Challenges and Opportunities of Pharmaceutical Regulation in Nigeria

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Abstract
Background: Pharmaceuticals are critical for the health and well-being of populations. However, they can be poisons, and drug disasters such as that of thalidomide and other less dramatic cases of drug injury, constantly remind us of the imperative of testing and control of medicines. Sadly, in Africa and Nigeria in particular, pharmaceutical regulation is severely constrained by limited national capacities to undertake core regulatory roles. Citizens have continued to be exposed to potentially harmful medicines, sub-standard and counterfeit products and irrational prescription of pharmaceuticals. This study seeks to deepen the understanding of how pharmaceuticals are regulated, what regulatory constraints there are, and proffer policy solutions to improve regulatory capacity and performance in Nigeria.
Method: The study adopted a mixed method approach, using questionnaires and semi-structured interviews to collect data from key pharmaceutical actors in Nigeria. The questionnaires were analyzed using SPSS version 20.00, while interview data was transcribed, coded and content analysis undertaken. Key themes were identified and interpreted.
Results: 80% of business premises were formally registered with the Pharmacy Council of Nigeria, while 83% of questionnaire respondents were satisfied with overall regulatory performance. 60% of retail pharmaceutical retail outlets surveyed had at least one regulatory inspection in the last one year preceding the study and 6.7% of the sample had not had an inspection visit. Qualitative interviews revealed a number of regulatory capacity challenges ranging from inadequate financing, infrastructural deficits, socioeconomic to official corruption.
Conclusion: We conclude that improving services at pharmaceutical retail outlets to achieve health system objectives will require a modification of current rigid control approach by integrating market driven strategies that creatively engages all stakeholders, while recognizing appropriate relationships and balance between needs and standards.
Key words: Retail pharmacy outlets; Regulation; Challenges; Opportunities; Public Health; Policy; Nigeria

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I. INTRODUCTION

Pharmaceuticals are critical for the health and well-being of populations. However, they can be poisons, and drug disasters such as that of thalidomide and other less dramatic cases of drug injury, constantly remind us of the imperative of testing and control of medicines.[1,2,3,4] In the context of pharmaceutical care therefore, policy-makers frequently aim at balancing consumer access to safe, effective and affordable medicines, using a mix of regulatory levers.[5] The concept of regulation can be broadly defined as "sustained and focused control exercised by a public agency over activities which are valued by a community," but in healthcare, it reflects "any set of influences or rules exterior to the practice or administration of medical care that imposes rules of behavior."[6,7] Regulation serves three key functions: performance and quality improvement, ensuring that minimum standards are achieved and providing accountability for both performance levels and value for money.[8] Therefore, to achieve effective regulation of pharmaceuticals would require a comprehensive legal and legislative framework that clearly specifies appropriate governance structures, technical expertise of regulators, sustainable funding, and performance monitoring strategies.[9,10] The legal framework provides the power base to carry out intended functions and the autonomy to execute core regulatory mandate, while appropriate structure allows for coordination of regulatory activities. Financial adequacy and availability of sufficient numbers and quality of human resources serve to determine performance.[11] These then define the core regulatory functions in pharmaceutical context and include; marketing authorization, pharmacovigilance, post-marketing surveillance, quality control and Clinical trials oversight.[10]

Traditionally, marketing authorization is the first regulatory step in pharmaceutical regulation, undertaken by competent national authorities and purposed at verifying the quality, safety and efficacy of candidate products. Pharmacovigilance collects data and reports on adverse drug events of an approved medicine while in the market, while post-marketing surveillance identifies pharmaceutical related patient-relevant additional therapeutic benefits of new drugs, relative to existing alternatives, through periodic reviews of authorized products. Quality control aims to ensuring that products comply with regulatory specifications, and testing of post-marketing samples serves to deter negligent or fraudulent manufacturing and trading practice, thus addressing the challenge of substandard and falsified (SSFF) medicinal products. Clinical trials oversight of new drugs ensures the safety of research subjects and scientific integrity of clinical trial data.[12,11]

Globally, pharmaceutical regulation is constrained by limited national capacities to undertake core regulatory roles, with Africa demonstrating the weakest capability.[13,14,15,16] Weak pharmaceutical oversight in any country exposes drug users to potentially harmful medicines, sub-standard and counterfeit products and promotes irrational prescription of pharmaceuticals.[17,18,16] The regulatory weakness has been attributed to lack of adequate and trained enforcement staff, insufficient budgets and inadequate regulatory and legal frameworks.[12,24] In particular, drug Laws and policies are fundamental to regulatory activities and must be exhaustive, embedding all aspects of pharmaceutical practice. This being because regulatory agencies derive their power and authority to effectively perform core regulatory functions from them.

Pharmaceutical regulation in Nigeria is particularly weak, characterized by irregular regulatory inspections, weak enforcement and pervasive infringements and associated negative health outcomes.[10,20,21] Causative factors have included inadequate and often overlapping legislation, official corruption, poorly trained personnel and underfunding of regulatory institutions.[22,23] This has resulted in widespread unregulated and sometimes illicit sale of restricted pharmaceuticals, often without prescription and frequently by unqualified staff. There is also, high burden of fake, adulterated and substandard drugs in the market and an equally high prevalence of adverse drug events.[23,19,24] For example in 1990, 109 Nigerian children died following paracetamol syrup consumption and in 2004, three Nigerian hospitals reported cases of adverse reactions following the administration of locally manufactured infusions.[25,26]

The drug market in Nigeria is complex and consist of manufacturers/importers, wholesalers and retailers. Retailing is highly plural and fragmented, comprising of few formal pharmacies and a spectrum of non-pharmacies, such as patent medicine vendors, itinerant drug hawkers and general stores that also sell a variety of drugs and healthcare products.[27] Retail outlets are an important source of healthcare for a vast number of people and are often the first point of call for healthcare.[28,29,30,24] For example, patent medicine vendors account for over 70% of malarial treatments in the country.[31] Given their importance in health and well being, this study seeks to deepen the understanding of how this market is regulated, what regulatory constraints there are and proffer policy solutions for improved regulatory performance that promotes public health in Nigeria.

Legal and Policy Framework for Pharmaceutical Regulation in Nigeria

A number of legislative and policy instruments to regulate and control the pharmaceutical industry exist in Nigeria. These demonstrate the overarching commitment of the government to ensuring access to quality and effective drugs and their rational use, and include:

National Drug Policy 1990: This policy has the goals of improving availability, adequate supplies of drugs that are effective, safe, effective and affordable medicines and their rational use for all Nigerians. It also aims to stimulate enhanced local production of essential drugs on a sustainable basis.

Poisons and Pharmacy Act, Cap 366 of 1990: The Act regulates the compounding, distribution, marketing and dispensing of drugs and medicinal products in Nigeria.

Food and Drugs Act Cap 150 of 1990: This prohibits the sale of certain drugs, foods, cosmetics and devices in some disease conditions, as well as export, import, distribution and sale of specific drugs. It further proscribes misinformation regarding drugs and the manufacture of food and drugs in unclean environments.

Counterfeit and Fake Drugs (miscellaneous provisions) Act, Cap 73 of 1990: This Act bans the production, importation, distribution and sale of any banned, counterfeit, adulterated or fake drugs in the country. It also disallows persons to sell drugs in open markets without permission from regulatory authorities. .

Pharmacists Council of Nigeria, Decree 91 of 1992. The decree established the Pharmacists Council of Nigeria (PCN), which determines the standard of knowledge and skill required by persons seeking to become registered members of the pharmacy profession and establishes and maintains a register of persons qualified to practice as pharmacists. It also mandates the PCN to prepare and review the code of conduct for pharmacists and regulate and control pharmacy practice in all its ramifications.

National Agency for Food and Drug Administration and Control Decree No. 15 of 1993: The agency is responsible for regulation and control of imports, exports, manufacture, advertisement, distribution, sale, and use of foods, drugs, cosmetics, medical devices, bottled water and chemicals. It is also mandated to conduct appropriate tests to ensure compliance with standard specifications set by the council for the purpose of effective control of the quality of food, drugs, as well as their raw materials and their production processes.

Other roles of the agency are compilation of regulations and guidelines for the production, importation, exportation, sale and distribution of foods and drugs and registration of foods, drugs and chemicals. In addition, it is required to establish and maintain relevant laboratories or other institutions in strategic areas of the country as may be necessary for the performance of its functions.

Drugs and Related Products (Registration) Decree No. 19 of 1993: This decree outlaws the manufacture, importation, exportation, advertisement, sale or distribution of drugs, drug products, cosmetics or medical devices without prior registration. It also stipulates the registration procedure, conditions for suspension or cancellation of certificates of registration and clinical trials.[32,33]

This array of statutory provisions reflect government's resolve to have an ordered pharmaceutical terrain in Nigeria that supports availability of high quality, life saving medicines, and have given rise to two major regulators in the country: the Pharmaceutical Council of Nigeria (PCN) and the National Agency for Food, Drug Administration and Control (NAFDAC). The latter undertakes standards setting, registration and licensing of pharmacy graduates, as well as premises and professional practice. NAFDAC on the other hand is concerned with marketing authorization; licensing of manufacturing establishments; import and export control; inspection of manufacturing premises and distribution channels; market surveillance, product quality monitoring, pharmacovigilance, control of drug promotion and advertising; quality control; and oversight of clinical trials on drugs.[34]

II. METHODOLOGY

The study adopted a mixed method approach, undertaken across a number of places in Nigeria between September to October, 2015. 30 structured questionnaires were administered to a random sample of pharmaceutical retailers in Katsina-Ala council area of Benue State, to collect data on their perceptions of pharmaceutical regulation. This was followed by 12 in-depth semi-structured interviews with subjects from national and state ministries of health, representing policy formulators and heads of PCN and NAFDAC, representing regulatory authorities. Other key actors like pharmacists, drug whole sellers, static drug shop vendors and consumers were also interviewed. During interviews specific emphasis was placed on actors' experiences of the drug oversight processes, and the capacity and effectiveness of regulators.

The questionnaires were analyzed using Statistical Package for Social Sciences (SPSS) version 23.0, while interview data was transcribed, coded line by line into structured categories and content analysis undertaken. Key themes were identified and interpretation of results made. Documents dealing with legislative and judicial aspects of regulating the pharmaceutical sector in Nigeria were also reviewed. Ethical approval was obtained from the Benue State Government of Nigeria.

III. RESULTS

The questionnaires revealed that 80% of the business premises were formally registered with the Pharmacy Council of Nigeria, and 60% had at least one regulatory inspection in the last one year preceding the study. 6.7% of the sample had not been inspected at any time in the past year by any of the regulatory agencies. Regarding the level of regulation, 83% and 6.7%, were satisfied and dissatisfied with the regulatory performance respectively. On the contrary, provider and consumer interviews revealed that regulation was to a large extent unsatisfactory, characterized by widespread regulatory infringements and weak enforcement. For instance, retailers seemed to be well aware of existing regulations, but conceded to regulatory infractions for profitability motives, as reflected by this respondent:

"We are not getting too much money, but if you give injection, you will get more money, that is all, but it is not good, everybody knows." (R.09)

Retail drug outlets clients viewed drug retailer as business individuals making money, without regards to standards in a regulatory environment plagued with corruption officials and absence of regulatory agencies in some situations:

"Yes, I know of one of agency called drugs enforcement agency, but due to the corrupt nature, there are no proper regulations, when caught, the sellers bail themselves with money. (R 03)

"I know of NAFDAC, but sometimes they don't reach many places, like here you don't feel their presence at all, they are not in existence." (R 07)

A wide range of strategies were said to be adopted by regulators in pharmaceutical regulatory implementation and enforcement processes in Nigeria. These have been broadly classified under standard setting and eligibility testing, information dissemination and awareness creation and coercion and sanctioning. These categories of approaches can further be subsumed under the traditional administrative and bureaucratic style of regulation. A plethora of constraints hampering the effective regulation of the pharmaceutical industry were also identified related to inadequate funding, staff shortages, policy inconsistencies, litigations and judicial bureaucracies. Others are poor public uptake and utilization of health information, uncooperative drug manufacturers and vendors and fragmented regulation.

Inadequate Funding

Funding gaps appeared to have been the most important challenge impeding regulation as these excerpts reflect:

"There are challenges like the insufficiency of fund with which we need to get so many things done; we need to manage within the budgetary allocation of the federal government." (PCN)

Closely following on funding inadequacy and deriving from it was weak logistics and inadequate numbers of personnel.

"To work, we need vehicles, we need to reach the remote areas, to do that we need personnel. We are located in all state capitals, but we need to go to the remote areas, therefore we need more resources for these. (NAFDAC)

Funding of regulatory agencies is from fixed budgetary allocations and inadequacies existed in areas as critical staffing, logistics and infrastructural support, hampering sound regulatory activities.

Uncooperative Manufacturers and Vendors

Another important impediment to regulation was uncooperative conduct of drug manufacturers and vendors.

"The challenge is the issue of production of fake drugs, you have premises that are neither licensed by the Pharmacist Council of Nigeria to go into production, and neither is the product licensed by NAFDAC for production and release to the public. We have a challenge with production of fake products in Nigeria." (NAFDAC)

The economic behavior of firms appears to be mutually opposed to regulatory goals.

Institutional Constraints

Several institutional issues were cited by officials as limiting effective regulation. The composite included policy inconsistencies, judicial constraints and fragmented inter-agency coordination.

Policy inconsistencies

"The authority to regulate a set of drug vendors was reverted to PCN in April 2003 by ministerial directive and was under the purview of PCN for a time. It was re-delegated to various ministries in the state, then to local governments then back to the state ministry of health and then back to PCN again." (PCN)

This comment conveys a sense of regulatory inconsistencies and therefore ineffectiveness of strategies.

Judicial constraints

"Well, for some time back, in the early 90s up to 2003, there was a court injunction from the vendors that restrained the ministry from licensing and regulating them. Things went haywire; they were doing the things they want to do." (State regulator)

This remark implies that effective regulation was stymied by protracted legal tussle, meaning that for much of the time regulations were not enforced.

Sublime regulatory conflict between the two key pharmaceutical regulators also emerged, thereby weakening inter-agency collaboration.

Geographical Challenges

Several geographical challenges were found pose particular barriers to effective pharmaceutical regulation.

Large geographic land mass was said to be one barrier for regulators:

"Like I said earlier, every state is supposed to have the office, but you know we can't be everywhere, it is not possible. What we have now is zonal offices." (NAFDAC)

This explicitly points to the daunting task of effective regulatory coverage of the entire country, and consequent irregular or none inspection of drug vendors in rural areas and almost no sanctioning of infringements.

Trans-border smuggling of drugs

Inadequate regulatory manning of the country's vast land borders with its neighbours was said to provide porous routes for the flow of unregulated drugs into Nigeria.

"The challenges are many but just to mention a few; one, our borders are porous. We are aware that smuggling by this means is still there, those products do not pass through the regulatory procedure of NAFDAC." (State regulator)

Socioeconomic Factors

Regulators identified several social issues that tended to constrain the success of regulatory efforts. The issues are presented below.

Low public interest for information

"Nigerians are uninterested in information. They do not look for information and even if you give them information, they will not use it." (National Policy Actor)

This statement would suggest public lethargy to information seeking and apathy to utilization of available information.

Unemployment pressure

Frontline regulators appeared unwilling to enforce full compliance with regulatory standards, rather adapting a laissez faire disposition out of sympathy for the unemployed youths.

"..., remember the level of unemployment in the country. Many people go into establishing drug stores as a means of getting themselves a means of livelihood" (NAFDAC)

The sense in this statement is that regulators have become sympathetic to practitioners, since they are striving to eke out a living. This tacit non-enforcement of regulations could have been due to corrupt officials and regulatory capture by pharmaceutical actors.

IV. DISCUSSION

Challenges of pharmaceutical regulation

The adoption of bureaucratic and rigid approach to pharmaceutical regulation as revealed in this study is said to be the most frequent regulatory strategy used in most low and middle-in-come country settings.[35] Similar command and control orientation exist in Tanzania and Zimbabwe also.[36,15] This form of regulation makes regulators unable to align regulatory methods with contextual needs, resulting in regulatory ineffectiveness. The structure oriented approach may explain the absence of a basic regulatory law for patent medicine vendor practice in Nigeria, despite their numerical importance, extensive network and source of 70% of malarial treatments.[37] Furthermore, it has been reported that once private enterprises are left to operate outside the fringes of the law for long, they become formalized interests groups whose subsequent regulation becomes extremely challenging.[38,15]

Inadequate budgetary allocation was also found to be foundational to several regulatory challenges such as shortages of personnel and limited operational and logistics infrastructure. The link between limited budget availability and weak regulatory enforcement in the private sector with extensive networks has been documented in other African states.[39,40]

Policy summersaults by government was also discovered as contributory factor to regulatory ineffectiveness. This underscores the crucial role of robust policy formulation such as key stakeholder involvement, clear goal definition, policy articulation and others in determining implementation effectiveness. Ensor and Weinzierl[35] have shown that where policies are not designed in alignment with realism, frequent shifts become inevitable. The authors also blamed the failure of governments in low and middle income countries to regulate commercial drug dealers on the tendency to formulate unrealistic policy goals or policy inconsistencies. The plurality of regulatory agencies involved in drug regulatory activities might also have weakened regulatory effectiveness. Multiple regulators with sometimes overlapping roles have resulted in fragmented policy implementation and policy failure.[15,41]

Business firms are profit maximization entities and always behave in ways to only enhance earnings. Therefore, regulations that impose high compliance cost for example, are likely to be subverted as reported in this study. Several researchers have shown the relationship between high compliance costs and regulatory ineffectiveness.[35,15]

The laissez faire disposition of regulators towards enforcement of regulation because of high youth unemployment reported denotes serious effectiveness concern. Tacit non-enforcement of regulations could have been due to corrupt officials and regulatory capture by pharmaceutical actors, given the pervasive corruption culture in the country. In Tanzania, Wafula and colleagues,[42] found deep rooted corrupt practices in the forms of payment of bribes to inspectors, or drug sellers paying bribes for infringements uncovered during inspections. Further, in Uganda, it was demonstrated that unofficial practices by health workers resulted in gaps in regulatory enforcement and effectiveness.[43] Empirical evidence abound in much of sub-Saharan, where regulators looked away from pharmaceutical retailer infractions.[44,45,46,47]

The making of meaning and hence utilization of health information was also cited as constraining regulatory performance in Nigeria. Policy making processes that do not integrate policy beneficiaries from the planning stage all the way to implementation have not performed well.[48,47] The authors argued that mutual trust between the people and governments is a critical determinant of the utilization of publicly provided information. Generally, trust for government in Nigeria is low, overall.

Opportunities for improving pharmaceutical regulation:

The heavy reliance on bureaucratic approaches and a limited or lack of use of other ways of regulating the private sector, typifies this study. Innovative approaches that influence provider behavior through economic incentives and/or disincentive have been shown to be powerful tools in modifying provider behavior to align with social regulatory goals.[49] These strategies may assume the form of subsidies and rebates to reinforce regulatory compliance or fines and charges to discourage infractions. The fines and charges will broaden the scope to increase funding for regulatory activities and remuneration of regulators, as well as leverage a stronger basis for more sustainable regulation. Mandating private providers to submit data about their activities regularly

to government will help meet information needs of regulators and enable the regulatory system keep pace with a rapidly growing industry. Ignorance cannot be legislated or sanctioned away, therefore, information and training of providers and consumers especially, will be needed to overcome their low levels of knowledge and information needs about pharmaceuticals and their regulations. Changing the way consumers understand and use pharmaceuticals, further offers a cost-effective approach to pharmaceutical regulation. Armed with the right and timely information, consumers have the greatest motivations to enforce provider compliance, leveraging on market signals of informed buyers as observed in the west.[50,51] Enhanced public accountability of regulators and increased consumer representation on regulatory committees also can potentially improve regulatory effectiveness.

The rapid growth of the private sector, which has outpaced the regulatory system calls for more systematic researches commissioned by government that supports practice oriented regulation, compatible with contextual socioeconomic issues of the country. It will also generate better understanding of the rapidly changing terrain of pharmaceutical sector, whose activities inherently differ from government management and the means of influencing them different from pure bureaucratic administration.[52] Furthermore, strengthening of regulatory institutions through personnel development and a streamlined inspectorate based on a highly motivated and paid stock of staff, matched by transparent tools of sanctioning corruption practices and non-performance will be needed.

V. CONCLUSION

We conclude that there is a heavy reliance on administrative and bureaucratic approaches to pharmaceutical regulation in Nigeria, with attendant poor regulatory outcomes. A shift from this rigid and traditional regulatory method of drug oversight to innovative market based, incentivized approaches with intrinsic potential to modify provider behaviors. Changing the way consumers understand and use pharmaceuticals, further offers a cost-effective approach to pharmaceutical regulation. In addition, government should embrace practice oriented regulation through massive investments in research and development in the pharmaceutical sector to bring regulation in tandem with underlying socioeconomic forces in the economy.

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