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Review article

A desktop review of evaluation of implementation of national medicines policies in SADC countries

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ABSTRACT

A national medicine policy (NMP), formerly referred to as a national drug policy (NDP) is a document that serves as a political commitment and guide for action by the government to provide safe, efficacious, quality assured, available, affordable and rationally used medicines. This is the first study to review the implemented components of the NMPs of the 16 South African Development Community (SADC) countries over the past ten years (2011-2021). Information published between 2011 and 2021 of each country such as pharmaceutical profiles, official government documents, WHO/HAI/World Bank datasets and research studies on the implemented components were appraised. Significant progress has been made by 16 SADC countries over the period 2011-2021 in implementing the NMP. The most commonly implemented components included the concept of essential medicines, pricing, and regulation. Though traditional and herbal medicines component is yet to be implemented by the majority. The pharmacistpatient ratio of 1:2300 was below the target for all countries, prompting the need to strengthen the pharmacy personnel in the healthcare systems. Medicine pricing, affordability, and availability studies are necessary to develop equitable pricing policies that will improve the accessibility of medicines in all countries and the SADC region. With the exception of the Republic of Tanzania, SADC countries need to urgently revise their NMPs, thus adopting progressive processes such as incorporating Health Technology Assessment (HTA) in the NMP. All SADC countries require a strong, internationalistic evaluation culture built-in their policy formulation. As the first study to investigate the implemented NMPs in the SADC region, it could serve as a springboard for the countries to address their common pharmaceutical challenges thus improving their readiness for universal health coverage (UHC). Future in-depth cross-country studies in the SADC region are necessary to comprehensively evaluate the implemented components of NMPs.

1. Introduction

A National Medicine Policy (NMP), formerly referred to as a National Drug Policy (NDP) is a document that serves as a political commitment and guide for action by the government to develop all components of the pharmaceutical sector [1–5]. Its objective is to provide safe, efficacious, quality assured, affordable, available and rationally used medicines to meet the population's healthcare needs. It provides a comprehensive framework for coordinating the activities of all stakeholders involved in the pharmaceutical sector

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and also defines the role that each should play. A National Medicines Policy should be defined in each country to maximise population's equitable access to essential medicines [3].

A successful NMP is thus underpinned by the essential medicines concept, which refers to the idea that, when standard treatment guidelines are applied, better medicine supply, rational prescribing, and lower costs are achieved as a result. By incorporating the NMP into the national health system, its goals and objectives will be addressed in broad health plans including disease-specific programs, and efficiently allocated resources, thus enabling policy implementation to achieve those broader objectives [1,3].

An NMP is characterised by multiple, diverse stakeholders (see Fig. 1) who participate and coordinate to deliver medicines to patients. The overall process of procuring, distributing and dispensing is as important as the health outcome of medicines in a society. Therefore, regulating this sector requires a well-planned, comprehensive and integrated strategy to cover all stakeholders and to regulate their activities [6]. In the absence of such a formal document, there may be no general overview of what is needed to meet the population's health needs. Consequently, some government measures may conflict with others, since the various goals and responsibilities are not clearly defined and understood [1]. In addition, according to Dukes [3], NMP should also express the government's commitment to promoting good governance practices, including increased transparency and accountability.

The health policy and the level of service provision in a particular country are important determinants of medicine policy and define the range of choices and options [1]. On the other hand, the medicine situation also affects the way in which health services are rendered. Services lose their credibility if there is no adequate supply of good quality medicines, or if these are badly prescribed. Thus, the implementation of an effective medicine policy promotes confidence in and use of health services [1]. It is very difficult to implement a health policy without a medicines policy. These specific goals and objectives of a National Medicine Policy will depend upon the country's situation, the national health policy, and political priorities set by the government [1].

According to the 2001 World Health Organisation (WHO) guidance, the key components of a NMP should include legislation and regulations, quality assurance, supply management systems, financial strategies for medicines, affordability, rational use, selection of essential medicines, human resources development, research, monitoring and evaluation [3,7]. (See Table 1).

 Enforcement, which encompasses legislation and regulation including those enforced by law such as investigation, inspections, certification and control

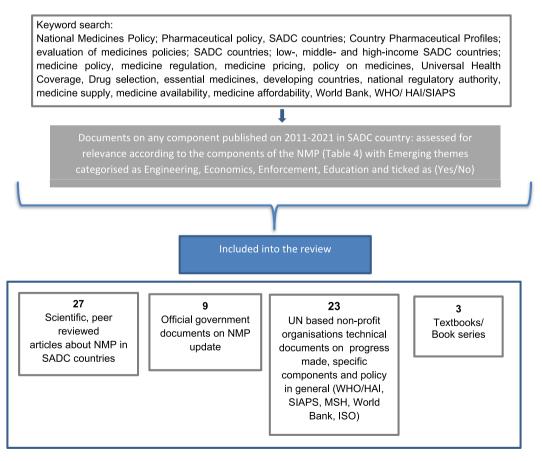


Fig. 1. Schematic diagram of the literature selection and inclusion.

Table 1

The components of a national medicines policy [3,8].

Legislative and regulatory framework

- · Legislation and regulation
- Drug regulatory authority
- · Medicine registration and licensing
- Pharmaceutical quality assurance, including inspection and enforcement
- Pharmacovigilance
- · Regulation of prescription and distribution
- Infrastructure for good governance in medicine

Choice of essential medicines

- Principles of essential medicine selection
- Selection process (market approval and selection based on national morbidity patterns)
- Selection criteria (sound and adequate evidence, cost-effectiveness)
- · Use of essential medicines
- · Traditional and herbal medicines

Supply management systems

- · Local production
- Supply system strategies and alternatives mix of public and private sectors
- · Procurement mechanisms
- Inventory control, including prevention of theft and waste
- · Distribution and storage
- · Disposal of unwanted or expired medicines

Rational use of medicines

- Multidisciplinary national body to coordinate medicines use policies
- Standard treatment guidelines as the basis for selecting medicines and training of health professionals
- Independent medicine information
- Rational medicine use training for health personnel
- · Education about rational use of medicines for consumers
- Promotional activities

Affordability

- Taxes or tariffs on essential medicines
- Distribution margins and pricing
- Measures to encourage competition through generic price information and negotiation
- Trade-related intellectual property mechanisms

Financial strategies for medicines

- · Role of the government in the pharmaceutical market
- Pharmaceutical financing mechanisms (public financing, user charges, health insurance, donor assistance)
- · Measures to improve efficiency and cost-effectiveness

Human Resources development

- Role of the health professions
- Role of government planning and overseeing training and development of human resources for the pharmaceutical sector
- · Human resources management and development plan
- · National and international collaborating networks
- · Motivation and continuing education
- · Ethical framework and code of conduct

Monitoring and Evaluation

- · Responsibilities and commitment
- · Baseline survey of the whole country
- · Indicators for monitoring
- · Periodic monitoring
- Independent external evaluation every two to three years

Research

- · Operational research
- · Pharmaceutical development and clinical research

Technical cooperation among countries

- Information sharing
- Harmonisation

Interesting to note that Imai et al. [9], grouped NMP key components as implementation areas according to the following framework, which allows comparative analysis of various pharmaceutical policies across different countries.

- Education and training, which includes programmes that influence selection and rational medicine use through dissemination of material which can be active or passive such as training and publication of an essential medicines list
- Engineering, which refers to organisational or managerial interventions such as supply management, quality assurance, human resource management, monitoring, evaluation and research.
- Economics, which embraces economic strategies for medicines and financial interventions such as pricing and affordability of medicines.

The final content of each NMP may vary among countries, depending on historical factors such as the country's institutional capacity to regulate and enforce the government's political values, the economic viability and the spending on pharmaceuticals. Typically, an NMP should have a lifespan of ten years to adapt to the changing environment and should be combined with periodic monitoring reviews. Therefore, It is imperative to regularly and holistically update the NMP, since its elements are continuously interlinked over time [4].

According to the WHO, 2001, the NMP document should be developed through a systematic process of consultation with all interested stakeholders as seen in Fig. 2, with a defined set of objectives and priorities, and a built-in commitment to ensure successful implementation, and follow-up. An NMP comprise of a complex and interlinked process of development, implementation and monitoring [7,10]. According to Walt et al. [11], the Walt and Gilson's model is a helpful tool to gain a comprehensive understanding of the complexity of policy development and implementation. This model proposes that not only the content of a policy determines how it's going to be developed and implemented, but also the context in which it occurs and the actors who are involved in the process [7]. Although the Monitoring and Evaluation (M&E) is traditionally perceived to be conducted at the final stage of the policy's life

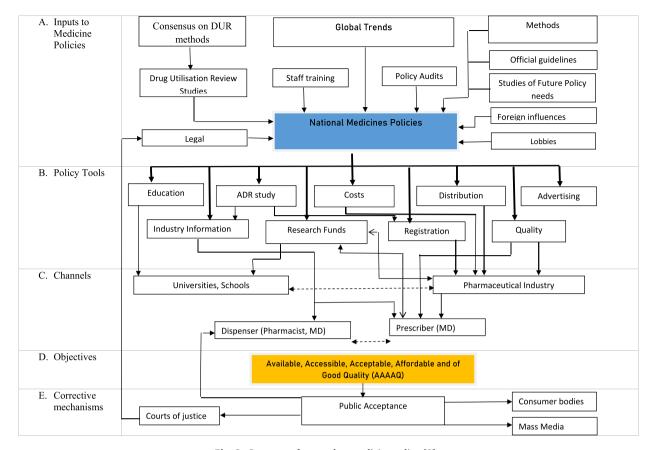


Fig. 2. Structure of a complete medicine policy [3].

cycle, Gray [7], suggests that it should be incepted at the policy development stage. This resonates with Hoebert et al. [4], and Almarsdottir [5], that an NMP should be dynamic and flexible to accommodate the changes over time, thus clearly defining the policy development process in the beginning. This will enable data to be collected before a new policy is initiated allowing a nation to learn from its own experience and improve its pharmaceutical reform activities.

Moving forward, the World Health Organisation recommends that the NMP should be presented and printed as an official government statement serving as a public declaration of the aspirations, aims, decisions and commitments of the national government to ensure that various government measures do not conflict with existing measures. It is important to ensure that its goals and responsibilities are clearly defined and understood by all stakeholders [5].

Countries will have different factors that may trigger the formulation of the NMP. Some may even present with similar challenges that exist beyond the boundaries of national borders. Such challenges can leverage the opportunity to harmonise best practices within their region [5,12].

Therefore, comparative analysis of NMPs can enable countries to share good governance principles with tangible local solutions allowing them to build trust, enabling data sharing and setting benchmarks. SADC in particular, requires cross-country comparative studies to gain insight of the available design and methodological options for policy analysis also amongst sub-Saharan African countries. A case study by Sehmi and Wale [13] showed that Ghana's progressive move to incorporate Health Technology Assessment (HTA) (a process of showing evidence-based value assessment of medicine or health technology) into its NMP, demonstrated sustained good governance and international cooperation. This study can serve as benchmark that can be used by SADC countries to adopt an internationalistic approach to comparative policy studies. Such studies will help to align countries' policies with the United Nations' health-related Sustainable Development Goals (SDG 3) that address human rights, and social protection. These studies have the potential to provide insight into the social and economic contexts of countries aimed at reducing inequities and promoting the well-being of communities [11,12,14–17].

While some research has been published about specific elements of the national medicines policy such as the recent study by Persaud, Jiang, and Shaikh et al. [18], no studies have been conducted to evaluate the implementation of NMPs in the SADC region. Moreover, little is known about the SADC as a region since the existing studies most global studies tend to collectively report top-line research on WHO countries grouped in continents [19]. Therefore, there is a strong need to understand the situation of the SADC region as a community with its countries sharing common objectives in meeting the Sustainable Development Goals. This will be the first study to investigate the implemented national medicines policies in the SADC region. It could serve as a springboard for the

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 Table 2

 Country-specific population, GDP per capita (in decreasing order), number of pharmacy personnel and NMP revision [19–25].

Country	Population	GDP/ capita	THE as a share of GDP	Number of pharmacists	PPR/ 100000	Number of Pharmacy Technicians	Date of NMP launch	Year of NMP revision	Time before last NMP revision	Time since the last NMP revision	Date of publication of any NMP-related component	
Seychelles	98 462	12720	5.10 %	4	4	56	Not yet	N/A	0	0	2012	
Mauritius	1 265 740	10230	5.80 %	497	39	1142	1996	N/A	0	0	2015	
Botswana	2 351 625	6640	5.80 %	153	6.5	258	1987	2002	15	21	2018	
South Africa	59 308 690	5410	8.30 %	15267	27	21713	1996	N/A	0	0	2016	
Namibia	2 540 916	4520	8.00 %	239	9.4	137	1998	N/A	N/A 0 0		2007	
Eswatini	1 160 164	3580	6.50 %	64	6	31	2000	2011	11	12	2018	
Angola	32 866 268	2230	2.50 %	2300	7	Unpublished	2007	N/A	0	0	2018	
Comoros	869 595	1450	4.60 %	15	2.5	26	1997	0	0	0	2004	
Zambia	18 383 956	1190	4.90 %	1286	7	814	1999	N/A	0	0	2018	
Lesotho	2 142 252	1100	9.30 %	30	0.16	59	1996	2005	9	18	2011	
Zimbabwe	14862927	1090	4.70 %	1419	10	520	1995	2011	16	12	2018	
Tanzania	59 734 213	1080	3.60 %	1194	2	1132	1993	2008	15	15	2018	
Malawi	19 129 955	580	9.30 %	293	1.5	221	1991	2009	18	14	2008	
Dem Republic of	89 561 404	550	3.30 %	2686	3	212	Not yet	2005	0	18	2018	
Congo							-					
Madagascar	28 411 367	480	4.80 %	6	0.02	Unpublished	1998	2005	7	18	2012	
Mozambique	31 255 435	460	8.20 %	103	0.32	1388	1985	1995	10	28	2013	

 $Key: GDP = Gross\ Domestic\ Product,\ THE = Total\ Health\ Expenditure,\ PPR = Pharmacist-Patient\ Ratio,\ NMP = National\ Medicines\ Policy.$

countries' readiness for planning and rolling out of universal health coverage (UHC).

More specifically, the aim of this paper is three-fold: 1) to evaluate the progress made in the implementation of the national medicines policies of SADC countries over the past ten years from 2011 to 2021; 2) to describe common regional and country-specific challenges, similarities and differences in the key components of the national medicine policies among the SADC countries; 3) to identify effective best practices among countries in the SADC to suggest future endeavours in policy development, implementation, monitoring and evaluation within the SADC region.

2. Methods

A cross-sectional literature review was conducted to gather data on the progress made in the implementation of the National Medicines Policy (NMP) in the SADC countries from 2011 to 2021. The review covered scientific journals, government and United Nations-based organisations agencies published between 2011 and 2021. Historical launch publications, textbooks or book chapters published the universal principles of NMP were also reviewed. A search was made across several databases like Google Scholar, PubMed, ScienceDirect and Elsevier journals for publication during the period 2011–2021. The search was further conducted in WHO/ HAI, SIAPS (Systems for Improved Access to Pharmaceuticals and Services. Countries were further classified according to their income levels according to the World Bank Atlas and thus health-related data was sourced from the databases such as ISO and World Atlas. Using the keywords such as "National mMedicines Policy", national drug policy", "SADC country-specific pharmaceutical profile", "evaluation of medicine policies", "implementation of national medicines policy", "SADC countries", developing countries or LIC, LMIC, HIC where applicable. The search yielded in scientific articles, formal government bulletins and WHO/HAI (World Health Organisation/Health Action International), SIAPS, International Standard Organisation (ISO) and the World Bank databases. To be eligible, the information sources needed to meet either or both two factors.

- (1) a component (s) of NMP existing according to Table 1 resulting in emerging themes that best describe the components were further clustered into categories in brackets: medicines regulation (enforcement) medicine availability (engineering), medicine pricing (economics) medicine selection/essential medicines (education).
- (2) an overview description on the progress of the NMP in the period 2011-2021 in the SADC countries. This included the management of the life cycle process of the NMP such as monitoring and evaluation, policy governance and revision.

The resulting information would be ticked (Yes = implemented, SE some extent/implementation occurring and No = not implemented/no data available) in Table 4. Finally, 27 scientific articles, 22 official documents from non-profit organisations such as WHO/ HAI, World Bank, SIAPS, and 9 official government country-specific reports and three textbooks/chapters totalling up to 61 information sources as seen in the schematic diagram below.

The majority of the SADC countries launched the NMPs in the mid-1990s, Albeit no formal NMP was launched in Seychelles (SYC) and the Democratic Republic of Congo (COD), these two economically polarised countries, did publish NMP components between 2012 and 2018, respectively. SADC countries' three letter codes are obtained from the International Organization for Standardization (ISO) ISO Alpha-3 code Online Browsing Platform SADC countries: AGO = Angola, BWA= Botswana, COD = Democratic of Congo,

Table 3 Common implementation challenges and lessons learnt.

personnel and staff throughout the medicine supply chain.

The reliance on United Nations (UN) organisations to foster reporting.

Observed implementation challenge	Insights and implications "take-home message"
The lack of understanding the structure of the NMP regardless of whether it is made explicit, excludes the active participation of the other role players limiting the scope and accountability of the implementation	Roles and responsibilities of the stakeholders must be clarified, levelling out conflicts of interest, promoting buy-in and reaffirming the legal obligations and accountability of each stakeholder. An opportunity exists to familiarise the non-pharmaceutical staff and the public
The lack of periodic multi-stakeholder engagement in the development, implementation and subsequently monitoring and evaluation but also the access to medicines. Consultation is crucial at all stages to allow an opportunity for the implementation team to negotiate priorities with other stakeholders and embrace the challenges brought by the change in context.	about the principles of essential medicines to fulfil their healthcare expectations, influence their perceptions and inform their preferences. The success of the implementation and revision depends of the continued, regular interaction with stakeholders. The interconnectedness of the components of the policy requires frequent, documented and transparent multistakeholder engagements to facilitate the successful implementation of the policy.
The lack of the dedicated implementation team and the active plan, makes the monitoring onerous and impossible to carry out.	The laissez-faire culture characterised by inefficiencies, conflicting priorities and a lack of accountability by different stakeholders contributing to the delayed revision
The lack of periodic monitoring and evaluation mechanisms and strategies to measure the impact of the decisions made in the preceding phase before the	M & E should be both a formative and a summative exercise in the policy analysis

The lack of political will and commitment and motivation of the health care The Human Resource Development for Health reforms should aim at key staff retentions and development The lack of trained staff, infrastructure, medicines to carry out pharmaceutical

All prescribers of medicines, health facility management should have shared values and objectives that are patient centric.

Ownership, and sustainable policy leadership is necessary to preserve institutional memory thus ensuring consistent policy data management

	ENFORCEMENT					EDUCATION				ENGINEERING				ECONOMICS		
Country	MRA	Inspections	Licensing	Registrations	EML	RMU	PV	тм	Research	HRD	SCM	M&E	TC	Medicines Affordability	Finance strategy	Pricing structure
Angola	YES	YES	YES	YES	YES	YES	NO	NO	NO	YES	YES	YES	YES	YES	NO	NO
Botswana	YES	YES	YES	YES	YES	YES	YES	NO	NO	YES	NO	NO	SE	YES	YES	YES
Comoros	NO	NO	NO	NO	YES	YES	NO	NO	NO	YES	YES	NO	YES	YES	SE	NO
Democratic Republic of																
Congo	YES	YES	YES	YES	YES	YES	YES	NO	NO	YES	YES	NO	YES	YES	YES	YES
Eswatini	SE	YES	YES	NO	YES	YES	NO	NO	SE	YES	YES	YES	YES	NO	NO	NO
Lesotho	SE	NO	NO	NO	YES	YES	NO	YES	YES	YES	YES	YES	YES	YES	YES	YES
Madagascar	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Malawi	YES	YES	YES	YES	YES	YES	YES	NO	NO	NO	NO	YES	NO	NO	NO	NO
Mauritius	YES	YES	YES	YES	YES	YES	YES	NO	NO	NO	YES	NO	NO	NO	NO	NO
Mozambique	YES	YES	YES	YES	YES	YES	YES	NO	NO	YES	YES	YES	YES	NO	NO	NO
Namibia	NO	NO	YES	NO	YES	NO	NO	NO	NO	YES	NO	NO	NO	NO	NO	NO
Seychelles	YES	YES	YES	NO	YES	YES	NO	NO	NO	NO	NO	NO	YES	SE	YES	NO
South Africa	YES	YES	YES	YES	YES	YES	YES	SE	NO	YES	YES	NO	YES	YES	YES	YES
Tanzania	YES	YES	YES	YES	YES	YES	YES	SE	NO	YES	YES	YES	YES	YES	YES	YES
Zambia	YES	YES	YES	YES	YES	YES	YES	NO	NO	NO	NO	NO	YES	NO	YES	NO
Zimbabwe	YES	YES	YES	YES	YES	YES	YES	SE	NO	YES	YES	NO	YES	YES	YES	YES

Key: yes data available some extent (SE) /implementation occurring, = no data available;

Abbreviations: EML/EMP- Essential Medicines List, IRIS= Institutional Repository Information Sharing, HRD= Human Resource Development, MRA= Medicine Regulatory Authority, M & E = monitoring and evaluation, RMU= Rational Medicine Use, PV= pharmacovigilance, SCM= Supply Chain Management, TC= Technical cooperation with other countries, TM= Traditional medicines

COM=Comoros, LSO = Lesotho, MDG = Madagascar, MOZ = Mozambique, MWI = Malawi, MUS = Mauritius, NAM=Namibia, SYC=Seychelles, SWZ=Eswatini, TZA = Tanzania, ZAF= South Africa, ZMB = Zambia, ZWE = Zimbabwe [47].

THE as a percentage of the GDP of upper-middle-income to high-income countries (GDP/capita 4096–12695) is on an average above 5 % for SYC, MUS, BWA. yet low-income countries like (GDP/capita <1085) MOZ, MWI and LSO showed almost double THE of 9 %. Angola, a lower middle-income country (GDP/capita of 2230), had the spends the lowest on health than any SADC country [20].

3. The achievements in the implementation of the national medicines policies in the SADC region

Although developing countries were among the first adopters of the NMP following the Nairobi Conference in 1985, they emerged as the last implementors with protracting revision periods [26]. This lack of implementation is multi-factorial attributed to factors inter alia, such as the countries' economic situation, political will, and competing healthcare priorities, motivation of the healthcare professionals. According to the WHO 2004, World Medicines Situation [48], eighty-eight 14/16 (88 %) countries have launched and implemented the NMP from 1987 to 2011 with the exception of the Democratic Republic of Congo and Seychelles as shown in Fig. 3.

Out of the 165 surveyed countries according to the WHO 2004, World Medicines Situation [48], 133/165 (81 %) had an existing NMP. Only about (97/155) 62,6 % had implementation plans, yet only 55/165 (33 %) were revised or updated after five- or ten years post-launch. Though the NMP revision period was over a five-year period, 27/55 (50 %) of the countries revised their NMP in contrast to the remaining 50 % that did not have the NMP or no revision at all. Consequently, The United Republic of Tanzania, being the first SADC country to adopt the essential medicines concept in 1970, has shown progressive implementation and integration of interventions with frequent revision of their policies [27,49]. It is also the first African country to be globally benchmarked and listed in WHO National Regulatory Authority (NRA) maturity level 3 in 2018 [50]. This is in stark contrast to more than 90 % of SADC countries which relied on UN-based organisations for technical assistance to generate local pharmaceutical data yet grapple to produce a drafted revised NMP document [24].

The common components of the NMP, though implemented in varying degrees within each component are the essential medicines concept, medicine pricing and medicine regulation with the exception of Seychelles, Zambia and Namibia (Table 4). According to the progress on traditional medicines published by WHO Regional Office for Africa, in 2011, Madagascar emerged as the only country that has implemented traditional and herbal medicines with active research in the African region. This is one component of the NMP that harbours a wealth of information not only in the SADC region but in Africa as a whole and can offer an opportunity to be integrated into the diversification of the healthcare approaches in the healthcare system.

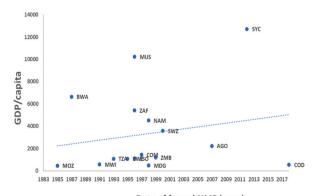
While implementation of the components of the NMP does occur in a non-sequential manner within the intended period, it is critical for the policy owners to engage the other affected stakeholders regarding any updates to the priorities and the progress of the implementation. This will provide clarity and direction to the parties involved and can ensure a successful and up-to-date policy document.

4. Expenditure on health

The country's economic situation as depicted by its GDP per capita and Total Healthcare Expenditure (THE) is known to be on the rise triggered by the ageing population and emergence of diseases and thus the demand for essential medicines Fig. 4 shows a stark contrast of low-income countries like MOZ, MWI and LSO with (GDP/capita <1085) spending almost double THE of 9 % of upper-middle-income to high-income countries, SYC, MUS, BWA (GDP/capita 4096–12695).

Angola, a lower middle-income country (GDP/capita of 2230), had the lowest expenditure on health of 2,5 % of any SADC country [22].

GDP/capita vs date of NMP launch



Date of formal NMP launch

Fig. 3. GDP/capita and the formal date of NMP publication per country [Source: 20,21,22,26].

THE as % of GDP vs GDP/ capita

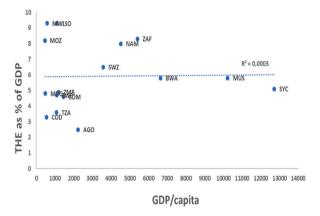


Fig. 4. GDP/capita vs percentage of Total Health Expenditure (THE). [Source: 22]

Therefore, there is a need for countries to develop pricing policies and monitor their pharmaceutical expenditure. Although a correlation between pharmaceutical expenditure and total health expenditure is poorly understood, WHO/HAI pricing surveys have been used to determine the extent of price differentiation and affordability in countries studies carried out in Comoros, Eswatini, South Africa and the Republic of Tanzania revealed the need to increase affordability of medicines and high median pricing ratios (MPR) that are higher than international reference prices [29,51–53]. This evidence, though rudimentary can inform policymakers and stakeholders in SADC countries to urgently address their domestic policies on pricing and pharmaceutical expenditure since they may improve the availability, affordability and accessibility of medicines thus eradicating disease burdens and promoting the well-being of populations.

5. Human resources

The pharmacist-patient ratio (PPR) and pharmacist/pharmacy personnel-patient ratio (PPPR) in all countries appeared to be below the WHO recommended benchmark of 43:100000 population (1:2300). This ratio is calculated using the number of registered pharmacists, and or pharmacy technicians per population (100 000/country population). The number did not include other prescribing healthcare professionals since the data was unavailable. Mauritius came out the highest with a PPR of 39 (Table 2), suggesting that the number of pharmaceutical services to the population is near optimal. The PPR is therefore necessary to provide an understanding of the quality of pharmaceutical care rendered to the patient and optimisation of professional pharmaceutical services in the healthcare system.

6. Implemented key components of the national medicines policies

A slow, incomplete implementation has been noted in the majority of the 16 SADC countries ten years post-launch between 2011 and 2021 as seen in Table 2 from reviewed reports and studies according to the following pillars:

Enforcement: WHO's Global Benchmarking Tool (GBT) Revision VI as the first globally accepted tool, provides countries with a systematic approach for strengthening their National Regulatory Authority (NRA) and categorises them into the following maturity levels (ML), namely, ML1: where some elements of regulatory systems exist; ML2: evolving national regulatory systems that partially perform essential regulatory functions; ML3: stable, well-functioning and integrated regulatory systems; and ML4: regulatory systems operating at an advanced level of performance and continuous improvement [54–56]. Although 80 % of the countries had an NRA with various core functions with the exception of Comoros, Eswatini and Lesotho (Table 4), South Africa and the Republic of Tanzania are the only two globally listed SADC countries to have advanced their NRAs operating at maturity level 3 [50]. Establishing an NRA to global ML 4 will improve the SADC countries' harmonisation and effectiveness to improve access to medicines.

Education: The essential medicines concept component was adopted by all countries with 50 % of the countries still yet having to set up a pharmacovigilance centre. Madagascar emerged as a leading country that has implemented traditional and herbal medicines with active research in the African region to date (Table 4). A comparative study of 137 essential medicines lists (including some SADC countries) by Persaud, Jiang & Shaikh et al. [18], emphasized the need to revise, validate and publish the essential medicines lists to provide an insight about the country's characteristics and their healthcare priorities.

Engineering: 69 % of the countries had published supply chain practices and models to address medicine availability issues, with 50 % of them reporting M & E in medicines and related supplies stock management through the practice of M & E is rudimentary in the entire policy areas. All countries by virtue of their developing and low economic status relied on technical cooperation and assistance from UN-based organisations with the exception of Botswana (Table 4).

Lastly in the **economics** pillar, 9/16 (56 %) of countries have a finance strategy for medicines with or without a pricing structure in place. South Africa, in exception, has a transparent, internationally benchmarked and regulated pricing structure which after its implementation, yielded in few published impact studies. These impact studies by Bangalee & Suleman [57], Wouters et al. [58], Moodley & Suleman [59], Perumal-Pillay [60] revealed the extent to which positive price regulation effects have generated smaller price increments in the price setting of medicines thus improving the affordability of medicines. Interestingly, a pharmacoeconomic impact study in the Comoros by Kassim, Alolga & Assanhou et al. [51], revealed higher procurement prices resulting in poor availability of medicines in the public sector. Therefore, pricing studies are a requisite for developing countries to understand their economic situation and how to best allocate resources in maximising access to medicines thus reducing financial inequities in communities.

7. Revision of the national medicines policy

50 % of the SADC countries have revised their policies within ten years post-launch in the period 2011–2021. The revision period appears to been over the five years post-launch ranging between 7 and 18 years. Interestingly, the remaining countries, have published the specific implemented components, without a complete revision of the NMP. This lack of sufficient details on all the implemented components of the NMP in all countries as concordant with the findings of Gligo [61], WHO [2], and Erasmus et al. [62], not only poses a threat to country's policy oversight, but also missed opportunities from the evolving NMP trends over time, correlation of the GDP on the healthcare system and the medicine budget. Therefore, NMP revision has a potential to provide insights about the impact of the implemented programmes in each country and the SADC region at large.

8. Observed challenges associated with implementation within the SADC region

The following observed common challenges emerged from the reviewed literature are tabulated against the possible insights and implications (see Table 3) [6,12,14,17,30].

9. Limitations and research gaps on the implementation of national medicines policies

Our study has limitations. Data compiled in the from each country was sourced from a variety of resources such as WHO/HAI/ World Bank/World Atlas databases websites, a process that was liable to errors, due to the validation of the data, and judgements had to be made about what to include in ambiguous cases by consulting specific literature resources.

The lack of up-to-date, peer-reviewed, publicly available studies and reports of SADC countries limits the comprehensiveness of the review to fully elucidate the successes and challenges faced by the countries.

The chosen period that this review namely, 2011–2021 captured all countries at different stages of implementing various components of their NMPs. This paper focused on what has been implemented to date and might not be a true reflection of the country's overall progress *in lieu* of its objectives.

This review included a mix of studies that focused on either overall policy analysis, cross-countries comparisons or policy-specific component studies. Their scope and extent do not permit an extrapolation of the findings to be a representation of the entire policy environment in each country. Although this review focused on SADC countries, future studies would be robust when compared to other sub-Saharan countries to gain insight of the NMP in the African continent.

Research gaps identified not only include the lack of policy design, methodological options and comparative studies of country-specific NMP various implemented components but also cross-country studies as influenced by income levels. These gaps are consistent with the results of Rida & Ibrahim [6], Perehudoff, Alexandrov & Hogerzeil [12], Nikfar et al. [14], Amaya, Bagapi & Choge et al., [30]. In the future, stakeholders could validate and update the information in the data sets used for this study and also provide information about how they are using the country's NMP to the database of global NMPs.

10. Policy implications

The ever-increasing medicine prices, disease burdens and the ageing population effects on the countries' resources to consistently implement, monitor and evaluate their established NMPs. Consequently, the lack of evaluated NMP not only results in country's each unaccounted performance, but hampers SADC regional harmonisation efforts and sharing of best practices to best utilise their resources in advancing towards universal health coverage.

11. Conclusion

This is the first desktop review to investigate the significant progress made by SADC countries in implementing their NMPs over time. The most commonly implemented components included the concept of essential medicines, pricing, and regulation in contrast to the least implemented traditional and herbal medicines component. Cross-country and global benchmarking studies are essential to advance countries' effectiveness in their implementation of NMPs thus prompting a strong urgent need for SADC countries to revise their NMPs. The results therefore provide insight into the trends of the commonly implemented NMP components by SADC countries over time.

Data Availability

Sharing research data helps other researchers evaluate your findings, build on your work and to increase trust in your article. We encourage all our authors to make as much of their data publicly available as reasonably possible. Please note that your response to the following questions regarding the public data availability and the reasons for potentially not making data available will be available alongside your article upon publication.

Has data associated with your study been deposited into a publicly available repository? Yes.

Please provide the name of the repository and the accession number here.

as follow-up to "Data Availability.

Sharing research data helps other researchers evaluate your findings, build on your work and to increase trust in your article. We encourage all our authors to make as much of their data publicly available as reasonably possible. Please note that your response to the following questions regarding the public data availability and the reasons for potentially not making data available will be available alongside your article upon publication.

Has data associated with your study been deposited into a publicly available repository?

- " Medicine Prices, Availability, Affordability & Price Components Database.
- 1. https://haiweb.org/what-we-do/price-availability-affordability/price-availability-data/
- 2. https://haiweb.org/survey-related-reports/
- 3. https://haiweb.org/what-we-do/price-availability-affordability/collecting-evidence-on-medicine-prices-availability/
- $\textbf{4.} \quad https://www.who.int/teams/health-product-and-policy-standards/medicines-selection-ip-and-affordability/who-hai-project-medicine-prices-and-availability.$
 - 5. http://www.haiweb.org/medicineprices/
 - 6. https://apps.who.int/gho/data/node.main.488?lang=en.
 - 7. https://www.who.int/teams/health-product-policy-and-standards/medicines-selection-ip-and-affordability/medicines-policy.

CRediT authorship contribution statement

William K. Modiba: Writing – review & editing, Writing – original draft, Visualization, Resources, Project administration, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. David R. Katerere: Supervision. Nontobeko P. Mncwangi: Supervision.

Declaration of competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: WILLIAM MODIBA reports financial support was provided by HEALTH WORKER SECTOR EDUCATION AND TRAINING AUTHORITY (HWSETA).

References

- [1] World Health Organisation, How to Develop and Implement a National Medicine Policy, Geneva, Switzerland, 2001, pp. 1–96. Available at:.
- [2] World Health Organisation, Using Indicators to Measure Country Pharmaceutical Situations Fact Book on WHO Level I and Level II Monitoring Indicators, Geneva, Switzerland, 2006, pp. 1–111.
- [3] G. Dukes, et al., National medicines policy, in: Managing Access to Medicines and Health Technologies, Management Sciences for Health, Arlington, VA, USA, 2012, pp. 63–82.
- [4] J.M. Hoebert, L. Van Dijk, A.K. Mantel-Teeuwisse, H.G.M. Leufkens, R.O. Laing, National Medicines Policies a review of the evolution and development process, Journal of Pharmaceutical Policy and Practice 6 (5) (2013) 1–10.
- [5] A.B. Almarsdóttir, J.M. Traulsen, National Medicine Policies Impacting Pharmacy Practice, Encyclopedia of Pharmacy Practice and Clinical Pharmacy, 2019, pp. 173–178
- [6] N.A. Rida, M.I.M. Ibrahim, Medicines pricing policy and strategies in developing countries: a review, Social and Administrative Aspects of Pharmacy in Low- and Middle-Income Countries (2018) 111–128. Elsevier Inc.
- [7] A. Gray, Factors Influencing Pharmaceutical Policy Implementation, Encyclopedia of Pharmacy Practice and Clinical Pharmacy, 2019, pp. 97–102, https://doi.org/10.1016/B978-0-12-812735-3.00315-0.
- [8] J.D. Quick, et al., National medicines policies. Managing medicine supply, management sciences for health, in: Collaboration with the WHO Action Programme on Essential Medicines, Kumarian Press, 1997 (chapter 5).
- [9] S. Imai, K.A. Sundell, K. Fushimi, Comparison of pharmaceutical policies to stimulate use of generics in Japan and Sweden, Health Policy and Technology 5 (2016) 189–195. Available at:. (Accessed 27 August 2019).
- [10] M.J. Roberts, M.R. Reich, Pharmaceutical Reform- A Guide to Improving Performance and Equity, The World Bank, Washington DC, 2011, pp. 1–332.
- [11] G. Walt, J. Shiffman, H. Schneider, S.F. Murray, R. Brugha, L. Gilson, Doing' health policy analysis: methodological and conceptual reflections and challenges, Health Pol. Plann. 23 (2008) 308–317, https://doi.org/10.1093/heapol/czn024.
- [12] S.K. Perehudoff, N.V. Alexandrov, H.V. Hogerzeil, The right to health as the basis for universal health coverage: a cross-sectional analysis of national medicines policies of 71 countries, PLoS One (2019) 1–15, https://doi.org/10.1371/journal.pone.0215577.
- [13] K. Sehmi, J.L. Wale, Where national medicines policies have taken us with patient involvement and health technology assessment in Africa, Front. Med. Technol. 4 (2022), 810456, https://doi.org/10.3389/fmedt.2022.810456, 1-9.
- [14] S, A. Nikfar, R. Kebriaeezadeh, Majdzadeh, M. Abdollahi, Monitoring of National Drug Policy and its standardised indicators; conformity to decisions of the national drug selecting committee in Iran, BMC Int. Health Hum. Right 5 (5) (2005) 1–10, https://doi.org/10.1186/1472-698X-5-5.
- [15] M.I.M. Ibrahim, A. Fatherlrahman, A.I. Wertheimer, Comparative Analysis and Conclusion, Pharmacy Practice in Developing Countries, 2016, pp. 449-467.
- [16] V. Burau, Transforming health policy and services: challenges for comparative research, Curr. Sociol. 60 (4) (2012) 569–578, https://doi.org/10.1177/0011392112438340.

[17] V.J. Wirtz, H. V Hogerzeil, A.L. Gray, M. Bigdeli, C.P. de Johncheere, M.A. Ewen, et al., Essential medicines for universal coverage, The Lancet Commission 389 (2017) 403–475.

- [18] N. Persaud, M. Jiang, R. Shaikh, A. Bali, E. Oronsaye, H. Woods, et al., Comparison of essential medicines lists in 137 countries, Bulletin of the World Health Organisation 97 (6) (2019) 394–404C.
- [19] World Health Organisation, Baseline Assessment of the Pharmaceutical Situation in Southern African Development Community Countries, Fact Book 2009. WHO/EMP/MPC/2011.2, Geneva, Switzerland, 2011, pp. 1–60.
- [20] World Bank, GDP by Country, 2017. Available at:. (Accessed 29 August 2019).
- [21] World Data Atlas (2018) Available at: < https://knoema.com/atlas/World Data Atlas Databank.worldbank.org. (Accessed 12 August 2021).
- [22] World Bank Data, Country Classification by income level (2022). Available at:. (Accessed 18 June 2023).
- [23] SIAPS, Democratic Republic of the Congo End of Project Report. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, Management Sciences for Health, Arlington, VA, 2017, pp. 1–17.
- [24] SIAPS Technical Highlight, Strengthening Capacity for Monitoring and Evaluating Mozambique's Regulatory System. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, Management Sciences for Health, Arlington, VA, 2017, pp. 1–70.
- [25] SIAPS, Toward Building Resilient Pharmaceutical Systems: SIAPS Final Report. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, Management Sciences for Health, Arlington, VA, 2018, pp. 1–70.
- [26] World Health Organisation, How to Develop and Implement a National Drug Policy, WHO Perspectives on Medicines, Geneva, Switzerland, 2003, pp. 1-6.
- [27] S. Ngozwana, A. West, A. Olajide, J. Byaruhanga, Pharmaceutical Manufacturing Plan for Africa- Business Plan, African Union, UNIDO, Addis Ababa, 2012, pp. 1–103.
- [28] Who Regional Office for Africa, Progress Report on Decade of Traditional Medicine in the African Region, Regional Committee for Africa Progress Report, 2011, pp. 1–7.
- [29] The United Republic of Tanzania Ministry of Health and Social Welfare, Medicine Price Monitor, Tanzania, 2014, pp. 1-12.
- [30] A.B. Amaya, K. Bagapi, I. Choge, P. De Lombaerde, S. Kingah, I. Kwape, et al., Monitoring Pro-poor Health-Policy Success in the SADC Region', PRARI Policy Brief No 7, The Open University, Milton Keynes, 2015 available at:. (Accessed 30 March 2022).
- [31] Z.-U. Babar, T. Gammie, T. Seyfoddin, S.S. Hasan, Patient access to medicines in two countries with similar health systems and differing medicines policies: implications from a comprehensive literature review, Res. Soc. Adm. Pharm. 15 (2019) 231–243.
- [32] A. Gray, F. Suleman, B. Pharasi, South Africa's National Medicine Policy: 20 years and still going? S. Afr. Health Rev. (2017) 49-58.
- [33] A. Green, C. Collins, A. Stefanini, The role of strategic health planning processes in the development of health care reform policies: a comparative study of Eritrea, Mozambique and Zimbabwe, Int. J. Health Plann. Manag. 22 (2007) 113–131, https://doi.org/10.1002/HPM.856.
- [34] K. Kunene, F. Fakudze, S. Mndzebele, F. Magagula, K. Shongwe, M. Vilane, Swaziland Pharmaceutical Strategic Plan 2012-2016: Baseline Survey Report, Management Sciences for Health, United States of America, Arlington, Virginia, 2013, pp. 1–30.
- [35] G.N. Mazibuko, E. Sagwa, H.R. Kagoya, J. Lukwago, Consolidating SIAPS' Five-Year Support to the Ministry of Health and Social Services for Strengthening Pharmacovigilance in Namibia, Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, Management Sciences for Health, Arlington, VA, 2016, pp. 1–29.
- [36] Ministry of Health, National Pharmaceutical Policy, second ed., Kingdom of Eswatini, Mbabane, 2011, pp. 1-15.
- [37] Ministry of Health and Social Welfare, National Health Policy, Swaziland Ministry of Health, Monitoring and Evaluation, Kingdom of Eswatini, Mbabane, 2015, pp. 1–15.
- [38] Ministry of Health and Child Welfare, The Zimbabwe National Medicines Policy, Directorate of Pharmacy Services, Zimbabwe, 2011, pp. 1-22.
- [39] Ministry of Health and Child Welfare, Annual Report 2016, Directorate of Pharmacy Services, Zimbabwe, 2016, pp. 1-37.
- [40] B. Pharasi, S. Banoo, Medicines, health products and technology, in: P. Matsoso (Ed.), The South African Health Reforms 2009-2014, Moving towards, Universal Coverage, Juta & Company Ltd, Cape Town, South Africa, 2015, pp. 182–199.
- [41] Seychelles Ministry of Health, Seychelles Pharmaceutical Profile, Seychelles Ministry of Health in collaboration with WHO, 2011, pp. 1-106.
- [42] Union of The Comoros, National Health Policy, Ministry of Health, 2005, pp. 1-25.
- [43] Union of The Comoros, National Health and Development Plan 2010-2014, Ministry of Health, Solidarity and Promotion of Gender, 2010, pp. 1-116.
- [44] World Health Organisation, WHO Medicines Strategy: 2000-2003 Framework for Action in Essential Drugs and Medicines Policy, Geneva, Switzerland, 2000, pp. 1–70.
- [45] World Health Organisation Zimbabwe Country Office, WCO Zimbabwe Annual Report 2017, World Health Organisation, Geneva, Switzerland, 2017, pp. 1–28.
- [46] World Health Organisation, Access to Medical Products in the South-East Asia Region: Review of Progress, WHO South-East Asia, New Delhi, 2019, pp. 1–80.
- [47] ISO-Alpha-3 codes. www.iso.org/obp/ui/#search. June 2023.
- [48] World Health Organisation, World Medicines Situation, second ed., Geneva, Switzerland, 2004, pp. 1–111.
- [49] United Republic of Tanzania Ministry of Health and Social Welfare, Pharmaceutical Sector Action Plan 2014 2020, Tanzania Mainland, 2020, pp. 1-71.
- [50] World Health Organisation, List of National Regulatory Authorities (NRAs) operating at maturity level 3 (ML3) and maturity level 4 (ML4) (2022). https://www.who.int/publications/m/item/list-of-nras-operating-at-ml3-and-ml4:1-2.
- [51] S.A. Kassim, R.N. Alolga, A.G. Assanhou, S.M. Kassim, L. Hongchao, M. Aixia, Medicine Pricing Impact on accessibility of medicines vis a vis the product of origin as pharmacoeconomic drivers in Comoros, J. Publ. Health Epidemiol. 7 (9) (2015) 274–293, https://doi.org/10.5897/JPHE2015.0762.
- [52] A.H. Kaiser I., B.C. Hehman, W.M. Forsberg, J. Sundewall Simangolwa, Availability, prices and affordability of essential medicines for treatment of diabetes and hypertension in private pharmacies in Zambia, PLoS One 14 (12) (2019), e0226169, https://doi.org/10.1371/journal.pone.0226169:1–18.
- [53] G. Shambira, F. Suleman, Retail pharmacy prescription medicines' availability, prices and affordability in Eswatini, Afr J Prm Health Care Fam Med 13 (1) (2021) 1–11, https://doi.org/10.4102/phcfm.v13i1.2986, a2986.
- [54] J. Guzman, E. O'Connell, K. Kikule, T. Hafner, The WHO Global Benchmarking Tool: a game changer for strengthening national regulatory capacity, BMJ Glob. Health 5 (e003181) (2020) 1–5, https://doi.org/10.1136/bmjgh-2020-003181.
- [55] World Health Organization, Evaluating and Publicly Designating Regulatory Authorities as WHO Listed Authorities: Policy Document, Licence: CC BY-NC-SA 3.0 IGO, Geneva, 2021, pp. 1–20.
- [56] World Health Organisation, WHO Global Benchmarking Tool (GBT) for Evaluation of National Regulatory System of Medical Products, Revision VI, Licence: CC BY-NC-SA 3.0 IGO, Geneva, 2021, pp. 1–350.
- [57] V. Bangalee, F. Suleman, Towards a Transparent Pricing System in South Africa: Trends in Pharmaceutical Logistics Fees, South African Health Review, 2016
- [58] O.J. Wouters, D.M. Sandberg, A. Pillay, P.G. Kanavosa, The impact of pharmaceutical tendering on prices and market concentration in South Africa over a 14-year period, Soc. Sci. Med. 220 (2018) 362–370, https://doi.org/10.1016/j.socscimed.2018.11.029.
- [59] R. Moodley, F. Suleman, Evaluating the impact of the single exit price policy on a basket of originator medicines in South Africa from 1999 to 2014 using a time series analysis, BMC Health Serv. Res. 19 (576) (2019) 1–13, https://doi.org/10.1186/s12913-019-4403-8.
- [60] V.A. Perumal-Pillay, T. Reddy, F. Suleman, An exploratory study into the use and pricing of schedule zero medicines post exemption from the single exit price policy in South Africa, Global J. Health Sci. 11 (3) (2019) 1–9, https://doi.org/10.5539/gjhs.v11n3p23.
- [61] N. Gligo, Public Institution and Explicit and Implicit Environmental Policies, Cepal Review, vol. 63, United Nations, Santiago, Chile, 1997.
- [62] E. Erasmus, M. Orgill, H. Schneider, L. Gilson, Mapping existing body of health policy implementation research in lower income settings: what is covered and what are the gaps? Health Pol. Plann. 29 (2014) https://doi.org/10.1093/heapol/czu063 iii35-iii50.