

## **Aligning the Forces of Profits and Consumer Behaviour for Population Health Gains: Reforming Patent Medicine Vendor Regulation in Nigeria**

Usar IJ<sup>1\*</sup>, Witter S<sup>2</sup>, McPake B<sup>3</sup>

*1 Department of Community Health, College of Health Sciences, University of Jos, Nigeria*

*2 Institute of Global Health and Development, Queen Margaret University, Edinburgh*

*3 Nossal Global Institute, University of Melbourne, Melbourne*

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### **ABSTRACT**

Patent and Proprietary Medicine Vendors are non-pharmacists who have legally stocked and sold over-the-counter medicines in Nigeria, for about a century now. Presently, they have become a sprawling network of pharmaceutical entrepreneurs, and serve as important sources of a wide range of health care services in urban and rural Nigeria. In some areas, they are the sole source of orthodox health care. However, the market is poorly regulated, with widespread regulatory infringements and safety concerns about products. We sought to analyse the regulatory framework for these entrepreneurs, determine its appropriateness and make recommendations to improve regulatory effectiveness in the market and ultimately, population health outcomes. The study was undertaken in Katsina -Ala local government area of Benue State, in North Central Nigeria. The Structure-Conduct-Performance paradigm was used to answer the question of whether government should concentrate on enforcement of existing policy or explore regulatory reforms, using triangulated cross-sectional data collected in 2015. It was found that the regulatory framework was premised on a rigid bureaucratic approach of standards setting, which is inappropriate to the complex health care needs of rural communities. We recommend strategies that blend strict enforcement of registration standards with accreditation and franchising to improve access to quality and safe drugs and their rational use at patent medicine vendor outlets in Nigeria.

**KEY WORDS:** Patent medicine vendor, Regulation, Market Rural areas, pharmaceuticals, Nigeria

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### **I. INTRODUCTION**

Modern pharmaceuticals have drastically reduced morbidity and mortality caused by most common diseases and brought great relief from pain and suffering for millions around the world.<sup>1</sup> However, a significant portion of the world, especially in sub-Saharan Africa, do not benefit optimally from these pharmaceutical advances, and lack consistent access to safe, effective and affordable medicines, or the ability to use medicines rationally.<sup>2,3</sup> Drug consumers often get inappropriate prescriptions for their illnesses, receive inaccurate drug doses or are sold inadequate drug quantities for their needs. In rural areas in particular, drugs are frequently prescribed or dispensed by untrained and sometimes unlicensed drug retailers.<sup>4</sup> These pharmaceutical entrepreneurs have been acknowledged as important sources of healthcare across much of Africa.<sup>2,5,6</sup> They are highly patronized because of their wide reach and responsiveness to consumer demand for health care services.<sup>7,8,9,10</sup>

In Nigeria, as in much of Africa, the phenomenon of drug shops is extensive and growing, and in some rural instances, they are the only source of health care in entire communities.<sup>11,12</sup> They procure, store and dispense a wide range of drugs,<sup>13,14</sup> and are reported to offer therapies for diverse and complex diseases including malaria, pneumonia, sexually transmitted infections and contraceptive services, in both rural and urban Nigeria.<sup>15,16</sup> For example, in the treatment of malarial fever, a major cause of infant and childhood mortality, medicine vendors account for 70% of all case management.<sup>17</sup> These functions have stimulated efforts to explore the possibility to use medicine vendors to expand access to essential health services and strengthen national health system performance.<sup>10,18</sup> However, several quality concerns exist, such as irrational drug use and the attendant danger of drug resistance, drug side-effects and counterfeit medicines. Also reported, are entrenched regulatory infringement, weak enforcement and consumer dissatisfaction.<sup>19,20</sup> Notwithstanding, opinions are converging that retail drug vending will remain a major source of health care for hundreds of millions of people now and in the future, especially as the world searches for effective strategies of attaining universal healthcare coverage with essential, safe and affordable medicines and their rational use.<sup>21</sup> From a

public health perspective of population health maximization and financial protection, this objective is one of prime importance for public policy.

This study therefore, sought to understand the regulatory framework for 'patent medicine vendors' (the name used in Nigeria for static drug shops), its appropriateness for context, and how behaviour in the market reflects regulatory objectives. The findings can inform regulatory reforms that serve to redirect the powerful motives of profit maximization and business patronage working cohesively for good health care at patent medicine vendor outlets in Nigeria and in similar contexts.

### ***Regulatory analytic framework***

Market failure, the absence of perfect markets in the real world is understood by economists as the essential rationale for government intervention. There are pronounced market failures in medicines markets.<sup>22</sup> Regulation can be understood as government actions on defined market variables to achieve desired market outcomes, and may be analyzed from the dimensions of what variable to regulate, which actor(s) to regulate and how best to undertake regulation.<sup>23</sup> Typically, conditions to regulate may include entry standards, price, quality, quantity, distribution and market competition. The dimension of who to regulate ranges from individual providers to the wider market, while the mode of regulation has broadly been categorized as legal restrictions, incentives and incentive regulation.<sup>24</sup>

Entry standards set requirements to be met to gain initial acceptance into a market, and can apply at different health system levels: input level requirements may specify standards for personnel, products and technologies. It can also deal with licensing and competitive practices at organizational and market levels. Price regulation may involve setting of price ceilings for drugs or products, or specifying fees for particular services. Quality regulation substantially overlaps with entry requirements, but additionally involves the control of drug quality and health training curricula approval. Regulatory activities related to distributional issues focus on improving availability of health professionals and services across all areas based on need, while regulation of market behaviour aims to influence the way and manner providers compete in the market.

### ***Regulation of patent medicine vendors in Nigeria***

Patent medicine vending practice is regulated jointly by the Pharmacy Council of Nigeria (PCN) and the National Agency for Food and Drug Administration and Control (NAFDAC). The latter regulates the drug supply chain from point of manufacture or importation to the final point of sale to end users, focusing on ensuring the quality and safety of pharmaceuticals through their entire lifespan. The Pharmacy Council is principally concerned with the practice of pharmacy in all its ramifications. For patent medicine vendors, the PCN sets practice standards regarding licensing, inspection, supervision and sanctioning of infringements. The current regulatory framework for drug shops' establishment is simple: requiring an ability to read and write English language, a minimum age of 21 years and clean, well ventilated business premises (PCN 2003).<sup>25</sup> In addition, practitioners are permitted to stock and sell only over-the-counter medicines. No formal training in pharmacy is required. However, patent medicine vendors may acquire proficiency in handling drugs in one of several ways: informal apprenticeships under a senior patent medicine vendor, working in pharmacies or hospitals, or having formal training in a health-related field.

## **II. METHODS**

The study was undertaken in Katsina-Ala Local Government Area (LGA) of Benue State, in north central Nigeria. The local council is located about 190 Kilometres north east of Makurdi, the state capital, and has a population of 249, 219. Katsina-Ala is rural with few tarred roads, no portable water and erratic electricity supply. It has a total of 48 government health facilities comprising a state general hospital and 47 local government clinics and dispensaries, complemented by one private pharmacy and 93 patent medicine vendor outlets (situated frequently in remote and underserved areas). The residents are mostly peasant farmers, and a few engaged in goods retailing. Katsina-Ala has the largest yam market in Nigeria and people across the country converge here to buy yams, and thus provides a good approximation of the cultural diversity of Nigeria.

Ethical approval was obtained from the Benue State Government, Nigeria and Queen Margaret University, Edinburgh. Subjects were recruited after informed consent was obtained and assurances of anonymity and confidentiality were given. Furthermore, retailers were guaranteed that information volunteered was not to be used for taxation purposes, nor was the study related to drug regulatory authorities, to encourage disclosure of commercially or legally sensitive information.

Data were collected using questionnaires, in-depth interviews and non-participant observations over 9 months in 2015. Firstly, a patent medicine vendor outlet census was undertaken to generate a sampling frame and map locations. 30 vendors were asked to fill out structured questionnaires related to socio-demographic characteristics, compliance with regulations, frequency of regulatory inspections and perceived regulatory infringements. 10 in-depth interviews were conducted with purposively selected, most enthusiastic retailers

across the council area to explore in detail retailers' self-perceptions and behaviours in the market. Similarly, 30 patent medicine shop clients were systematically surveyed, and a further 10 purposively selected for in-depth interviews. In addition, five key informant interviews were undertaken with state and federal level pharmaceutical regulatory officials. All interviews were conducted in English, except for consumers who could not speak English, and digitally recorded. The rest were conducted in their native language (Tiv or Hausa) and translated into English.

Qualitative interviews were manually analysed based on predetermined thematic areas, which were constantly refined throughout the analytical process, guided by ideas with potential for better understanding of the patent medicine vendor market and its regulation in Nigeria.

### **III. FINDINGS**

#### ***Provider characteristics and motivation***

Of the 30 providers sampled, two completed primary level education, 17 (56.6%) attained secondary school education and 11 (36.7%) had post-secondary qualifications. The mean years of drug retailing experience was 3.53 years, and a range of 1-10 years. The market structure was low concentrated (few sellers), as measured by an inverse Herfindahl-Hirschman Index of 0.01 (1/total number of drug shop in the market). There was also strong oligopolistic pricing behaviour among providers, as identical products were observed to sell at same price throughout the market, even though providers denied any price collusion, as asserted by this interviewee:

'We do not fix prices in meetings, but even if you get to Katsina-Ala or Zaki-biam, a card of ampiclox is sold at ₦100.' (R 04)

#### ***How patent medicine vendors view their role and competencies***

Patent medicine vendors cited issues of affordability and availability of drugs in formal health facilities, arguing they provided reliable and cheaper alternative access to products in a manner that suit consumer convenience. The retailers also perceived that they played a complementary role to the formal health system by referring cases, and receiving prescriptions from them in turn.

'There is only one general hospital here and it has no drugs, they are either on strike or not working so, we get the drugs to ease the pains of the masses.' (R 03)

All vendors unanimously agreed that profit was the key motivation for establishing the business. They perceived themselves as knowledgeable enough to sell drugs, but acknowledged competency gaps and desired knowledge improvement through training:

'We want the government just as they are having the School of Medicine, School of Midwives, to have a school also for patent medicine practice, so that people will respect us more.' (R 08)

#### ***Regulatory legitimacy and compliance***

Patent medicine vendors recognized the appropriateness of regulation over medicine production and sale, but were dissatisfied with current regulation, framing it as irregular, corrupt and duplicative. One said:

'We want to avoid uncontrolled, unskilled, uncertified and unlicensed person presenting themselves as people's doctor' (R 10)

The retailers conceded to regulatory violations, for example sale of prescription drugs, but justified these by citing consumer demand and remoteness of the areas they served:

'Yes, some of the drugs we sell, our license did not cover it, but since we are in local area, where sometimes, we only find one pharmacy or not, we do have those essential drugs.' (R 07)

#### ***Consumer views and knowledge***

The survey showed that consumers perceive patent medicine vendors as offering important health services, but beset with quality issues related to provider qualifications, competencies and quality of products and services. Notwithstanding, clients still used drug shops because of their cheapness, nearness, product availability, scope for credit and quick services. Consumers demonstrated weak knowledge of diseases and drug use, and low understanding of regulations governing patent medicine vending, and asked for greater government intervention in the market through better provider training and improved regulatory oversight. Medicine vendors were viewed as providing emergency services, or temporary treatment before definitive treatment was sought at higher level healthcare facilities:

'Well, I feel the medicine store sellers too are of help, because in emergency situations, they address immediate problems that may arise.' (R 04)

The study also found that consumers placed high value on the quality of goods and services they bought and this consideration was key in choosing where drugs were obtained. However, consumers raised concerns about the competencies of providers, labeling them as unqualified:

‘... , just take a look at this young boy selling. He came here as a little boy, who sold since then to this level, after getting independence from his Oga (Master). He is now selling on his own. He is just a quack.’ (R 09)

Another said:

‘... , in most cases, people who are not qualified to operate in the system are found operating medicine shops; I have seen a situation where drugs meant for adults were given to little children.’ (R 07)

In like manner, concerns were raised regarding drug quality, describing drugs bought as ineffective, causing adverse effects, or fake:

‘Some of them sell fake drugs, such that even if you take it, it will not work. I bought drug for chest pain, but the pain got worse and I suffered a lot of negative effects on it.’ (R 01)

‘If they see that you don’t have any understanding concerning drugs, they may give you less quality and collect plenty money or give you different drug entirely.’ (R 09)

Consumer knowledge of patent medicine vending regulations and drug use varied widely. Most consumers had little to no knowledge of laws regulating the market, as reflected in these responses:

‘No one has told us about laws guiding the sale of drugs. We do not know which drug to buy and which one not to buy.’ (R 10)

‘Well, we just buy them not minding whether they’re genuine or not, we don’t know how to identify genuine drugs.’ (R 07)

Probed on regulatory enforcement activities and their impact on provider practice, one respondent said:

‘Yes, I know of one of agency called drugs enforcement agency, but this time around, due to their corrupt nature, there are no proper regulations; when caught, they bail themselves with money.’ (R 03)

Regarding compliance with regulations by patent medicine vendors, it emerged that providers covertly and overtly infringed the rules, as reported by this respondent:

‘Sometimes, they display the drugs in the shop, and other times, they will tell you to wait, they will get into private rooms and bring the drug for you.’ (R 10)

These findings explicitly reflect consumers’ valuation of patent medicine vendors, the desires for quality and weak knowledge of drugs, amidst low provider competence and weak regulatory enforcement.

### ***Regulatory effectiveness***

Regulatory staff understood their roles as that of ensuring the production and sale of safe and effective medications in the country by regulating, inspecting and controlling pharmaceutical and pharmacy practice.

Enquiries about regulatory compliance by patent medicine vendors revealed a shared feeling among officials that medicine vendors often breached their permissible practice both in scale and scope, as expressed in this response:

‘If you go out to their shops, you will see that they hide the prescription drugs in some places, and when you request, they will take it from there. Also, some of them stock even more than a pharmacy shop.’

Probing around enforcement and sanctioning of erring vendors revealed weak enforcement of regulations, attributable to inadequate funding, poor infrastructure and low operational personnel. It also appeared that there was tacit acceptance by regulators of infractions:

‘I have not seen, but only heard about such behaviours they exhibit.’

When further pressed about the open sale of prescription only drugs by patent medicine vendors one official said:

‘If I am keeping a blind eye to what they are doing, it is not a license. They have no permission to sell those drugs, so for the fact that we are silent does not mean that they have that liberty.’

Despite the acknowledged widespread sale of prescription drugs by retailers, regulatory agency officials remained adamant on not expanding the list of drugs patent medicine vendors sell, citing public safety concerns. They maintained that patent medicine vendors were poorly trained and lacked the competencies to administer regulated drugs, preferring to replace them with a more professional cadre of providers. Asked to speculate when the change would be, one official rhetorically responded:

‘When would all rural areas of Nigeria have infrastructural facilities or social amenities? That is the question that is very pertinent and I don’t think anybody can answer that.’

The implication of this response is that patent medicine practice will remain a prominent feature on the health landscape of the country into the foreseeable future.

## **IV. DISCUSSION**

We discuss key findings in relation to contextual realities in Nigeria and the body of literature on static drug shops. The finding that patent medicine vendors are profit seekers, with low knowledge base of drugs has been reported in eastern Africa, and characterized as being more economic agents than repositories of specialized health knowledge adequate for safe medical applications.<sup>26,27</sup>

Consumers in this study resorted to patent medicine vendor shops based on convenience value of closeness to home, long opening hours, quick services, affordable charges and credit buying. These desirable features of patent medicine vendors are known to influence healthcare seeking behavior in other resource constrained settings, particularly in Africa.<sup>2,28,29</sup> The high patronage of drug shops by individuals for health care has important implications both for therapeutic outcomes and policy. On the one hand, the accuracy of diagnosis and appropriate treatment of ill-health early in the course of a disease is a key determinant of long term health outcome, and underscores a need for some level of technical competence on the supply side. Secondly, appropriate therapeutic choice and dosage regimen is crucially important determinant of the socially undesirable outcomes of antimicrobial resistance and related phenomena of drug toxicity, drug misuse and abuse.<sup>30,31</sup>

Low visibility of regulatory actors was reported by both providers and clients in the market, with regulatory officials conceding to irregular inspections and non-sanctioning of erring providers. This is consistent with many health systems in sub-Saharan Africa, especially in rural areas.<sup>31,32,33</sup>

The market demonstrates a number of inefficiencies, exemplified by poor provider knowledge of diseases and drugs and low consumer information base, both justifying intervention. This study showed that standard setting, provider training, inspection and sanctioning and consumer awareness creation are the main regulatory interventions adopted, but have failed to discipline the market. Market interventions based on these traditional approaches have had limited impact in improving market performance.<sup>9,31</sup> Furthermore, regulatory measures are inappropriate for the healthcare needs of local communities, where for much of the time, public health facilities cannot supply essential medicines and patent medicine vendors serve as the sole source of medications. Therefore, continuing to restrict patent medicine vendors to non-prescription drugs fails to meet the needs of people for health-improving medications.

The reach of drug shops in rural and difficult to reach communities has stimulated efforts to use them to leverage improved access to lifesaving medicines and strengthen health system performance through several initiatives.<sup>10,34</sup> This opportunity can best be utilized if the potential of drug shop owners is developed through good policies that embed the right goals. From a public health viewpoint, these policy objectives must focus on improving availability, affordability and acceptability of quality products and services and their rational use.<sup>35</sup> As a result, strategies to effectively resolve failures in patent retail market in Nigeria must target these essential elements cohesively. The strategies are considered along the four domains of market-led initiatives, regulatory tightening, widening of regulatory scope and institutional capacity strengthening.

### ***Market led initiatives***

Provider behavioural intervention that fails to recognize the role of profits in constraining the effect of educational training to improve adherence to regulations may not work. Current efforts at influencing provider knowledge improvement to ensure quality of services at drug shops have focused on participation in continuing medical education programmes,<sup>25</sup> which occurred on an ad hoc basis and far-between. Further, the capacity of training to increase the number of patent retailers who can sell common medicines correctly on a sustainable basis is said to be limited.<sup>36,34</sup> Market led efforts have to be incorporated into these educational activities.

The powerful forces of profits of retailers can be addressed through incorporation of accreditation and franchising strategies as part of an integrated regulatory approach. The Accredited Drugs Dispensing Outlets (ADDOs) intervention in Tanzania trains and certifies drug shop retailers, monitors adherence to regulations and facilitates access to microfinance. It also permits sale of a limited number of prescription drugs, as well as access to reliable sources of quality drugs, in one integrated approach and has greatly aided performance at drug shops.<sup>27,37</sup> Also, medicine vendors can be encouraged to meet regulatory standards through franchising.<sup>38,39</sup> The franchisor sets practice standards, trains and supervises the franchisee, in addition to extant public regulatory requirements. Both are mutually reinforcing and can potentially redirect the profit interests of providers to align with public health goals of access expansion to essential, safe and effective drugs in rural areas, and their rational use.

Regulatory efforts in this study have focused on the supply side, with little attention to the equally important role of demand. It is established that well-informed consumers are capable of influencing provider behaviour in line with social ends.<sup>40</sup> Health literacy effectiveness is related to the degree of public participation in its development.<sup>41,42</sup> Thus, consumer involvement in designing regulatory reforms that focus on changing the way consumers understand and use pharmaceuticals remains the most cost-effective approach to regulation, especially in poor resourced countries like Nigeria. The strategy is minimalist interventionist in the market, yet capable of instilling high provider adherence to rules.

### ***Regulatory tightening for drug packaging***

To ensure that only effective and safe drugs enter the patent medicine vendor market and ultimately reach the public, stricter regulatory enforcement presents the best scope, particularly on manufacturers. Regulatory agencies can require drug manufacturers to improve packaging and labelling of products,

accompanied by simpler and accessible instructions about dosages, actions and side effects. Manufacturers may also include translations of drug instructions in major local languages to enhance consumer awareness. This innovation has the potential of addressing the issues of inappropriate dosing and poor information giving that characterize the market, as well as lowering drug contamination rates and degradation linked with poor dispensing practices observed at drug shops. Adoption of new low-cost, easy-to-use technologies may also enhance the capacity of detecting sub-standard and counterfeit drugs and improve ease of access to credible drug information. These could potentially reduce client dependence on providers and improve the quality of care at medicine vendor outlets.<sup>43</sup> The strategies would be most effective under the framework of a restructured and streamlined regulatory infrastructure.

#### ***Widening of regulatory scope and re-legislation***

Currently, patent medicine vendors are regulated by Pharmacy Council of Nigeria (composed exclusively of pharmacists). This arrangement has failed to win the trust of patent medicine vendors, who view pharmacists as rivals in the drug market. Therefore, creating an autonomous regulatory body for patent medicine vendors could generate a number of important outcomes, like enhanced sense of importance and recognition, greater feeling of professionalism and improved trust and regulatory compliance by retailers. Other advantages may be more frequent regulatory inspections and scope for direct interchange with providers at local levels. This policy proposal may be resisted by pharmacists, who traditionally view all matters related to drug as their prerogative. Government will need to constructively engage with pharmacists, clearly explaining the important roles of patent medicine vendors, given inadequate qualified pharmacists. The policy design must incorporate mechanisms that will shield it from capture by organized unionism.<sup>44</sup>

Current regulatory bodies of patent medicine vendors have no representation in local government governance structures. Adding this layer of regulation could improve regulatory inspections and compliance by patent medicine vendors in rural areas at more reasonable costs.<sup>45</sup>

The educational requirement for drug vendors of just ability to read and write is technically inadequate.<sup>25</sup> However, some providers in the market were observed to have acquired health-related certification in community health extension worker, community health officer, pharmacy technician or nurse assistant. Raising the bar on educational attainment of patent medicine vendors may potentially lower the need for frequent training of providers, as well as the number of regulatory visits, as otherwise is required by extant guidelines.

#### ***Regulatory capacity strengthening***

Even if government adopts the range of flexible regulatory mechanisms discussed this far, licensing, registration and standards setting will remain government's central role. Therefore, attracting and retaining skilled regulatory staff remains crucially important to any patent medicine vendor regulatory reforms. A well trained, highly motivated regulatory staff complement will form the core of any government policy initiative. Both financial and non-financial incentives of workers should be improved in order to discourage corruption and conflict of interests among staff members. Sustained poor staff remunerations may result in regulatory capture and create a potential for scarce skilled personnel exodus from the public sector into the private sector they should be regulating.<sup>46,33</sup> Government must also match improved pay with explicit disciplinary measures against non-performing and corrupt staff members.

## **V. CONCLUSIONS**

The patent medicine vendor market in Nigeria is large and growing, but characterized by high levels of regulatory infractions and low quality of products and services and perverse market failure. Government's efforts to regulate the market have hinged on rigid adherence to bureaucratic rules and enforcement. Frontline drug regulators however, have adopted a laissez faire attitude to inspections and sanctioning, with attendant perverse market failure.

Therefore, the development of new market-driven mechanisms and collaborative approaches that align with current structural and regulatory trends in global health systems offer a better prospect for effective control of the patent medicine vendor market in Nigeria and other similar settings. These initiatives advocate a shift of patent medicine vendor regulation from one entirely state-led, to one of broader, mutually reinforcing strategies that incorporate market level issues and consumer participation.

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