Drug Regulation and Control in Nigeria: The Challenge of Counterfeit Drugs

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Abstract: The primary objective of this study is to establish the factors that have contributed to the preponderance of counterfeit drugs in Nigeria despite the laws. Data was gathered by a combination of the use of questionnaires and oral interviews. The results suggest that drug laws were adequate falling short only in their implementation. The task forces were rated as ineffective arising from corruption, communication gaps, lack of adequate funds, lack of vehicles, etc.

Keywords: Laws, Counterfeit drugs, Nigeria

Introduction

Background To The Study

In Nigeria today, there is an influx into the market of fake machine parts, fake motor spare parts, fake chemicals, fake and adulterated food items, amongst many others. It may appear that almost every existing product has a fake counterpart. The era 1985-2000 in Nigeria has heralded the regime of faking and quackery, counterfeit drugs, quack doctors, illegal chemist shops and hospitals. Drugs are no exception (Ohuabunwa, 2002). The menace of fake drugs became prevalent in the last decade and the present situation is alarming in the West African sub-region, including Nigeria. Empirical observations have shown that there may be more fake than genuine drugs in circulation (Osibo, 1998). The counterfeiting practices in developing communities include:

- (i) Counterfeiting when demand for an expensive product is high.
- (ii) Tampering with original packages with drugs packed in large pack sizes.
- (iii) Swapping of labels of two products manufactured by the same company.
- (iv) Exploiting similarity in appearance between the original preparation and the counterfeit.
- (v) Labeling low price products with a high price product label.
- (vi) Passing off a company's product for another.

A disturbing aspect of the counterfeit drug menace is that the effects of consuming such drugs go unnoticed most of the times except in such cases where it results in mass deaths. There are generally no reliable data on the mortality or morbidity arising from the consumption of counterfeit drugs in Nigeria. In 1947, 14 children were reported dead after being administered chloroquine phosphate injections and in 1990, 109 children died after being administered fake paracetamol (Aluko, 1994). Usually such incidences stimulate governments into taking positive steps, principally arising from public outcry.

The trend in the last decade prompted the public and particularly the professional bodies, notably Pharmaceutical Society of Nigeria, to pressure the government to take definite steps towards controlling the preponderance of fake drugs in Nigeria. The government responded by promulgating the counterfeit and fake drugs (miscellaneous provisions) decree No. 21 of 1988. This decree prohibited the sale and distribution of counterfeit, adulterated, banned, and fake drugs or poisons in open markets and without a license of registration. It also created penalties for the breach of the provisions of the decree and a taskforce was established in each state of the federation charged with the responsibility of seizing any drug or poison illegally displayed in unlicensed or unregistered premises. Shortcomings in the decree led to its being repealed by decree No. 21 of 1989 and subsequent amendments.(4).

The Drug Situation In Nigeria

There is a large market for drugs in Nigeria. Out of over 130 existing pharmaceutical manufacturers only 60 are in active manufacturing. This is despite the installed capacity of the industry to produce between 50% and 75% of the nation's drug needs. Capacity utilization is below 30% and about 70% of the drugs are thus imported. (Okoli, 2000).

(a) Availability:

Drug availability in the public and private health care delivery system in Nigeria is in a poor state. Various reasons have been adduced for this trend (Erhun, 1996). These include:

- (i) Inadequate funding of hospital Pharmacies and the "out of stock syndrome"
- (ii) Involvement of unqualified persons in the procurement and distribution of drugs
- (iii) Inadequate storage facilities, transportation and distribution.

The adoption of an essential drugs program through the promulgation of Decree 43 of 1989 on Essential Drugs was a step taken to ensure the availability of drugs. Ordinarily, branded drug prescribing is still quite common in many public health institutions, contrary to specifications of the Essential Drug Act (Govt. of Nigeria, 1990). This has partially eroded the expected gains of the essential drugs program.

In 1996 a health intervention program was put in place under the Petroleum (Special) Trust Fund. A drug revolving fund (DRF) was established under the scheme that ran parallel to the existing DRF in public health institutions. Under this scheme, local manufacturers produced the drugs directly on a contract basis. To a large extent this intervention increased drug availability in the public health institutions. The scheme was however phased out in 1999 (Erhun, 2000)

(b) Distribution:

The drug distribution network in Nigeria is in a state of chaos because it consists of open markets, patent medicine stores, community pharmacies, private and public hospitals, wholesalers/importers and pharmaceutical manufacturers. It is a common scene in Nigeria to see petty traders who sell kola nuts, cigarettes, and oranges, among other items, in market kiosks, motor parks, and road sides hawking drugs that range from over the counter items to antibiotics (popularly called "capsules") (Adelusi-Adeluyi, 2000). The medicines are usually left under the sun in such conditions that could facilitate the deterioration of the active ingredients.

Patent medicine stores are owned by the holders of patent and proprietary medicine vendors licenses. Ordinarily the patent medicines should be sold in their original packs. Over the Counter (OTC) drugs are the only drugs authorized to be sold by the vendors but they generally sell all types of drugs as determined by their financial capability. Considering the knowledge base of these vendors, whose minimum academic requirement to obtain a license is the first school-leaving certificate, they are not in a good position to differentiate between fake and genuine product (Erhun and Adeola, 1995).

Community pharmacies are statutorily registered with the Pharmacists Council of Nigeria. A superintending Pharmacist, who is also registered and licensed, oversees the pharmacy anytime it is opened for business. With such pharmacies there should not be any serious problem of the sale of fake drugs. Unfortunately however, there are many unregistered "pharmacies" thriving. And in such premises drugs are purchased from doubtful sources with its attendant danger to the health of the public (Erhun and Adeola, 1995).

(c) Drug Related Laws In Nigeria:

There are various laws that regulate and control the manufacture, sale, and distribution of drugs in Nigeria. They include:

- (i) Poisons and Pharmacy Act, Cap 366 of 1990. This Act regulates the compounding, sale, distribution, supply and dispensing of drugs and provides different levels of control for different categories of drugs and poisons.
- (ii) Food and Drugs Act Cap 150 of 1990. This Act prohibits the sale of certain foods, drugs cosmetics and devices as treatment for certain diseases. The Act prohibits the importation, exportation, distribution and sale of specified drugs. It also prohibits practices such as misleading packaging, labeling, and advertising, as well as manufacturing food and drugs in unsanitary conditions. It conveys the power to appoint inspecting officers and food and drug analysts.
- (iii) Counterfeit and Fake Drugs (miscellaneous provisions) Act, Cap 73 of 1990. This Act prohibits the production, importation, manufacture, sale and distribution of any counterfeit, adulterated banned or fake drugs. It also prohibits persons to sell any drug in an open market without permission from the proper authority.
- (iv) Pharmacists Council of Nigeria, Decree 91 of 1992. It repealed the Pharmacists Act of 1964. This decree established the Pharmacists Council of Nigeria which is charged with the following responsibilities: (a) Determine the standard of knowledge and skill required of persons seeking to become

registered members of the pharmacy profession, (b) Establish and maintain a register of persons qualified to practice as members of the Pharmacy profession, (c) Prepare and review the code of conduct, and (d) Regulate and control the practice of the Pharmacy profession. The Council has an investigating panel and disciplinary committee to discipline erring pharmacists as appropriate.

- National Agency for Food and Drug administration and control Decree No. 15 of 1993. This is (v) the decree establishing the National Agency for Food and Drug Administration and control (NAFDAC). The Agency performs the following functions: (a) Regulate and control the importation, exportation, manufacture, advertisement, distribution, sale, and use of food, drugs, cosmetics, medical devices, bottled water and chemicals, (b) Conduct appropriate tests and ensure compliance with standard specifications designated and approved by the council for the effective control of the quality of food, drugs, etc., as well as their raw materials and production, including processes in factories and other establishments. (c) Undertake appropriate investigations into the production premises and raw materials for food, drugs, etc. and establish relevant quality assurance systems, including certification of the production sites and regulated products. (d) Undertake inspection of food, drugs etc. (e) Compile standard specifications and regulations and guidelines for the production, importation, exportation, sale and distribution of food, drugs, etc. (f) Undertake registration of food, drugs, etc. (g) Establish and maintain relevant laboratory or other institutions in strategic areas of Nigeria as may be necessary for the performance of its functions. The Federal task force on counterfeit and fake drugs established under the provisions of the counterfeit and fake drugs (miscellaneous provisions) Act operates within NAFDAC.
- (vi) Drugs and related products (registration) Decree No. 19 of 1993. This decree makes provisions for the prohibition of the manufacture, importation, exportation, advertisement, sale or distribution of drugs, drug products, cosmetics or medical devices unless it has been registered in accordance with the provisions of the decree. It also stipulates the procedure for applying for registration of a drug product, conditions under which information supplied by an applicant is disclosed, and provisions for the suspension or cancellation of certificates of registration and clinical trials. Penalties for contravention of provisions of this decree are also stipulated therein.

The aforementioned laws show that the government has positively responded by legislation to forestall a chaotic drug distribution situation in Nigeria. But empirical data has shown that the situation is far from adequate.

Rationale for the study

Drug availability, distribution and control are major concerns in health development as drugs constitute an important aspect of health development technology (Silverman, Lydecker, and Lee, 1990). In Nigeria particularly since the mid 1980s shortages of drugs and other technologies have become pervasive threats to the medical care system (Ohuabunwa, 2002). The major problem however seems to lie within the drug distribution channel. Indeed the network in the country has always posed problems in the supply of drugs from manufacturers to the end users – the patient. The sum total of the effects is the increase in the sale and distribution of counterfeit drugs, which have grave consequences for the health of the people of Nigeria.

The main purpose of this study is to examine the factors that have contributed to the preponderance of counterfeit drugs despite the existence of laws and regulatory agencies. To achieve this purpose the following questions would be answered:

- (i) What are the underlying causes for the availability of fake drugs in Nigeria?
- (ii) Are the laws governing counterfeit and fake drugs adequate to curb the menace of drug faking and counterfeiting?
- (iii) To what extent have task forces been able to control the proliferation of counterfeit drugs in Nigeria?

This study is significant because the people's right to health include the right of access to a reliable standard of healthcare and assurance that drugs received are not only genuine but safe, effective, and affordable. It is also the responsibility of government to protect its citizens from the clutches of unscrupulous members of the society. The Nigerian government has designed various ways to do this, and it is expected to equip the regulatory agencies with materials and manpower to effectively perform their duties. Very few studies if any have been undertaken to evaluate these measures put in place by government. The outcome of this study should reveal the

strengths and weaknesses of the task forces that have been the main organ set up to control this menace. The result of this investigation would be instructive to regulatory bodies in the third world.

The major problem encountered in this study was the initial reluctance of regulatory bodies to divulge vital information that will reveal their level of performance.

Methodology

Survey methods employed in collecting data for this study are questionnaires and oral interviews to clarify issues. The views of stakeholders and specific organizations relevant to this study (i.e., regulatory and non regulatory agencies) were sought. Amongst the regulatory bodies were: (i) Federal Task Force on Counterfeit and Fake drugs, (ii) The National Agency for Food and Drug Administration and Control (NAFDAC), and (iii) The Pharmacists Council of Nigeria. These are the three bodies relevant to the study. It was intended to interview staff in these organizations for their views on the subject matter of this study. In none of the three organizations did staff agree to participate. They gave the same reasons: They were civil servants and could therefore not disclose some of the information being requested without appropriate authority. As a result of this development, the chief executives of the organizations were contacted. The executives either completed the questionnaire directly or delegated the responsibility to a very senior staff that could provide valid responses to the questions. The views expressed were thus the official views of the organizations.

The non-regulatory bodies include (i) The Pharmaceutical Society of Nigeria, (ii) Nigeria Association of General Practice Pharmacists, (iii) Nigerian Association of Industrial Pharmacists, and (iv) the Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria (PMG/MAN). It was observed that all of these organizations have organized at least a national symposium/seminar on counterfeit drugs in the last two years preceding the study. They all therefore have consensus positions on the subject matter of this study. It was therefore decided that the position of these organizations rather than those of individuals within such organizations would be more representative.

Pharmaceutical Society of Nigeria is the main professional organization of Pharmacists in Nigeria. Established in 1927, it has a membership of over 7000 Pharmacists. It is represented in the 36 states of the Federation including the Federal Capital Territory. It has four technical groups that cater for the technical interests of the group members. Two of the four groups, which are relevant to this study, are included in this work. The first, Nigerian Association of General Practice Pharmacists, makes up about 50% of the entire membership of the PSN(Pharmacists Council of Nigeria, 1999). Membership of this group is opened to community Pharmacists. The second, Nigerian Association of Industrial Pharmacists, is comprised of Pharmacists employed in the pharmaceutical industry.

The Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria is the technical wing of the latter. This Group has membership drawn from mostly multinational pharmaceutical companies. Specific questionnaires were designed for the regulatory and non-regulatory agencies. They were administered to the chief executives of the organization who either completed it directly or designated an appropriate subordinate to do so. The questionnaire for the Federal Task Force on counterfeit and fake medicines sought to know the following:

- Adequacy of the laws governing the eradication of counterfeit drugs in Nigeria.
- Why counterfeit drugs are common.
- The performance of the state task forces.
- Methods employed by the task forces in carrying out their duties and the major problems affecting performance.
- How seized goods are prevented from going back into the drug distribution chain.

The Questionnaire for the Pharmacists Council of Nigeria (PCN) and NAFDAC sought to establish the following:

- How these institutions perceived the problem of counterfeit drugs.
- Reasons for the preponderance of counterfeit drugs.
- What the institutions were doing to check influx of counterfeit drugs.
- Adequacy of laws regulating counterfeit drugs.
- How cordial the relationship of PCN was with the federal and state task forces.
- Suggestions on how the problem of counterfeits drugs could be curbed.

The Questionnaire administered to the non-regulatory agencies was aimed at determining:

- The organization's perception of the problem of counterfeit drugs.
- The reasons underlying the availability of counterfeit drugs.
- The organization's role in eradication of counterfeit drug problems in Nigeria.
- Assessment of the laws governing the eradication of counterfeit drugs.
- The working relationship with the federal and state task forces.

Results and Discussion

All the seven organizations responded to the questionnaire giving a response rate of 100%. Respondents were unanimous that the problem of counterfeit drugs in Nigeria was real and was capable of undermining the health care delivery efforts of the federal and state governments.

Table 1 shows the reasons given by the organizations for the preponderance of counterfeit drugs in Nigeria.

Table1: Reasons Adduced for Availability of Counterfeit Drugs in Nigeria	
Reason	# of Respondents (N=7)
Laws are inadequate	6
Ineffective enforcement of existing laws	7
Non Health Professionals in Drug Business	6
Loose control systems	2
High cost of drugs	5
Greed	3
Ignorance	7
Corruption	4

(i) Availability Of Counterfeit Drugs

The following reasons were adduced for the preponderance of counterfeit drugs in Nigeria.

(a) Ineffective Enforcement Of Existing Laws

The laws regulating pharmacy practice were adjudged as generally adequate (85.7%). During an interview conducted for this study, a past president of the Pharmaceutical Society of Nigeria stated:

"It is disturbing that in spite of the existence of appropriate legislation, illegal distribution of medicines continue to flourish, giving the impression that the government is insensitive to the harmful effect on the people of this country of medicines distributed unlawfully, some of which are of doubtful quality, safety and efficacy."

All the respondents (100%) indicated that the laws were not being properly enforced. The lack of enforcement of drug laws is common in the developing countries. For example, a case has been made for a stricter application of the national drug policy in Bangladesh as a way of controlling numerous small pharmaceutical manufacturers who market substandard drugs (Roy, 1994).

Some respondents (60%) were also of the view that the penalties for offenders were too light. An example given was the $\mbox{N}5,000.00$ fine and/or two years imprisonment when convicted for hawking or selling drugs on illegal premises. The view was expressed that this should be increased to about $\mbox{N}10,000.00$ and/or three years imprisonment particularly to scare and discourage those who hawk drugs. The lack of comprehensive documentation on prosecution of offenders tends to further suggest (albeit arguably) ineffective enforcement.

(b) Non Professionals In Drug Business

Eighty-eight percent of the respondents in this study indicted that non-professionals in the drug business were contributing to the availability of counterfeit drugs. Pharmacists are authorized by law to manufacture, sell, distribute, import, export, dispense, and compound drugs. Community or retail pharmacists have registered premises for the sale and dispensing of drugs. However there are persons (non

pharmacists) who are also authorized to sell patent medicines. These are holders of patent and proprietary medicine vendor's licenses. These vendors unfortunately are generally involved in the sale of virtually all categories of drugs including antibiotics, narcotics, toxoids, and antihypertensives, in addition to what can be classified traditionally as patent medicines (Erhun, 1992). Such non professionals were stated as less capable to identify counterfeit and fake drugs.

(c) Loose Control Systems

One of the functions of NAFDAC is the regulation and control of imported products. This is done by having inspectors at the various airports and seaports. In April 1996 the task force on the decongestion of ports directed that officials of NAFDAC and Standards Organization of Nigeria (SON) should quit the ports and be invited when necessary. This was criticized as capable of encouraging the influx of fake and adulterated drugs. Before a drug is released into the market it must be registered by NAFDAC. One of the conditions for registration is the analysis and testing of the drug to ensure quality and safety. respondents (57.1%) were of the view that the Forensic laboratory at Oshodi in Lagos, which is the major public laboratory for the purpose of quality control analysis, is not adequately equipped to cope with the volume of requests particularly for the analysis of imported products. We could not obtain the statistics of the requests for the drug analysis that were turned down for reasons of inadequate equipment. NAFDAC officials are also expected to go on routine inspection of premises where drugs are manufactured to ensure they comply with Good Manufacturing practices (GMP), but this is hardly done according to NAFDAC as a result of logistic problems. The majority of respondents (85.7%) attributed this situation to inadequate funding. These loose control systems were thought be exploited by unscrupulous persons to manufacture, import and distribute fake and adulterated products. An assessment of 96 samples of chloroquine and selected antibacterial from Thailand and Nigeria indicated that 36.5% of the samples were substandard with respect to pharmacopoeia limits (Shakoor, Taylor, and Behrens, 1997). Access to essential drugs in developing countries have been linked to poor quality and counterfeit drugs as a result of the way the pharmaceutical market is regulated (Pecoul et al., 1999). The Nigerian situation does not seem to depart from this trend.

(d) High Cost of Drugs

Seventy-one percent of respondents indicated that high cost of drugs was a reason why counterfeit drugs were available. Most genuine drugs are very expensive. This can be explained by the fact that local input in drugs manufactured in Nigeria is quite small. Most of the raw materials are imported and equally attract an unnecessarily high tariff. The devaluation of the Naira (Nigerian currency) has also worsened the situation. The high prices make drugs unaffordable, hence people opt for cheaper drugs that are spurious in many cases and even patronize quacks with fatal consequences. High prices of essential drugs have also been reported in Mexico (Molina-Salazar and Rias-Vilchis, 1998).

(e) Greed

Forty-three percent of respondents indicated that the greed of regulatory officials have contributed to the preponderance of counterfeit drugs. A respondent described this as -

"Get rich quick syndrome/value system that encourages corrupt enrichment. In the bid to get rich there are those that believe that the end justifies the means. In some cases people collude with some foreigners to import substandard product."

The data shown in Table 4 show that paracetamol, ciproxin, ampicillin and maloxine were substandard drugs actually imported from foreign countries. This could very easily occur where collusion exists.

(f) Ignorance

Ignorance was regarded by all (100%) respondents as contributing to the problem of counterfeit drug availability. Most respondents (70%) as a reason why people easily fell victims of fake drugs gave the low level of literacy. Statistics from the Federal Ministry of Education estimate the literacy rate in Nigeria

as a little over 34% of the adult population of about six million. In fact over 40% of the entire population of Nigeria have no formal education UNESCO believes that this has grown up to 50.7%. A resident representative of UNDP in Nigeria has said that either way a sizeable proportion of the adult population in Nigeria is believed to be unable to read or write (Clinsman, 1996).

Given that drug fakers have become very sophisticated in their activity, it is becoming increasingly difficult to distinguish between a genuine drug product and a fake one. The task would even be more difficult for those that are not literate.

(g) Corruption

Fifty-seven percent of the respondents indicated that corruption was a contributory factor to the availability of counterfeit drugs. A respondent indicated that

"The effectiveness of various regulatory bodies is negatively affected by the high level of official corruption and manipulations in the Nigerian health care system."

Another respondent stated that

"It is common knowledge that the law enforcement agents including drug law enforcement officials are paid off to look the other side while the business of counterfeit and fake drugs flourishes."

The recent promulgation of the anti corruption law by the National Assembly is a confirmation of the magnitude of the problem of corruption in Nigeria.

ii. The Task Forces

The establishment of the task forces on counterfeit drugs was generally (100%) seen as a welcome development in the fight against fake drugs. However, all respondents regarded the coordination, monitoring and control by the task forces as deficient. Some flaws were noted in the general composition and nature of the task forces as shown in Table 2. The following were specifically identified.

- a. The task forces should not be under one agency (NAFDAC) as experience has not shown this to be effective.
- b. The task forces should be centrally coordinated or controlled so that various agencies that require their services can easily have access to them and make them accountable after an assignment. This contrasts with the situation of the setting up of state and federal task forces.
- c. The task forces should have been structured to report directly to the Pharmacists Council of Nigeria, which is the body that registers where drugs are sold and manufactured.
- d. Some respondents (42.8%) attributed the faulty coordination to the heads of the various state task forces who being military officers take directives from superior military officers rather than the chairman of the Federal task force who is a civilian.
- e. That membership should comprise of both civilians and armed forces members who are Pharmacists.
- f. The decree setting up the task forces should be modified to ensure that they receive adequate funding for their operations.

Since the promulgation of the counterfeit and fake drugs (miscellaneous provisions) decree, the existence of the task forces has been sporadic. They had been characterized by short life spans. The situation with the task forces at May 1996 (i.e., about 7 years after the decree was promulgated) is shown in Table 3. As of that date, there were 30 states in Nigeria including Abuja. It is clear from the table that the task forces were either not existing or non functional in many states of the federation. This would have implications for their performance. Only 28.6% of the state task forces had been inaugurated and functional; 33% of the state task forces were yet to be constituted. This situation could support the reason for a central coordination and control.

	Table 2: Suggestions on how performance of task forces could be improved upon		
	Item	# of Respondents	
.*.	Tools former about discount will add by one account.	(N=7)	
*	Task forces should be controlled by one agency	5	
*	The structure of state and federal task forces should give way to one central task force.	5	
*	Military officers should not be part of task forces	3	
*	Membership of task forces should be exclusive to Pharmacists	6	
*	Corrupt officials should be identified and dismissed	7	
*	Seized products should be destroyed rather than being Allowed to go into circulation	7	
*	Specialized Problems facing Task Forces -		
	Lack of adequate funding	7	
	 Lack of vehicle and necessary equipment 	7	
	Shortage of manpower	5	
	Inadequate training of task force personnel	5	
	 Inadequate security for non military members of the task forces 	3	

Table 3: Status of some State Task Forces on Counterfeit & Fake Drugs as at May, 1996			
State	Status of Task Force		
Abia	Inaugurated and functional		
Abuja	Reconstituted a year ago but not yet inaugurated		
Adamawa	Inaugurated in January 1996 and started functioning in march 1996		
Akwa Ibom	Inaugurated but called Task force on fake and counterfeit drug and illegal clinics ^a		
Bauchi	Inaugurated and functional		
Borno	In existence for two years but not functional		
Delta	Not yet reconstituted since Chairman went abroad		
Edo	Inaugurated 2 years ago with a Pharmacist as Chairman		
Enugu	Joint task force with Anambra state. 4 of the 6 members are Pharmacists		
Imo	Dissolved in 1995 but not yet re-constituted		
Jigawa	Not reconstituted		
Kaduna	Not inaugurated because of shortage of funds		
Kano	Inaugurated and has been functioning for one year		
Kwara	Chairman transferred arising from routine military posting. Yet to be reconstituted		
Lagos	Inaugurated in August, 1995 but because operational in March, 1996.		
Niger	Functional since 1995		
Ondo	Not yet reconstituted Moribund for 4-5 years		
Oyo	Not yet reconstituted		
Plateau	Inaugurated in February, 1996		
Rivers	Not functional		
Taraba	Inaugurated		

^a This is an anomaly because matters of drugs are on the exclusive list and have federal jurisdiction, while issues regarding clinics are a state affair. The issue is being resolved.

Our study attempted to identify the methods employed by the task forces in achieving their set goal. The methods were found to include surveillance, going out on "raids" at least once a week, investigations, prosecution of offenders, and public enlightenment. The products seized during raids were kept in warehouses, and an inventory of the products were taken and signed by the owners, task force officials and the police. For seized products, after relevant investigation and analysis, if the products were confirmed to be fake, they were burnt to ensure that they did not enter the drug distribution chain. We could not establish if this was done in all cases. A respondent stated that -

"Some of the products seized by the task forces tend to go back into circulation. Similarly some premises sealed for sale of fake drug products get re-opened within 24 hours."

The above procedure not withstanding, 40% of the respondents were of the view the task forces had been a complete failure, while 60% felt that they were ineffective. The following quoted reasons were adduced for the ineffective performance of the task forces:

"Generally, the task forces have been working on the principle of settlement and favoritism and as such have compounded the problem they were established to solve".

"The working relationship of the chairmen of the task forces who were normally military officers and the other civilian members is not normally cordial. Such strains affect the productivity of the body".

The Pharmacists Council of Nigeria (PCN) regulates the practice of Pharmacy through the inspection of Pharmaceutical premises amongst other activities. It was thus deemed necessary to find out if the activities of the task forces had any effect on those of the PCN inspectors. The PCN response indicated that there was a conflict. A direct quotation of the PCN response is as follows: "the performance of the task force has not been adequate. As a result, illegal drug manufacturing, distribution and retailing outlets spring up everywhere. These are major sources of fake and adulterated drugs. The presence of these premises makes it difficult to regulate and control the practice of pharmacy. Some of them are so organized that they file suits against government and/or its agencies."

On the whole it is not clear whether the task forces have been able to live up to the expectations for their establishment. In the United States enforcement has remained the dominant means for drug regulation despite the fact that it is overused (Rasmussen and Benson, 1999). This may partially be attributed to the measure of success that has been achieved by this means. Further studies may be necessary to critically examine alternatives to the use of task force in Nigeria particularly in the current circumstance where they have proved ineffective.

iii. Seizures of Fake Drugs

Despite the "no pass" mark given to the task forces, they have also been able to make a few seizures of some fake drugs as shown in Table 4. Different classes of drugs have been faked and counterfeited. Almost half of the seizures consist of antibacterials. This has serious implications with respect to the problem of antibacterial resistance in the community. It may appear that the prosecution of offenders is normally slow. A former Minister of Health in Nigeria was quoted as saying

"Of the 426 cases reported, only five have been heard and nine pending before the tribunal, while many cases which should have been prosecuted ended mid-stream" (The Guardian (Health Column), 1994).

iv Public Enlightenment on Fake Drugs

Public awareness on drug matters has been described as well below average by the Pharmaceutical society of Nigeria. In view of the fact that public awareness is one of the cheap methods of curbing the incidence of fake drugs the various organizations in this study were requested to indicate whether they were educating the public on fake drugs. Twenty-nine percent of the respondents have been involved in public awareness creation on counterfeit drugs.

The main strategy employed was public enlightenment campaigns through aggressive electronic and print media. Some pharmaceutical companies sponsor television programs. "Drugscope" was identified as one of such sponsored programs that enlighten the public generally on drugs, diseases and the need to obtain drugs from registered pharmaceutical premises. The state branches of the Pharmaceutical Society of Nigeria organize Pharmacy Week during which periods they feature seminars and other events on drugs and drug matters. A ready example is that of the Lagos branch held in August 1996 during which an enlightenment campaign on drugs was held at a local motor park. There are also radio jingles, personality interviews, and public alert notices that warn about the existence of counterfeit drugs.

Table 4: Some Drug products seized by the Task forces on			
counterfeit and fake drug from 1993 to 1996			
Drug Product	Comment/Action		
Chloroquine phosphate	An imported substandard product seized and burnt		
Tarivid	Illegally imported		
Ampicillin capsules	3 fake brands containing talc, and starch with no Ampicillin		
Vitamin B tabs	Illegally imported without product registration		
Paracetamol	Fake paracetamol from India illegally imported		
Maloxine	Unregistered substandard product from India in circulation		
Ciproxin	Fake products originated from India		
Ciprosyn	Fake products originated from India		
Pyremol	Sale and distribution of fake product		
Halothane solution	Expired product on sale		
Ferrous gluconate	Fake product in circulation		
Ivermectin	Illegal sale of product		
Bactrim syrup	Sale of valium syrup as bactrim syrup		
Ampicillin Caps	Substandard product imported from Greece		
Indomethacin)		
Gentamicin injection) Re-labeled expired drugs on sale and distribution		
Tetracycline)		
Nitrofurantoin)		
Metronidazole	Solid and distributed as chloroquine tablets		
Chloridiazepoxide	Fake product illegally manufactured sold and distributed		
Chlorpheniramine	Sold and distributed as chloroquine tablets		
Chloroquine	Imported unregistered product		
Demovate cream	Fake product on sale		
Fansidar	Fake product on sale		
Tetracycline Caps	Illegal distribution		
Propanolol tabs	Fake product on sale		
Erythromycin tabs	Fake product on sale and distribution		
Indomethacin	Illegal distribution		

Conclusion and Recommendation

From the data obtained in this study some general inferences could be made:

- The laws governing the manufacture, sale, distribution, importation and exportation of drugs are not adequate enough to control the illegal manufacture and sale of drugs in Nigeria.
- The implementation and enforcement of the various drug laws are deficient.
- The task forces on counterfeit and fake drugs have been partially effective considering their staff strength, fund allocation and other necessary equipment, which are inadequate. However, they have essentially failed with respect to prosecution of offenders.

In the light of the findings the following recommendations could be useful at various levels:

- (i) There is an urgent need for government to implement the provisions of the existing laws.
- (ii) The government should adequately equip and fund the central laboratory to analyze medicines suspected to be fake. Such a laboratory could also have training facilities for laboratory technicians in drug analysis. Lessons from the World Health Organization would be useful in this respect (Anonymous, 1999).
- (iii) A more spirited effort needs to be made by NAFDAC to ensure the registration of all drug products either locally manufacture or imported. Offenders should be speedily prosecuted.

- (iv) The state task forces on counterfeit and fake drugs that are not in existence should be reconstituted and invigorated. The task forces should be adequately funded to be able to acquire the necessary facilities for their operations.
- (v) Pharmacists through the various non-regulatory agencies should be in the vanguard of disseminating information about suspected counterfeiting activity to their professional colleagues, public and law enforcement agents.
- (vi) Pharmaceutical industries should have established drug surveillance units to monitor their products in the market to detect faking.

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