**Drug promotional activities in Nigeria: Impact on the prescribing patterns and practices of medical practitioners and the implications**

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**ABSTRACT**

Objective: Pharmaceutical companies spend significant amount of resources on promotion influencing the prescribing behaviour of physicians. Drug promotion can negatively impact on rational prescribing, which may adversley affect the quality of patient care. However, little is know about these activities in Nigeria as the most populous country in Africa. We therefore aimed to explore the nature of encounters between Nigerian physicians and pharmaceutical sales representatives (PSRs) and how these encounters influence prescribing habits. Methodology: Cross-sectional questionnaire-based study conducted among practicing physicians working in tertiary hospitals in four regions of Nigeria. Results: 176 questionnaires were completed. 154 respondents (87.5%) had medicines promoted to them in the previous three months, with most encounters taking place in outpatients’ clinics (60.2%), clinical meetings (46%) and new medicine launches (17.6%). Information about potential adverse effects and drug interactions was provided in 41.5%, and 27.3% of cases, respectively. Food, in the form of lunch or dinner, was the most common form of incentive (70.5%) given to physicians during promotional activities. 61% of physicians felt motivated to prescribe the drug promoted to them, with quality of information provided being the driving factor. Most physicians (64.8%) would agree to some form of regulation of this relationship between medical doctors and the pharmaceutical industry. Conclusion: Interaction between PSRs and physicians is a regular occurrence in Nigeria, influencing prescribing practices. Meals and cheap gifts were the most common items offered to physicians during their encounters with PSRs. The need for some form of regulation by professional organizations and the government was expressed by most respondents to address current concerns.

**1. INTRODUCTION**

In 2015, the pharmaceutical industry spent an estimated USD 69.2 billion on various forms of pharmaceutical promotion and advertising in 31 countries, 3.2% up from 2014[1](#_ENREF_1). Most of this spending was on detailing (61.2%), followed by providing drug samples (10.8%), meetings (10.5%), direct-to-consumer advertising (8%), digital (3.8%), mailing/others (3.1%), clinical trials (2.1%) and other forms advertising (0.5%).

The World Health Organization defines pharmaceutical promotion as “all informational and persuasive activities by manufacturers, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs”2. Typically, product detailing by pharmaceutical sales representatives (PSRs) is via hospital or clinic visits, drug launches, visits to conferences and through continuing medical education programmes[2-4](#_ENREF_2). During their visits, PSRs can offer gifts, invitations to luncheons/dinners and free samples[5](#_ENREF_5). Pharmaceutical companies also sponsor meetings and conferences, offer research grants and honorarium to physicians, and sponsor clinical trials[3](#_ENREF_3),[4](#_ENREF_4),[6](#_ENREF_6),[7](#_ENREF_7). However, there are increasing concerns among patients regarding such activities[8](#_ENREF_8) due to their impact on prescribing and consumption of medicines.

Pharmaceutical promotion and other marketing activities can influence both prescribers[9-13](#_ENREF_9) and users of promoted medicines, potentially negatively impacting on medicine utilization patterns[11](#_ENREF_11),[14](#_ENREF_14),[15](#_ENREF_15). In addition, potentially adding to costs; for example, the total costs of proton pump inhibitors in Ireland when adjusted for population size with limited counter actions to pharmaceutical company activities versus Sweden with extensive health authority activities promoting generics first line when available16. Spurling *et al* in their review found that in studies examining prescribing quality, five studies found an association between exposure to pharmaceutical company information and lower quality prescribing whilst four did not, and one study found associations with both lower and higher quality prescribing. 38 studies found associations between exposure to companies and a higher frequency of prescribing whilst 13 did not. Five studies also found evidence of higher costs following company interactions, whilst four studies found no association and one study found an association with lower costs15. Vancelik et al also found that pharmaceutical companies were highly influential in prescribing by ambulatory care physicians in Turkey17; similarly, Akande et al in Nigeria18. There are also concerns that information, especially around the risks and side-effects of medicines, are often missing from pharmaceutical company presentations, especially where they are the principle source of information as seen in a number of lower and middle income countries (LMICs)18-20. There are also concerns if only favourable findings are published and promoted by pharmaceutical companies21,22, especially with less than 70% of studies undertaken actually published23. In addition, as mentioned, there are concerns with physician trust if patients believe physicians have been unduly influenced by pharmaceutical companies with gift relationships8,24.

Consequently, we believe it is important to regulate the interaction between the pharmaceutical industry, health providers and patients, especially where there are currently limited regulations and limited continuous professional development post qualification, coupled with high co-payments, as seen in many LMICs including Nigeria25,26. Whilst most developed countries have national legislation regulating drug promotion involving voluntary codes among professional organisations, including those working in key positions in the industry27,28, most of the day-to-day regulation is turned over to pharmaceutical companies which have their own codes of practice27-29.

In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) has the mandate to regulate and control the advertisement of medicines30. However, it is unknown if any code of practice or guidelines are in place to address the promotion of prescription drugs promotion or direct to consumer advertisement in Nigeria. The Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria (PMG-MAN) is the umbrella of the Organization for Manufacturer of Pharmaceuticals and Allied Products in Nigeria, and currently PMG-MAN has no code for the marketing of prescription drugs. This is a concern as Nigeria is the most populous country in Africa with an estimated population of 185.9 million in 201631, with currently appreciable population growth. As a result, an appreciable opportunity to waste considerable resources for both the government and patients with inappropriate use of medicines.

We did not find any information on spending on pharmaceutical promotion in Africa, or the number of PSRs, in our review of the literature and the internet. However, we found an increased number of PSRs in the emerging markets of Asia Pacific (+3.7%) and Latin America (+0.3%), and their declining numbers in the established markets of North America (-0.9%), top 5 in Europe (-2.7%), other European countries (-2.7%) and Japan (0.9%) from 2014 to 2015[1](#_ENREF_1). These trends suggest that Africa is likely to be a region of intensified activities in the future, in particular its largest and likely most profitable markets such as Nigeria.

Currently, there is limited information available on the nature of the encounters with PSRs and their impact on prescribing in Africa despite publications showing an impact 18,32-40. In Nigeria, only a few published studies have evaluated the interactions between Nigerian medical doctors and PSRs39,40. However, these studies did not address issues relating to physicians’ attitude towards PSRs and typically covered only one geopolitical region.

Consequently, the objectives of this study were to explore the nature of current encounters between Nigerian physicians and PSRs, the types of medicines promoted and the extent to which these encounters influenced subsequent prescribing patterns. Subsequently, use these findings to provide guidance to Nigerian authorities and other relevant stakeholders on possible next steps to improve prescribing practices. This needs to be addressed to enhance the appropriate use of medicines and reduce out-of-pocket payments for patients in Nigeria. This is particularly important as Nigeria strives towards universal healthcare. Further, the findings and suggestions of this study can potentially guide other LMICs striving to control the influence of pharmaceutical promotion activities on their physician prescribing habits.

**2. METHODOLOGY**

***2.1 Study design***

This was a cross-sectional survey conducted among practicing physicians in tertiary health facilities in Nigeria.

***2.2 Study Site(s)***

Convenience sampling was used to select six tertiary health care facilities located in four out of the six geo-political zones of Nigeria: South-west, South-east, North-central and North-west. The rationale for selecting these facilities was the availability of personnel to carry out the study. We chose tertiary health care facilities for this study as they are the main training centres for physicians in Nigeria. As such, they play a very important role in establishing the prescribing habits of doctors and are therefore important targets for promotional activities by pharmaceutical companies.

***2.3 Study Instrument***

We developed 17-item structured questionnaire based on the literature on pharmaceutical promotion[3](#_ENREF_3),1[6](#_ENREF_24),25,26 . The questionnaire consisted of three parts. The first part collected information on the socio-demographic characteristics of the respondents, the second on drug promotional activities, and the third on the effect of promotional activities on doctors’ prescribing practices (Appendix A). The survey was piloted among 10 physicians working in the general outpatient department of a tertiary healthcare facility in Lagos, Nigeria. Necessary amendments were then made based on responses received to enhance the clarity and the robustness of the subsequent findings.

***2.4 Sampling***

*2.4.1 Sample size calculation*

The sampling frame consisted of an estimated 1110 physicians working in the six selected tertiary health care facilities located in four geo-political zones of Nigeria. Using the Raosoft® software[41](#_ENREF_3), we calculated a sample size of 167 participants under the assumption of a 50% response rate, at 7% margin error and 95% confidence interval. Assuming a non-response rate of 5% from the piloted study, we obtained a final corrected minimum sample size of 175. However, a larger sample size of 250 physicians was used to allow adequate power of the study.

*2.4.2 Participant Selection*

Physicians working in the selected tertiary health care facilities were chosen through stratified random sampling. The number of questionnaires sent to each of the participating tertiary health care facilities was proportional to their physician population. With each hospital, questionnaires were distributed between different departments based on the number of physicians working in each department.

The names of all physicians (including medical interns) working in the clinical departments of selected hospitals were compiled from departmental staff lists and participants chosen using a random number interval. The selected physicians were approached during regular departmental meetings in each hospital and invited to participate in the study.

*2.4.3 Data collection*

The questionnaire was then administered by designated doctors in each of the participating centres for a period of approximately 30 minutes to those who agreed to take part in the study. Information was collected on promotional encounters between doctors and PSRs in the three months prior the survey. Data collection took place during the first two weeks of February 2016. There was no financial reward for taking part in the study.

***2.5 Ethical consideration***

The questionnaires were completed anonymously to ensure confidentiality. The acceptance of the doctors to complete the questionnaire was taken as explicit consent. A waiver for ethical approval was given as the study did not involve patients and sought only information about habits/clinical practice.

***2.6 Statistical Analysis***

The information obtained from the questionnaire was coded, entered and analyzed using IBM SPSS version 19. Univariate and multivariate analyses were conducted to test for the association between prescription of promoted medicines and the following variables: drug information provided during the promotional encounter, cost and efficacy of the drug, personality of the PSR, quality of the drug presentation and demographics of the participants. Pearson Chi-square or Fisher’s exact test and the Mann-Whitney test were used in the univariate analysis and binary logistic regression was used for the multivariate analysis. A p- value of <0.05 was considered significant.

**3. RESULTS**

***3.1 Descriptive analysis***

Of the 250 questionnaires distributed to participants, 210 were returned, giving a response rate of 84%. However, 34 of which were incomplete and consequently were excluded. A total of 176 duly filled questionnaires were subsequently analysed for this study. The highest proportion of respondents were male doctors (80.7%), residents (50%%) and internal medicine residents (35.8%) (Table 1).

Table 1: Distribution of the respondents according to their demographic and professional characteristics

|  |  |  |
| --- | --- | --- |
| **Parameters**  | **Median** | **N (%)** |
| General characteristics*Age(yrs)**Years of practice**Gender**Male* *Female*  | 32 yrs4.0 yrs | 142 (80.7)34 (19.3) |
| ***Physician’s cadre in hierarchical order*** |  |  |
| *Interns (House Officers)* |  | 61 (34.7) |
| *Medical Officers* |  | 16 (9.1) |
| *Residents* |  | 88 (50) |
| *Consultants* |  | 11 (6.2) |
| ***Specialty*** |  |  |
| *Internal Medicine* |  | 63 (35.8) |
| *Family Medicine/General Practice* |  | 43 (24.5) |
| *Obstetrics and Gynaecology* |  | 25 (14.2) |
| *Surgery* |  | 22 (12.5) |
| *Paediatrics* |  | 12 (6.8) |
| *Others* |  | 11 (6.2) |

The median age of the respondents was 32 years, with a mean age of 32.5±6.9 years. The median number of years of practice was 4 (IQR – 1-5). Overall, 68% of the physicians had been practicing for five years or less, 21% had been practicing between six and ten years and 11% had been practicing for more than ten years.

One hundred and fifty-four respondents (87.5%) had medicines promoted to them in the previous three months. In the majority of cases (86.4%), this happened over the course of one to five encounters with PSRs. Outpatients’ clinics (60.2%), clinical meetings (46%), drug launches (17.6%), medical conferences (11.9%) and other organized events (8.5%) were the main points of drug promotion. The most commonly promoted medicines where indicated were anti-hypertensives (n=21), antimicrobials (n=14), multivitamins (n=12) and anti-lipidemic medicines (n=7) (Figure 1).

Figure 1: Groups of promoted medicines

The information provided during the promotional encounters included the generic name of medicines (n=137, 77.8%), brand names (n=140, 79.5%), clinical indications (n=142, 80.7%), contra-indications (n=96, 54.5%), the pharmacological effects of drugs (n=114, 64.8%) and dosing information (n=124, 70.5%). Information about potential adverse effects, drug interactions and storage conditions was provided in 73(41.5%), 48(27.3%) and 18(10.2%) of the cases, respectively. The majority of the respondents (68.2%) had received some gifts or incentives during their encounters with PSRs. Food, in the form of lunch or dinner, was the most common incentive offered (n=124, 70.5%), followed by gift items such as ward coats, pen and calendars with the names of the medicine/company branded on them (n=121, 68.8%), cash (n=7, 4%), conference sponsorship (n=6, 3.4%) and free drug samples (n=4, 2.3%).

Over half of the respondents (60.8%) felt motivated to prescribe the promoted medicines. The factors that may influence this included the perceived quality of information provided (63.6%), cost and efficacy of the presented medicine (51.1%), the reputation of the pharmaceutical company (28.4%), the quality of the presentation (18.2%), the personality of the PSR (9.1%) and the nature of the gifts/incentives (4.5%). Thirty-five percent of the physicians who were motivated to prescribe the promoted medicines would do so using the brand names, while 55.1% would use both brand and generic (INN – International non-proprietary name) names.

More than half of the respondents (53.4%) would consult additional sources of information before considering to prescribe the promoted medicines. The sources of medicine information included the internet (39.2%), formularies such as the British National Formulary (BNF) and the Monthly Index of Medical Specialities (MIMS, a commercial prescribing guide), (30.1%), (Figure 2). Other factors influencing prescribing habits included their residual knowledge of pharmacology from medical school (79.5%), knowledge obtained during the medical internship (79.5%), influence of more senior colleagues (57.4%), availability of such medicines at the hospital pharmacy or nearby pharmacies (75%), whether the medicine would be affordable for the patient (75.6%) and patients’ requests (21.6%). Finally, 60% and 50.2% of interns and residents mentioned that their prescribing choices were influenced by the opinion of senior colleagues.

Figure 2: Alternative sources of information for prescribing

Most doctors (n=114, 64.8%) agreed that the relationship between doctors and pharmaceutical medical representatives should be regulated. The Nigerian Medical Association (NMA), the Pharmaceutical Society of Nigeria (PSN) and NAFDAC were the identified organizations that could regulate this relationship. The forms of control suggested were outright prohibition of gifts and incentives from the pharmaceutical representatives (n=36, 20.5%), allowing physicians to receive only low-priced gift items (n=47, 28.7%), declaration of monetary/expensive gifts and stoppage of industry sponsored conferences/CME (n=2, 1.1%).

In the univariate analysis (Table 2), more years of medical practice, the perceived quality of the information provided, the cost and efficacy of the medicine, the personality of the PSR, the receipt of gifts and expected rewards from the pharmaceutical company were significantly correlated with motivation to prescribe the promoted medicines.

Table 2: Demographics, cadre, and promotional drug variables compared for participants that are motivated or not motivated to prescribed promotional drugs

|  |  |  |  |
| --- | --- | --- | --- |
| **Characteristics** | **Motivated (n= 109)** | **Not motivated (n= 70)** | *P* value |
| Frequency (%)\* or median (IQR)\*\* |
| ***Demographics*** |
| Median (IQR) age of the participants (years) | 32 (28-34) | 31 (28-34) | 0.309 |
| Median (IQR) years of practice | 4 (2-7) | 2 (1-6) | 0.030\* |
| ***Specialty*** |  |  |  |
| *Family medicine* | 12 | 5 | 0.127 |
| *Obstetrics and gynecology* | 17 | 8 |  |
| *Surgery* | 11 | 11 |  |
| *Paediatrics* | 7 | 5 |  |
| *General Practice* | 18 | 8 |  |
| *Others* | 10 | 1 |  |
| **Gender** |
| *Male* | 86 | 56 | 0.897 |
| *Female* | 21 | 13 |  |
| **Cadre/ Level** |
| *Interns* | 29 | 32 | 0.051 |
| *Medical officers* | 11 | 5 |  |
| *Residents* | 61 | 27 |  |
| *Consultants* | 6 | 5 |  |
| **Promotional drug variables** |
| *Adequate information provided during promotion* | 112 | 64 | 0.000 |
| *Reputation of the drug marketing company* | 50 | 126 | 0.055 |
| *Quality of the presentation* | 32 | 144 | 0.026 |
| *Cost-benefit ratio of the drug* | *90* | 86 | 0.000 |
| *Personality of presenter* | *16* | *160* | 0.022 |
| *Gifts*  |  *8* |  *168* |  0.020 |
| *Future benefits from company* |  *6* |  *170* |  0.045 |

Table 3 shows the results of the multivariate analysis of variables potentially associated with motivation to prescribe promotional medicines. The odds of the motivation to prescribe the promoted medicines were significantly lower with the reputation of the pharmaceutical company (adjusted odds ratio: 0.24, 95% CI: 0.08- 0.74) but higher with the quality of presentation (adjusted odds ratio: 27.09, 95% CI: 8.43-87.11) and the cost-benefit ratio (10.90, 95% CI: 8.43- 28.48) of the promoted medicines.

Table 3: Multivariate analysis of predictors that motivated the participants to prescribe promoted drugs

|  |  |
| --- | --- |
| Variable | OR (95% CI) |
| Unadjusted | Adjusted┘ |
| *Adequate information provided during promotion* | 0.55 (0.15 – 2.44) | 0.61 (0.19 – 2.04) |
| *Reputation of the pharmceutical company* | 0.20 (0.07- 0.65) | 0.24 (0.08- 0.74) |
| *Quality of the presentation* | 29.16 (9.32 – 88.21) | 27.09 (8.43 – 87.11) |
| *Cost-benefit ratio of the drug* | 12.80 (6.10 -30.36) | 10.90 (4.18 -28.48) |
| *Personality of the pharmaceutical sales representative* | 5.35 (0.76 -22.35) | 3.37 (0.56 -20.28) |
| *Age of the physicians* | 1.02 (0.82- 1.09) | 1.02 (0.91- 1.14) |
| *Specialty of the physician* | 0.70 (0.55- 1.00) | 0.80 (0.64- 1.00) |
| *Year of practice* | 0.89 (0.78 – 1.02) | 0.95 (0.84 – 1.08) |

┘Adjusted for 8 covariates (age, specialty and year of practice of the physician, adequate information provided during promotion, reputation of the drug company, quality of the presentation, etc), OR= odds ratio, CI= confidence interval.

**4. DISCUSSION**

We were encouraged by the high response rate in our study (84%), which was appreciably higher than that seen by Pinto et al (25.5%)42. This study revealed that the majority (87.5%) of respondents had recent encounters with PSRs and received various forms of gifts/incentives from them. A study published in 2007 on medicines’ promotion in a teaching hospital in Ilorin, Nigeria, found that 89% of the doctors had encounters with PSRs in the preceding 6 months and more than two-thirds reported that their prescribing habits were affected by the promotional drug material received [18](#_ENREF_25). This can be a concern if this leads to inappropriate prescribing especially if there is bias in the promotion materials16,21,22. However, as mentioned, Spurling et al found a variable association between exposure to pharmaceutical company information and lower quality prescribing, a higher frequency of prescribing and higher costs15, with Vancelik et al finding pharmaceutical companies were highly influential in the prescribing practices of ambulatory care physicians similar to Godman et al Akande et al816-17. On the other hand, the importance of physician-PSR interactions as an efficient and convenient source of drug information has been noted in a number of studies26,32, and the adoption of structured educational programmes for young physicians and medical students on the interaction with PSRs can help improve their ability to maximise on the benefits of such interactions33,34,43.

Among the medicines promoted to physicians were antihypertensives, antimicrobials and cholesterol-lowering agents. The branded forms of these medicines can be expensive for individuals paying out-of-pocket in a resource poor country, hence the need for generics. A concern is that almost a third of those motivated to prescribe the medicines being promoted would do so by brand name only. Studies have shown that prescribing by generic names could reduce the cost of medicines by as much as 90% or more, reducing overall medicine cost for the class as well as overall healthcare costs [44-47](#_ENREF_31) . This is especially important for Nigeria where the majority of health care expenditure is still currently out-of-pocket, with medicines being responsible for a substantial part of healthcare costs 48-50. This is being addressed in other African countries with pharmaceutical companies offering medicines for as little as 1US$/patient/ month as part of improved access programmes51. There is now little controversy surrounding the prescribing of good quality generics with a number of meta analyses and other studies showing no difference in outcomes between generics and originators across a range of medicines and disease areas52-60, although recognizing there are some medicines which should not be prescribed by INN such as lithium and certain anti-epileptic medicines61-63, with generic immunosuppressants now less of an issue64. However, there are still concerns with the quality of generics in Nigeria, which needs to be addressed to enhance their use50. There are also concerns if interactions with PSRs increases empiric treatment with antibiotics enhancing potential antimicrobial resistance (AMR). Ethical drug promotion in developing countries has been identified as a means of containing AMR65.

It can be argued that the majority of encounters between doctors and PSRs in our study were reasonable such as an offer of a lunch or dinner as an incentive for doctors to take time out of their schedules to listen to information provided about by pharmaceutical companies or offers gifts. While this may hold for doctors in high income countries, the case may differ for those in resource poor countries35,42,66-68. A previous study in South East Nigeria indicated that 60% of the surveyed doctors felt influenced after receiving gratifications in the form stickers, food and souvenirs to prescribe promoted medicines40.

Among the predictors to be motivated to prescribe promoted medicines, the odds of motivation were lower with greater years of practice. Similarly, the odds were lower when the pharmacological information of the medicine provided during the promotion activities were inadequate compared to when adequate information was provided. These findings are appropriate as they were expected since clinical and prescribing experiences are known to improve with years of practice of a doctor. Previous studies evaluating prescribing patterns of doctors in Nigeria have shown that junior doctors perpetrate the most prescribing errors and inappropriate prescribing69. Adequate pharmacological information of promoted medicine is essential for rational and appropriate prescribing70,71. By contrast, the odds of the motivation to prescribe the promoted medicines were higher when the quality of the presentation was good compared to a poor quality presentation. Similarly, the odds of motivation were higher with a high cost-benefit ratio of the promoted medicine compared to those medicines with a low cost-benefit ratio. Rational and appropriate prescribing entails cost-benefit considerations, which is particularly important in LMICs where the cost of medication is typically borne by the patient72.

In this study, two thirds of respondents felt there should be some form of regulation between doctors and pharmaceutical companies and it was felt that this should be provided by the NMA in conjunction with the PSN and the NAFDAC.  Regulatory measures suggested by the respondents was either stopping the PSRs from offering gifts or offering only gifts with a low monetary value. In an international cross-sectional survey on educational initiatives for medical and pharmacy students about drug promotion, the majority of the respondents admitted that many countries do not have a functioning drug regulatory agency or other national private or public sector organizations responsible for overseeing drug promotion43. This may have informed the suggestion of most respondents in the current survey that drug promotion should be regulated by the two major associations for healthcare providers and NAFDAC, which is in keeping with the findings in high income countries42,73. The American Medical Association42 and the FDA73 are known to have played prominent roles in containing greater interactions between doctors and pharmaceutical companies in the US.

Following increasing concern among health authorities and civil society in other countries, national legislations regulating the advertising and promotion of medicines have been developed in many developed countries with the United Kingdom and Australia as example67,68 . The pharmaceutical industry themselves have also developed voluntary codes of conduct to address concerns, outlining ethical principles that should guide the promotion of medicines, and the interactions between pharmaceutical companies and the health care community, across countries[29](#_ENREF_18) . For example, these principles and rules outline the kind of interactions PSRs can have with health care professionals and what claims can be made about the prescription medicines being promoted, as well as other areas of interaction with the health care community such as clinicals trials and interactions with patient representatives[28](#_ENREF_18) .

There are a number of examples of such codes including the 2012 International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practice, the 2009 Code on Interactions with Healthcare Professionals of the Pharmaceutical Research and Manufacturers of America (PhRMA) and the 2014 Code of Conduct of the European Association of Researching Pharmaceutical Industries (EFPIA)[74-76](#_ENREF_39) . Such industry self-regulatory codes have also been developed in emerging economies such as India, China and South Africa[77-79](#_ENREF_42). However, evidence from Sweden and the United Kingdom shows that industry self-regulation does not always work [80](#_ENREF_45). This is due to four main inherent challenges. Firstly, self-regulation by pharmaceutical companies can be perceived as a conflict of interest as the codes are developed and implemented by the party with financial motivations; secondly, they are voluntary. Thirdly, due to general lack of pre-vetting and reactive monitoring, breaches are typically brought to light, and sanctions only administered, once the campaigns have already affected health professionals and consumers. Fourthly, financial penalties can be too low to be really effective[81](#_ENREF_46).

In Nigeria, while there is some regulation for the advertising of pharmaceutical products by NAFDAC30, there is currently no regulation by the Government on pharmaceutical company promotion and there is no body monitoring unethical promotional practices. Consequently, this research highlights a need for the Nigerian government to develop a code of conduct that will address some of the raised concerns. In view of our findings, we recommend the development of a legal provision on all pharmaceutical promotion, which is currently missing as the existing legislation only covers the advertising of medicinal products. There could for instance be financial and other consequences for pharmaceutical companies that violate the laws, if and when established, similar to other countries82, 83. However, getting the necessary manpower to enforce any developed code of conduct as well as obtaining the resources to address identified problems are potential challenges in resource limited countries such as Nigeria.

Limited information was also given to physicians regarding adverse drug affects, potential drug-drug interactions and storage conditions of promoted medicines, by PSRs during their interactions with physicians, which is similar to other countries[20](#_ENREF_17). This has been a consistent problem, and is a short-sighted approach, as the lack of key information could potentially lead to serious adverse reactions for patients or even withdrawals if vital information is not disclosed[84,85](#_ENREF_50) .

On the implementation side, drug and therapeutic committees (DTCs) should be key players in hospitals in the training of physicians in the appropriate use of medicines along with clinical pharmacologists and clinical pharmacists. We are already seeing such activities grow across Europe to enhance appropriate use of medicines in hospitals given increasing pressures for funding new medicines70,71,86,87, providing examples to Nigeria. There are also ongoing programmes among public hospitals in South Africa to improve the functioning of DTCs and the reporting of adverse drug reaction in hospitals to enhance the appropriate use of medicines as well as reduce the need and influence of PSRs[88-91](#_ENREF_51) .

There are various reports that regulation of interaction between medical students, interns, residents and PSRs influences their future relationship and practice92,93. In the nearest future, medical students, interns, and residents who have interacted with PSRs are not willing to further interact with the industry once they started to practice43,92,93. This underscores the importance of education of physician in training on how to critically evaluate the adequacy of pharmacological information of promoted drugs before prescribing. Such educational training has been recognized by the WHO and Health Action International (HAI) and contained in a practical guide handbook on understanding and responding to pharmaceutical promotion43.

Consequently, the next stage of our research will be to document further current DTC activities in Nigeria and the implications, building on the recent findings from a pilot study[94](#_ENREF_55). Furthermore, we will start promoting the fact that the university curricula of medical doctors, nurses, and pharmacists in Nigeria should now include education about pharmaceutical promotion, the need for regulations and the existing regulatory framework in the country, alongside general education about the appropriate use of medicines.

Efforts should also be geared towards encouraging all professionals in Nigeria to use the WHO and HAI practical handbook to guide their understanding and response to pharmaceutical promotion43. Educational activities continue as part of continuous professional development once physicians are qualified along with activities to potentially strengthen DTCs in hospitals as learning organisations. Finally, independent information on efficacy and safety of medicines should be made available to health professionals and patients. In countries with developing health care systems, limited availability of this information is often the reason for physicians to rely on promotional material[19](#_ENREF_16) to the detriment of patients and the healthcare system.

***4.1 STUDY LIMITATIONS***

This study was conducted among physicians working in tertiary health care facilities in Nigeria, almost all of which are located in urban centres and managed by the government. As such, our findings may not be applicable to physicians working in other care settings (e.g. private and faith-based health facilities). The majority of the respondents were also young (< 40 years) with limited years of practice (average of 4 years) suggesting they were junior doctors. This may not represent the majority of doctors in Nigeria as

 only a limited number of consultants participated in the survey. Previous questionnaire-based studies involving doctors in Nigeria though have also shown that consultants very rarely participate in such surveys95,96. It is to be hoped that future studies would address this problem. Nonetheless, we believe our data is representative of doctors in Nigeria since the population of residents and interns at any point in a year is far more than those of the consultants in all teaching hospitals in Nigeria. In addition, given the sensitivity of the topic, some respondents may not have been fully honest in their responses.

However, we believe these limitations are offset by the multi-centered nature of the study, the focus on teaching hospitals where future physicians are trained and the anonymity of completed questionnaires. As a result, we believe our findings provide important insights regarding the current extent and impact of pharmaceutical promotion among teaching hospitals in Nigeria. Such findings can be used to inform interventions and policy changes aimed at improving pharmaceutical promotion practices in line with international best practices to enhance the quality of future prescribing. Future studies will be conducted among a larger selection of hospitals in Nigeria with opportunities for interventions, and post-intervention analyses, based on recommended changes.

**5. CONCLUSION**

Our findings on the impact of pharmaceutical promotion in Nigeria on prescribing habits are a concern as this may negatively impact on the quality of prescribing and the cost of treating both communicable and non-communicable diseases in Nigeria. Enhancing the quality and efficiency of prescribing is key to improving patient outcomes, reducing out-of-pocket expenditure on medicines for patients, and reducing expenditure for health care systems. Greater efforts, not just in regulating, but most importantly in ensuring that regulations are implemented, are needed. Rigorous studies on the impact of pharmaceutical promotion can make an evidence-based case for this need. Strengthening the implementation of regulations of pharmaceutical promotion requires monitoring and evaluation of regulatory effectiveness in Nigeria. This will help in reducing inefficiencies in prescribing and the use of medicines, especially as African countries are striving for universal access. Practical steps towards reducing the impact of drug promotion on inappropriate physician prescribing in Nigeria would include enforcement of generic prescribing in healthcare facilities providing their quality can be assured as well as the establishment of functioning DTCs to guide future medicine use including the uptake of new medicines into the healthcare system.

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**AUTHORS' CONTRIBUTIONS**

JOF, KAO and OOO were responsible for the conception and design of the study and initial draft of the manuscript. OOD, AA, TAS and OOE participated in the acquisition of data and critical review of the manuscript for intellectual content. JOF, KAO, OOD, AB and BG participated in data analysis and interpretation. AB, AF, AS and BG critically reviewed the manuscript for intellectual content and updated successive drafts. All co-authors gave their final approval of the manuscript to be published.

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**APPENDIX A**

**SURVEY OF IMPACTS OF DRUG PROMOTIONAL ACTIVITIES ON THE PRESCRIBING PATTERNS AND PRACTICES OF DOCTORS IN SOME SELECTED TERTIARY HEALTH FACILITIES**

Introduction:

Dear Sir/Madam,

This study is being carried out among doctors in tertiary health institutions in some Nigerian cities to gain insight into the impact of drug promotional activities on their practices. The purpose of this study is not to indict you or any organization. It is a self- sponsored research for academic purposes only. Your honest response is therefore important and will be greatly appreciated. You are to respond on the basis of anonymity and your responses will be given the utmost confidentiality required. Thank you.

SERIAL NUMBER: ………………………………

SECTION A (DEMOGRAPHY AND PROFESSION)

Age last birthday -----------------------------------

Sex , Male = 1, Female = 2

Number of year/s of Practice --------------------

Professional status

House officer = 1, Medical officer=2, Senior medical officer and above=3, Registrar=4, Senior Registrar=5, Consultant =6.

Area of Practice

 General Practice = 1, Family Medicine=2, Internal Medicine = 3, Surgery = 4,

 Pediatrics = 5, Obstetrics & Gynecology = 6, Psychiatry = 7, Ophthalmology = 8, Ear Nose andThroat (ENT) = 9, Dentistry =10,

 Others = 11, pls specify………………….

SECTION B (DRUG PROMOTIONAL ACTIVITIES)

How many times have you had drug/s promoted to you in the last 3 months……………………

In which of the settings below did such activities/interactions take place?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Settings | Mark X | Frequency in last 3 months |
| a | Outpatient clinic visit |  |  |
| b | Statutory Clinical meetings  |  |  |
| c | Organized outdoor events |  |  |
| d | Drug launch |  |  |
| e | Conferences |  |  |
| f | Others, pleases specify……… |  |  |

Multiple responses allowed.

Can you please list the names of drugs promoted to you in the last 3 months

…………………………………………………………………………………………………………………….

…………………………………………………………………………………………………………………….

…………………………………………………………………………………………………………………….

Please indicate the information provided during the promotional events you have had?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Information | Yes | No |
| a | Generic name of the drug |  |  |
| b | Brand name of the drug |  |  |
| c | Clinical indications |  |  |
| d | Contraindications/Cautions |  |  |
| e | Pharmacological effects of the drug |  |  |
| f | Mode of action |  |  |
| g | Pharmacokinetics |  |  |
| h | Dosing information |  |  |
| i | Potential adverse effects |  |  |
| j | Average duration of treatment recommended |  |  |
| k | Potential drug interactions |  |  |
| l | Available dosage forms |  |  |
| m | Product and package descriptions |  |  |
| n | Route of administrations |  |  |
| o | Drug additives used |  |  |
| p | Storage conditions |  |  |
| q | Expiration dates/shelf life |  |  |
| r | Name/Address of manufacturers |  |  |
| s | Alternate sources of information about the drug  |  |  |
| t | Drug local registration information/NAFDAC no |  |  |
| u | Name/address of the drug marketer |  |  |
| v | Reference materials/ Relevant Publications |  |  |
| w | Cost of the drug |  |  |
| x | Others, pls specify………………………….. |  |  |

Were gifts or incentives distributed at such fora

Yes = 1, No =2

Kindly indicate the type/s of gifts/incentives you have once received from a pharmaceutical organisation

|  |  |  |
| --- | --- | --- |
|  | Items | Mark X |
| a | Food items (launch/dinner/snacks/drinks) |  |
| b | Souvenirs (e.g. pen, writing pads, mug, keys holders, wallets, clock, organizers, ward coats) |  |
| c | Cash  |  |
| d | Sponsorship to conferences |  |
| e | Others,pls specify ……………………. |  |

SECTION C (PRESCRIBING HABITS)

Have you in any way being motivated by the promotional activity/ies to prescribe a drug?

Yes = 1, No = 2

What contributed to your being motivated to prescribe such drug/s?

|  |  |  |
| --- | --- | --- |
|  | Factor/s | Mark X |
| a | Information provided during the promotion encounter |  |
| b | Reputation of the organization |  |
| c | Personality of the pharmaceutical sales representative |  |
| d | The gifts/motivational items received |  |
| e | Perceived future benefits from the company |  |
| f | The quality of the presentation |  |
| g | The cost and efficacy of the product |  |
| h | Others, please specify ………………………………… |  |

If yes to 12 above, in what form is/are the drug/s prescribed?

Generic name only = 1, Brand name only =2, Both brand and generic names = 3, Acronyms = 4

Apart from the drug promotional forum/a, did you source for more information about such drugs before prescribing?

Yes =1, No = 2.

If yes to 15 above, what was/were the source/s of such additional information sort?

|  |  |  |
| --- | --- | --- |
|  | Source | Mark X |
| a | Print materials received at presentation |  |
| b | Drug formulary/ies (e.g. BNF, MIMS) |  |
| c | Posters and bill boards |  |
| d | Peer reviewed journals |  |
| e | Print medias |  |
| f | Electronic medias |  |
| g | Pharmacology textbooks |  |
| h | Colleagues |  |
| i | Internet resources |  |
| j | Other, please specify ……………………………… |  |

Other than drug promotional activities, which of the following factors has influenced your prescribing practices?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Factors | Yes | No |
| a | Knowledge acquired from medical school |  |  |
| b | Knowledge acquired during internship |  |  |
| c | Knowledge acquired during postgraduate training |  |  |
| d | Senior colleagues influences and preferences |  |  |
| e | Drug availability |  |  |
| f | Common practice in medical community |  |  |
| g | Personal experience with the drug |  |  |
| h | Affordability to patients |  |  |
| i | Patient’s priority |  |  |
| j | Out of curiosity |  |  |
| k | Others, pls specify……………………………… |  |  |

Do you agree that the relationship between doctors and pharmaceutical medical representatives should be regulated? Yes =1, No = 2.

If yes, in what form should the regulation be

|  |  |  |
| --- | --- | --- |
|  | Regulation |  |
| A | Stopping all kinds of gifts  |  |
| B | Allowing only souvenirs/gift with small monetary value |  |
| C | Declaration of monetary value of expensive gifts/ sponsorships |  |
| D | Stopping industry sponsorship of conferences/CME |  |
| E | Others….. |  |

Thank you.