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A cross-sectional descriptive study: Evaluation of pharmaceutical marketing materials in implementing world health organization guidelines.

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Abstract

Pharmaceutical companies employ numerous methods for drug marketing like Advertisements in journals, Videos, Flyers, Books, gifts, Drug promotion literatures and flip charts. In the current study 176 DPL were collected. The DPL were analyzed and categorized in accord to the class of drug promoted to study on the most advertised group of drugs. All the DPL were evaluated for fulfilling WHO guidelines. Antimicrobials were the most promoted followed by cardio-vascular agents and drugs for Gastro-intestinal disorders. Out of 176 DPL collected 96.59% had the active ingredient per dosage/ regimen mentioned. The side effects and major adverse drug reaction were quoted only in 27.27% of DPL. The DPL analyzed in the study had brand names, active ingredient and the therapeutic uses but lagged the information in regard to side effects, contraindications and drug interactions. DPL provides knowledge about newer drug molecules hence providing details about its contraindications and precautions will lead to safer treatment to patients. With combined effort of industries and medical practitioners; ethical drug promotions can become a part of drug marketing.

Keywords: Drug promotion literatures (DPL); Drug Category; Pharmaceutical marketing; WHO guidelines; prescription

1. Introduction

The modern pharmaceutical companies started drug production from mid-1800. It began with the production of alkaloid drugs like Morphine and quinine[1]. Soon with the development of Pharmacology; synthetic chemical manufacturing and marketing across globe was fashioned. Advertising and employing sales officers are standard strategies of pharmaceutical companies for marketing their products. Since 1980 pharmaceutical companies are using different methods to promote new drug marketing[2]. One of the most renowned strategy used by Pharmaceutical companies for drug marketing was direct to physician marketing (DTP)[2,3]. Pharmaceutical companies employ numerous methods for drug marketing like Advertisements in journals, Videos, Flyers, Books, gifts, Drug promotion literatures and flip charts[4]. The advertising flyers and brochures are often of no medical educational values[5,6,7]. Few studies have quoted that Drug promotional literature provides constructive drug information and highly contented for medical professionals to prescribe the product[8,9,10]. The drug promotions targets to entice the physicians which may led to inappropriate prescription and treat to the patients[11,12,13]. At times it may also lead to increase in treatment cost[14]. Government statutory bodies like OPPI (Organization of Pharmaceutical producers of India), and ensures patients safety by monitoring drug promotional activities in India. Further in January 2007 the self-regulatory code of pharmaceutical marketing practices lead to strict adherence to code of conduct by drug manufacturers[15].

The WHO conference of experts on rational use of drugs took place in Nairobia in November 1985. This conference resulted in creating ethical criteria for drug promotions cross the globe. World health organization has laid down ethical criteria's for drug promotion to support and motivate the improvement of health care through the rational use of

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medicinal drugs[8]. As drug promotion indirectly influence the prescription behaviour of physicians it is required to analyze the drug promotional literatures in accord to the Evidence based medicine[16,17]. The effectiveness and accuracy of DPL in health care is always a dispute[16]. The raising alarm of hazards caused by irrational prescription has directed health professionals to study the vast extent of the problem. This study is proposed to evaluate the drug promotional literatures in India using the standard WHO guidelines.

2. Methodology

The study was a cross-sectional observational study carried out after the approval of institutional review board. A total of 176 drug promotional literatures were collected from departments like general Medicine, General Surgery, Orthopedics, Obstetrics and gynecology, Dermatology, Psychiatry, Pediatrics, Ophthalmology, ENT and Dentistry. The DPL with inadequate information and those depicting details about instruments, medical devices like stunts and prosthesis, two or more drugs in single DPL, ayurvedic medicines and acupuncture equipment's were excluded from the study.

The DPL were analyzed and categorized in accord to the class of drug promoted to study on the most advertised group of drugs. All the DPL were evaluated for fulfilling WHO guidelines as follows[18]

- International nonproprietary name/Brand names
- Content of active ingredients per dosage/Regimen
- Other ingredients/ adjuvants
- Approved therapeutic uses
- Dosage form/regimen
- Side effects and major ADR
- Precautions
- Contraindications and warnings
- Major interactions
- Name and address of manufacturer
- Reference to scientific literature as appropriate

The DPL were analyzed for accuracy and details exhibited in the literature. The source of literature quoted in DPL was analyzed for its authenticity. The claimed references where categorized as: (a) Meta-analysis, (b) Original research (c) Review article (d) Case reports/short communications (e) Books and (f) Websites. Statistical analysis was done by mean, average and percentage calculation.

3. Result

A total of 176 DPL were collected and Antimicrobials were the most advertised drug (24.53%), this can lead to misuse of antibiotics resulting in more antibiotic resistance. The cardiovascular drugs were the next to be highly promoted (17.61%). Among the Cardiovascular drugs; The Anti-Hypertensive was the most promoted agents. The Gastro-intestinal agents (11.36%) and the Drugs acting on Blood (10.79%) were the next most promoted group of drugs. Figure: 1 shows the commonly promoted drug categories. The DPL were analyzed for fulfillment of WHO criteria's. It was observed that none of the promotion literatures fulfilled all the 12 WHO criteria's. Around 98.86% of DPL had mentioned the International non propriety names and all the collected DPL had mentioned the brand name (100%). The content of active ingredient was mentioned in 96.59% of DPL whereas the adjuvants which may pose danger to patient's health were mentioned only in 2.27% of DPL's. Table :1 shows the evaluation of Drug promotion literature according to WHO criteria. Most of the DPL did not mention about the side effects, contraindication, precautions and drug interactions which are also major information to decide on patient's treatment.

The DPL had references given by Pharmaceutical companies to substantiate the information's produced in the promotions. A total of 249 citations were found in the 176 DPL's. The most cited references where original articles (39.36%) which included the randomized control trials, randomized prospective control trials, observational studies, retrospective studies, case control studies, Non-randomized trials, clinical trials, animal studies and in-vitro studies. The review articles quoted were about 28.51% and meta-analysis around 9.24%. 26 references quoted were not retrievable. Table:2 Depicts the analysis of references cited in DPLs. The non-retrievable references quoted where mostly from websites and few references where from books.

Table 1 Evaluation of Drug promotion literature according to WHO criteria

S.NO	WHO Criteria	Number of DPL	Percentage of DPL
1.	International nonproprietary names	174	98.86
2.	Brand names	176	100
3.	Content of active ingredients per dosage/Regimen	170	96.59
4.	Other ingredients/ adjuvents	4	2.27
5.	Approved therapeutic uses	169	96.02
6.	Dosage form/regimen	165	93.75
7.	Side effects and major ADR	48	27.27
8.	Precautions	46	26.13
9.	Contraindications and warnings	46	26.13
10.	Major interactions	32	18.18
11.	Name and address of manufacturer	96	54.54
12.	Reference to scientific literature as appropriate	114	64.77

Table 2 Analysis for source of literature cited

Type of reference	Retrievable	Non-Retrievable	% Retrievable	% Non-Retrievable
Meta-analysis	23	--	9.24	--
Original research	98	--	39.36	--
Review article	71	--	28.51	--
Casereports/short communications	12	--	4.82	--
Books	8	9	3.21	3.21
Websites	11	17	4.42	4.42
Total	223	26	89.56	89.56

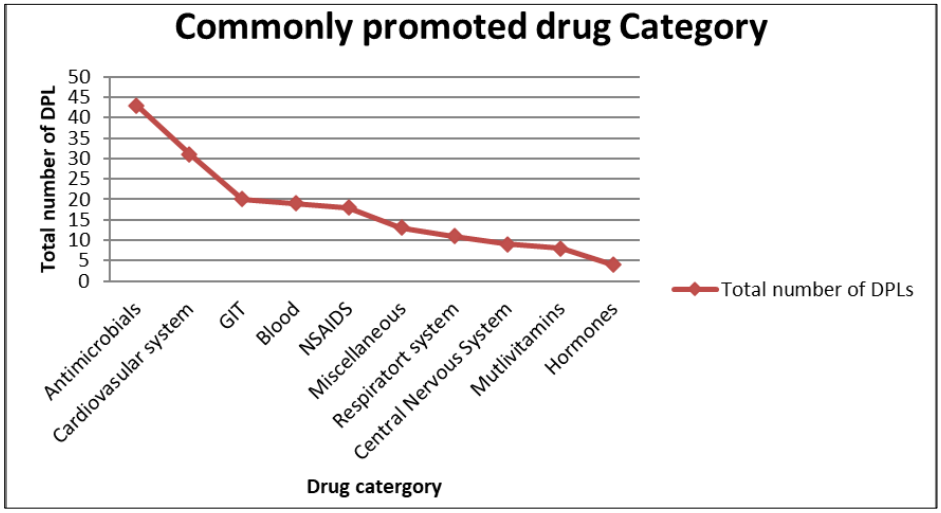

Figure 1 The commonly promoted drug groups

4. Discussion

The pharmaceutical companies are one of the highest profitable companies. India holds around 20,000 formulation in market[19]. With huge troll in competition the pharmaceutical industries behest to incorporate the evidence based medicine into drug promotional literatures[17]. The drug promotional literatures reach the health care professionals unswervingly, hence the details furnished in DPL must be reliable, informative, truthful, accurate and evidence based. It should be commercial based to promote prescription of the drug for better profit. Avaricious marketers provide false information in the DPL which may be hazardous to patients. A study by Rohra et al quoted that Pharmaceutical marketers spent around 11 billion dollars to promote marketing and 8000 to 13000 dollars/ year on health professionals for drug promotion[20].

The interpretation of ethics will vary from one part of the world to others. World health organization brought uniformity in ethical criteria's to promote drug across the globe. The goal of WHO criteria was to maintain the promotional practices within acceptable ethical standards. The health care professionals depend on Journals and Promotional literature to update themselves about recent drugs. The act of dependence on DPL has great impact on prescription behaviour of physicians [16,19]. The current study shows that anti-microbial agents were the maximum promoted group of drugs. The continuous indiscriminate and excessive use of antibacterial agents has diverted medical era into the emergence of antibacterial resistance[21,22]. Drug promotional literatures are printed proof which indirectly directs the physician in gratuitous prescriptions leading to antibiotic resistance. The rise in antibiotic resistance culminates our hope on life saving anti-microbial agents. The modern life style has created a path for inevitable prescription of drugs for various cardio-vascular diseases. The study showed that anti-hypertensive agents, Diuretics and anti-lipidemic agents were commonly promoted among physicians. The other group of drugs promoted were Non-steroidal anti-inflammatory agents, drugs for cough, bronchodilators, multivitamins, drugs acting on central nervous system and drugs acting on endocrine system.

It was observed that none of the DPL followed all the 12 WHO criterias of drug promotion. Out of 176 DPL collected 96.59% had the active ingredient per dosage/ regimen mentioned. The side effects and major Adverse drug reaction were quoted only in 27.27% of DPL. The ADR of drugs also determine the treatment strategies especially in elderly population and in patient with co-morbid diseases. Hence specifying the ADR in DPL will help the health care professionals to arrive with safer drug therapy. A study by Rupawala et al reported that drugs with narrow therapeutic index and anti-diabetic drugs account for more ADR's[23]. Study by Vlassov et al showed that less than 5% of DPL provided information about side effects[24]. Lack of information in concern to side effects may provide insufficient knowledge about the drug resulting in hazardous prescriptions. 26.13 % of DPL had precautions and contraindications the remaining DPL where devoid of these details. DPL provides knowledge about newer drug molecules hence providing details about its contraindications and precautions will lead to safer treatment to patients. Study by Mali et al showed that DPL had provided minimum safety information's[25]. Study by Jadav SS et al had similar proof quoting only 1.5% of DPL had safety information in them[26].

A total of 249 references were collected from the 176 DPLs out of which 26 were not retrievable. 223 references were retrievable out which 98 were research articles. The non- retrievable references where mostly website references. The references in the DPLs are the only authentication for the source of information provided in the DPLs.

The limitation of the study was constrained sample distribution. The sample must be aimed to be collected all over India to have a clearer idea about the drug promotions in different states of the country. This will provide scientific proof for developing and implementation ethical laws for drug manufactures and health care professionals. With combined effort of industries and medical practitioners; ethical drug promotions can become a part of drug marketing.

5. Conclusion

The DPL analyzed in the study had brand names, active ingredient and the therapeutic uses but lagged the information in regard to side effects, contraindications and drug interactions. Though a drug molecule passes through various regulation bodies specify its safety in the DPL provides information about the safety of the drug directly to the physicians. This will provide more confidence for medical practitioners to prescribe the newer drugs. Hence providing details about its contraindications and precautions will lead to safer treatment to patients. The combined effort of industries and medical practitioners can facilitate ethical drug promotions in drug marketing.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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