Public Policies: A Look at the Applicability of Drug Policy in Mozambique Over the Last 8 Years

Criscêncio Luís Sande Botão

Faculty of Health Sciences, Zambezi University

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ABSTRACT

This article addresses public policies, focusing on drug policy in Mozambique, which has been in place for almost ten years. Its purpose is to describe the salient aspects of drug policy in Mozambique, almost ten years after its introduction, that can be improved and/or enhanced to fully meet the needs of the population. Methodologically, this is a qualitative and exploratory study, therefore, an updated literature review on the subject was conducted. Based on this, the main theoretical concepts related to the topic are discussed, as well as their interconnections. Despite the policy ensuring the state's role as the number one guarantor of healthcare for the population, on the one hand, by creating and urging the drug regulatory authority as an interventionist entity to guarantee the quality of medical and surgical supplies, and on the other hand, by allowing community healthcare through dispersed public pharmacies, the methodology used led to the conclusion that there is no specific regulation for good manufacturing, marketing, and distribution practices that could refer to the supply of medical and surgical supplies.

Keywords: Public policies, drug policy in Mozambique

INTRODUCTION

Public policy is a crucial foundation that serves as a compass for any state or government in its social and economic development process, as it is within public policy that the differentiating factors leading to good comprehensive social performance should be found. It is from this perspective that this article, whose primary objective is to describe the salient aspects of the drug policy in Mozambique, almost ten years after its introduction, aims to improve and/or refine it in order to fully meet the needs of the population. Structurally, it includes the concepts and theories on public policies, where the polysemy of their interpretation underlies. Subsequently, it takes a pedagogical approach to the need to understand the public policy cycle, whose analysis, associated with the phases, allowed, through various perspectives on policy evaluation, to bring a local perspective, specifically in the analysis of the policy on Medicines, Vaccines, Biological Products and Health Products for Human Use in Mozambique, This study, using a qualitative and exploratory methodology and conducting a literature review, concluded that the policy ensures the state's role as the primary guarantor of healthcare for the population. This is achieved, on the one hand, by creating and establishing a drug regulatory authority as an intervening entity to guarantee the quality of medical and surgical supplies, and on the other hand, by enabling community healthcare through widely distributed public pharmacies.

Problem Statement

The Medicines Policy in Mozambique was initially approved through Law No. 04/98, of January 14, whose objective was to ensure the regular availability of effective, safe, good quality medicines at affordable prices for the entire population and to guarantee their rational use. However, guided by the need to adopt new approaches driven by current challenging phenomena, particularly diseases arising from various situations, such as climate change, the use of computational means, such as Artificial Intelligence (AI), among others, and taking as one of its assumptions the aforementioned factors, 19 years later Mozambique approved the new Law on Medicines, Vaccines, Biological and Health Products for Human Use, consequently repealing the previous one.

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Therefore, on the one hand, although the objectives are still relevant, with the advent of COVID-19, one of the most significant pandemics in world history, which in mid-2019 exposed the gaps in government interventionist approaches, and eight years after the approval of the last law, on the other hand, despite the existence of isolated interventions, such as the joint United Nations program on HIV/AIDS and Roll Back Malaria, it is urgent to ask to what extent it responds to the population's aspirations in the pursuit of its purposes?

Concept and theories on public policies

It is opportune to reflect on the term public policies (PP) as polysemous, there being no single definition of what a public policy is (Barreiro & Furtado, 2014). Therefore, when considering the positions of Souza (2006) and Barreiro and Furtado (2014), it appears that, for the former, public policy as an area of knowledge and academic discipline was born in the United States of America (USA), breaking or skipping the stages followed by the European tradition of studies and research in this area, which then focused more on the analysis of the State and its institutions than on the production of governments. For the latter, who also advocate public policies as polysemous, it is evident that the term is quite competitive, bringing an approach of agreement in relation to its multiplicity of interpretations. It is important to combine this with the intervention of Fernandes and Almeida (2019), According to which, the policy process seeks to build the idea that public policies are shaped in all their facets and phases by different types of actors, contexts, and institutions.

Therefore, it is noted that the authors establish relationships according to beliefs and interests in defending a value or interest, and their actions are affected by the context and institutions in which they operate. In a more holistic approach, the three interventions also elucidate that, depending on the angle/perspective from which each one views the policy process, the analysis that this article intends to present can be considered framed within the policy process, as an instrument for improving the drug policy in Mozambique.

Therefore, understanding Madeira's (2014) argument is crucial, as he states that PP represents the set of programs and actions of the state, directly or through delegation, with the objective of facing challenges and seizing opportunities of collective interest. It presupposes the recognition that there is an area or domain of life that is not private or solely individual.

It is noted in the statement above that PP can be understood as a state subterfuge that must necessarily demand public interest, without which institutions do not exist.

Therefore, Madeira's approach to the state subterfuge demands a placement of the state's extreme responsibility in providing tools that are best suited to achieving the objectives defined or to be defined.

However, when considering public policies as what the government chooses to do or not do" (Muller, 1987, cited in Höfling, 2001, Souza (2006) citing Dye (1984)), one finds agreement on the primary responsibility of governments to provide conditions for their communities. And this assumption implies a deep understanding of the cycles that public policies should demand.

Public Policy Cycle

In Raeder's opinion (2014), the PP cycle is an approach that has qualities highlighted by several authors who address the topic. The weaknesses were pointed out by Dias (2012), Jenkins-Smith (1993, p.44), cited in Raeder (2014), which include: (a) The different 'stages' are not linked by a causal component; (b) It does not offer a clear basis for empirical testing; (c) The succession of stages does not accurately describe the process; (d) The legalistic and top-down focus leads analysts to neglect other important descriptive-explanatory factors; (e) The policy cycle is improperly taken as the temporal unit of analysis, when the focus should be on multiple and interactive cycles involving multiple levels of government.

Therefore, it is clear that defining the elements to be incorporated into the PP cycle is crucial, since indicating isolated and disintegrated variables can culminate in a deficient PP.

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However, incorporating problems into the government agenda, the starting point for developing public policy proposals and government action, involves a series of steps that begin with the government's "acceptance" of an issue. This allows us to identify how it reaches the public debate and how it captures the attention of policymakers (agenda setting), thereby generating public policy options.

Next, it becomes necessary to legitimize the decision, at which point political support is sought from the actors involved with the public policy to obtain its approval. Finally, the formulated policy is implemented through operationalization in programs and projects by the competent areas (Pinto, 2008 citing Costa & Melo, 1998).

Two terms stand out here, namely compliance and legitimation, that is, if the government does not comply with what constitutes the population's concern, it will hardly have the legitimacy to carry it out, aspects that we will address later,

It is understood, therefore, that the PP cycle aims to understand the demand for the needs of its elaboration and its subsequent implementation, hence, from the perspective of the PP cycle theory, the models of policy analysis, according to Araujo and Rodrigues (2017), come to consider the analyses of political science, economics, psychology, sociology, history and organizational studies, therefore, insofar as, by combining all these areas, its phases will be easily understood.

Phases of the Public Policy Cycle

According to Barreiro and Furtado (2014), citing Secchi (2010:36, 44, 49), Rua (1997:9), Romano (2009), (Salama, 2008) and (Oliveira, 2006), the first moment of a public policy is the identification of the problem, which consists of verifying the distance from the current state to the ideal state.

Now, the approach of the authors previously cited clearly shows that the identification of the problem is the sine qua non condition for the public policy formulation process to take place. Therefore, they report that three issues are important for identifying the problem: (i) the perception of the problem, which consists of an intersubjective verification; (ii) the delimitation of the problem, which resembles the process of knowledge construction; and (iii) the assessment of the possibility of resolution, which can be analyzed analogously to the hypothesis in science.

The second phase would be the formation of the agenda, which is conceptualized as "the set of problems or themes understood as relevant" (...) The author differentiates, in this step, the political agenda from the formal agenda and the media agenda. The alternatives available to the public agent are related to mechanisms for inducing behavior. These are: rewards, coercion, awareness-raising, and technical solutions. (Barreiro & Furtado, 2014, citing Secchi, 2010:36, 44,49, Rua, 1997:9, Romano, 2009, Salama, 2008, Oliveira, 2006),

However, between the process of problem formulation and agenda formation in public policy, there are a series of observations and questions that must be accommodated, without which public policy may be doomed to failure, as indeed was emphasized by the authors, fundamentally in the previous passages.

However, the selection of the alternative to be adopted is made based on a comprehensive and detailed analysis of each alternative and its consequences.

The third phase is decision-making, the moment when interests, actions, and methods are made explicit. In this step, the author differentiates three dynamics of alternative selection: from problems to solutions, from solutions to problems, and a continuous comparison of solutions and problems.

Now, whatever the policy, including that of medicines (the subject of this article), it must necessarily observe the initial phases mentioned, because non-observance may imply erroneous interpretation of the subsequent phases. Therefore, only after observing the first phases does one proceed to implementation, which is the fourth phase of the process (cycle); it is the phase in which "the concrete results of the public policy are produced" (Barreiro & Furtado, 2014).

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Rua (1997:9), Romano (2009), (Salama, 2008) and (Oliveira, 2006) also add that it is in this phase that obstacles and failures affecting the most diverse areas of public policy are identified, opening space for further discussions.

The penultimate phase would be the evaluation of public policy, in which the implementation process and the performance of the public policy are examined in order to better understand the state of the policy and the level of reduction of the problem that generated it. Finally, the author refers to the extinction of public policies, which occurs when the problem is solved, when it becomes ineffective, or when the problem loses importance.

As can be seen, this article focuses on this phase, although understanding its limitations, associated with a greater depth on the subject, since little information has been made public about the evaluation of public policy (specifically that of medicines).

Therefore, after the penultimate phase, one begins to get a clear idea of which elements may have been less accurate and which should be improved. Thus, according to Lasswell (1956), cited in Jann and Wegrich (2007), a model of the political process composed of seven stages: intelligence, promotion, prescription, invocation, application, termination, and evaluation, can complement the phases discussed here. Insofar as they are all part of the monitoring and evaluation process.

Although this sequence of stages has been contested (in particular, that termination occurs before evaluation), the model itself has been highly successful as a basic framework for the field of political studies and has become the starting point for a variety of typologies of the political process. Today, the differentiation between agenda setting, policy formulation, decision-making, implementation, and evaluation (eventually leading to termination) has become the conventional way of describing the chronology of a political process.

However, Jann and Wegrich (2007) add that policy formulation presupposes the recognition of a political problem. The very recognition of the problem requires that a social problem has been defined as such and that the need for state intervention has been expressed. Therefore, understanding the evaluation of public policy can allow for a better understanding of whether or not to change it.

Evaluation of public policies

Evaluation has the power to increase the efficiency and effectiveness of the public sector (…) in other words, despite the recognition of evaluation as an important tool, it has not become an indispensable process that takes part in the management process (Cotta, 2001; Garcia, 2001; Mokate, 2002; Faria, 2005 cited in Trevisan & Van Bellen, 2008).

According to the same authors, this process has been justified by the need for "modernization" of public management, in a context of seeking to revitalize and legitimize the reform of the State (…) "last stage" of the so-called "policy cycle", defining it as: (a) activity aimed at assessing the results of a course of action whose life cycle is ending; (b) to provide elements for the design of new interventions or for the improvement of ongoing policies and programs; and (c) as part of the accountability and responsibility of state agents, that is, as a central element of accountability (Faria, 2005).

Here, we highlight the approach outlined by Faria, in calling for accountability, as it allows for a better understanding of the processes related to the evaluation of public policies. Along these lines, Ala-Harja and Helgason (2000) warn that, initially, there is no consensus as to what constitutes public policy evaluation, since the concept admits multiple definitions, some of them contradictory.

The above fact is explained precisely because the field of public policy is permeated by a variety of disciplines, institutions, and implementers, encompassing diverse issues, needs, and people, whose polysemous characteristic makes it a tool to be interpreted according to the perspective being evaluated.

It should be noted, however, that, as with the new public administration movement, policy evaluations are currently undergoing a phase of criticism of the "managerialism" of their conceptions (Trevisan & Van Bellen, 2008). For this reason, we once again refer to Madeira's analysis (2014), according to which the evaluation of

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public policy presupposes the observance of its different dimensions in the context of development, namely, in the economic dimension, where macroeconomic aspects and fiscal policy are conveyed, in the social dimension, social protection, support for the needy, in the territorial dimension, economic and social infrastructures, in the environmental dimension, sovereign international policy, and in the political/institutional dimension, strengthening of the state.

Therefore, it is on this basis that Mozambique's drug policy, approved by the Law on Medicines, Vaccines, Biological and Health Products for Human Use, will be evaluated, taking into account its 8-year time horizon since its publication and entry into force.

National Policy on Medicines, Vaccines, Biological and Health Products for Human Use.

The National Medicines Policy was approved by Law No. 4/98, of January 14, which approves the Medicines Law and creates the National Medicines Council. However, it was revised by Law No. 12/2017, of September 8, with the aim of adjusting it to the current stage of socio-economic development and the market for medicines, vaccines, biological and health products in order to ensure the availability of effective, safe, good quality products under accessible conditions for all citizens in need of medication and to guarantee their rational use.

However, this analysis will focus on Law No. 12/2017, of September 8. It consists of 10 chapters, 56 articles and 3 sections.

Therefore, the assumptions for its formulation (fundamentally the first Law - Law No. 4/98, of January 14th) were intrinsically related to the historical context, calling upon the State to assume responsibility as the guarantor of citizens' right to health, promulgated in its 1975 Constitution, which stated that "all citizens have the right to medical and sanitary assistance, under the terms of the Law, as well as the duty to promote and defend public health" (Art. 89).

Consequently, in the specific revisions of the 2004, 2018, and 2023 constitutions, the objective of health remained, and it was explicitly stated that: "It is the State's responsibility to promote, regulate, and control the production, marketing, and use of chemical, biological, pharmaceutical products and other means of treatment and diagnosis" (Art. 116/5). Pharmaceutical assistance and the organization of this subsector were political priorities of the post-independence socialist government in 1975, along with the creation of the National Health System (SNS), defining health as fundamental to development (Sachy, 2016).

Since the 1970s, Mozambique has received emergency donations of medicines, mainly from the United States. In the 1980s, it joined the economic rehabilitation program of the International Monetary Fund and the World Bank, and the privatization of national companies, increased private participation in the service sector, and the activity of NGOs in the country were implemented (from 7 in 1980 to 70 in 1985 and 180 in 1990). The neoliberal economic reform, with a decrease in spending on the social sector, including health, was conditioned by adherence to these policies, which continues to the present day.

It is in this context that the National Medicines Policy emerged, approved by Law No. 04/98 of January 14th, whose objectives were to ensure the regular availability of effective, safe, good quality medicines at affordable prices for the entire population and to guarantee their rational use, following a structure that took into account the institutional and constitutional environment by basing its area of action on the role of the State.

However, with the aim of adapting to the current stage of socio-economic development and the market for medicines, vaccines, biological and health products, in order to ensure the availability of effective, safe, good quality products at accessible prices for all citizens in need of medication and to guarantee their rational use, Law No. 12/2017, of September 8, was approved. Its objectives are to regulate the production, distribution and marketing of medicines, vaccines, biological and health products; to establish a national quality assurance system for medicines; to establish an efficient pharmacovigilance system aimed at the early detection of adverse drug effects; and to regulate biological, health and vaccine products, which in recent years have gained ground in the treatment of common diseases in Mozambique, as recommended by the World Health Organization (WHO) They should be treated at the same level as other medicines; ensure that the local production of medicines is

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carried out in a way that respects the good manufacturing practices recommended internationally; facilitate the medicines registration system and address aspects of the practice of the pharmaceutical profession; create the legal framework that guarantees aspects relating to sanctions and infractions concerning the diversion, counterfeiting of medicines, and smuggling of medicines, vaccines, biological and health products for human use.

However, the logistical process of surgical medical material, as a key tool in the acquisition, storage and distribution process for the National Health Service (NHS), is not clear in the policy under analysis. Likewise, there is still no specific regulation for good manufacturing, marketing and distribution practices that could also mention the supply of surgical medical material.

It also does not specify when and under what circumstances other institutions and/or ministries can or should be called upon, for example for pandemic and endemic issues.

Currently, the National Formulary of Medicines (FNM) is used to meet the needs of primary and secondary levels of healthcare. Tertiary and quaternary levels depend on specific lists, due to the particularities of the required medicines, which are determined by the current Directorate of Hospital Pharmacy of the Ministry of Health.

In this sense, it is appreciable and possible to interpret that the presented chronology suggests the attempt and solidity of implementing a drug policy contextualized with the precepts of the moment and always with a vision for the future, even though the inclusion of aspects previously advanced is not yet clarified and regulated.

However, in addition to the Mozambican state, the major actors in the development and implementation of the policy necessarily involve international support and NGOs, namely the World Health Organization (WHO), the Global Fund (GF), the United States of America (through various initiatives such as PEPFAR, the President's Emergency Plan for AIDS Relief; TB, tuberculosis, the U.S. Agency for International Development - USAID), India and China (the two largest suppliers of MMMCs to Mozambique), the Global Network for Neglected Tropical Diseases (strengthens institutional capacities to plan, implement and monitor the control, elimination or eradication of neglected diseases), the Joint United Nations Programme on HIV/AIDS and Roll Back Malaria (promote the integration of program activities into general services. The Roll Back Malaria strategy includes strengthening the procurement and distribution of medicines, quality control in laboratories, training and monitoring the quality of medicines).

However, regardless of the support from the aforementioned organizations, Mozambique needs to strive for greater autonomy, which will allow for policies that truly address the primary needs of the population. In this context, evaluating local drug policy from a global perspective is of paramount importance, as it will allow for an understanding of weaknesses and strengths that need improvement in due course.

Evaluation of the Policy on Medicines, Vaccines, Biological and Health Products for Human Use

The evaluation of the Medicines policy approved by Law No. 12/2017, of September 8, taking into account the elements of public policy evaluation presented in this article, namely in the following dimensions:

In the economic dimension, the policy does not allow the dispensing of medicines for outpatient use in situations where there is no pharmacy because it is too expensive (Article 28). However, the policy does not specify in concrete terms the clear and objective fiscal aspect to finance the availability of medicines. This allows us to infer that dependence on international actors conditions the timely acquisition, storage and distribution of medicines.

In the social dimension, the policy does not clearly present social protection or support for those in need, emphasizing primarily the perspective of commercial regulation, fundamentally in aspects of licenses, import, export, and marketing (Articles 13 to 27).

In the territorial dimension, the policy is silent on aspects of infrastructure such as warehouses and their form of communication with primary health care units to meet the needs of the population.

In the environmental dimension, the policy has a perspective of regulating the marketing and not the dispensing of medical devices, and does not substantiate financing through its own fiscal means; therefore, its sovereignty is still compromised by the fact that it is dependent on support from international actors.

In the political/institutional dimension, regarding the strengthening of the state, the policy itself ensures the state's role as the number one guarantor of health care for the population, when it creates and urges the regulatory authority for medicines to be proactive and guarantee the quality of medical devices (Article 6).

It is considered moderate, since, with the aspects included in the 56 articles, it was not possible to respond quickly to pandemic events such as COVID-19.

Concluding Remarks

Having reviewed the Medicines Policy approved by Law No. 12/2017, of September 8, it is evident that the logistical process for surgical medical supplies, as a key tool in the acquisition, storage, and distribution process for the National Health Service (SNS), is not clear in the policy under analysis. In other words, it does not present how and in what ways it should be done to guarantee a response to the community.

There is no specific regulation for good manufacturing, marketing, and distribution practices that could refer to the supply of medical and surgical supplies.

It does not specify the process of interaction with other state institutions in the acquisition, supply, and distribution of medical and surgical supplies.

The policy ensures the state's role as the number one guarantor of healthcare for the population, on the one hand, by creating and urging the regulatory authority for medicines as an intervening entity to guarantee the quality of medical and surgical supplies, and on the other hand, by allowing community care through dispersed public pharmacies.

Suggestions

The policy should include standards of good manufacturing, marketing, and distribution practices that could relate to the procurement of surgical medical supplies.

Similarly, the methods of interaction with other state institutions in the process of acquiring, supplying, and distributing medications and surgical medical supplies should be clarified.

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