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Leadership Effectiveness and Regulatory Performance in the Public Sector: The Experience of the National Agency for Food and Drug Administration and Control (NAFDAC)

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Abstract:

This paper examined the impact of leadership on the performance of NAFDAC, the agency in charge of pharmaceutical regulation in Nigeria, citing instances from the decade-long tenure of Professor Dora Akunyili, its Director-General from the year 2001. It assessed the transformations in the fortunes of NAFDAC from a non-performing, relatively unknown, back-bencher and unsung regulatory agency to a vibrant, popular, internationally-celebrated agency within a few years as a result of the leadership provided for the agency by the leader and her leadership team. The paper observed that the dramatic changes in the accomplishment of the regulatory agency since 2001 when Akunyili took over as Director-General can be traced to personal leader characteristics, a good understanding of the situation, a followership already yearning for change, a favourable political environment and the leadership's appreciation of the political dimensions of regulation. While noting the various challenges facing the agency in its quest for more relevance and greater achievements, particularly the lack of effective co-operation and collaboration by relevant stakeholders, the paper concludes that the agency can advance further by improving on its performance with determination and march ahead to achieve its objectives by embracing greater dialogue with relevant stakeholders, maintaining effective collaboration with local and international stakeholders and by maintaining discipline, motivation and internal cohesion.

Key words: Leadership; Regulation; Regulatory agency; Performance

1. Introduction

Regulation is an idea in the public domain through which government seeks to control certain aspects of life of the citizenry in the public interest. With advancements in science and technology, as well as industrialization, life now moves on the fast lane and government must control the direction and pace of development to ensure that life is not just bearable but enjoyable for majority of the citizens. Public policies must be geared towards the utilitarian principle of the pursuit of the greatest happiness of the greatest number of people in the society. As a symbol of the expansion of government activity, regulation helps to monitor and direct the activities of citizens in modern states and the economic and social relationships they enter into with one another. The philosophical basis of regulation is that unrestrained private enterprise could not, or would not resolve the social and economic conflicts that arise between private capital and public goals in a free market economy in the public interest. Regulation is mostly at the instance of government as it seeks to control particular aspects of citizens' lives for common or public purposes.

2. Regulation and Its Types

There are different types of regulation, depending on the aspect of life of the citizenry in focus and the degree of independence that is deemed appropriate for the regulatory institution or agency. The first aspect of life of the citizenry that governments focus upon is usually the economic. Economic regulation therefore seeks to control or regulate the economic interest and business practices of the citizenry within a state. Private interests become subject to government regulation if and when their activities poses a threat to the interests of members of the public. The history of effective regulation in modern times began with the passage of the Interstate Commerce Act of 1887 in the United States of America through which the Interstate Commerce Commission (ICC) was established (Gerston, Fraleigh and Schwab, 1988:5).

Economic regulation attempts to control economic issues like prices, quality and conditions of service and products that are offered to members of the public. Instead of the hypothesized self-balancing behaviour of the market in *laissez fair* economics through the 'invisible hands' of supply and demand, it was observed that private capital would rather cheat members of the public by sacrificing worker, product quality and/or safety, as well as public health considerations on the altar of profit, the first and most important goal of capital. It is government's response to various challenges in an effort to ensure or enforce corporate responsibility, responsiveness and reliability. Social regulation on the other hand, is a product of the inevitable need for government to regulate various aspects of life of the citizenry not for the sake of the wallet but in the interest of the existence and survival of mankind as members of a technologically-driven society.

For instance, environmental pollution is a problem in many modern societies. For instance, the quality of air, water, manufacture and uses of agro-chemicals and pesticides, and sundry other activities must be controlled in human societies. Also, government has to regulate the manufacture, sales, distribution and use of drugs and other pharmaceutical products in order to ensure that they are safe, effective, available and affordable for the citizenry. The safety of working environments, building construction, air and road transport, quality of education, the banking system, e.t.c all have to be monitored, regulated and controlled to ensure that the citizen is not unduly exposed to physical, social and economic hazards.

By its design and implementation structures, regulation is either direct or indirect. Direct regulation aims to achieve set regulatory targets through legislative, administrative enforcement and legal systems to monitor and enforce standards and to impose sanctions or penalties for violations. Direct regulation involves some steps or procedures which are by no means exhaustive, variations depending on the nature of the regulated industry, the mandate of the agency and the targets of regulatory action.

One, an agency must determine the rules and regulations that it wants to enforce on the regulated industry and the targets that it wants to meet. For instance, NAFDAC determines what food additives are allowed for use in the food industry; monitors the level of active ingredients in drug products; establishes and enforces Good Manufacturing Practices (GMP) for pharmaceutical regulation and determines the level of toxicity allowed in drug products for man and animals, among other things.

Two, a regulatory agency must establish sanctions and penalties for non-compliance. Three, it must establish a monitoring and evaluation system so as to detect instances of non-compliance. Depending on the level of co-operation that the agency enjoys from the regulated industry, it may encourage self regulation and carry out regular supervisory and audit functions. Finally, the agency must detect violations of rules and standards (if any) and deploy administrative and enforcement mechanisms that the regulations allow as a way of imposing sanctions (Myrick Freeman III, A (2000:197).

Contrary to direct regulation, indirect regulation is one in which action is not located in a particular single agency. Rather, it consists of motley of legal processes, administrative procedures and professional control measures that are tailored towards encouraging industry compliance with government policy. Tax structure, import and export tariff regimes, professional registration requirements, e.t.c are used to enforce compliance.

Each of the two regulatory methods has its advantages and disadvantages. The direct regulatory method could be effective but costly in terms of creating an agency that will require specialized staffing, operations, logistics, implementation and enforcement structures. Furthermore, direct regulation is characteristically confrontational, adversarial and sometimes emphasizes punitive sanctions over incentives for compliance. It therefore places greater demand on the regulator in terms of cost, time and effort. Conversely, indirect regulation may not require the creation of specialized agencies, may not require the recruitment of specialized staff, is not as confrontational or adversarial as direct regulation and therefore is cheaper. However, it may not achieve outstanding results.

3. Meaning and types of Agencies

Olaleye (2005:16) defines an administrative agency as "a governmental authority other than a court and other than a legislative body, which affects the rights of private parties through adjudication, rule-making, investigation, prosecution, negotiation, settlement, or informational action. An administrative agency may be called a commission, board, authority, bureau, office, administration, department, corporation, division or agency". Such may be called a regulatory agency if it is primarily responsible for the regulation of a particular aspect of public life. Whatever the nomenclature, an agency operates on the basis of the powers conferred on it through administrative law.

In general, there are two broad types or categories of regulatory agencies, according to the degree of independence that they enjoy in the performance of their official duties. They include independent and executive controlled agencies (Gerston Fraleigh and Schwab, 1988: 4). Independent agencies are created by the legislature to assume complete responsibility for a policy area or issue. Because of their quasi-judicial status, they can investigate issues, deliberate on them, take policy positions and execute such. Members of the boards of such agencies are appointed by the executive for a fixed tenure but subject to ratification by the legislature. The independence of such agencies derives from the fact that they enjoy a fixed tenure and cannot be unilaterally fired by the executive without legislature input.

Furthermore, independent agencies may enjoy a secure source of funding that is not subject to the dictates of the executive. Due to political reasons and the desire of the executive to control policy agenda, such agencies are not common in Africa. An example of an independent agency in the United States of America was the Interstate Commerce Commission (ICC) that was established in 1887 (Gerston Fraleigh and Schwab (1988: 5).

The second category of agencies is the executive-controlled agencies. They regulated policy, but often under the control of the head of the executive arm of government or any of his lieutenants. This means that leaders of such agencies perform at the pleasure of the executive and may be removed by him after legislative consultation if they fail to meet his expectations. The tenure of office leaders

of such agencies is therefore not secure. NAFDAC is a regulatory agency with a Director-General who serves at the pleasure of the President. Although affiliated to the Federal Ministry of Health, the DG of NAFDAC reports indirectly to the President through the office of the Minister of Health (not the Ministry of Health). NAFDAC does not go through the Ministry of Health in order to avoid delays caused by the requirements of bureaucracy which could otherwise slow or bog down the agency as it fulfills its mandate.

4. NAFDAC and Regulation of the Nigerian Pharmaceutical Industry

The work of NAFDAC as regulator of the Nigerian pharmaceutical industry is a particularly difficult one due to the nature and characteristics of the industry. As such, a regulatory agency that will deal with its problems will require outstanding and fearless leadership. The most outstanding characteristic of the pharmaceutical system is that it is very susceptible to corruption for several reasons.

The first reason is that the sale of pharmaceutical products is lucrative, particularly because the final customer (patients and their families) are more vulnerable to opportunism than they are in many other products markets, mainly because of asymmetric information (Cohen, Mrazek and Hawkins, 2007: 31). They argue further that even under normal circumstances; pharmaceutical suppliers (drug manufacturers, importers, wholesalers, prescribers and pharmacists) would rather maximize profit in their dealings with their clients. If left uncontrolled, however, they would not only maximize profit but would go outside legal, ethical and professional norms of the health sector. Due to this, they see regulators as their worst enemy and would rather oppose rather than support regulatory action.

A second reason for the difficulty of NAFDAC's job in regulating the pharmaceutical industry is government's intervention in the industry. In many countries, government is involved in regulating the pharmaceutical industry, either directly or indirectly because of the imperfect nature of the market, the need to improve efficiency in resource allocation; and the need to protect the health of members of the public.

However, bureaucracy pervades most government ministries and institutions and this breeds corruption easily, particularly in the areas of bidding, drug supply, quality, pricing and availability of supply. Mainstream government ministries often oppose regulators who attempt to challenge their bureaucratic power. For example, the Federal Ministry of Health expects NAFDAC to report directly to it, being a parastatal under its oversight powers. However, many officials of the ministry are not happy and are antagonistic to the agency for reporting directly to the Presidency through the Minister of Health. Meanwhile, the minister is a political appointee rather than a bureaucrat. By reporting to the Presidency through the Minister, however, NAFDAC has been able to avoid the negative effects of civil service bureaucracy but has incurred the wrath of ministry officials for that purpose.

A third reason why NAFDAC's regulatory work is difficult is because the drug and pharmaceuticals supply chain in Nigeria is very complex, chaotic and uncoordinated. Therefore, distinguishing authentic from fake products is difficult. Majority of Nigerians still secure their drugs from the open market where there can be many middlemen dealers in fake, substandard, adulterated and expired drugs. Weak regulations and non-deterrent measures constitute problems for NAFDAC in effectively regulating the Nigerian pharmaceuticals market and many decision-points are vulnerable to corruption. Therefore, Klitgaard's (2000:1-5) analysis of conditions favourable to corruption holds true for the Nigerian pharmaceutical industry. According to him, monopoly power coupled with the exercise of discretion where accountability and transparency are lacking will always breed corruption. Hence the formula: $\text{Monopoly (M) + Discretion (D) - Accountability (A) - Transparency (T) = Corruption (C)}$.

In the face of the foregoing challenges, NAFDAC requires forthright, outstanding and determined leadership to regulate the Nigerian pharmaceutical industry effectively. This paper examines the nature of the leadership which Professor Dora Akunyili provided at NAFDAC from April 2001-2010 and how it impacted on the functioning of the agency.

5. Definition and Importance of Leadership

Defining leadership is one of the most difficult things in social psychology. Ironically, more has arguably been written on it than on any other topic in the behavioral sciences. This situation accounts for the numerous definitions of the subject-matter of leadership in the literature. The multiplicity of definitions also reveals different approaches that lay emphasis on various issues related to leadership. Terry (1960) defined leadership as "the activity of influencing people to strive willingly for group objectives". Khatz and Khan (1978) defined it as "the influential increment over and above mechanical compliance with routine directives of the organization". In this perspective, leadership is seen as what is required to make group members strive, without being coerced, for the attainment of their common (or organizational) purpose (s).

Stodgill (1974) defined leadership as "the process influenced the activities of an organized toward goal setting and goal achievement". It involves getting people to work collectively for the achievement of a common goal or a set of goals. Tannebaum (1959) defined leadership as "inter-personal influence exercised in a situation directed, through the communication process, toward the attainment of a specialized goal or goals". This agrees with the view of Morgan and Turner (1976:12) who defined leadership as influence exercised in a situation through the communication process toward the attainment of specific goals". Stressing the responsibility of leadership to motivate followers, McFarland (1976:214) defined leadership as the "ability of an individual to influence others to work beyond ordinary levels to achieve goals".

Thus, leadership can be seen as a process of inter-personal influence which aims at making people work voluntarily towards the achievement of national, organizational or group goals (Bakare, 1990:13). Indeed, as Stodgill (1974) argues, there is consensus on the fact that a leader is one who ensures that his followers attain set goals because they want to, not necessarily because they have to. A leader must work on his subordinates to the extent that they want or desire to co-operate with other to achieve group goals.

Linking leader- characteristics with the attainment of group objectives, Etzioni (1967:116) conceived leadership as power based predominately on personal characteristics". Thus, leadership involves decision making and the exercise of authority (Dubin, 1961:348). In modern times, however, it is more useful to view leadership in terms of the traits, behaviors, contingency powers and occupation of an administration position. In this connection, leadership can be viewed from a dialectical standpoint, as a socially constructed reality through the interactions of both leaders and followers.

From a dynamic and social influence perspective, we conceptualize leadership as a process wherein an individual member of a group or organization influences the interpretation of events, choice of objectives and strategies, choice of inputs, organization of work activities, the motivation of people to achieve the objectives, the maintenance of co-operation relationships, the development of skills and confidence by members, and the enlistment of support and co-operation from people outside the group or organization". Thus leadership can also be seen as a form of influence.

However, more critical definitions view leadership as a process of power-based reality construction and, therefore, focus upon the hierarchical forms of power expressions, power relationships and the dominance it reflects. From this perspective, one can suggest that many ideas in the literature on leadership tend to be andocentric in nature, rarely acknowledging the limited representation of ethnic groups and women in senior leadership positions.

This view may be closely applicable to societies with excessive gender-dominance. Examples can be found in many societies of Africa where male-domination of the political and family sectors are a reality. In such societies, the political, legal, religious, economic and other sectors are male-dominated even when there are no evidences that females cannot perform creditably there. This is also exacerbated in Islamic societies where women are mostly considered to be part of a man's properties and consequently, articles of inheritance. However, in places like Nigeria and South Africa, things are changing as more women are now occupying leadership positions.

In a sense, the leader is someone who motivates the members of a group towards the attainment of group goals. Such motivation may be situationally-contingent, but the leader assists the group in setting goals, providing resources with which to meet such goals, sharpening group focus and steering the group towards maximum attainment of group goals at the least cost possible. The leader is a pacesetter that knows how to extract support from group members and compliance with laid-down regulations that could lead to the attainment of corporate goals.

The leader is sensitive to the various motives that could be at work in followers and finds ways of aligning such with organizational objectives and targets. Regardless, therefore, of the definitional approach, leadership generally incorporates the following: possession of influence through the provision of information, direction and focus. In addition, the leader sees to the provision and channeling of resources towards the attainment of group goals. Finally, leadership involves the motivation of group members towards goal attainment.

6. Elements of Leadership

The nature and process of leadership can be understood by studying the social transactions between leaders and followers. In this connection, Hollander (1978) has argued that the tripartite elements of leadership include the leader, the followers and the situation. Thus, we can represent the leadership process or 'locus of leadership' mathematically with the following function:

Leadership process = (L, F, S) Where: L =leader; F= followers; and S = the situation. The components of each element of the leadership equation are defined by the 'locus of leadership', made up of the following:

The Leader	The Follower	The Situation
Authority and Legitimacy, Competence, Motivation, Personality characteristics, Assessment of the situation, Supervision style, etc.	Hopes, Aspirations, Expectations, Drives and Motivations, Personality Characteristics, Competence, etc.	Tasks, Resources, Rules, Social Structure, Internal/External Environment, History, etc

Table 1

7. Impact of Leadership on the Performance of NAFDAC

Good leadership is necessary for the effective performance or attainment of the goals of any organization. The necessity of this requirement, however, is more pronounced in the case of regulatory agencies such as NAFDAC. In the first instance, unlike other establishments or organizations that obtain loyalty through patronage by willing clients, NAFDAC is a regulatory agency. As noted by Adinuba (2003:7), "every regulatory agency is, by definition, the policeman of a given industry. It therefore, hardly enjoys the affection of the industry operators because they are at the receiving end any time the big stick is wielded".

The above situation of expected hostility or at best, non co-operation from regulated interests is enough to make optimum goal attainment difficult for a regulatory agency and its leadership. Also, the level of freedom or independence which an agency enjoys is important to the attainment of its set goals. NAFDAC is not an independent regulatory agency but an executive-controlled one that reports to the Presidency through the Minister for Health. The above conditions, coupled with the fact that the agency has not been adequately funded by government, are daunting challenges for the leadership of a regulatory agency.

Before the Akunyili leadership, NAFDAC had experienced its pioneer leadership from the time when the agency became a separate parastatal under the Federal Ministry of Health in 1991 until 2001. Professor Dora Akunyili, became the Director-General of the agency in 2001 and led the agency till 2010. The popularity and outstanding performance of the agency since 2001 when Professor Akunyili took over as the Director-General are not comparable to what in retrospect, looks like the lackluster performance of the agency under its pioneer leadership. Adinuba (2003:7) noted that under that leadership:

Our...country...had been dumping ground for all manner of (drug) products, resulting in organ failures and dramatic rises in reported cases of cancer and drug-resistant ailments. The general consensus is that until two years ago (2001), NAFDAC did not work in a way to command the respect of the public...Nigeria became perhaps the only country in the world where prescription drugs were not just sold over the counter but hawked on buses and exposed to the scorching sun, tropical rain and the wind. It is estimated that up to 60% of drugs sold in the Nigerian market then were fake, substandard, adulterated or expired...Nigerian manufactured drugs were consequently banned even in West African countries like Ghana and Sierra Leone.

However, NAFDAC's story changed barely two years after the appointment of Professor Akunyili as Director-General, due to her outstanding performance. Comparing the performances of NAFDAC under the pioneer and the Akunyili leaderships, Adinuba (2003:7) noted that:

The dramatic changes in NAFDAC...bear an eloquent testimony to the primacy of the quality of human capital in shaping the performance and future of every organization. Mrs. Akunyili and her team are still working with the same law which their predecessors used...NAFDAC's transformation should make a rewarding study to students of management and leadership. A manager or leader performs three basic functions, namely, to inspire the confidence of the people to set an agenda to be accomplished, and to create a new ethical atmosphere in an organization or community.

NAFDAC under the leadership of Professor Akunyili and her team were able to work to command the respect of Nigerians and other countries by reducing the incidence of fake drugs that enter into circulation in Nigeria from 60% when Akunyili took over as Director-General in 2001 (Adinuba, 2003:7) to 20% in 2004 (Oyeyemi, 2004:32). The agency was able to achieve that feat by putting in place, a series of strategies aimed at turning around the fortunes of the agency for the better.

Some of the strategies include organization of sensitization workshops for drug marketers; media sensitization of Nigerians on the danger of fake drugs; re-organization of the agency to improve efficiency; and improved training and empowerment for NAFDAC staff. Other strategies included upgrading of drug registration requirements; sharpening of the enforcement division of the agency; and introduction of holograms and tamper-proof security featuring on NAFDAC-regulated products. This has resulted in more arrest of fake drug merchants and closure of the major open drug markets in the country namely Aba (2002); Kano (2004) and Onitsha (2007). Other achievements included the development of partnership and greater collaboration with local and international stakeholders in countering the movement of fake, substantial and adulterated drugs across international borders. In addition, NAFDAC adopted the Good Manufacturing Practices (GMP) which takes NAFDAC officials to various countries like India and China among others, to inspect production factories/sites for drug and other pharmaceutical products coming into Nigeria. For this purpose, NAFDAC appointed accredited laboratories in the various countries of origin to effect pre-shipment analysis and certification of drugs and other pharmaceutical supplies coming into Nigeria.

Regulation requires political support because it is as much a question of politics as it is of the economy. The Akunyili-led NAFDAC has been able to surpass the records of the agency under the previous leadership in terms of political patronage. Between 2001 and 2008, the agency has been able to secure active political support from the three arms of government particularly the executive under the Obasanjo's Presidency (Olugbenga, 2008a).

The delays that were hitherto experienced by the agency in relating to the Presidency under the preceding leadership were removed under the Obasanjo presidency because the Director-General was able to secure direct audience with the President through the late first lady, Mrs. Stella Obasanjo (Olugbenga, 2008a). The situation did not change under the Yaradua presidency because the DG had to excuse herself from an interview with this researcher during on May 28, 2008 to answer an immediate call from the President). Between 2001 when Professor Akunyili took over the headship of NAFDAC and 2008, the agency had impounded and destroyed fake, substandard and adulterated food and drug products worth ₦28.25 billion (N.T.A News, Friday, September 5, 2008), a great achievement when compared with the performance of the agency before 2001.

The achievements of the agency under the leadership of Akunyili have elicited various from different audience. While those who are negatively affected by the activities of NAFDAC have attempted to disrupt the smooth running of the agency, other have continued to sing the praise of the agency, showering medals and encomiums on the Director-General and the agency. Pointers to the negative reactions to the agency's laboratories in Ikoyi, Lagos and its offices in Kano respectively and the assassination bid on the person of the Director-General in December, 2005 by people suspected to be working for disgruntled elements in the regulated pharmaceutical industry.

8. Profile of the NAFDAC Director-General

Professor Dora Nkem Akunyili, the Director-General of NAFDAC, is an internationally renowned pharmacist, pharmacologist, scholar, administrator, leader, and renowned regulator who brought her academic training, experience, personal discipline and

commitment to bear on her job as Director-General of a nearly moribund regulatory agency. As an academic, she has presented twenty (20) research based scientific papers, published two (2) books and thirty-seven (37) journal articles. She has also delivered four hundred (400) papers locally and internationally on regulatory matters. In leadership training prior to her appointment as NAFDAC Director-General, she served on six (6) senate committees and various Faculty of Pharmaceutical Sciences Committees of the University of Nigeria, Nsukka. Also, she was South-Eastern Nigeria Zonal Secretary of Petroleum (Special) Trust Fund (P.T.F) between 1996 and 2000.

Upon assuming duty as NAFDAC Director-General in 2001, Professor Akunyili's industry, selfless service, determination, honesty and transparency earned the agency a very high rating locally and internationally. Realizing that leadership is a teamwork and that no leader can single-handedly turn things around in an organization, Professor Akunyili carefully re-organized, re-oriented and re-motivated the NAFDAC workforce that she met and put together a dedicated leadership team that could help her realize her mandate and her dreams for the agency.

In recognition of the agency's achievements under her leadership, Professor Akunyili has received over four hundred and seventy (470) local and international awards and recognitions, prominent among which was the integrity award by the world's foremost anti-corruption watch-dog, Transparency International in May, 2003. That organization had in 2001 rated Nigeria as one of the two most corrupt countries worldwide. The award bestowed on her in South Korea made Akunyili the first African and first woman ever to be given the award.

Other awards included Agribusiness, International Euro Market and Trans-business Awards respectively in 2003, 2005 and 2006 by the European Marketing Research Centre (EMRC) in Brussels, Belgium; Special Award for combating Economic crime by International Chamber of Commerce by the Commercial Crime Services, London (2004); Pharmacist of the Year Award by the International Pharmaceutical Federation (FIP) (2005); Honorary Degree of Doctor of Laws by University of Bristol, London (2006); Honorary Georgia Citizen by the state of Georgia, USA (2006); Conferment with the National Order of the Federal Republic-OFR- and recognition as an Icon of Hope for Nigerians by the President, Federal Republic of Nigeria (2002); and Person of the Year 2005 Award by Silverbird Communications Ltd, Nigeria (2006) (Olugbenga, 2008b).

9. Achievements of NAFDAC under the Akunyili Leadership

Upon assuming office as NAFDAC Director-General in 2001, Professor Akunyili put in place a leadership that was able to confront successfully, the challenges of regulating the pharmaceutical industry in Nigeria. The efforts of NAFDAC in repositioning the agency involved combating the major challenges of regulating the drugs and pharmaceuticals industry in Nigeria. According to Klitgaard (2000), such efforts would naturally include:

- Generating consciousness among stakeholders. This includes educating decision-makings and the public about corruption in the pharmaceuticals industry and its negative effects on society;
- Adding systems analysis to consciousness-raising to determine where pharmaceutical systems are vulnerable to corruption; and
- Deciding what strategies to apply to prevent corruption in the first place.

In the Nigerian pharmaceutical industry, however, the main effort is in the area of countering corruption that already exists in the system. The first and major impact of the Professor Akunyili-led NAFDAC was in the area of generating consciousness in the members of the public on the dangers of fake, substandard and adulterated food and drug products. The agency ran media campaigns on radio, television and the print media. Also, it engaged in advocacy visits to relevant stakeholders and institutions, apart from establishing NAFDAC safety clubs in schools and colleges to sensitize students on the dangers of fake drugs and the need to avoid drug abuse.

Since the Akunyili leadership of the agency, Nigerians have become orientated not only to look for NAFDAC registration numbers before purchasing products; they also want to see the expiry dates and the manufacturers' addresses. The belief is that fake drugs business thrives partially on ignorance; but when people are sufficiently sensitized, they will purchase less fake products and the incidence of fake, counterfeit and adulterated drug products will reduce. From a record of 60% in 2001, NAFDAC brought the incidence of fake drugs in Nigeria down to 20% in 2004 (Oyeyemi, 2004:32).

Another achievement of the Akunyili leadership at NAFDAC was the positive behavioural changes in its staff. This became manifested in a new culture of transparency, accountability, hard-work, and integrity. The anti-corruption, hard-work and tenacious spirit of the Director-General rubbed off on the agency's staff, thus bringing about greater effectiveness and improved public perception of the agency in recent years. The many awards conferred on the Director-General from local and international fronts are a testimony to this.

Also, due to the achievement of reduction in the incidence of fake drugs in Nigeria by the Akunyili leadership, the once-dying pharmaceutical sector of the economy got revived as Nigerian-made drugs once-more became accepted in other countries, including those in the West African coast where such were rejected in the past, indicating a renewed confidence in Nigerian made drugs in the West African community. This prompted Ghanaian drug regulatory authorities to lift a subsisting ban on 'Made in Nigeria' drugs (Akunyili, 2004:18).

Furthermore, NAFDAC's activities under the Akunyili leadership resulted in an increase in the productivity of the Pharmaceutical Manufacturing Group of the Manufacturers Association of Nigeria (PMGMAN). For instance, Glaxo Smithkline was reported to have recorded a 77% growth in sales around 2002, which its General Manager attributed to "NAFDAC living up to its responsibilities of enforcing strict compliance to product regulation" (*The Guardian*, January 29, 2003:45).

Under the Akunyili leadership, NAFDAC stopped the importation of fake drugs to Nigeria from source, that is, countries of production. To achieve this, the agency embarked on Good Manufacturing Practices (GMP) inspection of factories within and outside Nigeria by her officials before their pharmaceutical products could be allowed into the Nigerian market. NAFDAC also appointed laboratory analysts in India to certify products coming into Nigeria from the country, while it became mandatory for importers to register their products with NAFDAC and to submit necessary pre-shipment information.

The Akunyili-led NAFDAC recognized the importance of politics and political support to the success of regulation. It therefore sought and secured the political support of the Presidency early in its administration. In the words of the Director-General:

The agency is appreciative of the political will of government in helping us to strengthen our regulatory activities. The President... (did) a lot to empower NAFDAC in her war against fake and counterfeit drugs...The government's political will is further reinforced by the ...new policies...approved by the Federal Government. (Akunyili, 2004:17).

The Director-General listed some of the Federal Government's interventionist policies that helped the agency to include the following:

- Outright ban on importation of drugs and other regulated products (food, cosmetics, chemicals/detergents, medical devices and all drinks) through land borders;
- The designation of Calabar and Lagos (Apapa) sea ports, and Murtala Mohammed, and Aminu Kano International Airports as exclusive ports of entry for the importation of drugs and pharmaceutical and raw materials;
- Release of shipping and cargo manifests by Nigeria Ports Authority, shipping lines and airlines to NAFDAC inspectors; and
- The return of NAFDAC to the ports in October 2001 to facilitate the reduction of fake drugs in Nigeria. (Akunyili, 2004:17).

Realizing that Nigeria's expansive borders, air and seaports constituted a challenge to effective product regulation, the Professor Akunyili-led NAFDAC created two new directorates-Ports Inspection and Enforcement Directorates-for more effective surveillance at all ports and for better enforcement at the airports, land borders and within the country. With political support from the Federal Government, a new guideline came into force, that any aircraft that lifts drugs to Nigeria without obtaining NAFDAC's authorization from their clients will be grounded (*NTA News*, Wednesday, April 4, 2007).

Also, the Akunyili leadership initiated a process of better interaction between NAFDAC and regulated industries and other stakeholders. For this purpose, it created a Professional Liaison Unit (PLU). It also put in place a Standard Operating Procedure (SOP) for regulatory purposes. This is in addition to the upgrading of the agency's laboratories at Oshodi, Yaba, Kaduna and Maiduguri to international standards in addition to the establishment of new ones in Kaduna, Rivers, Cross-Rivers and Anambra States (Akunyili, 2004:17; Adegun, 2008:248).

Other achievements of the agency under the leadership of Professor Akunyili included expedited registration processes for regulated products; construction of warehouses to accommodate seized products prior to destruction; building of houses at several border communities to accommodate NAFDAC staff on border patrols; and the hoisting of NAFDAC website (www.nafdacnigeria.org) to facilitate improved communication and to make the agency and its activities better known to the world.

Another outstanding achievement of NAFDAC under the leadership of Professor Akunyili was the establishment and strengthening of pharmaco-vigilance and adverse drug reaction monitoring processes nationwide. By means of these programmes, official reports are submitted by medical practitioners and pharmacists, thus enabling the agency to issue alert notices, stop circulation of such products and ultimately track and stop the manufacturers of such products.

10. Challenges of NAFDAC under the Akunyili Leadership

Although the agency recorded tremendous improvements under the leadership of Professor Akunyili, it was also faced with a lot of challenges, some of which were quite enduring. One was the problem of uncoordinated drug distribution networks in Nigeria, which is the best represented by the existence of open drug markets in different parts of Nigeria, notably Onitsha, Kano, Aba and Lagos. The efforts of the agency to regulate these markets met with serious resistance and comparatively little success. The agency was only able to weather the storm through innovative ideas like series of meetings, advocacy meetings with institutions of socialization, in addition to sensitization programs for regulated interests that demonstrated resilience. Some of the agency's programmes, such as closures of the various open drug markets, occasionally caught regulated industries and their allies off-guard. This meant the agency had to be very vigilant.

Another challenge that faced the agency was the series of attacks on its properties, facilities and staff. Examples of these included the burning of the agency's laboratories at various periods in Ikoyi and Kano, and a failed assassination attempt on the life of the agency's Director-General. It was suspected that such attacks on NAFDAC officials and properties were master-minded by operators of the various illegal drug markets that the agency was regulating across the federation.

A third challenge of NAFDAC under the Professor Akunyili leadership was that of galvanizing and securing stakeholders' support for its regulatory efforts. This became very crucial because regulation of the pharmaceuticals industry is not a single-agency affair but one that requires full support from different institutional stakeholders. Unfortunately, the Pharmaceutical Society of Nigeria (PSN) and the Pharmacy Council of Nigeria (PCN) did not give the agency sufficient necessary support in critical aspects of regulatory policy. An example was the lack of stakeholders' support that led to the abandonment of NAFDAC's proposal to restructure the drug distribution channels in the country by dismantling existing open drug markets and establishing what it called the Zonal Drug Distribution Centres

(ZDDC) across Nigeria (Olugbenga, 2013:33-44). In spite of NAFDAC's assurances that pharmacists would manage the centres, the agency had to abandon the idea due to media attacks on the programme by the Pharmacists Council of Nigeria (PCN), even after the National Assembly had promised to allocate N800 million to the project (Oyedemi, 2005:32). The PSN and PCN, however, alleged that NAFDAC failed to make wide consultations with relevant stakeholders before engaging on the idea (Olugbenga 2008c).

Finally, there was lack of effective inter-governmental co-operation amongst the federal, state and local government councils and this affected the work of the agency where it mattered most, namely the states and local government councils. Although citizen's interests are similarly affected at all levels of government, the agency could not harness all relevant resources and secure the maximum cooperation of relevant institutions in the states and local government councils due to lack of harmonization of applicable laws at the various levels of administration. NAFDAC's business was treated mostly as the concern of the federal government, notwithstanding the fact that citizens are affected by the agency's work at every stratum of government.

11. Conclusion and Recommendations

In spite of the above challenges facing its leadership, NAFDAC can improve on its performance by overcoming the obstacles mentioned above through several means. One, the leadership of the agency should continue with, and improve on its dialogues and consultation with relevant stakeholders in order to sustain its enforcement activities. This is because collaboration in the policy arena remains a potent tool to reign in aggrieved elements who may be opposed to regulation. The failure of the agency's ZDDC project in 2001 was due to poor consultations with political and professional stakeholders in pharmaceutical regulation in Nigeria.

Two, the leadership of NAFDAC must continue to motivate its staff to sustain loyalty and strengthen internal unity. Some means of doing this include staff training in cutting-edge practices in regulation, good welfare packages and fairness in dealing with staff of the agency. Given the above conditions, staff of the agency should be ready to give their best to the agency in terms of dedication and loyalty, especially when job security is assured.

Three, regulation is political. Therefore, the leadership of the agency must be ready to sustain its political engagement with the Presidency and the National Assembly. On its part, the National Assembly should assist the agency by providing better funding for the agency to strengthen her enforcement activities. Also, it should review the laws of the numerous agencies and professional bodies whose mandates overlap with those of NAFDAC in order to avoid conflicts. Furthermore, the National Assembly should study and streamline the various drug laws that have been passed in Nigeria since independence. This will help the agency's leadership to interpret and apply relevant laws without equivocation. It will also help the agency to avoid unprofitable distractions which jurisdictional conflicts with other organizations may breed.

Lack of effective inter-governmental co-operation amongst the federal, state and local government councils is one of the problems affecting the effectiveness of the agency. It is therefore recommended that state governments should give more support to the agency and its activities. This could be done indirectly through better collaboration with the agency by raising greater public awareness for NAFDAC's programmes, such as sponsoring airtime for the agency's programmes and by allowing the agency to run its advertorials at subsidized rates on state-owned electronic and print media. State and local government councils can also donate vehicles, laboratory equipment and other logistic inputs to facilitate better coverage of rural areas by NAFDAC. An example is the donation of an office accommodation to the agency in 2008 by Ejule community in Kogi State, making it the first state in Nigeria where NAFDAC has two offices.

Also, the Federal Government should equip the Nigeria Customs Service (NCS), to carry out more effective patrol of Nigeria's expansive borders in order to checkmate the activities of drug smugglers through the borders. The Nigerian Navy (NN), Nigerian Ports Authority (NPA) and the management of Federal Airports Authority of Nigeria (FAAN) should all be equipped to give more support to NAFDAC in stopping illegal importation of drugs into Nigeria.

Furthermore, NAFDAC requires more enforcement powers than she presently has. This issue was raised by a wide spectrum of respondents from different parts of Nigeria during our fieldwork on means of enhancing the work of the agency. The agency should therefore be given more powers so that its operatives and officials can carry light weapons after due training in the handling of such weapons. This will mitigate the spate of attacks on the agency's staff by unscrupulous segments of the regulated interests.

Finally, the Federal Government should consider making the agency partially, if not totally independent while its funding should be charged to the consolidated revenue fund to avoid its total subjugation to the whims and caprices of the executive, and to secure the future of the agency. This is because; securing the health of citizens is a task that goes beyond the life and tenure of any particular administration. A regulatory agency in the pharmaceuticals sector needs some degree of financial autonomy and independence of action in order to pursue its mandate properly. A situation where the Director-General is completely under political control of the executive is not healthy for optimum regulatory performance and may not secure the future of the agency.

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