

Analysis of Cameroon's National Drug Management System Using a Continuous Improvement Approach: The Case of Douala City

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Abstract

Some third world countries are still struggling to put in place effective national drug management policies capable of improving the health of their populations. This study consisted in analysing the national drug management system in Cameroon from February 2017 to June 2022 using a PDCA continuous improvement approach. We were able to observe the existence of a strategic planning with very low financial means, the weakness of the regulatory framework, a decentralised import policy with two sub-systems, a pharmaceutical industry that is not very competitive, the absence of system audit procedures and also the absence of a formal framework for consultation between the various structures of the National Pharmaceutical Regulation Authority (General Inspectorate of Pharmaceutical Services and Laboratories) and the National Pharmacy Directorate, The Directorate of Pharmacy, Medicines and Laboratories, the Directorate of Operational Health Research, the National Laboratory for Quality Control of Medicines and the National Centre for the Supply of Essential Medicines and Medical Consumables) and the weaknesses of the regulatory framework reduce the continuous improvement of the current system and increase the illicit traffic of fake medicines, an activity that exposes the medicine to poor storage. The example of the city of Douala, the economic capital of the country, showed us that out of 560 households surveyed in the vicinity of drug sales outlets in the neighbourhood, the percentage of people exposed to the consumption of medicines exposed to storage risk is 44.17%. Adopting a risk-based approach such as PDCA would be a very important element in decision making, awareness raising and ensuring increasingly compliant medicines in the country.

Keywords: Health System; Medicines; Storage; Continuous Improvement; Risk

Introduction

Background

The effectiveness of drug supply systems is integral to the strength of health care systems. Appropriate human resources, sustainable funding, comprehensive information systems, and coordination between partners and health facilities are essential to ensure uninterrupted availability and accessibility of essential

medicines. Long-term procurement strategies are lacking in many countries [1], particularly in sub-Saharan Africa. Access to essential drugs is contingent upon well-functioning supply chain systems that move drugs from the manufacturer through to end use [2].

The World Health Organisation (WHO) has developed tools to assess drug supply management systems in countries with the aim of identifying system strengths that need to be capitalised on

and weaknesses that need to be addressed in order to improve the system. WHO provides guidance and advocates for safe and efficient drug supply systems to improve availability and access to essential drugs [3]. The WHO has established a model process for the good governance of medicines programme in 3 phases: phase 1 national assessment, phase 2 development of a national good governance framework and phase 3 which is the implementation of the good governance programme. In 2009, 10 countries in the world were still in phase 1, namely Colombia, Ecuador and Costa Rica in the Americas, Indonesia and Pakistan in Asia, Morocco, Ethiopia, Kenya, Mozambique and Cameroon in Africa [4]. If African countries are to institute price-sensitive procurement agencies, or multinational buying cooperatives, to negotiate steep discounts off global list prices for medicines, this may not lead to expanded access in the presence of inefficient and ineffective drug supply chains [5].

Problem

The preamble to the Constitution of the Republic of Cameroon of 2 June 1972 enshrines the right of all Cameroonians to health. To realise this right and improve its health policy, the Ministry of Public Health has brought together the legal framework relating to pharmaceutical regulation around a national pharmaceutical policy (PPN) adopted in September 2000 and implemented within the framework of the Health Sector Strategy (HSS) from 2001. Ranked 164th out of 191 countries assessed by WHO in 2001, Cameroon's health system is weak. Consequently, it does not respond effectively to the needs of the population. In 2009, Cameroon adopted a vision for 2035: «Cameroon: an emerging country, democratic and united in its diversity». In this vision, the country set itself four general objectives, including « [6,7] to reduce poverty to a socially acceptable level». Knowing that [7], in general, purchasing drugs and medical consumables represent nearly 40% of current health expenditure [8]. Achieving this objective in the health sector will require improvements in the supply of care and services and guaranteed access for the majority to quality health services. These improvements will make it possible to take up the challenge of developing human capital, which consists of providing the Cameroonian population with good health, education, knowledge and professional skills. In addition, the second phase of Vision 2035 (2020-2027) identifies the following social objectives: (i) densification of social infrastructure; (ii) expansion of the social security system; and (iii) strengthening of mechanisms to combat social exclusion [7].

However, drug management is critical in achieving this goal because one of the subgoals is to achieve a 50% increase in the availability of drugs and other quality pharmaceutical products by 2027. However, the acquisition of essential drugs and the development of human resources are the two pillars that will require the most financial resources in the coming years [7]. The main question of our study is how do we improve our national drug management system to better align with these important goals?

Methodology

Data collection method

To carry out our study, we consulted all available national documentation related to the management of medicines in Cameroon through:

- Site of the Directorate of Pharmacy, Medicines and Laboratories (DPML; www.dpml.cm)
- MINSANTE website (www.minsante.cm)
- Cameroon's medical announcements (www.annuaire-medical.cm)
- A survey of households (560) living in the vicinity of non-pharmacy drug sellers and in dubious conditions. We also conducted semi-direct interviews with MINSANTE staff and pharmacy stakeholders in Cameroon. The topics covered included the different parameters of the supply chain, management monitoring and government policies related to drug management in Cameroon.
- Articles published in various national and international journals, documentation of dissertations, theses and archives.

Data synthesis method

In order to better synthesise the information, we carried out a triangular analysis based on three elements, namely the documentary review of all the information gathered in the documents collected, then well-targeted interviews with the various actors in the sector in order to better understand the information previously gathered and, thirdly, we made general observations in Cameroon and in particular in the city of Douala, which is the economic capital. A city open to international trade and with a very large working population.

To better illustrate the interactions between all the elements of the drug management system in Cameroon, we chose PDCA's Wheel of Deming tool for setting up management systems using a process approach. The PDCA cycle can be applied to each process and to the quality management system as a whole [9].

The PDCA cycle is beneficial for:

- Streamlining and improving a repetitive work process
- Developing a new operational process
- Engaging in continuous improvement
- Chain iterations with immediate results
- Limiting errors and optimising results
- Quickly evaluating multiple solutions [10].

Results

Presentation of the national medicines management system

- The national drug management system in Cameroon is an axis of the health system strengthening sub-component.
- The central body of this system in the Ministry of Health is the Directorate of Pharmacy, Medicines and Laboratories.

International and national requirements

Internationally:

The main actor is the WHO, through its multiple completed programs and several studies on the measures to ensure good public health through drug quality. We can cite the Good Governance for Medicines Programme (WHO Good Governance for Medicines Programme, 2009).

Nationally

To follow the correct approach taken by WHO, Cameroon has put in place a solid regulatory framework to comply with WHO requirements according to the level of local development.

Regulatory framework

Cameroon has an arsenal of regulatory texts governing the management of medicines. We have the law on the exercise of the profession of pharmacist in Cameroon, a decree on the code of ethics of pharmacists, a decree laying down procedures for the approval of pharmaceutical products, a decree on the organisation of the government by missions assigned to health, a circular on

instructions on the pricing of pharmaceutical products in the public sector, a circular on the control of imports of pharmaceutical products in general, a circular on good practices in the management of pharmaceutical products. To mention only these, the drug management system is based on texts that can be subject to regular inspections to ensure their respect by the different actors [11].

National policies

The provision of a national prevention policy (NPP)

The major objectives of the 2008 NPP are to ensure the Cameroonian population's access to essential drugs, the quality of drugs, their rational use, and their financial accessibility.

The PDPN national pharmaceutical master plan

To improve the programming and planning of the 2008 NPP objectives, a National Pharmaceutical Master Plan (PDPN) is being proposed.

Develop an efficient pharmaceutical and pharmacovigilance control and surveillance information system.

Promote the ethical imperative in the practice of the pharmaceutical profession, particularly in research and clinical trials.

Provide the country with qualified, competent, and motivated pharmaceutical sector personnel [12].

PDCA analysis of the system

Plan

Under the responsibility of the Head of the Pharmaceutical Standards and Legislation Department, the drug management system is planned through the Standards and Legislation Office to establish a national policy and set the achievement objectives.

The strategic planning objectives have been set and are directly taken into account in the planning of the Sustainable Development Goals (SDGs). One approach aims to introduce a third-party payment scheme for the population, eliminating pre-financing constraints and improving needs quantification (traceability) since the informal system creates deficits (lack of quantification). The national drug management system will also provide for a planning table of actions to be implemented concerning the overall objective of the strategy to strengthen the system.

Achieving the overall objective of increasing the availability and use of quality medicines and other pharmaceutical products by 50% in all health districts requires, among other things, an increase in the percentage of health facilities that do not have a stock of at least one tracer drug, as shown in figure 1, but also a reduction in the average number of days that tracer drugs are out of stock per quarter in health facilities, as illustrated in figure 2.

Figure 1 shows us a cross-sectional forecast of health care institutions with at least one traced drug stock after 2022.

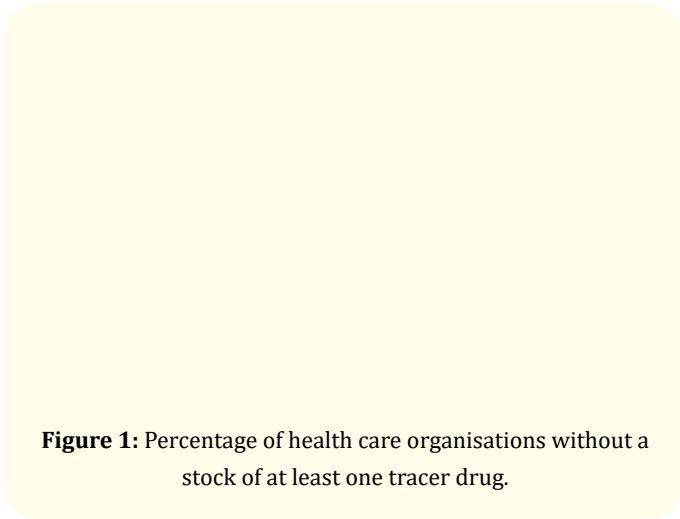
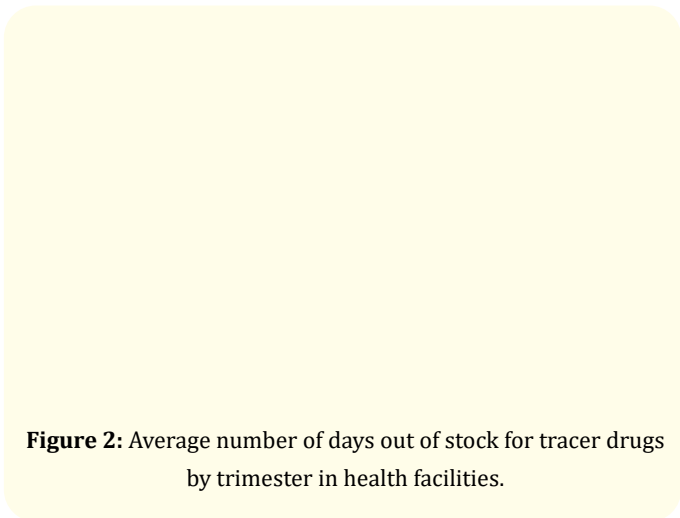


Figure 2 shows the predicted decrease in the stock-out rate in the country’s health facilities.



Hazard identification and risk assessment

The lack of a risk assessment document related to national drug management in Cameroon hinders the national drug management system.

System implementation (Do)

The activities for performing the national drug management system are placed under the authority of the approval service of the drug sub-directorate and based on the definition of the functions of the various actors and the application of good practices related to drug manufacture, transport, and storage in the territory.

The information collected during this study made it possible to identify the actors involved in the supply and distribution systems of drugs and other health products in Cameroon.

The pharmaceutical supply system in Cameroon

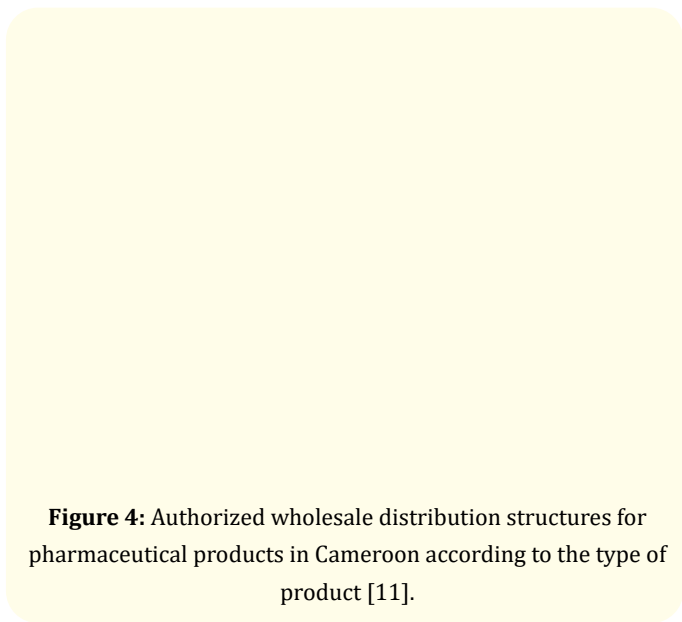
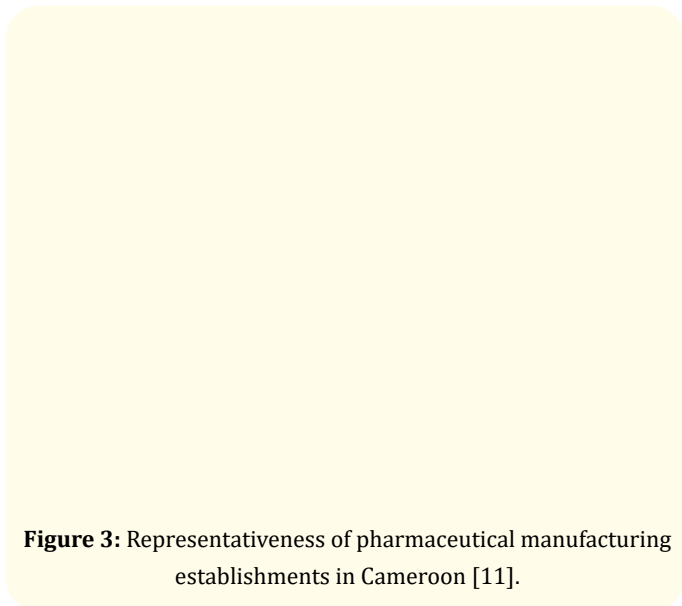
The new organisation was based on a three-level pyramidal structure: the central decision-making level, the intermediate regional level, and the peripheral operational level [7].

The national drug supply and distribution system in Cameroon is three-tiered and that the 1st and 2nd category hospitals all purchase from:

- CENAME
- The not-for-profit central purchasing office
- The private for-profit wholesale or distribution establishments.

We also have local producers and distributors as shown in Figures 6 and 7. A study published in 2019 in Cameroon showed that, with regard to customers, the companies have 5 main customers distributed in terms of order frequency, namely: 28.6% for wholesale distributors, 21.4% for CENAME, 21.4% for pharmacies, 14.3% for hospitals/clinics, and 14.3% for the private sector [13].

Figure 3 shows that only three regions are represented by the local production of drugs is centred around two large cities Yaounde (Center) and Douala (Littoral). Other towns are served by drug transport, for a total of seven establishments. With about 7



medicines controlled by LANACOME makes it difficult to ensure the conformity of medicines on the territory. Our industry is therefore not very competitive with performance indicators below those observed in some countries with comparable economies such as Cote d’Ivoire and Senegal [13].

Guides and good practices

We also have guides and good practices as benchmarks related to the functional organisation:

- The manual of standard operating procedures for drug management in Cameroon, MINSANTE 2014
- Good manufacturing practices for pharmaceutical products: main principles, WHO 2014
- Good wholesale distribution practices for pharmaceutical products, MINSANTE 2011
- Good manufacturing practices for pharmaceutical products, MINSANTE 2011
- Management and destruction of drugs and other pharmaceutical products unfit for consumption, MINSANTE 2016 [11].

At this level, we observed a good practical arrangement of documents relating to the proper functioning of a drug management system. However, the absence of an emergency management plan regarding risks associated with drug management weakens this system and further exposes populations to the consumption of drugs of questionable quality.

Quality control of drugs and other pharmaceutical products

The drug quality assurance system in Cameroon is based on numerous pillars: laboratory quality control, pharmaceutical inspection and market surveillance, approval, pharmacovigilance, import control, rigorous selection during the acquisition process, the proper drug storage, and the fight against counterfeit drugs and illicit trafficking in pharmaceutical products. All of these pillars are poorly implemented in Cameroon.

The National Laboratory for Quality Control of Medicines and Expertise (LANACOME) is responsible for quality control. However, this process is not systematic for imported drugs, and only a small proportion of circulating batches are checked before

local firms, Cameroon is far from the 36 drug production firms in Ghana [14].

Figure 4 shows that there are a higher number of distributors of conventional drugs in the territory compared to other types of distributed products, for a total of 50 structure.

The provision of several supply circuits and the absence of a regulatory provision obliging national manufacturers to have their

marketing after obtaining the MA. Counterfeiting has grown, and the illicit drug sector is believed to represent around 30% of the pharmaceutical market in African countries [15]. Inspection of pharmaceutical establishments remains very irregular due to a lack of logistical and financial resources.

System check (Check)

Concerning the audit of the system, we noted the absence of a formal procedure for auditing the system based on the steering and implementation control documents.

The verification of the system is a critical step in our system because it allows us to stop and question with regard to the good practices defined and performed above. Our national drug management system initially has a laboratory and blood transfusion service located at the Office of Standards, Legislation, and Approvals of Medical Analysis Laboratories to perform this task.

All the structures of the private system are subject to pharmaceutical regulations concerning the practice of pharmacy and therefore to the control of the DPM and IGSP [12].

The pillars of this verification are reliant on:

Strategy evaluation: Performed through internal and external evaluations, particularly at mid- and full-term. Periodic supervision reports from each level of the health pyramid include audits of health activities, finances and accounting, control and inspection, and activity from structures at all levels will form the basis for these evaluations [7].

These health sector diagnostics enabled us to identify a major problem: the poor capacity of the health system to contribute to the development of a healthy and productive population. Indeed, faced with the weakness of its six pillars (leadership and governance, human resources, healthcare provision, infrastructure, drugs and health technologies, financing, and health information system), the current health system does not adequately prevent events that adversely influence health [7].

Case of the city of Douala

A survey was conducted in the city of Douala to determine the drug consumption patterns of people living near street drug vendors.

The results of this survey of 560 households in the city of Douala located near street drug retailers on their drug consumption habits gave the following results: 250 households are most oriented towards the pharmacy, 222 towards the street drug retailers and 88 towards the pharmacopoeia

Figure 5: Percentage on the orientation of the populations of the city of Douala to the consumption of medicines.

Figure 5 shows that the prevalence of medicines among street retailers is quite high at 39.64%, very close to the 44.6% prevalence in hospitals and very far from the 15.7% prevalence in the pharmacopoeia. This result shows that despite the fact that the city of Douala is one of the two cities with drug production units, the circuit is still fallible and exposes the population to the consumption of drugs with storage risks.

On the other hand, a study conducted on the supply of drugs to the population in semi-rural areas in Cameroon had a prevalence of 53% for drugs sold on the street (grass) [16]. This shows that the prevalence of street drug use is higher in rural areas.

We also have the non-respect of the storage conditions of medicines, exposing the population to the risk of consuming toxic or ineffective medicines [17].

The details of the orientations according to the different age groups are given in figure 6.

Figure 6 shows that the majority of susceptible populations are oriented towards the consumption of medicines sold by

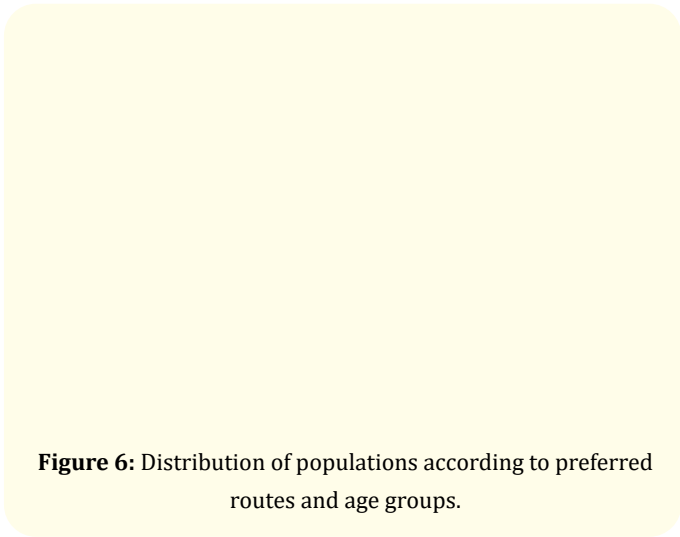


Figure 6: Distribution of populations according to preferred routes and age groups.

street retailers, and that this is the preferred orientation for large families. This means a total of 1,389 people for street retailers compared to 1,284 for pharmacies and hospitals and 471 for the pharmacopoeia.

Details of the prevalence of drug use among street retailers are shown in figure 7.

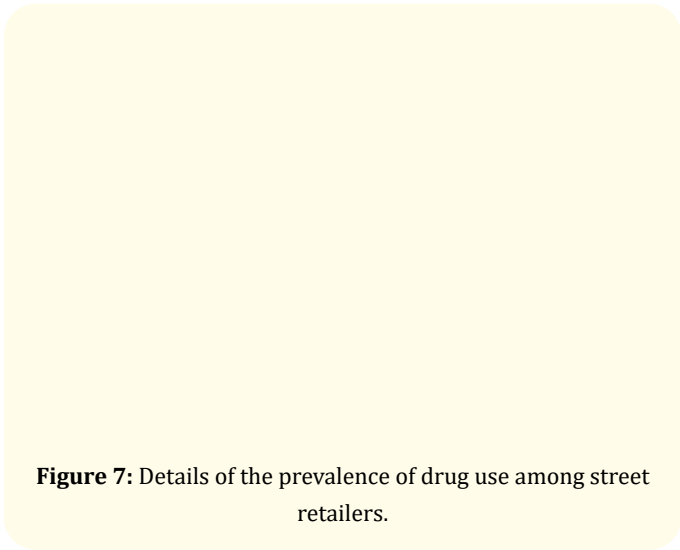


Figure 7: Details of the prevalence of drug use among street retailers.

The distribution by neighbourhood shows us that the districts with the highest population numbers are Douala III with neighbourhoods such as Japoma, Nyalla, Logbaba, Ngogpassi, Village, Yassa, PK 12, PK13 and Douala V with neighbourhoods

such as Bonamoussadi, Makepe, PK 14, 15. This also corresponds to the neighbourhoods where the highest number of people live in Douala. As shown in figure 7.

It can be seen that in these households, the majority or 44.92% are adults, 23.23% are children, 21.67% are adolescents and 10% are infants. As shown in figure 8.

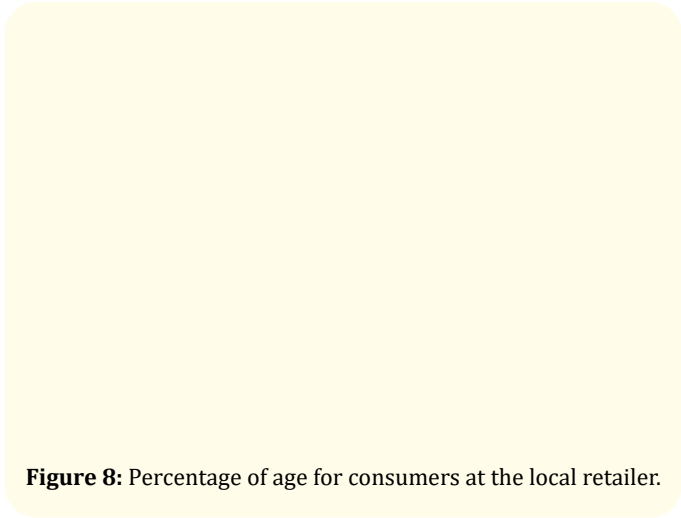


Figure 8: Percentage of age for consumers at the local retailer.

The storage of essential medicines must obviously respect good storage and sales practices. Unfortunately, a major problem in Cameroon is the self-medication of the population, which is often used for economic and social reasons.

However, this supply is fuelled by the scourge of smuggled medicines found in the streets of most Cameroonian cities, especially Douala. And these medicines are managed by untrained people who do not respect the good practices put in place by the WHO and consequently expose the medicines to poor storage.

The numerous major challenges associated with the strategic management and governance of the health sector and the development of a national strategy on governance motivated the selection of the institution for this pillar of the health system as a component. The entire cross-section for better analysis.

In 2003, geographic access to drugs was estimated to be 66% [18], and in 2008, the level of availability of tracer drugs was estimated to be 86%. In 2015, the average number of days of out-of-stock was estimated to be 16 days per year [19]. Supply difficulties, mismanagement, and insufficient working stocks at all levels of SYNAME are, among other things, at the root of these shortages.

An effort to regulate prices is attempted during the drug approval process, allowing the manufacturers of generics and specialities to significantly reduce their prices [7].

Medicines benefit from an exemption from customs duties, VAT, and consumer tax. However, the SGS tax of around 1% is still applied. Local drug production is low. Despite these efforts, a sizeable segment of the population [20] sources their pharmaceuticals from the streets.

System improvement (Act)

Improving the national drug management system is the last step in our continuous improvement wheel and encompasses activities such as research in the field and working and sectoral conferences. The definition of system improvement actions resulting from the audit carried out in the previous step.

The health sector strategic system

The 2016-2017 Health Sector Strategy document summarises two other documents: “Inventory and diagnosis of the health sector” and “Strategic choices of the health sector”. The development of the resulting deliverables was preceded by the production of the «HSS Assessment Report 2001-2015» [7].

This methodological note reports on the process and work tools used to develop the 2016-2027 Health Sector Strategy. This methodology was based on the two reference documents: (i) the Methodological Guide for Strategic Planning in Cameroon, 2011 edition [21], all stages of which have been respected with adjustments when necessary; and (ii) the WHO Guide for the Development of a National Health Policy and a National Strategic Health Plan [22].

The description of the methodology is centred around the three points:

- The institutional and organisational framework. The involvement and participation of all stakeholders in the process. The major stages and the course of the process.

It is organised in the form of annual, semi-annual, mid-term and end-of-cycle reviews, accompanied by reports according to a framework defined and shared at all levels of the health pyramid. Given the inherent inadequacies in monitoring the implementation

of the expired HSS, technical assistance, particularly at the national level, is essential and will be considered during the first years of implementation of the strategy [7].

Priorisation of objectives

The implementation of strategic interventions in health system strengthening and specifically in drug management based on the following priority criteria: Consistency of the specific objective with the orientations of the sector. Capacities of the actors to achieve the specific objective according to the Strengths, Weaknesses, Opportunities, and Threats to the system. Contribution of the specific objective to the achievement of the overall objective. Time horizon for achieving the specific objective. Operational cost of implementing the specific objective.

The specific objective by 2027 is to increase the availability of quality drugs and other pharmaceutical products and their use in all health centers by 50%. And the Priority actions for the cycle 2021-2027 is the Consolidation of the achievements of the first cycle.

Strengthening of local production; Promotion of the rational use of quality drugs; Strengthening of quality assurance and availability of drugs [7]. Although the majority of criteria are satisfactory for this prioritisation, the cost remains the lowest criterion, which can be an obstacle to executing necessary actions.

Funding

Axis of financing (2016-2027)	COST (BILLIONS)
Health promotion	362.8
Disease prevention	682.2
Curative case management	1,385.60
Health system strengthening	3,101.60
Strategic management and governance	291.90
TOTAL	5,824.1

Table 1: Financing the health strategy by axis.

The total cost of the different strategic axes developed is estimated at CFAF 5,824 billion for the period 2016-2027, with an annual average of CFAF 485 billion distributed as shown in figure 9.

Figure 9: Total cost per pillar of the health system for the period 2016-2027 [7].

It can therefore be seen that financing of medicines and other pharmaceutical products is the third most important of the five areas of the sub-component «health system strengthening». However, it is essential to plan for these actions within this budget over the period itself in order to take better account of potential risks. In direct comparison with developed countries such as Canada, this budget of \$495.2 billion over 12 years is a far cry from the estimated minimum of \$23 billion per year for a developed country such as Canada with a population of around [23].

Discussion

In 2003, the Ecumenical Pharmaceutical Network (EPN-Ecumenical Pharmaceutical Network) collaborated with the WHO on a descriptive and comparative multicountry study of the activities of sixteen professional supply organisations, including drug supply organisation (DSO) EPN members and their contribution in this area in eleven countries of sub-Saharan Africa [3].

During the debriefing, quality assurance emerged as the key priority area in the action plan developed by participants to improve DSO delivery. Only half of the DSOs regularly checked the quality of the lots they obtained, and few kept samples for the specified time period. All DSOs said they could not thoroughly inspect their suppliers' premises to verify compliance with GMP. These results perfectly [24] agree with the analysis performed on our drug management system.

In 2010, a study of 439 health facilities and 24 districts based on improving the supply chain of essential medicines in low-income

countries showed that the results of a large-scale randomisation exercise in Zambia when implementing a more direct two-tier distribution system yielded the following results: a significant decrease in the frequency of stock-outs for first-line paediatric malaria medicines from 47.9 to 13.3% over one year compared to a three-tier distribution system as is the case in Cameroon [25]. [25]

Another study conducted in 2018 found that in countries more advanced than Cameroon in terms of establishing good governance of medicines, such as Benin, the multiplication of supply channels by transnational actors leads to dysfunction in the management of medicines at national level. Even if they allow to buy at lower prices thanks to grouped purchases, their efficiency remains questionable. Among the dysfunctions observed, we have stock-outs, overstocking, and expiry of products. Two specific mechanisms have been put in place to make transnational actors accountable and to ensure that the principles of alignment, harmonisation and coherence are respected in the provision of health products, namely the CNAPS and the Common Basket. The DPMED which is the regulatory agency of Benin is designated to ensure the coordination of the CNAPS. In Cameroon, we still have a three-tier system and [26,27] CENAME, which does not centralise supplies, weakens the system, unlike in Benin.

A similar study done in 2020 on key success factors in supply chain management of essential medicines in the public health system in Malawi reveals as a success factor the collaboration of supply chain partners in coordinating data sources for demand forecasting and planning to avoid over- and under-stocking of essential medicines [28]. In Cameroon, we observed that the absence of a formal framework for consultation between the various PRNA structures (IGSP, DPML, DROS, LANACOME, and CENAME).

Conclusion

At the end of our study, we found that the national drug management system in Cameroon already has important elements for its functioning. For a state that was still in phase 1 of the application of the WHO good governance of medicines, it has important elements for phase 2, which is the development of a national framework for good governance, namely the creation of a central body within MINSANTE, which is the DPML, the provision of a regulatory framework for the management of medicines, the

provision of good practices for the production, distribution and destruction of medicines, and the provision of a quality manual with management procedures. However, we note the formal absence of a general audit procedure for the application of these documents. This does not facilitate the management of the system and the timely detection of deviations. However, work is carried out but with great frequency on the evaluation of the medicines management system. We have the sectoral health strategy of MINSANTE or the work of the WHO or the United States Agency for International Development (USAID). All these evaluations reveal the same causes that weaken our system, namely the proliferation of illicit medicines that are generally handled by untrained people.

To reduce the illicit trade, we need to provide access to affordable care by pooling the communal costs of care and unity in health so that the rich and healthy can contribute to improving the health of the poor and sick. This strategy will lead to an overall improvement in the health of the population. The organisation of the drug management system of many African countries is the source of the weakness in their healthcare systems.

Summary

For some, Third World countries are still struggling to put in place effective national drug management policies capable of improving the health framework of their populations. This study consisted in analyzing the national drug management system of Cameroon from February 2017 to June 2022 based on a PDCA continuous improvement approach. We have observed the existence of strategic planning with very limited financial resources, the weakness of the regulatory framework, a decentralized import policy with two subsystems, an uncompetitive pharmaceutical industry, the absence of system audit procedures but also the absence of a formal framework for consultation between the various structures of the National Pharmaceutical Regulatory Authority (General Inspection of Pharmaceutical Services and Laboratories, The Directorate of Pharmacy, Medicines and Laboratory, The Directorate of Operational Research of Health, The National Laboratory for Quality Control of Expertise Drugs and the National Center for Supply and Essential Medical Drugs and Consumables) and weaknesses in the regulatory framework reduce the continuous improvement of the current system and increase illicit trafficking in fake medicines, an activity that exposes the medicine to improper storage. The

example of the city of Douala, the economic capital of the country, showed us that out of 560 households interviewed near the pints of drug sales at retailers in the district, the percentage of people exposed to the consumption of drugs exposed to the risk of stpkeage is 44.17%. A risk-based approach such as PDCA would be a very important element for decision-making, awareness-raising and to ensure increasingly compliant medicines in the territory.

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