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A Partnership Model for the Control of Unethical Marketing of Medical Drugs in Nigeria.

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Abstract

The study assessed the effects of enforcement of anti-counterfeit drug laws (penalties) on the unethical marketing of medical drugs in Nigeria, particularly the South Eastern States. The study was a survey design. Stratified, simple random, convenience and judgmental sampling procedures were adopted. A research question and one null hypothesis guided the study. The population consisted of 5621 respondents, comprising 3444 healthcare professionals, (doctors, pharmacists, nurses), 1641 drug consumers, 390 licensed drug firms and 146 senior staff of the Regulatory Agencies in Abia, Anambra, Ebonyi, Enugu and Imo States. Five University Teaching Hospitals were used for the study. A sample of 985 respondents was used. Primary and Secondary sources of data were accessed. The questionnaire was validated using the opinions of experts. Pilot study was conducted and the scores subjected to Cronbach's Alpha technique. The reliability coefficient was 0.947, indicating high degree of internal consistency of the research instrument .The mean (x) and criterion mean scores were used to answer the research question. Z-test statistical technique was applied in testing the hypothesis at 0.05 level of significance and 4 degrees of freedom. The findings of the study revealed that enforcement of existing penalties had non-significant positive reduction in unethical marketing of medical drugs. The partnership model (Regulatory Excellence Model) was designed to enhance the control of unethical marketing of medical drugs in Nigeria and further recommendations were made.

Keywords: Medical Drugs, Unethical Marketing, Model, Enforcement, Penalties, SDSI, NAFDAC.

1. Background of the Study.

With a population of over 150 million people, Nigeria represents a large market for medical drugs. Medical drugs are the integral part of healthcare delivery system, faced with risks and uncertainties. They are expected to perform the multiple functions of restoring abnormal physical states, correcting or modifying organic malfunctions and preventing disease disorders in the human body or in animals (Okoye, 2005: 44). When the potency of the drugs cannot accommodate the functions of mitigation or prevention of disease disorder, uncertainties usually surround their production and they pose great risks to public health. Medical drugs are rarely sold directly from manufacturers to retailers or consumers. The dynamic link between manufacturers and consumers is bridged by a network of intermediaries, scattered across different countries in the globe. The complexity of the distribution chain makes it vulnerable for substitution of counterfeit drugs in the chain. The distribution chain consists of open markets, patent medicine stores, and community pharmacies, private and public hospitals. The patent medicine stores are owned by the holders of the patent and proprietary medicine vendors' licenses. The major threat to the drug distribution chain is the secondary market, comprising small and loosely regulated wholesalers and retailers typically State licensed or registered companies scattered all over Nigeria. This market controls good chunk of the drug distribution network, using their go-to-market approaches, namely, sale of counterfeit drugs, drugs that have degenerated due to poor storage and handling, drugs with wrong packaging / unapproved labels, drugs with fake NAFDAC numbers, drugs in unregistered pack sizes, including drugs re-labeling, re-validating of expired drugs, among others..Bulk packaged drugs are repackaged in smaller bottles for better commercial utility. Repackaging constitutes the greater vulnerabilities of the entire drug distribution chain with constant inflow of counterfeit drugs. Internet provides counterfeiters with new and powerful means to sell drugs through auction sites, stand-alone e-commerce sites and e-mail solicitations. The on-line environment is attractive to drug counterfeiters due to the relative ease of deceiving consumers (OECD, 2007:14).The high profitability of drugs counterfeiting which exceeds that of illegal drug trades, with low risk of

detection and relatively light penalties, provide attractive environment for the inhuman business. Interpol has discovered a disturbing relationship between drug counterfeiting and terrorist activities. Drugs counterfeiting crime is becoming the preferred method of financing for a number of terrorist groups (OECD, 2007:15). Counterfeiters tend to have upper hand in view of the enormous volume of drugs being legitimately marketed and the ease with which counterfeit drugs can be concealed. They target drugs with high profit margins, taking into account, the size of the market to be exploited, the technological and distribution challenges associated with the undertaking (OECD,2007:11)Broad range of counterfeit drugs are produced and marketed as genuine drugs carrying holograms and other imprints (Okoghenun,2010:5).Recently,NAFDAC intercepted a drug whose original brand did not have hologram but the counterfeit had hologram and consumers were buying the counterfeit in place of the genuine drug (Oloja,et al,2011:16). The list of drugs subject to counterfeiting include; medicines for treatment of cancer, HIV, malaria, osteoporosis, diabetes, hypertension, cholesterol, cardiovascular disease, obesity, infections and prostate diseases, etc (OECD, 2007:12). The drugs are usually imported at the lowest costs possible and sold cheaper than genuine drugs. These counterfeit drugs wind up in the bloodstreams of the unsuspecting patients. Thousands of drug consumers have been poisoned. When demand for an expensive drug is high, drug counterfeiters swap labels of two drugs manufactured by the same company, exploit similarity in appearance between the original preparations and the counterfeits, label low price drugs with high price labels and pass off a company's drug product for another (Erhun, 2001:23). Other unethical practices of the drug firms include re-validating of expired drugs to bear future dates, wild drug performance /off—label claims, dishonest/misleading advertising, etc. The profound effects of counterfeit drugs on public health and the nation's economy are rather unquantifiable. The Federal Government of Nigeria established the regulatory agencies to dictate how drug firms produce, promote, price and distribute their products. They include National Agency for Food and Drugs Administration and Control (NAFDAC) which regulates foods, drugs and cosmetics, Pharmacists Council of Nigeria details the standards required for professional practices in line with international codes and Consumer Protection Council (CPC) provides speedy redress to consumer complaints and seeks ways and means of removing or eliminating from the market, hazardous products and causing offenders to replace such products with safer and more appropriate alternatives. In spite of the stringent measures adopted by the regulatory agencies, the nation is still experiencing high incidence of counterfeit drugs. Erhun (et al, 2001:32) attributed the preponderance of counterfeit drugs to the inadequacy of the laws governing pharmaceutical activities and the deficiency in the implementation and enforcement of the existing laws. Akunyili (2010:56) identified enforcement as the weakest link in the chain of regulatory activities. According to Chukwuemeka (et al, 2011:132), the drug regulatory policies in Nigeria are more than efficient. The weak regulatory regime as evidenced by the preponderance of counterfeit drugs in Nigeria was therefore attributed to poor enforcement of the existing drug laws, among others. This study focused on the effectiveness of the enforcement of the existing anti-counterfeit drug laws (penalties) on the unethical marketing of medical drugs in Nigeria, particularly the South Eastern States of Nigeria.

1.1 Statement of the Research Problem.

Most of the nation's health policies like the National Programme on Immunization (NPI) and Roll Back Malaria Programme have suffered setbacks due to the challenges of counterfeit drugs. Studies have revealed strong positive correlation between counterfeit drugs and high failure rate in malaria treatment and control (Chukwuemeka, et al, 2011:132). Counterfeit drugs have been closely related to global public health problems, causing liver damage, kidney and heart failures, disabilities, injuries and even death (Akunyili, 2010:36).It has been estimated that upward of 2000 children per day die in Africa as a result of taking counterfeit malaria medications (Rago, 2009). The evil of counterfeit medicines is worse than the combined scourge of malaria, HIV/AIDS, armed robbery and illicit drugs and violates the right to life of consumers (Akunyili, 2010:36). Unethical marketing of medical drugs have debilitating effects on the nation's economy. It reduces incentives to invest in the development of new medicines. Employment is affected as jobs are lost due to drugs counterfeiting. Counterfeit drugs crowd genuine drugs out of the market and exert downward pressures on prices. Brand images and reputations of genuine drug firms are damaged. Governments loose much revenue as drug counterfeiters evade taxes. Potential losses include corporate income taxes, value added taxes, excise taxes, import tariffs and social insurance charges. Criminal networks and organized crimes thrive through drug counterfeiting. Terrorists' activities are financed and public institutions are weakened when criminals bribe officials to market counterfeit

drugs at the expense of public health. Huge amount of resources are wasted in combating drug counterfeiting. Counterfeit drugs impact negatively on the country's gross national product (GNP) as productivity is greatly hampered (Okoye, 2005:49). Destruction of seized drugs also raises environmental issues. Foreign direct investments are affected by drug counterfeiting. When an action or choice is motivated by the desire to do a right thing, it is ethical (Bovee, et al, 1992:62). If the action is motivated by the desire to do a wrong thing or avoid doing the right thing, it is unethical. The pharmaceutical activities of manufacturing and marketing of counterfeit drugs are clearly unethical. The Regulatory Agencies have adopted stringent measures to regulate the activities of the drug firms within the framework of the existing drug laws. Various penalties were imposed to ensure ethical compliance. In spite of the elaborate safety measures, strict regulations and battalion of enforcement personnel of the regulatory agencies, the stream of counterfeit drugs continues unabated. The contributory factors as outlined by (Erhun, et al, and 2001:27) include ineffective enforcement of the existing laws, high cost of genuine drugs, loose control systems and corruption, among others. In view of these contending factors, the study was designed to determine the effects of enforcement of existing penalties on the unethical marketing of medical drugs in Nigeria with the aim of proffering solutions.

1.2 Objectives of the Study.

The broad objective of the study is to design a partnership model for effective control of the unethical marketing of medical drugs in Nigeria. The specific objective is to assess the effects of the enforcement of the existing anti-counterfeit drug laws (penalties) in the control of the unethical marketing of medical drugs in Nigeria, particularly the South Eastern States.

1.3 Research Question.

To what extent has the enforcement of existing penalties contributed to the reduction of unethical marketing of medical drugs in Nigeria, particularly the South Eastern States?

1.4 Delimitation of the Study.

The five University Teaching Hospitals in the South Eastern States of Nigeria constituted the study centers and included;Abia State University Teaching Hospital, (ABSUTH), Abia State; Ebonyi State University Teaching Hospital,(EBSUTH),Ebonyi State; Imo State University Teaching Hospital, (IMSUTH), Imo State; Nnamdi Azikiwe University Teaching Hospital, (NAUTH), Anambra State; University of Nigeria Teaching Hospital, (UNTH), Enugu State. The study was extended to the South-East Offices of the National Agency for Food and Drugs Administration and Control (NAFDAC), Pharmacists Council of Nigeria (PCN) and Consumer Protection Council (CPC). The Standard Organizations of Nigeria(SON) was not relevant to this study because it regulates and controls all items except the seven categories of item regulated by NAFDAC, medical drugs inclusive (Akunyili, 2010:99). The study covered a decade of activities in the Nigerian drugs market, ranging from 2001 to 2011.

1.5 Hypotheses of the Study.

To guide the study, these hypotheses were formulated and tested at 0.05 level of significance;
Ho: The enforcement of existing penalties has no significant effects on the unethical marketing of medical drugs.
H1: The enforcement of existing penalties has significant effects on the unethical marketing of medical drugs.

2. Review of Related Literature.

2.1 Theoretical Framework.

The study was anchored on the Social Control theory, postulated by E.A. Ross in 1901 and further developed as Social Bonding theory by Travis Hirschi (Hirschi, 1969:18-20). The theory is concerned with how human behavior is regulated within the society. It stipulates that people are inherently motivated to deviance and due to social bonds and fear of punishment; they do not act on these instincts.. It specifies that no society can afford to denounce criminal activity, without duly accepting its responsibility because most delinquent behavior is the result of "unmonitored" social control by the authorities (Borade, 2010). The Social Control theory insists that it is mostly people that have nothing to lose by conforming to delinquency who are drawn toward the anti-social behavior of exchanging human lives for financial gains. Increasing the penalties for non-conformity may curb the inhuman activities of these nothing –to- lose people. The import of the Social Control theory is the crucial role of the society, viz, the Government (Executive, Legislature & Judiciary), regulators, operators, drug consumers, public, traditional rulers & religious leaders, in the control of the unethical marketing of medical

drugs. According to Wolpe (1988), every individual in the society must see himself as a moral entrepreneur, saddled with the responsibility to challenge definitions of deviance.

2.2ConceptualFramework.

Drug regulation is the totally of all measures which governments take to ensure the safety, efficacy and quality of drugs, as well as the relevance and accuracy of product information (Ratanawijitrasin, et al, 2002: 7-8). The success or failure of drug regulation however depends on implementation. The regulation of medical drugs has four dimensions, viz, administrative elements, regulatory functions, technical elements and level of regulation (Ratanawijitrasin, et al, 2002:12). The administrative components are the input factors that allow for functioning of drug regulation, including policy, legislation /regulation, organizational structures, human and financial resources and mechanism for planning, monitoring and evaluation. The regulatory functions include licensing of persons, premises, inspections of pharmaceutical establishment (market authorization), quality control, control of drug promotion/advertisement, monitoring of adverse drug reaction (ADR) and speedy redress of consumer complaints through negotiations, mediation and conciliation. The technical elements include the existence and type of standards, norms, guidelines, specifications and procedures. The level of regulation indicates level at which the various regulatory functions are performed. It should be noted that the political structure of any country determines the overall governance of drug regulation.

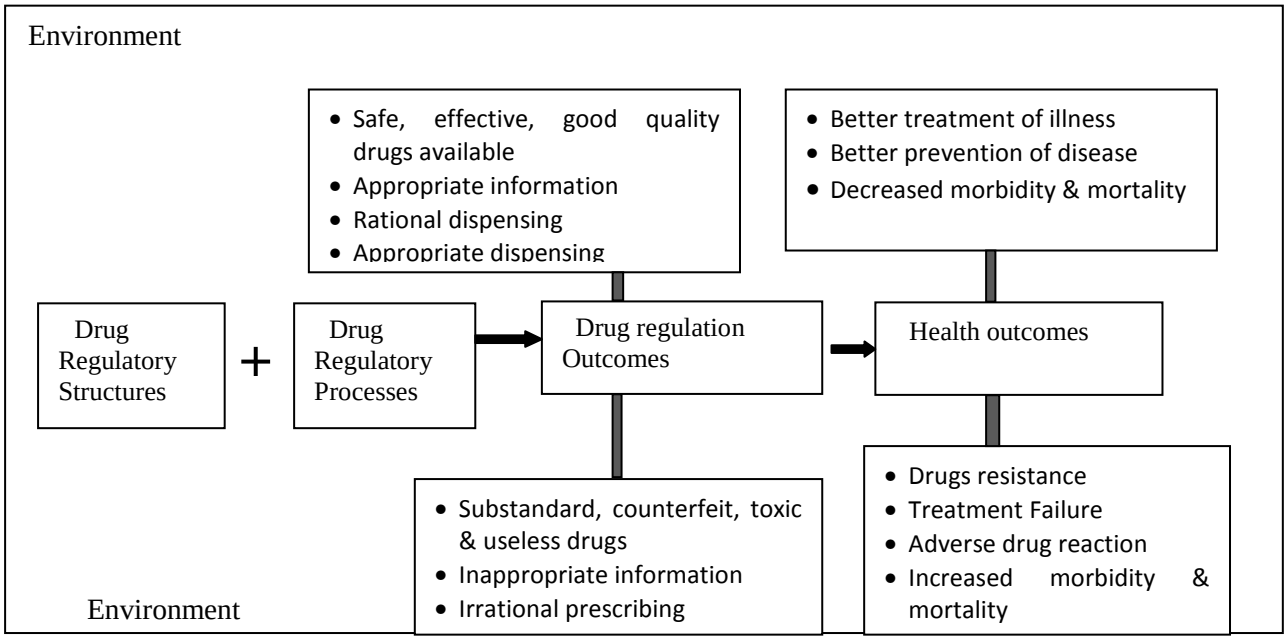

Figure 2.1. Drug regulation: Interconnections between structures, processes and outcomes.

Source**:** Ratanawijitrasin, S and Wondemagegnehu, E., (2002: 120). Effective Drug Regulation, A Multicountry Study. Malta: World Health Organization, Library Cataloguing-In-Publication Date. NLM Classification. QV 33:120.

Figure 2.1 shows the interconnections between regulatory structures, process and outcomes. The framework enhances an understanding of the fundamentals of drug regulation and control. In assessing drug regulatory performance, it is imperative to consider the following steps; identify regulatory structures, decide whether the regulatory processes are well designed and implemented, measure intermediate outputs at the individual regulatory function level and measure the final outcomes to ascertain whether drug regulation objectives have been met(Ratanawijitrasin, et al, 2002: 118). The regulatory structures are the legal and administrative settings of the agencies, charged with the responsibility of drug regulation. The legal support involves granting legal authority to the agencies to perform regulatory functions and impose sanctions when violations occur. The drug regulatory processes entail the application of appropriate methods and strategies to implement the activities. The outcomes are the final results obtained when the regulatory agencies carry out the different regulatory activities and functions. Outcomes can be measured in terms of quality of pharmaceutical products marketed, proportion of licensed pharmaceutical facilities, proportion of pharmaceutical facilities meeting certain required

standards,eg,GMP, number of illegal products and number of illegal facilities (Ratanawijitrasin, et al, 2002:9).Outcomes are often not readily measurable because a long period of time may elapse before relevant outcomes can be seen. If the regulatory performance is effective, safe, effective and good quality drugs will be available in the market with accurate information on the labels and inserts and the functions of prescribing and dispensing drugs by healthcare professionals become achievable. The public will be assured of better treatment in the event of illness and prevention against diseases with attendant reduction in morbidity and mortality rates. With ineffective drug regulation, the outcomes are devastating, viz, substandard, counterfeit, toxic and useless drugs find their ways into the bloodstreams of patients, causing serious injuries and even death. Unethical marketing practices like label tampering, deceptive advertising, mixing of counterfeit with genuine drugs, irrational prescription and dispensing are features of lax regulation, with eventual health outcomes like drug resistance, treatment failure, adverse drug reactions and persistent illness, leading to increased morbidity & mortality. The effectiveness of the measures adopted by the regulatory agencies relates to the drug efficacy, safety, quality and rational use objectives (Ratanawijitrasin, et al, 2002:121). The efficacy objective is achieved when the drugs available in the market are efficacious for stated diseases and conditions. No counterfeit drugs are distributed. When the drugs are adequately safe and possess correct active ingredients, the safety and quality objectives are attained. If the drugs are used in accordance with approved claims and methods, the rational use objective is achieved.

2.3 Business Excellence Model

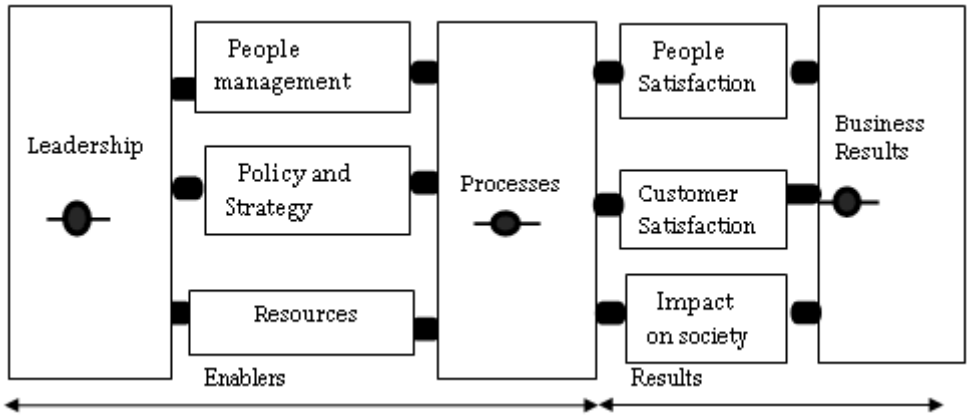

Figure 2.2 The Business Excellence Model.
Source: Oakland, J., S., (1999) "Total Quality Management (TQM) "in *the IEBM Encyclopedia of Marketing*, N. J. Baker; London: Thomson Learning.

Quality service delivery by the regulatory agencies can be achieved through the application of Business Excellence Model (Oakland, 1999:698). Business Excellence Model (BEM) as an aspect of Total Quality Management, (TQM) has been used to change individual minds and attitudes as well as communities and nations. TQM directly and covertly alters the values, culture and mind-sets within an organization. BEM incorporates nine functional areas, viz, leadership, people management, policy and strategy, resources, processes, people satisfaction, customer satisfaction, impact on society and business results (Oakland, 1999:698). As shown in figure 2.2, effective leadership drives policies and strategies, using available resources and working through people in the organization to achieve desired goals. The transformation processes which include actions, methods and operations lead to the satisfaction of customer needs and expectations, culminating into people satisfaction. The impact on the society reflects public good, with the attendant financial and non-financial implication. The application of the Business Excellence Model demands senior management's total commitment to manage processes, change the culture of the organization, improve communication and focus on the customer welfare. The model aims at changing mind-set from the old ways of doing things to the new, from the past to the future. People's management involves transformation of the individuals both in the regulatory agencies and the drug firms.The transformed individual will perceive new meaning to his life, to events, to duties, to members of the public and to interactions between his colleagues. The individual will have a basis for judgment of his own

decision and for transformation of the organization he belongs to. He will understand the system he works in and apply its principles in every relationship with other people. BEM insists that top management develops problem prevention mentality. A complete change of mindset is required to unscramble the intuition of rushing into inspection/ detection mode in tackling the problems of unethical marketing of medical drugs. The deficiency of the strategy of detection has been the bane of drug regulation in Nigeria. The strategy of prevention is appropriate, even if it entails stiffer penalties to establish the culture of deterrence. The top management has a responsibility to develop a mission statement that will be strictly adhered to, identify the critical success factors and outline processes for continuous improvement of regulatory standards. By implication, the core of Total Quality Management is the involvement of everybody. The unethical marketing of medical drugs must be challenged by every citizen of this country and should not be the exclusive duty of the regulatory agencies. The Regulatory Excellence Model (REM) was derived from the partnership concept.

2.4 Constraints to Implementation of Business Excellence Model.

The constraints faced by chief executives and directors in the implementation of the Business Excellence Model are mainly in the area of proliferation of theories and packages. The operators get confused and irritated as the tasks of implementation become daunting. Failure to meet the requirement in any part of the quality chain has a multiplier effect. Failure in one part of the system creates problems elsewhere, leading to yet more failures and more problems. (Oakland, 1999: 687).

3. Methodology

The survey research design was used. The target population was 5621, comprising Healthcare Professionals (3444); Licensed Drug Firms (390); Drug Consumers (1641) and Regulatory Agencies (146). The stratified, simple random, convenience, judgmental sampling procedures were adopted as the sampling techniques. The sample size was determined using Yamane (1967 cited in Eboh, 2009:94) formula, i.e,$n = N / I + N(e)^2$,where, n =sample size,N=actual population, e =level of significance, I =constant. The sample size for each category of respondents was estimated using Bowley's proportional allocation statistical technique; nh = nNh /N, where, nh = the number of unit allocated to each category of respondents. Nh = the number of respondents in category, n =the total sample size N= total population. The sample size for this study was 985, made up of HCP (358); Drug Consumers (322), Licensed Drug firms (198) and Regulatory Agencies (107).Data were generated from both primary and secondary sources. The sources of primary data included questionnaires, focused group discussions, personal (face to face) interviews and observations. The questionnaire embraced the use of five point Likert Scale format, viz, Strongly Agree (5points), Agree (4points), Undecided (3points), Disagree (2points) and Strongly Disagree (1point) with the aggregate(criterion)mean score of 3.0. The instrument was subjected to face-to – face validity by giving it to marketing experts who examined the items to ensure they were in line with the objectives of the study. The instrument was checked for reliability using Cronbach's Alpha technique. Pilot survey was used. A total of sixty respondents were administered with sixty copies of questionnaires. Each category of respondents was served with fifteen copies of questionnaires. The return rate was hundred percent. Five copies of the questionnaires were rejected due to inconsistencies and fifty five analyzed. The reliability coefficient was 0.947, indicating high degree of internal consistency of the research instrument. A total number of 985 questionnaires were distributed, 898 were returned, representing 91.2 percent while 87 were not returned, (8.8 percent). Out of the 898 returned questionnaires, 32 were rejected, representing (3.60 percent) due to discrepancies while 866, representing 96.40 percent were utilized for the study. The hypothesis of the study was tested, using Z-test (two-tail) statistics, at 0.05 level of significance and four degrees of freedom.

4. Data Presentation and Analyses

The data derived from the study were presented in tables and analyzed as shown below.

Table 4.1. Literacy Levels of Respondents.

Qualifications	Regulatory Agencies	Licensed Drug Firms	Drug Consumers	Healthcare Professionals	Total	Percentage
WASC/SSC/ GCE	_	124	57	10	191	22.0
OND/NCE/RN	-	11	34	69	114	13.2
HND/BSC/BA	76	35	127	102	340	39.3
MBBS	-	-	-	108	108	12.5
MSc, MBA, MPhil, PhD	20	5	65	23	113	13.0
Total	96	175	283	312	866	100.0

Sources: Field Survey, 2011.

Table 4.1 showed that 39.3 percent of the respondents had first degree/Higher National Diploma certificates, 13 percent were holders of Ordinary National Diploma, National Certificate in Education/Registered Nursing Certificates and Masters/Doctor of Philosophy degrees respectively. The medical doctors were 12.5 percent while 22 percent of the respondents had ordinary level school certificates. Majority of the holders of the West African School Certificates/ General Certificates of Education (124, representing 14.0 percent of the respondents) were proprietors of the licensed drug firms, indicating the dominance of non-professionals in drug business.

Table 4.2. Usage Rate of Medical Drugs.

Rate	Regulatory Agencies	Licensed Drug Firms	Drug Consumers	Healthcare Professionals	Total	Percentage
Daily	21	45	136	58	260	30.0
Weekly	50	74	117	94	335	38.7
Monthly	25	46	30	132	233	26.9
Rarely	-	10	-	28	38	4.4
Total	96	175	283	312	866	100.0

Source: Field Survey, 2011.

Table 4.2 showed that the four categories of respondents were consumers of medical drugs. The weekly consumption rate was 38.7 percent, followed by daily (30.0 percent), and monthly (26.9 percent). Only 4.4 percent of the total number of respondents rarely used drugs. The findings implied that any respondent could be a victim of counterfeit medications.

4.1. Research Question:

To what extent has the enforcement of existing penalties contributed to the reduction of unethical marketing of medical drugs in South East, Nigeria?

Table 4.3. Use of Mean ($\overline{X}$) Scores of Respondents to Answer the Research Question.

Item	Statement	Agree. SA+A	Disagree U+D+SD	Total scores	Total no of respondents	Mean score	Result
1	The enforcementof existing penalties has reduced the cloning of fast moving drugs in South East, Nigeria.	2339	295	2634	866	3.04	Accepted
2	The enforcement of existing penalties has reduced the marketing of drugs with zero active ingredients and fake NAFDAC numbers.	2105	402	2507	866	2.89	Not accepted
3	The terrorist activities funded through drugscounterfeiting hasreduced asa result of enforcement ofexisting. penalties	1856	524	2380	866	2.75	Not accepted
4	Enforcement of existing penalties has curbed the marketing of degenerated drugs arising from broken cold chains and poor handling	1413	546	1959	866	2.26	Not accepted
5	The marketing of drugs in unregistered pack sizes/unapproved labels and withoutexpiry dates has reduced due to enforcement of existing penalties.	2065	394	2459	866	2.84	Not accepted
6	The enforcement of existing penalties has reduced the marketing of expired and revalidated drugs.	1825	594	2419	866	1.80	Not accepted
7	The enforcement of existing penalties has led to permanent closure of the facilities of the illegitimate drug wholesalers and retailers in South East, Nigeria.	986	1007	1993	866	2.30	Not accepted
8	The marketing of drugs with active ingredients different and unrelated to the inscriptions on their labels has reduced due to enforcement of existing penalties.	1191	923	2114	866	2.44	Not accepted
	Total	13780	4685	1845	6928	21.2	
	Aggregate mean	1723	586	2308	866	2.67	Not Accepted

Source**:** Field Survey, 2011.

The mean, 3.0, was used as a criterion for accepting or not accepting the statements of the questionnaire in order to answer the research question (Nwankwo, 2011: 244). The rule is that any statement with mean score of 3.0 and above is accepted as a true statement and any with mean score below 3.0 is unacceptable. Table 4.3 showed that item 1 had mean score of 3.04, indicating that the enforcement of existing penalties has reduced the cloning of fast moving drugs in South East Nigeria. Items 2 to 8 had mean scores below 3.0. The enforcement of existing penalties therefore had not contributed to reduction in the marketing of drugs with zero active ingredients and fake NAFDAC numbers, drugs that have degenerated due to improper storage, drugs in unregistered pack sizes/ unapproved labels and without expiry dates, and drugs with active ingredients different and unrelated to inscriptions on their labels. The terrorist activities funded through drug counterfeiting and marketing of expired /revalidated drugs has not reduced as a result of enforcement of existing penalties. The facilities used by the counterfeiters in the inhuman business had not been completely shut down through the enforcement of the existing penalties. The aggregate mean of 2.67 for the research question, indicated that the enforcement of the existing anti-counterfeit laws (penalties) had not contributed to remarkable positive reduction in the unethical marketing of medical drugs in South East, Nigeria.

Table 4.4 Analysis of Responses

Item	No of Resp. Agree (A)	Scores of Resp.A	Mean of Scores (X_a)	Std. Dev. of Scores. A (SD_a)	No. of Resp. Disagree (D)	Scores of Resp. D	Mean of Scores (X_d)	Std Dev. on scores SD_d	Total No. of Resp.
1	694	2339	3.37	23.40	172	295	1.72	22.25	866
2	624	2105	3.37	15.30	242	402	1.66	11.85	866
3	557	1856	3.33	5.64	309	524	1.70	3.53	866
4	434	1413	3.26	1490	432	546	1.26	1.93	866
5	624	2065	3.31	13.70	242	394	1.63	12.37	866
6	550	1825	3.32	4.35	316	594	1.88	0.55	866
7	322	986	306	41.14	544	1007	1.85	18.07	866
8	367	1191	3.25	27.81	499	923	1.85	15.10	866
Total	4172	13780	26.27	146.24	2756	4685	13.55	85.65	6928
Aggregate mean	521	1723	3.28	18.28	345	586	1.69	10.71	866

Source: Field Survey, 2011.

Table 4.4 showed the means and standard deviations of the responses on the effects of enforcement of existing drug laws (penalties) on the unethical marketing of medical drugs. The calculated Z-value shown in Table 4.5 was derived from Table 4.4.

Table 4.5 Test of hypothesis

Responses	No of respondents, N	Mean $\bar{X}$	Std Deviation SD	Degrees of freedom DF	Z-calculated	Z-critical	Level of significance	Decision
Agree	521	3.28	18.28	4	+1.15	_+1.96	0.05	Accepted
Disagree	345	1.69	10.17					

Source: Field Survey, 2011

Table 4.5 showed that the calculated Z-value (+1.15) was found in the region between -1.96 and +1.96 (i.e. critical values of Z) at 4 degrees of freedom and 0.05 level of significance. In applying the decision rule, the null hypothesis was not rejected. The p-value provided additional insight into the decision. The probability of finding a Z-value as extreme as +1.15 was 0.5000-0.3749 = 0.1251.The two-tailed p-value, 2(0.1251) = 0.2502, was greater than the significance level of 0.05 (i.e. P > 0.05). The null hypothesis was therefore not rejected and the conclusion that the enforcement of existing penalties had not contributed to significant positive reduction in unethical marketing of medical drugs was upheld to be true.

5. Discussion of Findings.

The literacy level of the drug distribution chain members was low. Out of 175 operators of the drug firms involved in the study, 124(representing 71.0 percent), possessed the ordinary level school certificates and only 35 (20 percent) had first degree/ Higher National Diploma Certificates. These firms were officially licensed to distribute and market medical drugs in the South Eastern States of Nigeria by the Pharmacists Council of Nigeria

(PCN). Some chain members were granted the Patent and Proprietary Medicine Vendors' license to sell only over-the –counter (OTC) drugs. In practice, they sold all categories of drugs, including Prescription-Only-Medicines and the minimum qualification to obtain the license is First School Leaving Certificate. The non-professionals with virtually little or no education dominated the drug business as importers, wholesalers and retailers in the open drug markets. According to Erhun, (et al, 2001:24), the involvement of these unqualified persons in the procurement and distribution of medical drugs had its implications in drug regulation and control in Nigeria. Usually, these unqualified persons do not have much at stake in terms of conformity to professional standards and their business interests are motivated by the desire to get-rich-quick. The Social Control theory stipulates that it is mostly these people that have nothing to lose by conforming to delinquency who are drawn toward the anti-social behavior of exchanging human lives for financial gains. These distribution chain members have been associated with the unethical marketing of medical drugs through direct involvement in drug re-packaging, compounding of syrups/lotions, revalidating of expiry date and distribution of counterfeit drugs. Erhun (et al, 2001:23-34) corroborated this finding by relating the activities of non-professionals in drug business to the preponderance of counterfeit drugs in Nigeria. Since legal provisions are essential for attaining regulatory goals, the implementation must be backed by law. All laws are meaningless unless they are enforced (Peter, 1989). The Nigerian drug regulatory environment is characterized by weak enforcement regime. Weak enforcement regime implies that either the counterfeiters are not sufficiently penalized for their actions or that the enforcement process is lax or both. The findings of the study revealed that the enforcement of the existing penalties (anti-counterfeit laws) by the regulatory agencies had not contributed significantly to the reduction in unethical marketing of medical drugs in South East, Nigeria. According to Erhun (et al, 2001:23-34), the enforcement of the various drug laws in Nigeria had been deficient. It was also revealed that the laws governing the manufacture, sales, distribution, importation and exportation of drugs were not adequate enough to control the inhuman trade. Akunyili (2010:56) affirmed that poor enforcement was contributory to the weak enforcement regime in this country. The devotion of insufficient resources to enforcement and inappropriate penalties for offences were adduced as being responsible for the weak enforcement regime. Considering the outcomes at each regulatory functional level, the study revealed that the enforcement of existing penalties had not reduced the marketing of drugs with zero active ingredients and fake NAFDAC numbers, drugs in unregistered pack sizes/unapproved labels and without expiry dates. The marketing of drugs that have degenerated due to broken cold chains/poor storage and unrelated to the inscriptions on their labels, abound in Onitsha Bridge Head and Aba drug markets. Terrorists had found drug counterfeiting a preferred method of financing their activities due to low risk of detection and relatively light penalties, compared to illegal drug trades. The enforcement of existing penalties had not imposed restrictions on the criminal networks and organized crimes. The cloning of fast moving drugs however had minimized in the South Eastern States of Nigeria due to the enforcement of existing anti-counterfeit drug laws. Available records have shown instances where the counterfeiters were neither punished under the law nor the enforcement actions publicized to act as deterrent. When the Pharmacist and Director of Tomak Pharmacy in Port Harcourt was arrested in 2008, for distributing counterfeit baby teething mixture, my pikin, and other unregistered drugs. No record of enforcement actions against the pharmacist was made public (Akunyili, 2010: 124). According to Akunyili (2005:28), the efficiency of the regulatory staff has been adversely affected by corruption and conflicts of interests, resulting in laws not being enforced and criminals not being arrested, prosecuted and convicted for crime. The operations of NAFDAC in South East and Onitsha in particular suffered a setback due to the refusal of the Abuja High Court Judge to allow trials of several people implicated in the assassination attempt of the former Director- General of NAFDAC, Professor Dora Akunyili.This unfortunate ruling actually emboldened the drug distribution chain members not only to resist inspections but also attack the regulatory staff. On June 3, 2006 the staff of NAFDAC and twelve armed policemen were physically attacked and driven out of Onitsha Head Bridge drug market by the counterfeiters. Six operational vehicles belonging to NAFDAC were destroyed (Akunyili, 2010:128). NAFDAC neither took enforcement actions nor subsequently commenced mass arrests of the counterfeiters for purposes of prosecution in the court till date. On October 26, 2010 the Pharmacists Council of Nigeria raided the Tenant Road drug market, Aba and recovered large volumes of counterfeit drugs. An anti-inflammatory analgesic, Phenylbutazone, with life threatening adverse reactions on bone marrow depression and renal failure was recovered. No record of enforcement of penalties was available. The drug market was re-opened on December

21, 2010 based on court order, boosting the confidence of the counterfeiters (Field Survey, 2011). The Social Control theory stipulates that people are inherently motivated to deviance and due to social bonds and fear of punishment, they do not act on these instincts. The theory further states that it is the responsibility of the control mechanisms like the law, enforcement agents and the physical paradigms within the community, to effectively and periodically address delinquent behaviors. The anti-social behaviors of the counterfeiters were indications of lack of major stakes (social bonds) in the community. Increasing the penalties for non-conformity and strictly enforcing them would help to address the delinquent behaviors of these nothing-to-lose people in our society. Since the enforcement of anti- counterfeit drug laws could not provide strong deterrence against unethical marketing of medical drugs, serious gap exists in curbing this inhuman business in Nigeria. Counterfeiters do not give up easily and have to be dislodged, roots and branches through a vote of no confidence from every drug consumer. According to Wolpe (1988), every individual consumer in the society must see himself as a moral entrepreneur, saddled with the responsibility to challenge the unethical marketing of medical drugs. This grave situation provoked the emergence of a cross-sector partnership forum in this study, referred to as Regulatory Excellence Model (REM).

5.1. The Regulatory Excellence Model (REM)

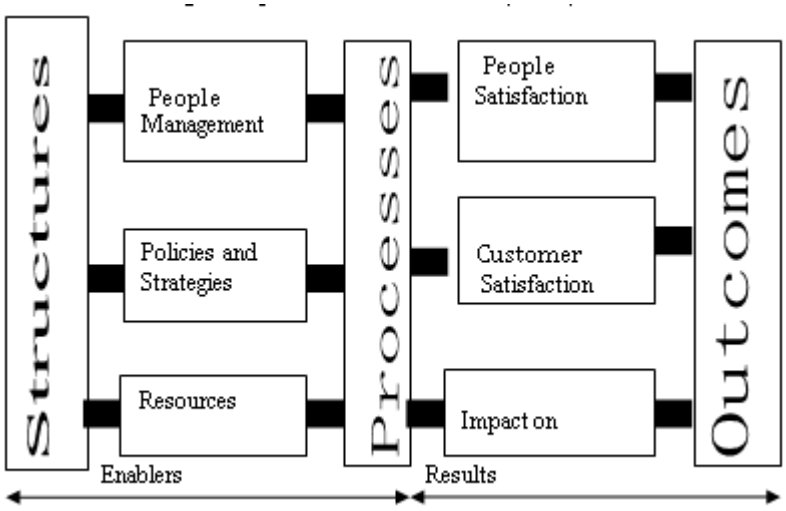

Figure 5:1 The Regulatory Excellence Model. **Source:** Adapted from Oakland, J. S. (1999: 697) "Total Quality Management (TQM)" In *The IEBM Encyclopedia of Marketing*, M.J. Baker, London Thomson Learning, for the purpose of this study.

The Regulatory Excellence Model was adapted from the Business Excellence Model and anchored on the framework of Ratanawijitrasin (et al, 2002:120) and the principles of Total Quality Management. It is an attempt at developing a cross-sector partnership forum for effective control of the unethical marketing of medical drugs in Nigeria. The Model has nine components, viz, structures, resources, policies and strategies, people management, regulatory processes, impact on society, customer/ people satisfaction and regulatory outcomes (figure,5.1). The structures include the formation of Stakeholders' Drug Safety Initiative (SDSI) by the collective efforts of the Chief Executives or top representatives of the Regulatory Agencies, Pharmaceutical industry and the Consumer Association. The SDSI should be carefully replicated in the thirty-six states of Nigeria, including Abuja and at the Local Government Councils levels. The aims and objectives of the Stakeholders' Drug Safety Initiative must be clearly defined and expressed in a mission statement at the national Level and effectively communicated down the line. The leadership hierarchy must be composed of individuals of proven integrity and totally committed to the shared vision of promoting public health. The stakeholders and the governments should collectively fund the initiative through value added taxes, certain percent of the profits of the drug firms (pharmaceutical industry), Internally Generated Revenues (IGR) from the Regulatory Agencies and special allocations from both federal, state and Local governments/ trade associations' contributions. The leadership of the Stakeholders' Drug Safety Initiative shall develop effective policies and strategies and create the resources

for achieving the mission or vision of the forum. All controls and procedures, quality audit and management review guidelines must be properly stated. The top management of the Stakeholders' Drug Safety Initiative must adopt strategic overview of quality service delivery. Developing a problem prevention mentality to unscramble the intuition of rushing into detection / inspection mode to solve regulatory problems is important. The regulatory processes involve working with and through people. The style of managing people must undergo transformation. The first step is the transformation of the individual staff. The individual when transformed will perceive new meaning to his life, to events and to interactions between people. He will have a basis for judgment of his own decisions and for the transformation of the organization he belongs to. The individual will understand the system he works in and apply its principles in every kind of relationship with other people. The experts in any business are the people who do the job every day of their lives. The energy that lies within them can be released into the organization through education, training, encouragement and involvement (Oakland, 1999:655). Attention must be paid to staff, making sure they are capable of meeting the regulatory challenges. Effective communication within the organizations, up, down and across stakeholders must be encouraged for strong co-ordination of the battle against unethical marketing of medical drugs. The commitment of every stakeholder from the top management to the junior cadre is indispensible because human lives are endangered. The Stakeholders' Drug Safety Initiative must consign regulatory functions to stakeholders on the basis of their areas of specializations. The pharmaceutical industry, for example, should undertake the task of tracking every step of how drugs are manufactured, imported and distributed in the country. Securing the actual drug product, its packaging and the movement through the drug distribution chain using cutting edge technological devices should be the functions of the Pharmaceutical industry. The Regulatory Agencies, among others, should heighten surveillance and awareness creation through sensitization programmes. The Consumer Association should embark on the education of members using well established communication networks. The consumers should be aware of their rights to safety, to accurate drug information and their responsibility to report counterfeit drug incidents promptly to the association. Public enlightenment workshops should be organized by the Consumers Association to educate members on the use of technological devices to detect counterfeit drugs and increase their perceptions of the dangers inherent in their preference for cheaper drugs. The collective responsibility of the stakeholders in the regulatory activities would lead to transparency in the activities of the drug firms. The resultant effects of the Stakeholders' Drug Safety Initiative in the society would be the promotion of public and economic health of the nation. The measures of the successes or failures of the Regulatory Excellence Model are the outcomes. The structural and process factors affect regulatory outcomes. Quality regulatory activities would ensure the availability of safe, efficacious and quality drugs, appropriate drug information, rational drug use and appropriate dispersing. The health outcomes include better treatment of illness, better prevention of disease and decreased morbidity and mortality. Non-commitment in the application of the Regulatory Excellence Model would invariably lead to weak regulatory regime. The consequences include the preponderance of counterfeit, toxic and useless drugs in the markets and health centers, inappropriate drug information and irrational use of drugs, among others. The health outcomes manifest in drug resistance, treatment failure, adverse drug reactions, increased morbidity and mortality.

5.2. Conclusion

The pharmaceutical activities of manufacturing, importing, exporting and marketing of counterfeit drugs are clearly unethical. The study revealed that the enforcement of the anti-counterfeit drug laws(penalties) had non-significant positive reduction in the unethical marketing of medical drugs in the South Eastern States of Nigeria. It is imperative therefore to note that the regulatory agencies acting as lone rangers in the Nigerian regulatory environment may be incapable of controlling the unethical marketing of medical drugs effectively. All the stakeholders, viz, the regulatory agencies, pharmaceutical industry (drug firms), healthcare professionals/ consumers (public) must brace up to challenge this inhuman business. Regulatory Excellence Model involves the enlistment of every sector of the society, viz, the government (Executive, Legislative, Judiciary), the public, the traditional institutions, religious leaders, trade/women/youth associations, media, students, etc, in the fight against the unethical marketing of medical drugs. The concerted efforts of the people would publicize and reinforce the enforcement actions to make the trade a taboo. The total commitment of the stakeholders to the shared vision, anchored on formidable leadership structures would drive effective regulatory processes to the

desired outcomes. Total consumer protection is a collective effort and its actualization demands collective inputs of the stakeholders. Counterfeit medicines are terrorizing the public and economic health of our nation.

5.3. Recommendations.

These recommendations were made in an attempt to control the unethical marketing of medical drugs in Nigeria, especially in the South Eastern States. The stakeholders have significant roles to play in this partnership venture.

1. The stakeholders should establish powerful consumer association, comprising public/civil servants, professional and trade associations, labor unions, students, etc, to assert the rights of the consumers and enhance their responsibilities.
2. The stakeholders, viz, the regulatory agencies, pharmaceutical industry and consumer association should jointly form cross-sector partnership forum (i.e. Stakeholders' Drug Safety Initiative, SDSI), to develop common unified actions for the control of the unethical marketing of medical drugs.
3. The leadership of the Stakeholders Drug Safety Initiative should be totally committed to the application of the Regulatory Excellence Model, to effect the reduction of the production, importation and marketing of counterfeit drugs to the barest minimum.
4. A high powered Stakeholders' Continuous Quality Improvement Team should be established with the oversight function of maintaining quality service standards and enforcement of anti-counterfeit drug laws.
5. The Government should strengthen the legal frameworks which include life jail terms for defaulters and corrupt regulators, confiscation of their property, establishment of Consumer Courts (of High Court Status) in all the States, permanent closure of open drug markets, imposition of three months prison terms to ward off intervention of "Very-Important Persons" in regulatory activities and ensure the security of the regulators.

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