. Whilst an inclusion criterion for this study population was a SAHPRA establishment license, 5 participants (n=5, 10%) of the study population do not have a SAHPRA Establishment license and therefore had been excluded from the results.

3.2. Exploring the knowledge and perceptions of medical device manufacturers regarding the processes for medical device registration

Data received from participants regarding the knowledge and perceptions of medical device manufacturers regarding the registration of medical devices through SAHPRA are represented using Table 4.2. Of the 45 included results from participants, 39 participants (n=39, 86.6%) indicated familiarity with the medical device regulation

Table 4.1: Employment of Participants (n=45)

Variable	Category	Frequency (%)
Sector Employed Within	Private	41 (91.11)
	Public	1 (2.43)
	Both	3 (6.66)
Work Experience	< 5 years	7 (15.55)
	5 - 10 years	12 (26.66)
	10 – 15 years	15 (33.3)
	>20 years	11 (24.4)
Do you own/ employed by a facility that is SAHPRA registered	Yes	44 (97.7)
	No	1 (2.2)
What type and size of company do you work for? (n =44)	Small Company (<50 employees)	25 (56.8)
	Medium Company (50 -249 employees)	12 (27.27)
	Multi-national company (greater than or equal to 250 employees)	5 (11.36)
	Other	2 (4.54)
What Class of Medical Device is manufactured at your company?	Class A (Low Risk)	14 (31.1)
	Class B (Low-moderate Risk)	12 (26.6)
	Class C (Moderate – High Risk)	9 (20)
	Class D (High Risk)	10 (22.2)
	More than one Class of device	**20 (44.4)**
Does your company have a local manufacturing facility within South Africa	Yes	32 (71.1)
	No	12 (26.6)

	I don't know	1 (2.22)
Does your company have an Establishment License from SAHPRA to manufacture Medical Devices in South Africa?	Yes	45 (100)
	No	0 (0)
	I don't know	0 (0)

system in South Africa of which the majority (n = 34, 75.5%) indicated positively that guidelines are available to ensure that the correct process is followed. Participants in the majority (n =32, 71.1%) indicated that SAHPRA does not communicate updates and amendments to the medical device manufacturers. No participants rated the medical device regulation system in South Africa as excellent, while the majority of participants, described the system as neutral (n =14, 31.1%) to very poor (n =11, 24.4%).

Table 4.2. Participants knowledge and perceptions of the processes for medical device registration (n=45)

Variable	Category	Frequency (%)
Are you familiar with the Medical Devices regulation system in South Africa	Yes	39 (86.6)
	No	3 (6.6)
	I don't know	3 (6.6)
Are guidelines available to ensure you follow the correct processes when registering Medical Devices in South Africa?	Yes	34 (75.5)
	No	11 (24.4)
Does SAHPRA communicate updates and amendments to the Regulatory Framework with Medical Device Manufacturers in South Africa?	Yes	13 (28.8)
	No	32 (71.1)
Is there any special format (e.g. summary technical documentation format) for the submission of a Medical Device Technical File/Dossier in South Africa?	Yes	22 (51.16)
	No	12 (27.9)
	I don't know	9 (20.9)
From your global experience, if any, how would you rate the Medical Device licensing and/or registration system in SAHPRA? (With respect availability of systems)	1 (Excellent)	0 (0)
	2 (Good)	2 (4.4)
	3 (Satisfactory)	13 (28.8)
	4 (Neutral)	14 (31.1)
	5(Poor)	5 (11.1)
	6 (Very Poor)	11 (24.4)
Does Medical Device Approval in South Africa involve a risk-based approach?	Yes	33 (73.3)
	No	3 (6.6)
	I don't know	9 (20)

Are there promulgated regulations that outline requirements for user/user facilities (hospitals, nurses, end users) to report adverse events?	Yes	31 (68.8)
	No	12 (26.6)
	I don't know	2 (4.4)
Do Medical Device Manufacturers in South Africa have post-approval responsibilities related to their Quality Management System (controls for design, manufacturing, packaging, labelling, auditing and documentation)?	Yes	25 (55.5)
	No	18 (40)
	I don't know	2 (4.4)
Do Regulatory and Medical Device Governance systems in South Africa influence the introduction of medical devices into health systems?	Yes	30 (66.6)
	No	11 (24.4)
	I don't know	4 (8.8)

While 86.6% of participants were familiar with SAHPRA's regulatory framework, awareness dropped to 73.3% when asked about the risk-based classification system. This suggests that while manufacturers recognise SAHPRA's role, the specific processes for device classification remain unclear. Previous studies on regulatory compliance in low-to-middle-income countries have similarly found that risk-based frameworks require stronger industry guidance to ensure alignment with international best practices (Ensor and Weinzierl, 2007). This indicates that an opportunity exists for SAHPRA to conduct industry-wide training on risk assessment principles, particularly for smaller manufacturers who may struggle with classification protocols. Through these results it was also found that whilst 86.6% have regulatory experience for 10 to 15 years, with global experiences, 31.1% have rated the medical device system in South Africa as neutral. This is a strong indication that significant strides have been made through the establishment of SAHPRA and the implementation of the new regulation, however, there are still challenges which prevent participants from rating the system any better. Of the 45 respondents that have been included into results for this study, 16 participants (n=16, 35.5%) have rated the medical device system poor and very poor. This ratio surpasses the 13% which have indicated non-familiarity with the medical device system. From this, we can deduce that not only those that lack knowledge in the industry find the system and availability of systems within the framework poor. Studies sited in this research report support that whilst the shift in medical device regulations have been encouraged as a positive development, the success of these changes depends significantly on its implementation which has been problematic due to the lack of skilled personnel and measures to ensure timely registration (Saidi and Douglas, 2018). This has been confirmed by responses from

the study, indicated in Figure 1 and Table 4.3 as challenges faced by the industry. This indicates another opportunity for SAHPRA in terms of policymaking, to target training for personnel and new entrants on the regulations to ensure increased efficiency. An interesting factor that was explored through the results of this study was whether larger companies have a better understanding and knowledge of the regulatory framework. Of the 25 respondents that are employed within smaller companies (less than 50 employees), only (n=3, 12%) indicated that not being familiar with the regulations, whilst of the 17 respondents that are employed within medium and multi-national companies, (n=3, 17%) indicated not being familiar with the regulations. This is a clear indication, that there is no bias or advantages regarding the type of companies or resources within a company that has influenced knowledge and perceptions of the medical device licensing and registration system. Amongst the studies sited in this report, we have ascertained that amongst the improvements and implementations made my SAHPRA to establish a medical device regulatory framework was the introduction of a risk-based approach to all aspects of licensing and registration. From the results of this study, when participants were asked regrading whether medical device approval in South Africa involves a risk-based approach, majority (n=33, 73.3%) indicated positively. This reflects significantly for the entity as it is an indication that whilst regulations are being set, there is a degree of implementation, also recognised by stakeholders and members of the industry.

3.3. Exploring the challenges and bottlenecks faced by Medical Device manufacturers during the registration process

Figure 1 represents data received from participants regarding challenges they as medical device manufacturers face during the registration process. Of the five statements provided, the most selected challenge faced by medical device manufacturers were the lack of competent professionals with appropriate individual expertise. The least selected challenged faced was the inspection and auditing of manufacturers, representatives, distributers and importers.

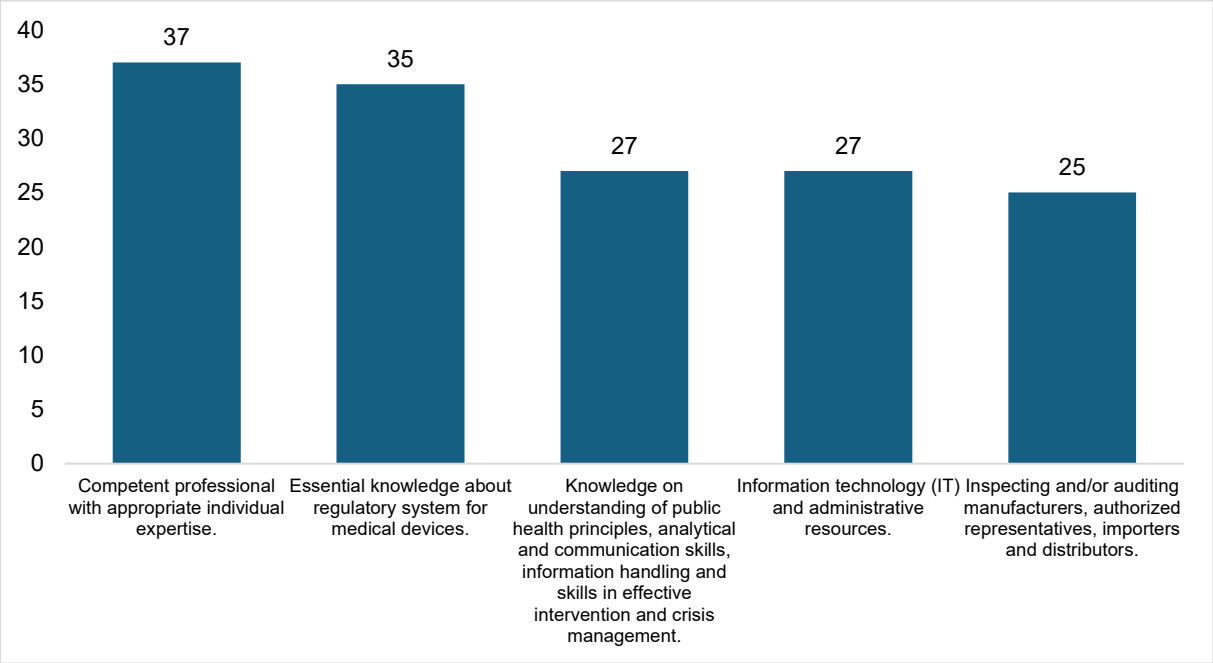


Figure 1. Challenges faced by medical device manufacturers in South Africa during the registration process through SAHPRA

Table 3 represents data derived from participant responses to rate how challenging aspects surrounding the registration process are. Participants were required to select a rating between Not Challenging to Most Challenging. All ratings in bold indicate the majority of responses. Whilst lack of effective legislation, difficulty in compliance with South African approval requirement and difficulty in understanding the Medical Device regulatory Requirements received majority ratings as Challenging, Lack of experienced and qualified staff, lack of systems (structure) to review and approve regulatory devices and lack of enforcement of medical device industry rules, regulations and policies received the majority responses as highly challenging. The majority of respondents (n=37, 82.2%) rated lengthy regulatory approval as the most challenging. The findings from this study indicate that lengthy regulatory approvals pose the greatest challenge to medical device manufacturers going through the registration process. The South African Health Products Regulatory Authority (SAHPRA) inherited a significant backlog of applications from the Medicines Control Council. The median approval times for new active substances (NASs) varied significantly within the Medicines Control Council with a median approval time of 1411 days in 2017 (Keyter et al., 2021) SAHPRA has implemented several strategies to reduce these timelines. For instance, the backlog clearance program initiated in 2019

reduced the median finalization time to 501 days (Moeti et al., 2023). The introduction of facilitated regulatory pathways, such as abridged and verification review models, has led to a 68% reduction in approval times for backlog applications (Keyter et al., 2021). SAHPRA introduced the Risk Based Assessment approach to classify the risk levels of medicines and streamline the review process. This approach significantly reduced the finalization time to 68 days for low-risk applications (Moeti et al., 2023). Facilitated Regulatory Pathways include abridged assessments and verification review models, which have been effective in expediting the review process for both new chemical entities and generics. SAHPRA has continuously refined its processes to prevent recurring backlogs. This includes the implementation of good review practices (GRevP), electronic document management systems, and the development of publicly available summaries for the basis of approval (Keyter et al., 2021). However, despite the concerted effort and implementation of the above strategies to combat the inherited backlogs and lengthy approval times, medical device manufacturers still struggle significantly with this aspect.

Table 4.3. Level of challenges faced by medical device manufacturers in South Africa (n=45)

Variable	Responses (%)*					Median (IQR)
	NC	N	C	HC	MC	
Lack of effective legislation	3 (6.6)	12 (26.6)	**16 (35.5)**	9 (20)	5 (11.1)	3 (3-2)
Lack of experienced and qualified staff	2 (4.4)	6 (35.5)	11 (24.4)	**15 (33.3)**	11 (24.4)	4 (4-3)
Lack of systems (structure) to review and approve regulatory devices (n=44)	3 (6.81)	2 (4.5)	11 (25)	**20 (45.4)**	8 (17.7)	4 (4-3)
High Cost for regulatory approval	0 (0)	6 (13.3)	13 (28.8)	**14 (31.1)**	12 (26.6)	4 (4-3)
Lengthy regulatory approval	1 (2.2)	2 (4.4)	12 (26.6)	12 (26.6)	**18 (40)**	4 (5-3)
Submission process for SAHPRA review & deficiencies	2 (4.4)	3 (6.6)	**16 (35.5)**	**17 (37.7)**	7 (15.5)	4 (4-3)
Difficulty in compliance with South African approval requirement	3 (6.6)	13 (28.8)	**19 (42.2)**	8 (17.7)	2 (4.4)	3 (3-2)
Difficulty in understanding the Medical Device regulatory Requirements	5 (11.1)	7 (15.5)	**15 (33.3)**	11 (24.4)	7 (15.5)	3 (4-3)
Lack of enforcement of medical device industry rules, regulations and policies	3 (6.6)	7 (15.5)	12 (26.6)	16 (35.5)	7 (15.5)	3 (4-3)
Total Challenges Score						

***Abbreviations:** NC, Not a Challenge; N, Neutral; C, Challenging; HC, Highly Challenging; MC, Most Challenging

*Majority rating in bold.

Data derived from this study indicate that of the participants surveyed, 62% of them consider Information Technology and administrative resources a challenge within the medical device industry and its regulatory framework. Healthcare providers in South Africa face significant challenges in the availability and accessibility of medical devices (Marais *et. al,* 2020). Logistical bottlenecks in the supply chain and poor public transport networks hinder the availability and accessibility of medicines and medical devices (Magadzire *et. al*, 2014). It is imperative to and noteworthy to acknowledge that together with ensuring that safe and reliable medical devices are registered and enter the market, it is equally important to ensure that these devices reach the intended users and institutions. In rural areas, the availability of assistive devices is particularly low, with only 2-22% of necessary devices available, and consumables at 2-47% (Magaqa *et. al*, 2021). The absence of comprehensive medical device regulations until the enactment of the Medicines and Related Substances Amendment Act of 2015 has historically impacted the quality and safety of medical devices in South Africa. Mobile information and communication technologies (ICTs) have the potential to improve healthcare quality, but their adoption is influenced by factors such as job relevance, usefulness, and support structures from national government and hospital administration (Banderker & Van Belle, 2009). High data costs and poor internet connectivity remain barriers to the utilisation of mobile medical applications (Banderker & Van Belle, 2009).

With the enactment of the new regulations, and the establishment of SAHPRA, successful implementation of these regulations depends on several factors, including the creation of a critical mass of skilled personnel and measures to ensure timely registration (Saidi & Douglas, 2018). The regulatory system needs to be robust, fit for purpose, responsive, transparent, and proportionate to the risk classification of medical devices. Scaling up the registration of medical devices in South Africa requires addressing the current gaps in skilled personnel, ensuring timely registration, and learning from international best practices. According to a study conducted by Saidi in 2016, the key resource utilisation challenges in scaling up the registration of medical devices in South Africa include the lack of a comprehensive system of regulation, insufficient human resources, and inadequate management of medical devices. Looking at responses this study, it is clear according to Figure 1, wherein participants were required to indicate challenges faced by medical device manufacturers in South

Africa during the registration process through SAHPRA, that 78% of respondents deem insufficient human resources as a challenge and hindrance to a smooth registration process. Table 4.3, wherein the level of challenges faced by medical device manufacturers in South Africa have been rated, it is reinforced by majority responses (n=15, 33.3%) that the lack of qualified staff involved in the registration process still is highly challenging. Amongst medical device manufacturers, from data derived through this study and as per Table 4.3, majority respondents (n=15, 33.3%) acknowledge the lack of a comprehensive regulatory system, posing a significant threat to the smooth operation of the registration process. The current resource utilization impacts the registration process for medical devices in South Africa by leading to a significant number of non-functional medical devices, lack of proper procurement plans, and inadequate engagement of biomedical engineers/technicians in the planning and procurement of medical devices. he implications of scaling up the registration of medical devices in South Africa on the healthcare system include the need for improved decision-making, development of an appropriate instrument to support decision makers, and efficient and evidence-based medical device and equipment prioritisation (Lilford *et. al*, 2015).

Investing in human capital, technology, and infrastructure at the SAHPRA can yield several key benefits and contribute to the organization's overall effectiveness. Human capital, which encompasses the intellectual, entrepreneurial, and productive potential of individuals, is a crucial strategic resource for economic growth and sustainable development (Krasnonosova, Mykhailenko & Yaroshenko, 2022). Improving the health and skills of the workforce can lead to increased productivity and economic growth, making large-scale investment in human capital necessary for optimal use of natural resources (Yadav, 2020). Whilst investment in human capital is crucial, investments made on technology can be significant too (Fontanazza, 2010). Technology investment can lead to innovative restructuring of the economy and sustainable economic growth by creating conditions for constant adaptation to scientific and technological progress. The development of human resources through technology investment can result in an efficient, effective, and well-prepared workforce, contributing to organisational excellence and sustainable competitive advantage (Sharif, Oudah & Salahaldin, 2023).

From the responses received during this study, another common challenge faced by medical device manufacturers is the communication of updates and amendments by SAHPRA. From Table 2, an evaluation of the knowledge and perceptions of the process for registration, (n=32, 71.1%) of participants indicated that SAHPRA does not communicate any updates and amendments. Addressing these communication gaps and providing the necessary support can significantly improve the preparedness of stakeholders for the registration requirements of medical devices in South Africa (Turner *et. al,* 2021). Amongst the support needed is training and capacity building, technical assistance, stakeholder engagement and ultimately resource allocation. There is a critical need for training programs to build the capacity of stakeholders, including manufacturers, healthcare providers, and regulatory personnel. This training should focus on understanding the regulatory requirements, preparing application packages, and navigating the registration process (Saidi & Douglas, 2018). Providing technical assistance to stakeholders can help them prepare better quality submissions, reducing the likelihood of deficiencies and rejections (Moeti *et. al,* 2023). This includes guidance on documentation, quality management systems, and compliance with international standards (Moeti *et. al*, 2023). Proactive engagement with stakeholders through workshops, seminars, and regular updates can help in addressing their concerns and providing clarity on the regulatory requirements (Baum *et. al,* 2025). This engagement should also include feedback mechanisms to continuously improve the regulatory processes. Adequate resources need to be allocated to support the regulatory authority in managing the registration process efficiently. This includes both human and financial resources to handle the volume of applications and ensure timely processing.

4. Conclusion

The findings of this study directly align with the revised research objectives. The high percentage of participants (86.6%) who were familiar with the regulatory system confirms that manufacturers are generally aware of the registration framework and guidelines available through SAHPRA. This supports Objective 1 which focused on assessing awareness and understanding of the regulatory process. Through their interactions with SAHPRA and from global experience, medical device manufacturers are becoming familiar with the system and registration process and interaction through this process, has expanded on knowledge as well. While most manufacturers are

aware of the regulations, there may be inconsistencies in how guidelines are understood or applied. The study also provides detailed insight into the challenges manufacturers face during registration. Participants highlighted operational bottlenecks including poor communication, lengthy approval times, and inconsistent enforcement of regulations. These findings are consistent with literature identifying similar inefficiencies in regulatory implementation across low- and middle-income countries. This addresses Objective 2, which aimed to explore operational challenges from the perspective of industry stakeholders.

The study adds value by capturing real-time perceptions from regulatory-facing professionals, offering a ground-level view of the system's performance. While SAHPRA's structural reforms reflect international best practice, results indicate a gap between policy design and stakeholder experience. Bridging this gap will require not just additional resources, but more transparent engagement between SAHPRA and the industry.

CHAPTER 5

This chapter presents the conclusions drawn from this study, the findings and interpretations of results in relation to set out objectives. Limitations to the study are also outlined as well as future recommendations to enhance efficiency of the medical device regulatory framework in South Africa.

Table 5.1. Objectives, Findings and Interpretation of results from this study

Objective	***Findings***	***Interpretation***
To assess the level of awareness and understanding among medical device manufacturers regarding the regulatory framework for device registration in South Africa	86.6% are familiar with the system, but only 75.5% find guidelines clear.	While most manufacturers are aware of the regulations, there may be inconsistencies in how guidelines are understood or applied.
To explore manufacturer experiences and perceptions of the key operational challenges encountered during the registration process	71.1% report that SAHPRA does not communicate updates; 24.4% rate the system as very poor. 40% consider lengthy approval times as the most challenging and. 45.5% indicate that the lack of systems (structure) to review and approve regulatory devices is another challenge	Poor regulatory communication can lead to compliance delays and uncertainty in regulatory expectations. Lack of systems for review and approval ultimately increases approval times.

Objective 1 of this study aimed at assessing the level of awareness and understanding among medical device manufacturers regarding the regulatory framework for device registration in South Africa. The findings of this study indicated that of the participants, majority (n=39, 86.6%) were familiar with the medical device regulation system, of which participants span from small companies to multinational companies, with as little as 5 years of regulatory experience, up to 20 years. A majority of participants (n=33, 73.3%) also indicated that they are aware that the SAHPRA employs a risk-based approach to the regulatory system. However, 75.5% do not find that the guidelines are

clear of the requirements. From this, we can infer that majority of medical device manufacturers have a good perception of the processes of medical device registration however, while most manufacturers are aware of the regulations, there may be inconsistencies in how guidelines are understood or applied. Objective 2 of this study was aimed at exploring manufacturer experiences and perceptions of the key operational challenges encountered during the registration process. Majority of participants, indicated amongst the most challenging aspects include poor communication from SAHPRA, a poor regulatory system, lengthy approval times and lack of structures to approve medical devices. Poor communication can lead to compliance delays, and the lack of structures and systems to review and approve devices ultimately increases regulatory approval times, which will be counter-productive for SAHPRA.

5.1. Limitations

Low response rates, despite repeated emails sent to manufacturers for participation, represented a major limitation to the study. An additional limitation to the study is the low representation of medical device manufacturers in the public sector Causing the results to skew to perceptions of one sector.

5.2. Future Recommendations

To guide SAHPRA in transitioning to a more efficient registration process while aligning with international standards, several policy recommendations can be made based on insights gained. Implementing facilitated regulatory pathways, enhancing transparency and communication, strengthening Good Regulatory Practices (GRPs), adopting international standards and harmonization, addressing resource constraints and using collaboration and reliance networks are all amongst the recommendations made to improve the medical device regulatory framework. The introduction of facilitated regulatory pathways can streamline review processes, leading to more efficient and transparent operations. This includes increased consistency and evidence-based decision-making practices (Keyter *et. al,* 2022). Engaging stakeholders through transparent communication can improve trust and cooperation,

leading to better regulatory compliance and performance and can lead to more thorough and timely reviews, better alignment of enforcement efforts, and improved identification of issues. Harmonization can streamline the evaluation process, reducing the workload and enabling faster access to medicines. This has been observed in other African regulatory bodies through initiatives like the East African Community Medicines Regulatory Harmonization (EAC-MRH) and the Southern African Development Community Medicines Regulatory Harmonization (SADC-MRH) (Ngum *et. al,* 2024),

5.3. Conclusion

This study set out to evaluate the efficiency of the medical device registration process in South Africa by assessing stakeholder awareness of the regulatory framework and identifying operational challenges faced during the registration process. The revised objectives allowed for clearer alignment between the study aim, the data collected, and the results presented.

Findings show that while manufacturers are largely aware of the existence of SAHPRA's regulatory system and guidelines, the practical implementation of these regulations continues to present challenges. Participants cited communication gaps, prolonged approval timelines, inconsistent enforcement, and a lack of accessible regulatory support as key barriers to efficient registration. These issues suggest that the bottlenecks faced are not due to lack of awareness, but rather structural and operational limitations within the regulatory authority itself.

The study also highlights the need for improved stakeholder engagement and transparency in regulatory operations. While South Africa's framework aligns with global standards, the lived experiences of industry professionals show that regulatory success depends on more than policy — it requires consistent, well-resourced, and collaborative implementation.

Ultimately, the study contributes meaningful insights into the real-world functioning of South Africa's medical device registration system. Addressing these identified gaps can significantly strengthen SAHPRA's ability to promote safe, timely, and equitable access to medical technologies.

References

Amaral, C.; Paiva, M.; Rodrigues, A.R.; Veiga, F. and Bell, V. (2024). Global Regulatory Challenges for Medical Devices: Impact on Innovation and Market

Amaral, J. R., Zhou, Y., & Singh, A. (2024). Stakeholder-centered regulation in medical device policy: A global perspective. Regulatory Affairs Review, 12(1), 5–18

Azevedo, M. & Hamdy, M., 2021. Post-market surveillance in emerging economies: Lessons from Brazil and Egypt. Journal of Medical Device Regulation, 18(2), pp.112–124.

Badnjevic, A.; Gurbeta, P.; Lejla; Deumic, A and Spahić, L. (2022). Post-market surveillance of medical devices: A review. Technology and Health Care.

Banderker, N. and Van Belle, J.P. (2009). Adoption of mobile technology by public healthcare doctors: A developing country perspective. Handbook of Research on Advances in Health Informatics and Electronic Healthcare Applications: Global Adoption and Impact of Information Communication Technologies.

Baum, D.; Baum, K.; Zamani, S. and Werth, D. (2025). Transparent transparency developing a scheme for understanding transparency requirements. Lecture notes in computer science (including subseries lecture notes in artificial intelligence and lecture notes in bioinformatics)

Balogun, E. and Luetge, C. (2025). Gap Analysis on Regulatory Frameworks for AI-embedded Medical Devices

Bianchini, E. and Mayer, C.C. (2022). Medical device regulation: should we care about it?

Bhatia, P. & Rao, M., 2021. Impact of regulatory reforms on local medical device manufacturing in India. Indian Journal of Health Policy and Systems, 7(1), pp.44–53

Bretthauer, M.; Gerke, S.; Hassan, C. and Mori, Y. (2023). The new European Medical Device Regulation: balancing innovation and patient safety. Annals of internal medicine.

Bryman, A. (2006). Integrating quantitative and qualitative research: how is it done? Qualitative Research.

Byrne, M. (2020). The Development and Commercialization of Medical Devices. Biotechnology Entrepreneurship (Second Edition), Academic Press.

Cai, Y.; Sui, L.; Wang, J. and Gao, Y. (2024). Post-marketing surveillance framework of cell and gene therapy products in the European Union, the United States, Japan, South Korea and China: a comparative study. BMC Medicine

Ceyhan, E.M.; Gürsöz, H.; Alkan, A. and Walker, S. (2018). The Turkish medicines and medical devices agency: Comparison of its registration process with Australia, Canada, Saudi Arabia, and Singapore

Chiku, C.; Maruta, T.; Mbiba, F. and Manasa J. (2024). Navigating regulatory landscape: A qualitative exploration of medical devices and in vitro diagnostic medical devices oversight in Zimbabwe through key stakeholder perspectives.

Classification Medical Devices IVDs Nov19 v2). SAHPRA, 2019

Creswell, J. W. (2012). Educational research: Planning, conducting, and evaluating quantitative and qualitative research (4th ed.). Boston, MA: Pearson.

Creswell, J. W. (2009). Research Design: Qualitative, Quantitative, and Mixed Methods Approaches (3rd ed.). Thousand Oaks, CA: Sage Publications.

Danks, L.; Semete-Makokotlela, B.; Otwombe, K. and Salek, S. (2023). Evaluation of the impact of reliance on the regulatory performance in the South African Health Products Regulatory Authority: implications for African regulatory authorities. Frontiers in Medicine.

De Maria, C.; Di Pietro, L.; Díaz Lantada, A. and Ahluwalia, A. (2018). Safe innovation: On medical device legislation in Europe and Africa. Health Policy and Technology.

Dureja, H. and Dhiman, S. (2021). SAHPRA - Relevance of the New South African Health Products Regulatory Authority and Opportunities Ahead. Journal of Regulatory Science.

Dlamini, T. & Sibiya, N. (2021). Regulatory experiences of South African medical device manufacturers under SAHPRA. South African Journal of Health Policy, 14(3)

Egbosimba, D., (2019). Medical devices industry: The problem of clinical evaluation reports.

Ekanoye, A. & James, M. (2018). Delays in medical device registration: A Nigerian case study. African Journal of Pharmaceutical Policy, 6(1), 33–42

Feraoun, F.; Feraoun, M. (2013). Nonclinical Safety Assessment: A Guide to International Pharmaceutical Regulations.

Fiedler B.A. (2017). Review regulatory guidelines by device classification type. Managing medical devices within a regulatory framework

Fontanazza, M. (2010). Investment in industry is leaner, but still alluring. Medical Device and Diagnostic Industry

Food and Drug Administration. (2024). U.S.-Japan Regulatory Collaboration.

Gadodia, G. (2023). Device classification. Translational Interventional Radiology.

Gallegos, A. (2025). Despite new FDA guidance, doctors say accelerated approval process still flawed.

Ghosh, S.; Shah, D.; More, N. and Kapusetti, G. (2021). Clinical validation of the medical devices: a general prospective. Bio sensing, theranostics, and medical devices: from laboratory to point-of-care testing

Gray, J.; Ross, J. and Badrick, T. (2022). The path to continual improvement and business excellence: compliance to ISO standards versus a business excellence approach. Accreditation and Quality Assurance.

Hagopian, C.O, (2019). Ethical Challenges with Nonsurgical Medical Aesthetic Devices.

Harrison, V. and Krebs, M. (2017). Medical devices - South Africa's changing landscape.

Helen, M. and Zamathiyane, M. (2016). Medical devices - then and (almost) now: medical law.

Hubner, S.; Maloney, C.; Phillips, S.D. and Fitzgerald, T.N. (2021). The evolving landscape of medical device regulation in East, Central, and Southern Africa. Global Health Science and Practice.

Imagawa, K.; Mizukami, Y. and Miyazaki, S. (2018). Regulatory convergence of medical devices: a case study using ISO and IEC standards

Jadhav, N.M. and Shendge, R.S. (2024). ISO 13485:2016- The gateway of global or regional harmonization for Medical Device Regulations. International journal of pharmaceutical quality assurance.

Jiang, N.; Mück, J.E. and Yetisen, A.K. (2020). The Regulation of Wearable Medical Devices. Trends in Biotechnology.

Jokura, Y.; Yano, K. and Yamato, M. (2018). Comparison of the new Japanese legislation for expedited approval of regenerative medicine products with the existing systems in the USA and European Union. Journal of Tissue Engineering and Regenerative Medicine

Kanfer, I., (2017). South Africa, AAPS Advances in the Pharmaceutical Sciences Series

Kanti, S.P.Y.; Csóka, I.; Adalbert, L., and Jójárt-Laczkovich, O. (2022). Analysis of the renewed European Medical Device Regulations in the frame of the non – EU regulatory landscape during the COVID facilitated change. Journal of Pharmaceutical Sciences.

Karthika, B. and Vijayakumar, A.R. (2022). ISO 13485: Medical devices – quality management systems, requirements for regulatory purposes. Medical device guidelines and regulations handbook.

Kaule, S.; Bock, A.; Dierke, A. and Grabow, N. (2020). Medical Device Regulation and current challenges for the implementation of new technologies. Current Directions in Biomedical Engineering.

Keyter, A.; Salek, S.; Banoo, S. and Walker, S. (2019). The South African Medicines Control Council: Comparison of Its Registration Process with Australia, Canada, Singapore, and Switzerland. Frontiers in Pharmacology

Keyter, A.; Salek, S.; Danks, L. and Walker, S. (2021). South African Regulatory Authority: The impact of reliance on the review process leading to improved patient access. Frontiers in pharmacology.

Keyter, A.; Salek, S.; Gouws, J. and Walker, S. (2020). Evaluation of the Performance of the South Africa Regulatory Agency: Recommendations for Improved Patients' Access to Medicines. Therapeutic Innovation and Regulatory Science.

Keyter, A.; Gouws, J.; Salek, S. and Walker, S. (2018). The Regulatory Review Process in South Africa: Challenges and Opportunities for a New Improved System. Therapeutic Innovation and Regulatory Science.

Keyter, A.; Banoo, S.; Salek, S. and Walker, S. (2018). The South African Regulatory System: Past, Present, and Future. Frontiers in Pharmacology

Kim, J.H.; Kwon, S.; Seol, J.E. and Kim, S.D. (2024). Regulatory framework for drug-device combination products in the United States, Europe, and Korea. Therapeutic innovation and regulatory science.

Klaaren, J. (2021). Regulatory Politics in South Africa 25 Years After Apartheid. Opens document details in a new tab Journal of Asian and African Studies.

Kramer, D.B.; Tan, Y.T.; Sato, C. and Kesselheim, A.S. (2014). Ensuring medical device effectiveness and safety: a cross--national comparison of approaches to regulation. Food and drug law journal.

Krasnonosova, O.; Mykhailenko, D. and Yaroshenko, I. (2022). Reproduction of human capital as a strategic priority for sustainable development of regions.

Levin, L. (2023). Understanding regulatory requirements and registration practices for medical devices in Germany: Perspectives of industrial experts. Journal of commercial biotechnology.

Li, Y. and Zhang, Q., (2020). Preliminary Review of Relationship between Medical Device Evaluation and Quality Management System in Premarket Approval. Chinese journal of medical instrumentation.

Lilford, R.J.; Burn, S.L.; Diaconu, K.D. and Manaseki-Holland, S. (2015). An approach to prioritization of medical devices in low-income countries: An example

based on the Republic of South Sudan, Cost Effectiveness and Resource Allocation.

Louw, T. & Petersen, R., 2023. Medical device registration delays and their effects on public sector procurement in South Africa. South African Journal of Health Management, 15(4), pp.190–204.

Maci, J.; Matejicek, M.; Peter, L. and Maresova, P. (2024). Medical device regulation and its impact on the industry: A case study of Czech companies

Magadzire, B.P.; Budden, A.; Ward, K. and Sanders, D. (2014). Frontline health workers as brokers: Provider perceptions, experiences and mitigating strategies to improve access to essential medicines in South Africa. BMC Health Services Research.

Magaqa, Q.; Ariana, P. and Polack, S. (2021). Examining the availability and accessibility of rehabilitation services in a rural district of South Africa: A mixed-methods study. International Journal of Environmental Research and Public Health.

Magubane, N. and Robles, W. (2017). African medicines regulatory harmonisation initiatives. Regulatory Rapporteur.

Maharaj, I. and Sunjka, B.P. (2019). A strategic framework for start-up medical device manufacturers in South Africa. South African Journal of Industrial Engineering.

Matcha, A. (2023). Innovations in Healthcare: Transforming patient care through technology, personalized medicine, and global health crises.

Meyer, J.C.; Schellack, N.; Stokes, J. and Steel, G. (2017). Ongoing initiatives to improve the quality and efficiency of medicine use within the public healthcare system in South Africa; A preliminary study. Frontiers in Pharmacology.

Mirel, S.; Colobatiu, L.; Fasniuc, E. and Muresan, D. (2014). Materiovigilance and medical devices. IFMBE Proceedings.

Moeti, L.; Litedu, M. and Joubert, J., SA. (2023). Common deficiencies witnessed in Module 1 assessed by the pharmaceutical evaluation and management

pre-registration unit within the South African Health Products Regulatory Authority. Pharmaceutical Journal.

Moeti, L.; Litedu, M. and Joubert, J. (2023). Regulatory registration timelines of generic medicines in South Africa: Assessment of the performance of SAHPRA between 2011 and 2022, Journal of Pharmaceutical Policy and Practice.

Moeti, L.; Litedu, M. and Joubert, J., (2023). The Implementation of a Risk-Based Assessment Approach by the South African Health Products Regulatory Authority (SAHPRA). Pharmaceutical Medicine.

Molefe, L. & Dube, T., 2023. Stakeholder perceptions on post-market surveillance in South Africa: A qualitative analysis. African Journal of Regulatory Affairs, 9(1), pp.56–67

Mooghali, M.; Rathi, V.K.; Kadakia, K.T. and Dhruva, S.S. (2023). Medical device risk (re)classification: lessons from the FDA's 515 Program Initiative. BMJ Surgery, Interventions, and Health Technologies.

Mpofu, S. et al., 2022. An audit of post-market compliance for high-risk medical devices in South Africa. Regulatory Science in Africa, 5(3), pp.97–110.

Murakami, M.; Suzuki, Y. and Tominaga, T. (2018). Rapid Globalization of Medical Device Clinical Development Programs in Japan. The Case of Drug-Eluting Stents. *Circ. J.*

Mwangi, J.M. (2016). Towards African Medicines Regulatory Harmonization: The case of the East African Community. Pharmaceuticals Policy and Law.

Nasir, F., Otieno, J., & Mutua, C. (2023). Medical device regulation in Kenya: Challenges and digital transformations. East African Medical Regulatory Review, 9(2), 45–58

Nasir, N.; Molyneux, S.; Were, F.; Aderoba, A. and Fuller, S.S. (2023). Medical device regulation and oversight in African countries: a scoping review of literature and development of a conceptual framework. BMJ Glob Health.

Nass, R. (2011). Experts tell you what to expect in 2011. Medical Device and Diagnostic Industry.

Ndaba, S., Maharaj, T. & Mokoena, N., 2022. Regulatory bottlenecks for local medical device innovators: A South African startup perspective. Journal of Innovation and Health Technologies, 4(2), pp.65–78

Ngum, N.; Ndomondo-Sigonda, M.; Habonimana, R. and Salek, S. (2024). Evaluation of the review models and approval timelines of authorities participating in the East African Medicine Regulatory Harmonisation initiative: alignment and strategies for moving forward. Frontiers in medicine.

Ocampo, J.U. and Kaminski, P.C. (2019) Medical Device Development, from Technical Design to Integrated Product Development. J. Med. Eng. Technol.

Palatino, V. (2023). Chapter 6: How to Get and Develop a Career in a Market Access Role in the Medical Devices' Industry. Career Options in the Pharmaceutical and Biomedical Industry: An Insider's Guide.

Pfeiffer, P.; Sander, H.; Fettke, P. and Reisig, W. (2022). Towards a Standard Process enabling AI-support for Safety and Conformity of Medical Devices. CEUR Workshop Proceedings.

Prineetha, M.; Tallapaneni, V.; Baskaran, M. and Satyanarayana Reddy Karri, V.V. (2020). European medical device regulations. International Journal of Pharmaceutical Research.

Quinn, A. (2022). Navigating the MDR's heightened surveillance and performance requirements. Regulatory Rapporteur.

Rahi, S. and Rana, A. (2020). Journey of medical devices - history to global.

Ramachandran, A., (2024). AI-Powered pharmacovigilance systems for enhanced drug safety and rapid adverse event detection.

Rodríguez, H.; De Lucia, M.L. and Liberti, L. (2022). Cooperation Agreements, Memorandums of Understanding, and Letters of Intent as Instruments to Facilitate the Implementation of Reliance in Latin America. Clinical Therapeutics.

Saban, M.; Zavala, D.; Lopez Osornio, A. and Rizzato Lede, D.A. (2024). Understanding WHO smart guidelines: narrative review of an innovative global digital health approach. Studies in health technology and informatics.

Saidi, T. and Douglas, T.S. (2018). Medical device regulation in South Africa: The medicines and related substances amendment act 14 of 2015. South African Medical Journal.

Saidi, T. (2016). Towards a medical device regulation in South Africa: an assessment of the medicines and related substances amendment act of 2015. Health and Technology

Salami, R.K.; Valente de Almeida, S.; Gheorghe, A.; Njenga, S.; Silva, W. and Hauck, K. (2023). Health, Economic, and Social Impacts of Substandard and Falsified Medicines in Low- and Middle-Income Countries: A Systematic Review of Methodological Approaches.

Setswe, G.; Witthuhn, J.; Muyanga, S. and Nyasulu, P. (2016). The new National Health Insurance policy in South Africa: Public perceptions and expectations. International Journal of Healthcare Management.

Sharif, A.A.; Oudah, B.K. and Salahaldin, A.D. (2023). Human resources development as strategic entrance to maximize the investment in human capital: Exploratory research for a sample of employees of NASA Iraq. AIP Conference Proceedings.

Shatrov, K. and Blankart, C.R. (2022). After the four-year transition period: Is the European Union's Medical Device Regulation of 2017 likely to achieve its main goals? Health Policy.

Shukla, S.; Gupta, M.; Pandit, S. and Singh, G.N., (2020). Implementation of adverse event reporting for medical devices, India. Bulletin of the World Health Organization.

Simon Ramaoka, T. and Kraemer-Mbula, E. (2022). Technology transfer and absorptive capacities in South Africa's medical device industry. African Journal of Science, Technology, Innovation and Development.

Sithole, T.; Mahlangu, G.; Capote, V. and Walker, S. (2021). Evaluation of the Good Review Practices of Countries Participating in the Southern African Development Community: Alignment and Strategies for Moving Forward, Frontiers in Medicine.

Sithole, T.; Mahlangu, G.; Walker, S. and Salek, S., (2022). Pharmaceutical Industry Evaluation of the Effectiveness and Efficiency of the ZaZiBoNa Collaborative Medicines Registration Initiative: The Way Forward. Frontiers in Medicine.

Strugo, V.; Katsoulis, L.; Chikoto, H. and Coetzee, M. (2011). Clinical Trials in South Africa. Global Clinical Trials: Effective Implementation and Management.

Tecante, K.E.; Sokija, A. (2022). The periodic safety update report and post market surveillance report under the new EU Medical Device Regulation

Tim, E.; Sabine, W. (2007). Regulating health care in low- and middle-income countries: Broadening the policy response in resource constrained environments, Social Science & Medicine, Volume 65, Issue 2.

Tomlinson, C. (2020). The tangled web of medical device regulation in SA

Tomlinson, C. (2019). The plan to revive medicines regulation in South Africa

Tonks, O. (2024). 2025 Predictions: Top Trends Shaping the Medical Device Industry

World Health Organization, 2018. *Essential Medicines and Health Products: Definitions of Substandard and Falsified (SF) Medical Products*.

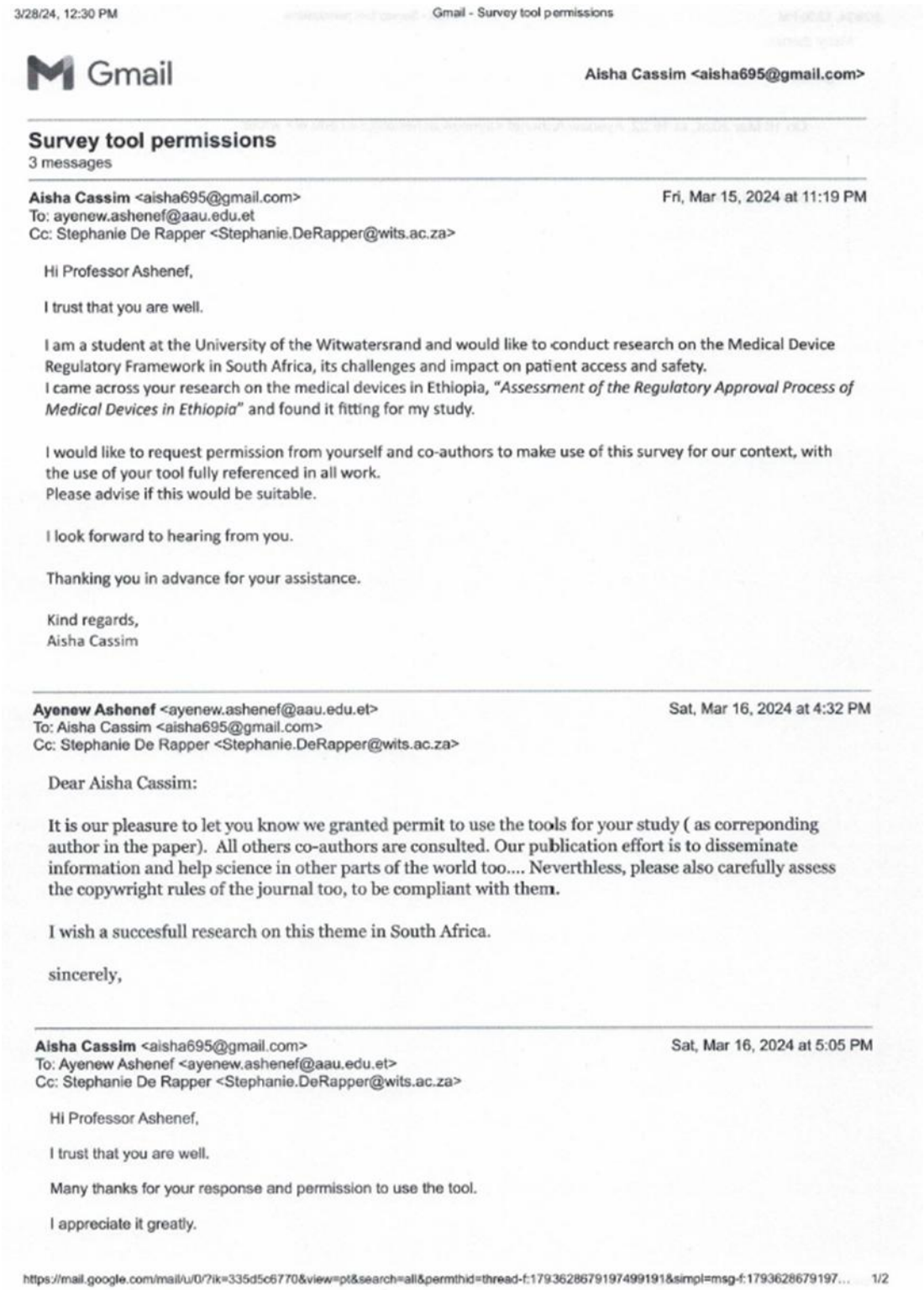
WHO support for medicines regulatory harmonization in Africa: Focus on East African community. WHO Drug Information, 2014

Yadav, M. (2020). Health as an economic dimension: A comparative study of india and china. Asia Pacific Journal of Health Management.

Zgirskas, A.; Ruzevicius, J. and Ruželė, D. (2021). Benefits of Quality Management Standards in Organizations. Standards.

APPENDIX A

Permissions to make use of Survey Tool



3/28/24, 12:30 PM Gmail - Survey tool permissions

Gmail

Aisha Cassim <aisha695@gmail.com>

Survey tool permissions
3 messages

Aisha Cassim <aisha695@gmail.com> Fri, Mar 15, 2024 at 11:19 PM
To: ayenew.ashenef@aau.edu.et
Cc: Stephanie De Rapper <Stephanie.DeRapper@wits.ac.za>

Hi Professor Ashenef,

I trust that you are well.

I am a student at the University of the Witwatersrand and would like to conduct research on the Medical Device Regulatory Framework in South Africa, its challenges and impact on patient access and safety.
I came across your research on the medical devices in Ethiopia, "*Assessment of the Regulatory Approval Process of Medical Devices in Ethiopia*" and found it fitting for my study.

I would like to request permission from yourself and co-authors to make use of this survey for our context, with the use of your tool fully referenced in all work.
Please advise if this would be suitable.

I look forward to hearing from you.

Thanking you in advance for your assistance.

Kind regards,
Aisha Cassim

Ayenew Ashenef <ayenew.ashenef@aau.edu.et> Sat, Mar 16, 2024 at 4:32 PM
To: Aisha Cassim <aisha695@gmail.com>
Cc: Stephanie De Rapper <Stephanie.DeRapper@wits.ac.za>

Dear Aisha Cassim:

It is our pleasure to let you know we granted permit to use the tools for your study (as correponding author in the paper). All others co-authors are consulted. Our publication effort is to disseminate information and help science in other parts of the world too.... Neverthless, please also carefully assess the copywright rules of the journal too, to be compliant with them.

I wish a succesfull research on this theme in South Africa.

sincerely,

Aisha Cassim <aisha695@gmail.com> Sat, Mar 16, 2024 at 5:05 PM
To: Ayenew Ashenef <ayenew.ashenef@aau.edu.et>
Cc: Stephanie De Rapper <Stephanie.DeRapper@wits.ac.za>

Hi Professor Ashenef,

I trust that you are well.

Many thanks for your response and permission to use the tool.

I appreciate it greatly.

https://mail.google.com/mail/u/0/?ik=335d5c6770&view=pt&search=all&permthid=thread-f:1793628679197499191&simpl=msg-f:1793628679197... 1/2

APPENDIX B

Survey Tool

Evaluation of the Regulatory Approval Process in South Africa to reduce challenges faced by Medical Device Manufacturers

Do you consent to participating in this research study? Completion of the survey will confirm consent.

□ Yes □ No

Question 1 - Socio-Demographic related questions

1. Within which sector are you employed?

   □ Public Sector

   □ Private Sector

   □ Both

2. Work Experience in the industry:

   □ < 5 years

   □ 5 – 10 years

   □ 10 – 15 years

   □ > 20 years

Question 2 - Medical Device Manufacturers

3. Do you own/ employed by a facility that is SAHPRA registered?

   □ Yes □ No □ Don't Know

4. What type and size of company do you work for? (Please select one option for the company size)

   □ Small Company (< 50 employees)

   □ Medium Company (50 to 249 employees)

   □ Multi National Company (greater than or equals 250 employees)

   □ Other - Please specify_____

5. What Class of Medical Device is manufactured at your company?

   □ Class A □ Class B □ Class C □ Class D

5.1. If your company manufactures more than one medical device, state the Class of each medical device?

6. Does your company have a local manufacturing facility within South Africa?

   □Yes □ No □ Don't Know

7. Does your company have an Establishment License from SAHPRA to manufacture Medical Devices in South Africa?

   □Yes □ No □ Don't Know

8. Are you familiar with the Medical Devices regulation system in South Africa?

   □ Yes □ No □ Don't know

9. Are guidelines available to ensure you follow the correct processes when registering medical Devices in South Africa?

   □ Yes □ No

10. Does SAHPRA communicate updates and amendments to the Regulatory Framework to Medical Device Manufacturers in South Africa?

□ Yes □ No

11. Is there any special format (e.g. summary technical documentation format) for the submission of a Medical Device Technical File/Dossier?

□Yes □ No □ I don't know

12. From your global experience, if any, how would you rate Medical Device Approval system in SAHPRA? (With respect availability of systems)

□ Excellent □ very good □ Good □Fair □ Poor

□ Very poor

Additional comments you want to address? (If any)_____

Question 3 - Challenges in Receiving Medical Device Market Approval in South Africa

13. The practice of regulating medical devices effectively and efficiently requires general professional competencies. Which of the following do you think are the gaps you observed in the South African Medical Device Regulatory system? (tick marks all applicable boxes)

□ Competent professional with appropriate individual expertise

□ Essential knowledge about regulatory system for medical devices

□ Knowledge on understanding of public health principles, analytical and communication skills, information handling and skills in effective intervention and crisis management

□ Information technology (IT) and administrative resources

□ Inspecting and/or auditing manufacturers, authorized representatives, importers and distributors.

14. For each statement on the left please tick mark (√) on the space which best describes the level of customers challenges

(5= most challenging; 4=high challenging; 3= Challenging; 2= Neutral, 1=Not a challenge (NC).

Please rate your challenges (as applicable) in receiving medical device Regulatory Approval in South Africa?						
No.	**Items**	**1**	**2**	**3**	**4**	**5**
14.1.	Lack of effective legislation					
14.2.	Lack of experienced and qualified staff					
14.3.	Lack of systems (structure) to review and approve regulatory devices					
14.4.	High Cost for Regulatory Approval					
14.5.	Lengthy Regulatory Approval					
14.6.	Submission Process for SAHPRA Review & Deficiencies					
14.7.	Difficulty in Compliance to South African Approval Requirement					
14.8.	Difficulty in understanding the medical device regulatory Requirements					
14.9.	Lack of enforcement of medical device industry rules, regulations and policies					

14.1. If there are other challenges that you face, that have not been listed, please specify:

_____

Question 4 - Access to Medical Devices in South Africa and Patient Safety

15. Does Medical Device Approval in South Africa involve a risk-based approach?

□ Yes □ No □ I don't know

16. Are there promulgated regulations that outline requirements for user/user facilities (hospitals, nurses, end users) to report adverse events?

□ Yes □ No □ I don't know

17. Does Medical Device Manufacturers in South Africa have post approval responsibilities related to their Quality Management System (controls for design, manufacturing, packaging, labelling, auditing, and documentation)?

□ Yes □ No □ I don't know

18. Does Regulatory and Medical Device Governance systems in South Africa influence the introduction of medical devise into health systems?

□ Yes □ No □ I don't know

18.1. If there are other challenges that you face, that have not been listed, please specify:

_____-

APPENDIX C

Study Protocol

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

FACULTY OF HEALTH SCIENCES

CANDIDATE'S SURNAME:	CASSIM	FIRST NAME/S:	AISHA	STUDENT NUMBER:	721207
CURRENT QUALIFICATIONS: BPharm (Honours)					
TEL: N/A	CELL: 0813057005	E-MAIL:aisha695@gmail.com		FAX: N/A	
DEGREE FOR WHICH PROTOCOL IS BEING SUBMITTED: Master of Science in Medicine (Pharm. Affairs)					
PART-TIME OR FULL-TIME: Part-Time					
FIRST REGISTERED FOR THIS DEGREE:	TERM : 01			YEAR: 2023	
DEPARTMENT: Pharmacy and Pharmacology					
TITLE OF PROPOSED RESEARCH: Examining the Efficiency of Medical Device Registration in South Africa since the establishment of the South African Health Products Regulatory Authority					
CANDIDATE'S SIGNATURE				DATE: 28.03.2024	
SUPERVISOR 1 (NAME & SURNAME): Dr Stephanie Leigh				100% Supervision	
SUPERVISOR'S QUALIFICATIONS: B. Pharm, M. Pharm, PhD					
SUPERVISOR'S DEPARTMENT: Pharmacy and Pharmacology					
SUPERVISOR'S ADDRESS / TEL / E-MAIL: Office 8M10, Department of Pharmacy and Pharmacology, 7 York road, Parktown, Johannesburg, 2198 / 011 717 2268 / Stephanie.derapper@wits.ac.za					

SYNOPSIS OF RESEARCH:

Introduction:

With the Medicine and Related Substances Amendment Act 14 of 2015 implemented as law, it has amounted to significant changes for Medical Devices regulations in South Africa. More specifically, this meant the establishment of the South African Health Products Regulatory Authority (SAHPRA). These changes were significant milestones for the health sector in South Africa and allowed for a dedicated regulatory framework for medical devices. Whilst the South African government has established SAHPRA, and provided for deliberate attempts to improve on the medical device regulation in the county, improvements can be made.

Aim/s:

This study aims to assess the efficiency of the medical device registration process in South Africa, through understanding the bottlenecks and challenges faced by medical device manufacturers, in their attempt to attain approval for medical devices.

Proposed Methodology:

A quantitative, exploratory research design has been selected for this research. The population of this study consists of Medical Device Manufacturers (which may or may play the role of importers and/or distributers). The population selected will consist of those working in the public and private sector. Data will be collected by means of the questionnaire / survey tool.

Expected Outcomes:

The study expects to gain insight on how far the South African Regulatory Framework for medical devices has come since inception in 2015, the challenges still faced and how the system can be improved to ensure patient access to safe medical devices. These aspects will be analysed from the perspective of the medical device manufacturer.

WITS ETHICS NOT REQUIRED: Yes (No) WITS ETHICS PENDING: (Yes) No WITS ETHICS APPROVED: Yes (No) (circle appropriate symbol)* ***Please note the final human ethics clearance certificate or animal ethics certificate must be available prior to starting research**		IF Y SUPPLY ETHICS CLEARANCE CERTIFICATE AS ATTACHMENT AND INCLUDE ETHICS NUMBER HERE:
As supervisor/s, I/we confirm that I have read the protocol which has been submitted for assessment.		
SIGNATURE OF SUPERVISOR/S:		
SIGNATURE OF HEAD OF DEPARTMENT:		
SIGNATURE PG OFFICE STAFF ……..	REGISTERED YES….. NO…..	STAMP

1. Introduction

A medical device is any instrument, apparatus, implement, machine, appliance, implant, and reagent for *in vitro* use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose (WHO, 2024). As with medicines, medical devices too are essential for patient care.

Medical devices are currently one of the fastest growing industries and still, countries struggle with access to quality devices and equipment that are appropriate for specific needs. Illegal reprocessing and re-packaging of syringes for sale, equipment that do not meet minimum quality standards, or the inability to provide post market surveillance of medical devices are serious concerns facing developing countries (Das et. Al, 2020). Regulatory frameworks describe the details for design, development and manufacture of medical devices so that products for retail are safe, effective and of good quality. This too allows for limited importation of products that pose risks to patient healthcare (Saidi & Douglas, 2019).Whilst medical devices are is such a rapidly growing

industry, it is imperative to note that medical devices are crucial for safe prevention, treatment and diagnosis of disease and illness (WHO, 2024). For this fundamental function to be materialised, medical devices must fulfil the function that they were designed for, whilst simultaneously, avoiding any patient harm. (SAHPRA, 2019). According to the WHO, in 2017, the approximate failure rate of medical devices that do not meet necessary safety requirements, in low to middle-income countries was 10.5% (WHO, 2017). Stringent medical device regulation is thus needed in order to achieve higher quality and more affordable medical care (WHO, 2017).

As a response to the high availability and access to medical devices that do not meet quality standards, according to a study conducted by Compliance and Risks, in which they studied the Global Regulatory Trends for Medical Devices, they inferred that there has been a sixty four percent increase in Regulations for medical device manufacturers since 2015 (Compliance & Risks, 2023). The Food and Drug Administration (FDA) in the United States of America, is responsible for ensuring the safety and effective nature of a medical device. The FDA regulates the ability of ~~manufacturer's~~manufacturers to market devices within the US. (US FDA, 2017) Medical devices undergo the FDA regulation process to market through either of three routes: Premarket Notification, Premarket Approval (PMA) or Humanitarian Device Exemption (HDE). The FDA is currently following post-market surveillance techniques in order to improve patient access to safe medical devices. (Lauer et al., 2017)

In Europe, the legislation sets out essential requirements, which are elements and procedures that companies should have in place, it defines the conformity assessment process and also sets out obligations on the

part of manufacturers. The legislation specifies notified bodied to assess devices and competent authorities which are organisations that govern clinical trials and oversee post-marketing surveillance. The European regulatory system ~~follow~~follows a risk-based assessment of medical devices. (Wizemann T, 2010)

In South Africa, since the Medicine and Related Substances Amendment Act 14 of 2015 has become law, it has steered changes for the regulatory framework of Medical Devices. The Act allowed for the establishment of the South African Health Products Regulatory Authority (SAHPRA). These were incredible milestones for in ~~South Africa~~South Africa, and this facilitated a committed regulatory system. This applied to all medical device companies, whether they manufacture, sell, import, export, distribute and/or wholesale medical devices. A phased approach for the regulation of medical devices was introduced. Currently, there are no medical devices, except those that are non-sterile, non-measuring Class A devices that can be manufactured, distributed or imported and exported without a SAHPRA medical device establishment license (SAMRC, 2022) SAHPRA makes use of reliance pathways for registration and marketing of medical devices with regulatory approval from other jurisdictions, including Australia, United States and the European Union to name a few.

Like any new organisation and institution, growing pains are almost certain. With time, these are rectified, improved and the chances of reaching their goal and mission increases. Whilst the South African government has enacted SAHPRA and the concerted effort to improve medical device regulation, there are challenges and areas for improvement. Through this research we will explore how the medical device regulation in South Africa has grown since inception, the

challenges faced and how it can be improved, to ensure that substandard devices are limited on the market, and ultimately to ensure patient access to safe medical devices.

2. Research Question

How can the current Medical Device registration process in South Africa be improved, to reduce challenges faced by medical device manufacturers?

3. Aim and Objectives

This study aims to assess the efficiency of the medical device registration process in South Africa, through understanding the bottlenecks and challenges faced by medical device manufacturers, in their attempt to attain approval for medical devices.

Through the following study objectives, this aim will be realised:

a) To determine the knowledge and perceptions of Medical Device manufacturers regarding the processes for medical device registration

b) To identify challenges and bottlenecks faced by Medical Device manufacturers during the registration process

4. Methodology

A quantitative exploratory research design was selected for this research. Research design as explained by Creswell (2012) mentions the plan to conduct research and the strategies of inquiry and specific methods. Qualitative research involves content analysis and quantitative research involves the analysis of data that has been collected using statistics in order to expound a phenomenon (Creswell, 2009) or to establish a relationship between theory and research (Bryman, 2006). Quantitative

research helps to test theories and uses surveys, interviews and data collection (Creswell, 2009). This research design will allow engagement from medical device manufacturers about their understanding of the medical device registration process as well as areas within which they have challenges with SAHPRA and ultimately the registration process.

4.1. Study Site and Design

The exploratory quantitative analysis of the current procedures, knowledge and perceptions will be conducted through medical device importers, distributors, wholesalers, and manufacturers. As of June 2024 (and as per Appendix C) there is 708 registered medical device manufacturers in South Africa that carry medical device establishment licenses from SAHPRA. To begin the study, we will evaluate the current, theoretical regulatory process in South Africa through the guidelines, timeframes and processes in place by SAHPRA particularly for design and development, manufacturing and distribution/retail. According to Creswell, a survey provides a quantitative account of trends and attitudes of a population just by examining a sample of the total population. From these results, we can make claims about the population. The objective is to test the impact of a certain intervention on an outcome (Creswell, 2009). In this study, a survey has been designed to allow the researcher to draw inferences about the functionality of the Medical Device framework in South Africa (Appendix A). The survey tool used was adopted from a study by Fufa et al., (2023) and the WHO benchmarking tool (Permissions given in Appendix B). The survey tool should take approximately 15 minutes to ~~complete~~complete, and this will be stipulated in the patient information sheet. By evaluating and analyzing responses by medical device manufacturers regarding the challenges they face and bottlenecks they experience with the registration process, we can draw conclusions

about how the system has grown in enabling patient access to safe medical devices in South Africa as well as areas that still require improvement. Within this study, we will not implore solutions or make recommendations for improvements.

4.2. Population and Sampling

The population of this study consists of Medical Device Manufacturers (which may or may play the role of importers and/or ~~distributers~~distributors). The population selected will consist of those working in the public and private sector. All medical device manufacturers will be approached for participation, despite how long they have been in operation or the ~~amount~~number of facilities they have. For the purposes of this study, ~~Medical~~medical device manufacturers of all products that assist with healthcare, without any exclusion, that possess a SAHPRA establishment license will be included in the study. The following inclusion and exclusion criteria will be applied. A clear stipulation will be made on the patient information sheet that only one person per company, employed within Regulatory Affairs or Quality Assurance, with knowledge on the registration of medical devices in South Africa and SAHPRA should complete the questionnaire.

4.3. Inclusion and Exclusion Criteria

In this study, we will include Regulatory and Quality Assurance professionals employed within Medical Device Manufacturing companies in South Africa, in both, the public and private sectors. Included in this study ~~is~~are Medical Device Manufacturers acting within the role of importers, ~~distributers~~distributors, wholesalers and/or retailers.

Excluded in this study ~~is~~are Regulatory experts, hospitals and Medical Device ~~distributers~~distributors and/or retailers that are not the ~~manufacturer~~manufacturers.

For the purposes of this study, regulatory professionals within manufacturing companies refer to those personnel employed to maintain regulatory licenses, ensure products meet specification and have the necessary approvals before manufacture and sale. Regulatory experts refer to personnel that are employed within regulatory authorities and/or regulatory auditors.

4.4. Sample Size

With the study being exploratory, significant coverage and input is required and therefore, samples will be specific and not random. The survey study size will be determined using the response rate of the questionnaires. To calculate response rates, we would divide the number of responses by the total number of the sample group.

Using a sample size equation, we estimate and expect 250 respondents, based on our total population. Sample size was calculated ~~used~~using the equation below:

Sample Size = [z2 * p(1-p)] / e2 / 1 + [z2 * p(1-p)] / e2 * N]

Where N = 708 (the total population size), z = 1.960 (the z-score), e = 5% (the margin of error) and p = 50% (the response rate)

With a response rate of 50%, a minimum-targeted amount of 250 returned questionnaires is expected (Ficham, 2008). Repeat reminder emails that contain the patient information sheet as well as the link to the survey will be sent out every week to increase response rates.

4.5. Validating the Tool

A pilot study will be conducted using three measures. Face validation, which is an informal review, specifically by a non-expert who would assess the clarity, comprehensibility, and appropriateness for the target-group~~,~~ ~~content~~. Content ~~validation~~validation, which is a formal assessment by an expert in the field will determine appropriateness of content and identify any misunderstandings or omissions and lastly integrated reliability between the researcher and supervisor. Based on the feedback, if necessary, the instrument will be adjusted and amended. We will conduct the pilot study through the University of the Witwatersrand.

4.6. Study Procedure

The survey will be distributed to all medical device manufacturers by the principal investigator as manufacturer details are accessible (as per Appendix C). We will enlist the assistance of The Medical Device Manufacturers of South Africa (MDMSA) in distributing to its membership. Appendix C has a list of potential Medical Device Manufacturers that will be included in the study. Those highlighted in green have committed to participation and those highlighted in red have declined participation. Responses are still being received. Once we have received ethics approval from the University of the Witwatersrand Medical Human Research Ethics Committee, the online REDcap survey link will be distributed. Upon opening the research link, a slight introduction regarding the research project will be offered, providing information on its purpose, the approximate time it would take to complete the survey and also a non-disclosure statement. Anonymity of participants will be maintained throughout the data collection process. Data collected will be anonymous as no identifiable data is collected from participants and all data collected will only be analyzed by the researcher and supervisor. In the introduction,

it will confirm that consent is inferred by opening the link and completing the survey.

4.7. Data Analysis

All responses from REDCap will be exported to a Microsoft Excel spreadsheet for quantitative and statistical analysis. Categorical variables such as demographics, classes of medical devices and existence of establishment licenses will be analyzed using descriptive statistics measuring numbers, frequency and percentages. Quantitative data will be represented in the form of graphs and tables.

5. Ethical Considerations

Ethics approval, to conduct this study will be appealed to the University of the Witwatersrand Medical Human Research Ethics Committee. All research tools that will be used within this study will be validated prior to usage. A study information document, wherein the purpose and description of the study is highlighted, the risks and benefits of participating in the study survey and the approximate time for completion of the study survey will be generated. All participants will be reassured of the anonymity and confidentiality of participation that will be maintained throughout the study.

6. Timing

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
2024												

Protocol preparation											
Protocol Submission											
Ethics Application and submission											
Literature Review Writing											
Ethics Approval											
Data Collection											
Data interpretation and Analysis											
Final Write up and presentation											

7. Funding

Funding for the study will be provided by supervisor RINC. Additional applications will be made for support funding from the NRF and Faulty Research Committee (FRC).

8. Budget

Proposed Budget:

Item	**Cost**
Data collection and Handling	R2000.00
Publication Charges	R20000.00
Total	**R22000.00**

9. Dissemination and Translation

The findings will be disseminated through conference preceding's and publications. The knowledge will be translated through engaging with key stakeholders in the regulatory community, including members of the Medical Devices Society of South Africa and SAHPRA. At these meetings recommendations will be given based on findings of this research

APPENDIX D

Study Ethics

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Research Office

1 **HUMAN RESEARCH ETHICS COMMITTEE (NON-MEDICAL)**
R14/49 Cassim

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER: H24/08/04**
PROJECT TITLE	Examining the Efficiency of Medical Device Registration in South Africa since the establishment of the South African Health Products Regulatory Authority
INVESTIGATOR(S)	Mrs A Cassim
SCHOOL/DEPARTMENT	Pharmacy and Pharmacology/
DATE CONSIDERED	19 July 2024
DECISION OF THE COMMITTEE	Approved Risk Level: Minimal
EXPIRY DATE	22 September 2027

DATE 23 September 2024 **CHAIRPERSON** pp. J. Kuiper
(Professor J Watermeyer)

cc: Supervisor : Dr S Leigh

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **A SIGNED COPY** returned to the Secretary electronically. Unreported changes to the application may invalidate the clearance given by the HREC (Non-Medical)

APPENDIX E

Turnitin Report

Aisha

ORIGINALITY REPORT

12%	12%	11%	1%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	wiredspace.wits.ac.za Internet Source	3%
2	samj.org.za Internet Source	2%
3	www.mdpi.com Internet Source	1%
4	www.ncbi.nlm.nih.gov Internet Source	1%
5	www.samrc.ac.za Internet Source	1%
6	hdl.handle.net Internet Source	1%
7	openmedscience.com Internet Source	1%
8	gh.bmj.com Internet Source	1%
9	Jack Wong, Raymond K. Y. Tong. "Medical Regulatory Affairs - An International Handbook for Medical Devices and Healthcare Products", Jenny Stanford Publishing, 2025 Publication	1%
10	www.sahpra.org.za Internet Source	1%
11	pmc.ncbi.nlm.nih.gov Internet Source	1%